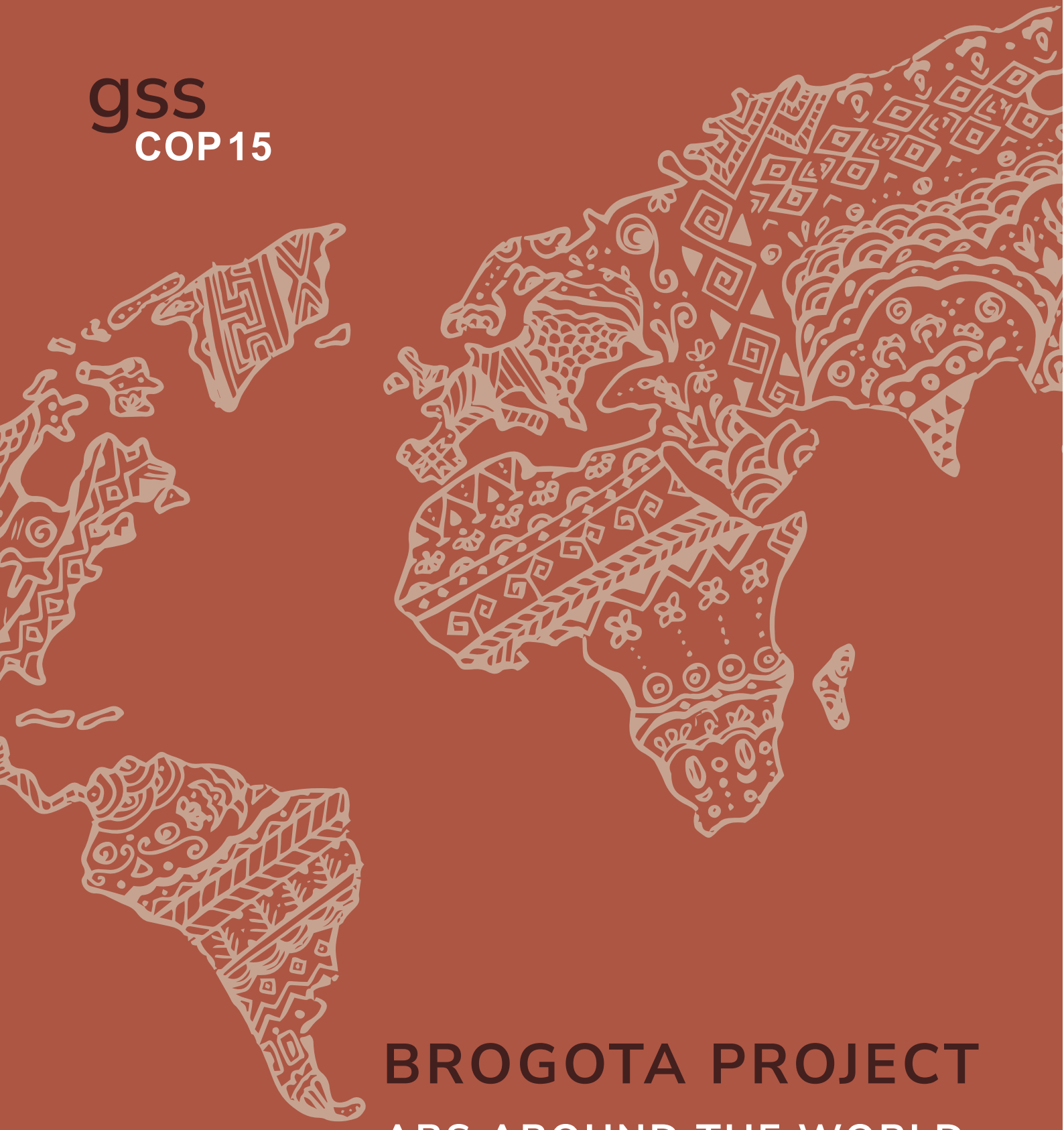
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COP15



BROGOTA PROJECT

ABS AROUND THE WORLD:

The Brazilian law contrasted with international regulations

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The Brazilian law contrasted with international regulations

3rd Edition

December 2022

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Preface

Braulio Ferreira de Souza Dias

It is with satisfaction and hope that I write this preface to the new updated edition of this comprehensive global survey of national ABS regulations. Satisfaction with the continuous progress in the establishment and implementation of national ABS regulations around the world, and hope that benefit-sharing will become a consolidated practice in all countries and among all providers and all users of genetic resources and associated traditional knowledge!

As I write this in Montreal during the CBD COP 15, I cannot avoid referring to the difficulties we have been facing to agree on the best mechanisms to ensure the promotion of ABS rules in the uploading of digital sequencies of genetic resources in large databanks and in the use of this information to promote more research and development of new technologies for the benefit of humankind.

We should respect the rights of the owners of such resources and knowledges and promote the fair and equitable benefit-sharing as a reward for the custodians of biodiversity and traditional knowledge and as an incentive to biodiversity conservation.

We should remember that digital sequencies of genetic resources do not fall from the sky but are produced by researchers accessing physical genetic materials coming from real places!

Braulio Ferreira de Souza Dias

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Conference of the Parties

Ana Paula Rodrigues Viana

To have a better understanding of what the Nagoya Protocol is and how it works, it is first necessary to note that within the Convention on Biological Diversity (CBD), there is a Conference of the Parties, also known as COP, which is the decision-making and implementation body of the principles of the Convention.

The Conference of the Parties is composed of all governments and organizations of regional economic integration that have ratified the Convention on Biological Diversity. Meetings occur periodically every two years. It is important to note that article 23 of the CBD establishes the rules that govern the Conference of the Parties.

During the COP, the parties discuss and define further details of the Convention, established through Protocols, Working Programs and Targets (Article 28 of the Convention on Biological Diversity).

Article 32 of the CBD establishes as a rule that a country can only be a party to the Protocol if they are already a member of the referred Convention, and item 2 of the same article adds that the member-country of the CBD can only participate in the discussion and decision-making process of the protocol after they have ratified it.

Since the institution of the CBD, 12 Conferences of the Parties have been held, as below:

- COP 1 - Nassau, Bahamas, November 28 to December 9, 1994
- COP 2 - Jakarta, Indonesia, November 6-17, 1995
- COP 3 - Buenos Aires, Argentina, November 4-15, 1996
- COP 4 - Bratislava, Republic of Slovakia, May 4-5, 1998
- COP 5 - Nairobi, Kenya, May 15-6, 2000
- COP 6 - Hague, the Netherlands, April 7-9, 2002
- COP 7 - Kuala Lumpur, Malaysia, February 9-20, 2004
- COP 8 - Curitiba, Brazil, March 20-31, 2006
- COP 9 - Bonn, Germany, May 19-30 2008
- COP 10 - Nagoya, Japan, October 18-29, 2010
- COP 11 - Hyderabad, India, October 8-19, 2012

- COP 12 - Pyeongchang, Republic of Korea, October 06-17, 2014
- COP 13 - Cancun, Mexico, December 02-17, 2016
- COP 14 - Sharm El-Sheikh, Egypt 2018

It is important to remember that after the COP meeting held in 2018, other meetings did not take place due to the pandemic. However, in December 2022 the COP 15 takes place in the city of Montreal, Canada, with the main objective of defining the Global Framework for Biodiversity post-2020.

The Post-2020 Global Biodiversity Framework has an ambitious plan to implement broad-based actions and bring about a transformation in the society-biodiversity relationship by 2030.

As previously explained, several COPs have been held over the last few years and between the intervals of the COPs. Meetings of Working Groups were held, with technical teams and specialists, responsible for previously discussing the aforementioned topics. Through these Working Groups, as well as their COPs, periodically (every 10 years on average) the strategies and goals to be followed by the member countries are defined.

Background of Nagoya Protocol

During the World Summit on Sustainable Development, held in 2002, it was advised that the Parties initiated the negotiations to establish an international regime on the sharing of benefits arising from access to genetic heritage and associated traditional knowledge.

The Parties initiated the discussions addressing the guidelines required for the establishment of an international regime of benefit-sharing, thus outlining the Bonn Guidelines.

Starting in 2004, 4 working groups were established between the meetings of COP 9 and 10, later evolving into a draft protocol (BELLORD e MOREIRA, 2012, p. 133).

The meetings were resumed in 2010, in the city of Montreal, Canada, with the Inter-Regional Negotiating Group further developing the draft text of the Protocol. Despite the Working Group having achieved some progress as to improve the understanding of the concepts of byproducts and usages, several other key concepts remained on hold, such as the enforcement mechanisms of the Convention (BELLORD e MOREIRA, 2012, p. 133).

Back to the main document, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was addressed during the 10th 15 Conference of the Parties, in 2010, in the city of Nagoya, Japan. However, the Nagoya Protocol only entered into force 90 days after the 50th ratification by the Parties.

In this sense, another important challenge to the implementation of the referred Protocol, as highlighted by authors Fiorillo and Diaferia (2012, p. 27), is that, in order for it to become valid, the Nagoya Protocol needed to be ratified by the countries and governments, which should adopt national laws and regulations on access and benefit sharing (article 33 of the Nagoya Protocol).

The Nagoya Protocol only entered into force from October 12, 2014, during the last meeting of the Conference of the Parties, held from October 13 to 17, 2014, in parallel with the 12th Meeting of the Conference of the Parties, in the city of Pyeongchang, South Korea.

Since then, there has been slow progress and difficulties by the countries in implementing the guidelines of the Nagoya Protocol. Given this scenario, is expected that the goal 13 of the Global Framework for Post-2020 Biodiversity, will define more clear and effective legal, political, administrative and training measures for its effective implementation.

Objectives, Guidelines and Concepts of the Nagoya Protocol

The Nagoya Protocol covers in its preamble, among other issues: (a) the importance of legal security; (b) the need for an innovative solution to deal with benefit-sharing in cross-border situations; (c) the global interdependence in relation to genetic resources in food and agriculture; (d) the interdependence relationship between genetic resources and associated traditional knowledge, as well as their importance for indigenous and local communities; (e) how this traditional knowledge is addressed by member-countries and the fact that the Protocol does not extinguishes or jeopardizes any pre-existing rights of indigenous and local communities (article 1 of the Nagoya Protocol).

Considering the issues related to legal security, an important aspect introduced by the Nagoya Protocol is that member-countries are responsible for inspecting and enforcing the applicable nor- ms, be it as a provider or as a user country. Another relevant aspect is the necessity for countries to establish clear and transparent laws, in particular to ensuring legal and regulatory security for users.

In article 2, the Nagoya Protocol includes some concepts that were left outstanding from the Convention, such as the concept of use of genetic resources, clarifying that it relates to the use of genetic resources in research and development activities on genetic composition and/or the bio- chemistry of natural resources.

As for the concept of byproducts, it is important to highlight the ongoing discussion related to that concept and its applicability. While some scholars understand that the concept broadens the scope already defined by the CBD, others disagree with that: [...] (e) “Byproduct” means

a naturally-occurring biochemical component resulting from the genetic expression or metabolism of biological or genetic resources, even if they do not contain functional units of heredity.

Article 3 of the Nagoya Protocol establishes its scope, stating that the current Protocol is applicable to genetic resources under article 15 of the Convention. In this sense, according to the do- 16 cument “Study on the Impacts of the Adoption and Implementation of the Nagoya Protocol to the Brazilian Industry”, carried out by the National Confederation of Industries (2014, p. 28 and 29), it is possible to highlight the limits of the scope of the current protocol, i.e. the areas which are not under the jurisdiction of any given country, such as international waters, deep oceanic soil, Antarctica.

Another important discussion is in relation to species considered to be market commodities, i.e. genetic resources from plant, animal or micro-organisms which are broadly used in trade and industry. In this sense, one can note that the mere commercialization of ingredients considered to be commodities does not fall under the scope of the Nagoya Protocol, unless there is a prior use of its genetic resources. The use of genetic resources can be understood as any access ac-

tivities, i.e. research and technological development activities.

Item 1 of article 5 establishes that the benefits arising from the use of genetic resources, as well as from their subsequent application and commercialization, should be fair and equitably shared with the Party providing the resources, be it the country of origin of the resources or a Party that has acquired the genetic resources in compliance with this Convention. The Benefit-sharing shall occur according to mutually agreed terms between the parties.

The Protocol clearly establishes, as detailed in item 4 of article 5, that the benefit-sharing does not necessarily need to be in monetary form, by making financial resources available to the provider; but it can also take place in non-monetary form. It also includes non-exhaustive examples of possibilities of non-monetary benefit-sharing.

It can be noted that article 8 brings special considerations in relation to the need for the national legislation to establish simplified processes and procedures for cases of non-commercially oriented research, as well as to stimulate research activities that contribute to conservancy and the sustainable use of biodiversity.

Article 9 reinforces that the Parties should encourage users and providers to apply their benefit-sharing initiatives, whether monetary or not, in the conservation of biological diversity. In this sense, there is no doubt that the benefits obtained from the current legal framework must be specifically used for the conservation of biodiversity or the associated traditional knowledge, and not as individual gains and/or benefits.

Besides these issues related to Benefit-Sharing, article 6 of the Nagoya Protocol establishes the requirement that the access to genetic resources can only take place after the prior and informed consent from the provider, that being the country of origin of the genetic resource or the country that has acquired the genetic resources in compliance with the Convention on Biological Diversity.

Several subitems are described under item 3 of the same article 6, but they all present the legislative, administrative and political measures necessary for obtaining the prior consent. 17

Apart from the prior and informed consent from the providing party and the benefit-sharing agreement, item 2 of article 17 establishes the requirement of a permit, or its equivalent, issued ac- cording to article 6, paragraph 3 (e) and then shared with the Access and Benefit- sharing Clearing House, which shall constitute an internationally-recognized certificate of compliance.

It is important to note that item 3 of the same article 17 makes it clear that the referred permit, or its equivalent, serves as proof that the genetic resource has been accessed according to the prior informed consent and that the mutually agreed terms have been established. Furthermore, item 4 establishes what should be included in the Certificate of International Compliance.

Hence, some articles acknowledge and reinforce issues related to the access to associated traditional knowledge, such as, for example, article 7, which presents the requirement of prior consent from the provider of the associated traditional knowledge.

As for the procedures, article 13 of the Nagoya Protocol determines that the Parties must establish a national focal point on access and benefit-sharing, responsible for making available

the in- formation required for seeking information related to the access to genetic heritage and associated traditional knowledge, as well as information on the procedures for obtaining the prior informed consent.

The Nagoya Protocol creates, in its article 14, the Access and Benefit Sharing Clearing-House and Information Sharing, as part of the clearing-house mechanism and a means of sharing information related to access and benefit sharing, and, on top of that, providing access to the relevant information for the implementation of this Protocol.

Article 15 establishes in its item 1, that each of the Parties shall adopt measures to ensure that the access to genetic resources under their jurisdiction takes place according to the prior informed consent and the mutually-agreed terms. It also establishes that the Parties must define the appropriate measures in case of non-compliance to these norms. In this

sense, the Nagoya Protocol establishes the necessity of holding accountable those who breach the national or international legislation.

In order to comply with the Protocol, article 16 establishes that the Parties shall adopt the effective, proportional and appropriate legislative, administrative and political measures to ensure that the access carried out in their territory has taken place according to the prior informed consent or the approval of the local and indigenous communities.

For the monitoring of the use of genetic resources, as established under article 17, each party shall adopt their own measures to monitor and improve transparency on the use of their resources.

In addition, the same article 17 establishes the need for creating checkpoints (item 01, subitems a and b), responsible for collecting and receiving information related to (a) prior informed consent; (b) the source of the genetic resources; (c) the establishment of mutually agreed terms and/ or the use of the genetic resources.

Articles 18 and 19 of the Nagoya Protocol present contract-related issues, making it clear that for the implementation of articles 6, paragraph 3 (g) (i) and article 7, each party shall urge providers and users of genetic resources and/or associated traditional knowledge to include in their mutually agreed terms: (a) the jurisdiction to whom they will submit any lawsuits for resolving disputes; (b) the applicable law; and/or (c) options for alternative dispute resolution, such as mediation or arbitration (GROSS, 2013, p. 20).

The issue of transfer of technology, in article 23, adds that the Parties must collaborate in programs of technical and scientific research and development, including activities of biotechnology research, as a means to achieve the objectives of this Protocol.

The parties must encourage countries outside the Protocol to join in as a member-country, ac cording to article 24. In this sense, the countries that are not parties to the Protocol may join in as observers, but cannot participate in the decision-making processes (item 2 of article 26).

The Protocol also defines that the Parties shall implement mechanisms to monitor their obligations (article 29).

It is important to note that the Nagoya Protocol seeks to establish guidelines not only for the so-called “provider countries”, but also to the “user countries”, as well as to harmonize the

legal and regulatory instruments for compliance with the guidelines of the Convention, ensure that providers gain advantage from the benefit-sharing, ensure legal and regulatory security to users and, most of all, ensure the sustainable use and conservation of biodiversity.

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ABS Law in Brazil and its international context

Francine Hakim Leal Franco

As part of the Convention on Biological Diversity (CBD), which in 1992 recognized that each country possesses sovereignty over the genetic resources existing in its territory, Brazil was one of the pioneers in the implementation of a national law that regulated the access to genetic heritage and associated traditional knowledge, as well as the fair and equitable sharing of benefits. In 2015, after extensive discussion between academy, public and private sectors, Law no. 13,123/2015 was published, becoming the Brazilian legal framework for access and benefit-sharing.

Despite the undeniable advances provided by the new law, after it came into effect and the processes and systems created by it began to be executed, in practice, it is still possible to identify a few obstacles to the complete implementation of the scenario outlined when the rule was elaborated. There is still certain resistance to access to traditional knowledge associated with genetic resources, in some sectors, as well as to genetic heritage, due to the regulatory complexity unattended by clear incentives. This resistance tends to be higher within smaller entities, which have a less sophisticated structure to meet the legal requirements, and this has led, in some cases, to the substitution of species from Brazilian biodiversity by species from other countries, or by products of non-natural origin. Another obstacle that has been reported is the volume of information required by the National System for the Management of Genetic Heritage and Associated Traditional Knowledge (SisGen) for carrying out registrations and notifications.

Brazil is a country of wide territorial extension, covering almost half of South America, and has the richest biodiversity in the world. There are more than 116,000 known animal species and more than 46,000 known plant species in the country, spread across six terrestrial biomes and three large marine ecosystems. Its different climate zones enable the formation of biomes (biogeographic zones), such as the Amazon Rainforest, the largest tropical rainforest in the world; the Pantanal, the largest floodplain; the Cerrado, with its savannas and forests; the Caatinga, composed of semi-arid forests; the fields of the Pampas; and the tropical rainforest of the Mata Atlântica. In addition, Brazil has a marine coast of 3.5 million km², which includes ecosystems such as coral reefs, dunes, mangroves, lagoons, estuaries and swamps. This ample variety of life is home to more than 20% of the world's total species found on land and water. The rich Brazilian biodiversity is a source of resources for the country, not only for the ecosystem services provided, but also for the opportunities represented by its conservation, sustainable use and genetic heritage (Brazilian Ministry of Environment, 2022).

Therefore, it is possible to realize that biodiversity has environmental, economic, social, and cultural importance for humankind. Regarding environmental functions, it is an important factor in the functioning and balance of all ecosystems in the world since each living organism has its role in nature and the removal of a single individual from the planet can already trigger an ecological disbalance. For humankind, biodiversity demonstrates its relevance as a source of food, energy, and as raw material for various products, as well as being used for leisure and tourism. However, it is important to note that the economic exploitation of biodiversity requires attention to local socio-ecological details.

The Convention on Biological Diversity (CBD) is the main international agreement designed to protect biological diversity for present and future generations. For this purpose, the CBD has established three fundamental objectives: the conservation of biological diversity, the sustain-

able use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. Aiming to put these objectives into practice, the CBD recognized that each country has sovereign rights over their own genetic resources and, therefore, is free to define the rules that will regulate its access and consequent benefit-sharing, according to each case.

As a country known for its megabiodiversity, it is comprehensible that Brazil was one of the first to implement a law regulating access and benefit-sharing related to the exploitation of genetic heritage and associated traditional knowledge.

At first, there was the publication of Provisional Measure Nº 2,052 in 2000, created with the intention of preventing biopiracy and ensuring, in a fair and equitable way, the sharing of benefits derived from the conduct of research and development with national biodiversity (Instituto Escolhas, 2021). Approximately one year later, a re-edited version of this first Measure was published, defined as Provisional Measure Nº 2,186-16/2001, which remained in force for almost fifteen years, until November 2015, when the new biodiversity law was published.

Several sectors that conducted research and technological development with access to genetic heritage and/or associated traditional knowledge were impacted by this legislation that, throughout time, proved to be ineffective in meeting its central objectives of promoting access to genetic resources and the corresponding benefit-sharing, as well as preventing biopiracy. Much of this is because it was a difficult and complex rule to comply with, resulting in the application of several fines. The number of registered accesses and benefits sharing, on the other hand, was very small.

After extensive discussion, Federal Law Nº. 13,123/2015, known as the Biodiversity Law, came into force. It revoked Provisional Measure Nº. 2,186-16/2001 and became the new Brazilian legal framework for access and benefit-sharing, regulated by Decree Nº 8,772/2016. The new text proposed in the Law sought to facilitate research, leverage technological innovation in production chains and generate benefits for society, as well as reduce financial and regulatory costs for the State and for users to conduct research.

The Law creates the Genetic Heritage Management Council (CGen), under the Ministry of Environment, which has an important role in the management of information on access and benefit sharing, including the maintenance of theNational System for the Management of Genetic Heritage and Associated Traditional Knowledge (SisGen), an online registration system. Through this system, users can promote registrations while carrying out access or shipment activities of Brazilian genetic heritage or associated traditional knowledge. Also, SisGen can be used for the notification of finished products and reproductive material, and for the management of benefit-sharing.

Since the new biodiversity legal framework came into force in 2015, a new timeframe for access activities with genetic heritage and associated traditional knowledge carried out in Brazil was also established. The access activities concluded before June 30, 2000, when the first Provisional Measure was published, are not subject to the requirements of Law Nº. 13,123/2015. Access activities conducted by national individuals and national legal entities between June 30, 2000, and November 16, 2015, when the Biodiversity Law was published, were liable to regularization, by signing a Term of Commitment, until the date of November 06, 2018. Processes for the regularization of activities conducted by foreign individuals and institutions remain with an open deadline at this time. Research and technological development activities involving genetic heritage and associated traditional knowledge performed between November 17, 2015,

and November 5, 2017, are provided for in art. 118 of Decree Nº. 8,772/16, which establishes that the user who applied for any intellectual property right, economically exploited finished product or reproductive material, or disclosed results, final or partial, in scientific or communication media in this period, must register the activities addressed in art. 12 of Law Nº. 13,123, 2015 and notify the finished product or reproductive material developed as a result of the access. The deadline for the registration or notification would be 1 (one) year, counted from the date the registration is made available by CGen. Once the registration or notification is made timely, the user will no longer be subject to administrative sanctions. The regular use of SisGen began on November 6, 2017, and as of this date, all obligations brought by the biodiversity legislation should be followed by users.

The Brogotá Project aims to bring the main elements of access and benefit-sharing legislation around the world. So that the contrast of the Brazilian Law with other norms can be evidenced along the study, we bring in this space some relevant elements of the operationalization of the Law in Brazil.

At first sight, the Brazilian law is very broad in its concept of access, understanding that research and technological development activities conducted on samples of genetic heritage or associated traditional knowledge characterize access and must be registered in the system before specific legal deadlines are reached. Considering the broadness of the concepts of research and technological development provided by the law, the result is that almost any R&D activity would be under the scope of the legislation and would impose obligations on the users of species that have Brazil as their center of origin.

This extensive comprehension of what constitutes access differs from several regulations established by other countries, which understand access as activities that actually focus on innovation, in discovery of new functions expressed by species, isolation of specific molecules and genetic components. Thus, the very concept of access in Brazilian legislation reveals itself as a possible disadvantage to the promotion of the use of Brazilian genetic heritage.

However, despite this first “barrier”, in comparison with other regulations in force around the world, the Brazilian legislation has several positive points.

In the international political context, we see a leadership role of Brazil on the subject, as a country that for more than 20 (twenty) years has regulated activities of access and benefit-sharing to its genetic resources. This role was debilitated by the country’s delay in ratifying the Nagoya Protocol, but it has been recovered by its background in international negotiations, given its experience in the subject and the importance of biodiversity conservation in Brazil.

Also in the structural context, Brazil stands out for having legal and non-legal regulations built together with the various sectors of society - industry, traditional peoples, academy -, cherishing dialogue. With a single designated competent authority, CGen, which concentrates the discussions and deliberations on the subject, and with representation from all interested sectors - government and civil society -, the current Brazilian legislation promotes clearer and more direct understandings about the obligations of each party and how they should be complied with.

In the technical operational field, the Brazilian regulatory scenario does not require prior government authorization for access, except in very particular cases, and brings a series of exceptions to the benefit-sharing rules, including for licensing operations, transfer and permission to use patents, which allows this obligation to be concentrated on specific groups along the

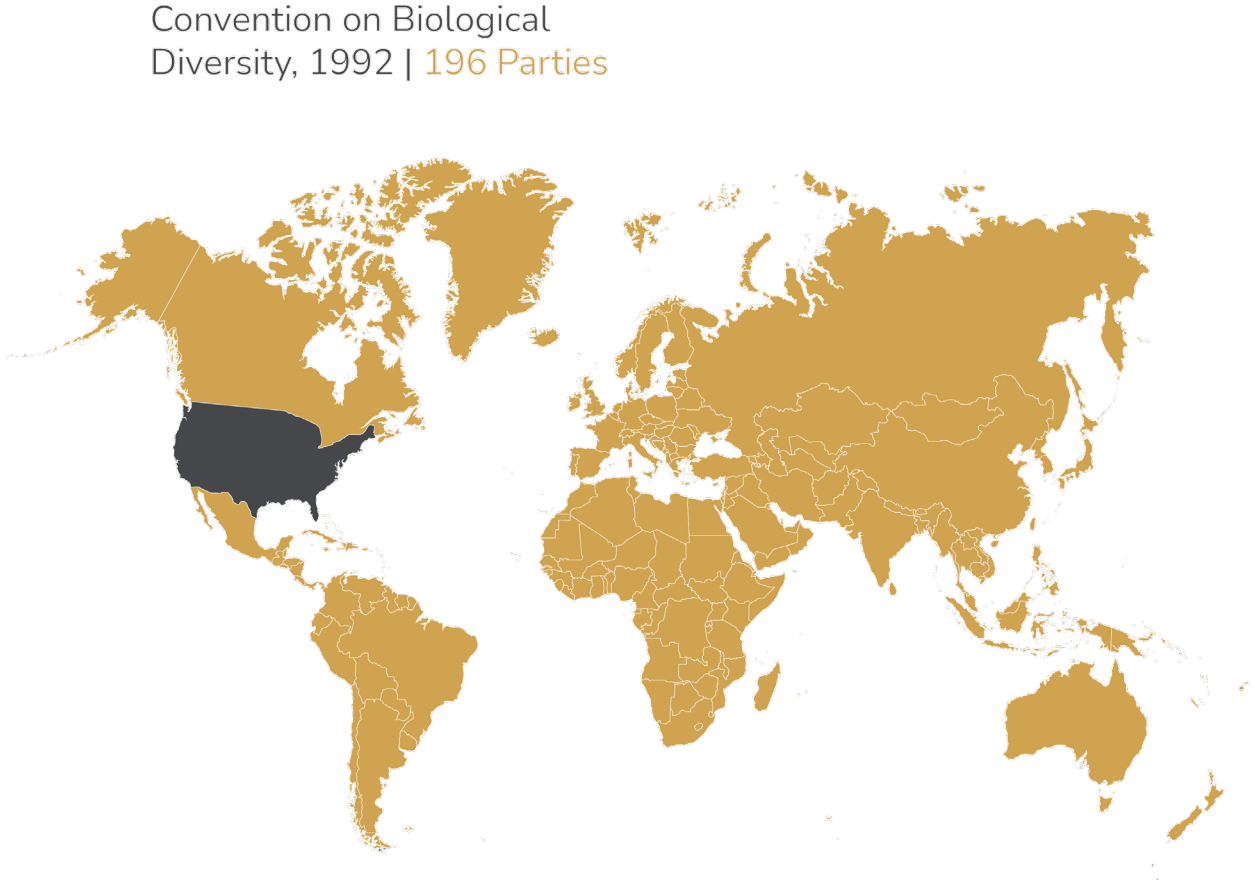
production chains, avoiding the cumulative sharing, and with values clearly predetermined in law. As a result, more than 5 (five) million reais have already been destined to the National Benefit Sharing Fund - FNRB, and another 14 (fourteen) million have already been presented in the form of more than 100 benefit-sharing projects, mainly directed to biodiversity conservation, capacity building, and consolidation of research and development infrastructure (Brazilian Ministry of Environment, 2022).

Furthermore, compared to other countries, Brazil has the advantage of having implemented an online platform, the SisGen, allowing users to self-declare their activities with genetic heritage and associated traditional knowledge, avoiding processes of prior authorization of access or approval of activities carried out. In this context, there are already more than 60,000 (sixty thousand) registered accesses and 13,000 (thirteen thousand) products and reproductive materials notified in the system so far (Brazilian Ministry of Environment, 2022).

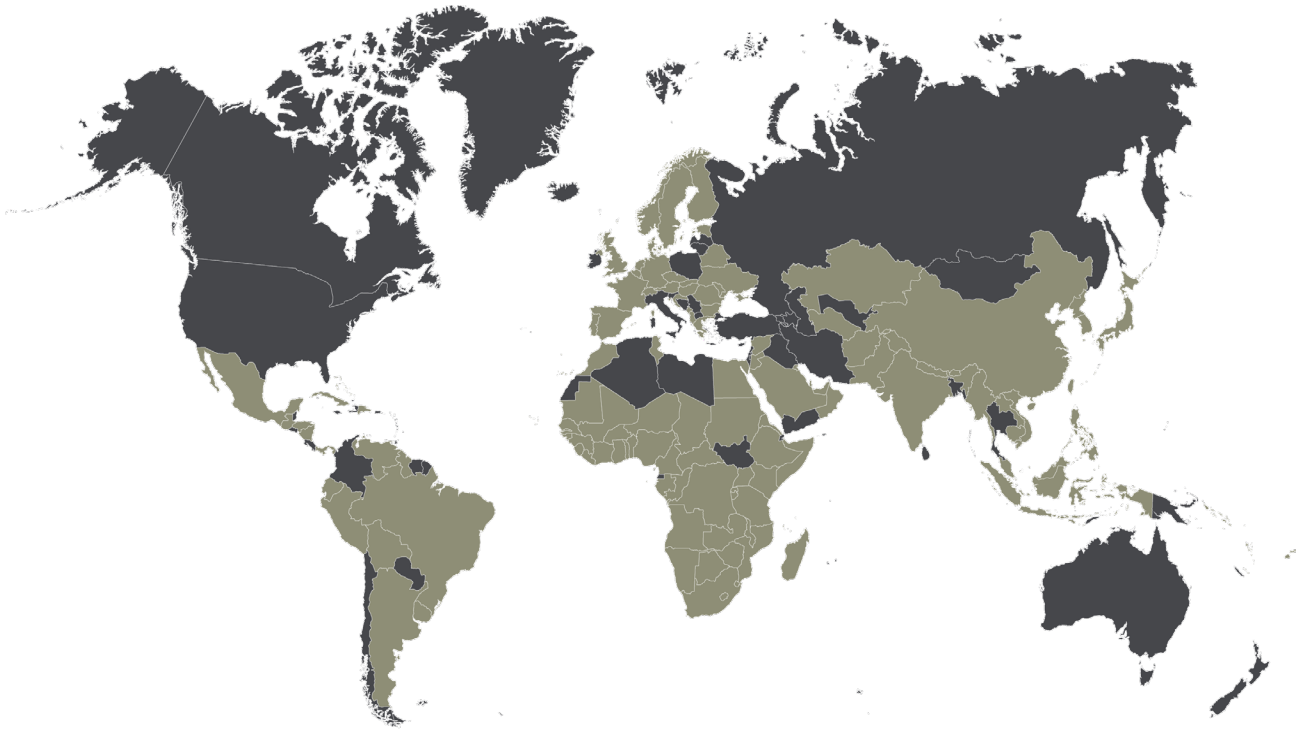
Despite its many facilities, even five years after its implementation, the system still presents several obstacles to its correct operation, particularly with regard to its use by foreign users, for whom SisGen demonstrates a series of incompatibilities, especially the language barrier, being available currently only in Portuguese.

The fact is that, despite being innovative and advantageous in many aspects, the Biodiversity Law and the regulatory system created by it still have points of improvement and, in this sense, civil society actors, among which is GSS, act with dedication and a watchful eye, together with the competent authorities, to promote the necessary changes to better comply with regulations and to promote the sustainable use of Brazilian genetic resources.

Along with the Brazilian action, in recent years it could be noticed an expressive movement of countries for the ratification of the Nagoya Protocol, in addition to the almost unanimous ratification of the Convention on Biological Diversity, as demonstrated below:



Nagoya Protocol,
2014 | 138 Parties

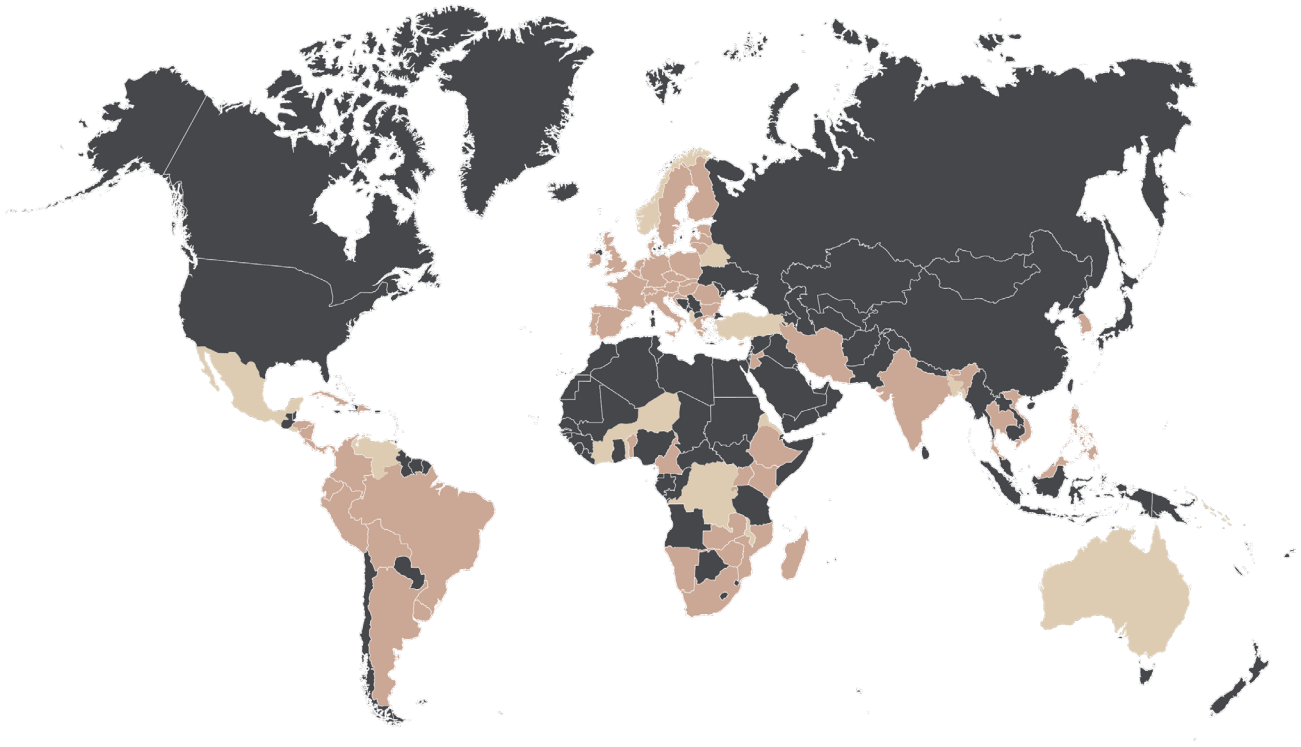


Furthermore, there is also a significant global progress in the implementation and updating of rules for access and benefit-sharing, and several countries already have specific and detailed legislation to regulate the issue, which can be seen in the map below:

Local ABS Legislation |
84 countries of 198

Countries with specific and detailed ABS legislation

Countries with broad ABS legislation



Therefore, it is from the Brazilian experience and the curiosity about how it differs from other regulations focused on the ABS theme that the present study arises, seeking to provide the reader with an overview with the main points of attention of each standard and allow the user to take the first steps towards the sustainable use of genetic resources around the world.

Disclaimer

This material is the result of a study that sought to identify and catalog the rules of access and benefit sharing in different countries. It is intended for Users of genetic resources and aims to facilitate the identification of the legal framework on the subject in the world.

The study was conducted only from secondary sources, with the ABS-Clearing House website and the Convention on Biological Diversity as its main sources. It is dynamic, as a “living study” in which the updates are constant. The user is aware that the rules and procedures detailed in this study may undergo changes, revocations or substitutions, which may cause the present evaluation to be outdated. Due to the time limit for this research ended in December 2021.

It should be emphasized that the legal norm is the only authentic legal reference and that the information contained in this publication does not constitute legal or technical advice on the subject. Thus, contact with competent governmental bodies and ABS representatives is encouraged.

The use of the information contained in this study is the sole responsibility of the User. Croda, Natura and GSS do not assume any responsibility for the use that may be made of the information contained in the present study.

INTERNATIONAL RULES





Africa

Algeria[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 12, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Protocol, but has been a signatory country since February 02, 2011.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following law regarding access and benefit-sharing:

- Law n° 14-07 from August 9th, 2014 - Loi n° 14-07 du 13 Chaoual 1435 regarding biolog-

1. The information hereinafter has been updated until 06/03/2020
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

ical resources.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

According to article 3 of Law 14-07, of 13 Chaoual 1435, the competent institution is the National Agency on Biological Resources (L'Organe National des Ressources Biologiques), which is responsible for examining all application forms of access and transfer of biological resources and associated traditional knowledge.

Moreover, article 4 of this Law, determines that the functions and assignments of this agency must be the object of a new regulation.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, articles 8 and 9 of Law 14-07 establish that in order to access the biological resources of the country, it is necessary to request authorization to the National Agency on Biological Resources. The requirements for such are:

1. For scientific research, the applicant must: provide all the necessary information so the Agency can evaluate the consequences of the access; demonstrate the research objective; inform all the results of its research in a detailed report that must be submitted to the Agency.

2. For commercial purposes, the applicant must: provide all the necessary information to the Agency evaluate the consequences of the access; make propositions of transferring and sharing of technologies developed by the access, as well as projects for the protection of the biological resource to be accessed; present a study on the consequences of the access to the biological resource and its ecosystem.

3. Besides that, every access to biological resources has the following obligations:

- Carry out the access in cooperation with Algerian scientists, communities or organizations, that will be indicated by the Agency on a case by case basis.

- A sample of the accessed genetic resource must be deposited into a national gene bank;

- The requirement must contain information on the objective of the access (if scientific or commercial), the collection sites, duration and dates of the operation, the means used in the access, the quantity of the accessed genetic material, and the identity of the responsible.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Law 14-07 does not differentiate the procedures for access to associated traditional knowledge from those undertaken in access to genetic heritage.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Article 18 of Law 14-07, explains that access to associated traditional knowledge is the object of a sui generis intellectual property right, but it does not present specific procedures for the request of patents.

2.6. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
According to article 11 of Law 14-07, in order to ship samples of genetic material abroad, the access authorization request needs to indicate the point of entry or exit of the samples in the country.

2.8 Does the current legislation or any ongoing bills address synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
According to art. 2 of Law 14-07, the benefit sharing may be monetary or non-monetary and is calculated on the use of genetic heritage or associated traditional knowledge. Article 17 establishes that access and benefit-sharing mechanisms will be established in a different regulation. Such mechanisms are yet to be created. In this sense, according to Algeria's Sixth National Report to the CBD, The Global Environment Facility in collaboration with the United Nations Development Programme is helping the country's Ministry of Agriculture, Rural Development and Fisheries develop specific mechanisms for the sharing of benefits.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 3.1, although Law 14-07 establishes the need for fair and equitable benefit-sharing no specific mechanism on the matter has been developed so far.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Law 14-07, in its articles 5 and 21, establishes the sanctions applicable to irregular access to genetic heritage, which are: prison sentence from 3 to 5 years, and payment of a fine from 500.000 dinars to 1.500.000 dinars.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
National Agency on Biological Resources - L'Organe National des Ressources Biologiques	The Agency examines all application forms of access and transfer of biological resources and associated traditional knowledge.

6. Websites

CBD Algeria Profile
https://www.cbd.int/countries/nfp/?country=dz

ABSCH Algeria Profile
https://absch.cbd.int/countries/DZ

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Algeria Profile. Available at: https://absch.cbd.int/countries/dz. Access on: 06/04/2020.

GOVERNMENT OF ALGERIA. Journal Officiel de la Republique Algerienne N° 48. Loi n° 14-07 du 13 Chaoual 1435 correspondant au 9 août 2014 relative aux ressources biologiques. Available at: https://www.commerce.gov.dz/telecharger/reglementation/346/article. Access in 06/04/2020.

Convention on Biological Diversity. National Focal Points. Country Profiles. Algeria Profile. Available at: https://www.cbd.int/countries/nfp/?country=dz. Access on 06/04/2020.

RÉPUBLIQUE ALGÉRIENNE DÉMOCRATIQUE ET POPULAIRE. Ministère de l'Environnement et des Énergies Renouvelables. Sixième Rapport National sur la Diversité Biologique. Available at: https://www.cbd.int/doc/nr/nr-06/dz-nr-06-fr.pdf. Access on 01/09/2021.

Angola[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since June 30, 1998.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since May 07th, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, Decree number 38/05 of June 3rd addresses scientific investigation on marine biological resources made by foreign researchers. Also, the Law No 06/17 establishes private access to forest and wildlife resources and benefit sharing - which is

1. The information hereinafter has been updated until September 01st, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

not regulated. According to the Interim National Report published in May 2019, there is a Draft law on Genetic Resources which is expected to be submitted to the National Assembly for approval.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mrs. Elizabeth Godinho Golcalvez
Director General
National Institute for Biodiversity and Protected Areas
Ministry of Environment
Cidade do Kilamba, Quarteirão Nimi Ya Luqueni
Edifício Q11/2 andar
Luanda
Angola

ABS National Focal Point
+244 22 233 4683
+244 22 233 2611
godinho1978@yahoo.com

6. Websites

ABSCH Angola Profile
https://absch.cbd.int/countries/AO

CBD Angola Profile
https://www.cbd.int/countries/?country=ao

Ministério do Meio Ambiente
http://www.minamb.gov.ao/

7. References

ACCESS AND BENEFIT SHARING CLEARING HOUSE. - ABSCH. Country profiles. Angola profile. Available in: https://absch.cbd.int/countries/AO. Access in: 01/09/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country profiles. Angola profile. Available in: https://www.cbd.int/countries/?country=ao. Access in: 01/09/2021.

GOVERNO DE ANGOLA. 5º Relatório Nacional 2007-2012 sobre a Implementação da Convenção da Diversidade Biológica em Angola. República de Angola. Ministério do Ambiente - Direcção Nacional da Biodiversidade. 2014. Disponível em: https://www.cbd.int/countries/?country=ao Access in 01/10/2016.

GOVERNO DE ANGOLA. Estratégia e Plano de Acção Nacionais
para a Biodiversidade (NBSAP). República de Angola. Ministério do Urbanismo e Ambiente. Luanda, 2006. Disponível em: https://www.cbd.int/countries/?country=ao Access in 01/10/2016.

Republic of Angola. Ministry of Environment. Sixth National Report on Biodiversity in Angola and the Achievement of the Aichi Goals 2011-2020. Access in 01/09/2021.

Republic of Angola. Interim National Report on the Implementation of the Nagoya Protocol. 2019.

Benin[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since September 28, 1994.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has issued and registered 20 IRCCs that are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"4 under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the country already has the following measure regarding access and benefit-sharing:

1. The information hereinafter has been updated until October 07th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Decree on National Guidelines on Access to Genetic Resources and Associated Traditional Knowledge and the Fair and Equitable Sharing of Benefits Arising from their Use in the Republic of Benin, 2016 (Décret N° 2018 - 405 - Directrices nationales pour l'accès et le partage des avantages issus de l'utilisation des ressources génétiques et des connaissances traditionnelles associées).

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The official profile on the ABSCH (The Access and Benefit-Sharing Clearing House) identifies Direction Générale des Eaux, Forêts et Chasse/Ministère du Cadre de Vie et du Développement Durable (Directorate General of Water, Forests and Hunting / Ministry of the Living Environment and Sustainable Development)as the competent national institution, which, according to article 23 of Decree, is responsible for authorizing access and providing advice on:

- Negotiation, procedures and conditions for obtaining PIC and concluding a MTA to access to genetic resources and/or traditional knowledge; 2. Monitoring and evaluation of arrangements for accessing and sharing benefits; 3. Implementation of and compliance with access and benefit-sharing arrangements; 4. Exam of application and signing of agreement or contracts

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to articles 16 until 19 of Decree 2018-405, all access activities in the country must have prior authorization. The Competent National Authority shall issue an opinion to the applicant at the end of the examination of the application for an access permit. In the event of a favorable opinion, the applicant is invited to continue the procedure for obtaining prior informed consent and negotiating the mutually agreed conditions, which shall be granted according to the procedures described below:

1. Prior Informed Consent procedure:

Foreseen among articles 20 and 28, the Prior Informed Consent procedure is subjected before the National Competent Authority when requesting access to genetic resources for commercial/non-commercial purpose. According to this decree, the applicant has to provide to the National Competent Authority all necessary informations in accordance with the access permit request form in Annex I. In cases of access to genetic resources in situ within limits of a protected or private area, the competent authority shall request authorization from the responsible or owner for the protected area to access to the resources. The owner has thirty days to give a motivated answer to the competent authority.

Authorizations may be refused when:

1. The applicant and the CNA do not reach an agreement concerning benefit sharing;

2. The benefit-sharing proposed by the applicant clearly does not correspond to its technical and financial capacities;

3. The activity or the risk of its potential application affects biodiversity significantly when restricting the sustainable use of the biological resource to which access is requested for its use or by exhausting it.

4. The refusal is always reasoned by the CNA.

2. Mutually Agreed Term procedure:
Among articles 29 and 34, this decree explains how to get this procedure for access to genetic resources and use of traditional knowledge. Initially, the development of the access contract and benefit sharing depends on the minutes signed in the context of MAT, being necessary for all the signatures to have a formal MAT. An important addend is that the if the user has a non-commercial contract under MAT signed, and intends to change the contract for a commercial or potentially commercial use, the user has to make a new request to the CNA in order to obtain a new prior consent given with knowledge of cause and must negotiate new mutually agreed terms.

It is important to highlight that article 17 mentions that request processing cannot exceed 60 days.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. the procedure is the same as described in item 2.3.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving access?

(X) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for the collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for the shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and it incides over economic exploitation and access to genetic resources and/or traditional knowledge. The responsibility to share the benefits lies on the user of Genetic Resources/Traditional Knowledge.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, the procedures, rules and values were established by the domestic legislation as presented below:

According to articles 40 until 42 of the Decree, the benefit-sharing can be done in a monetary or non-monetary manner beyond a Benefit-Sharing Agreement between user and the local community, in general, holder of genetic resource and traditional knowledge. This procedure may be done between a Model Contract Form Between Supplier and user for Commercial/ Potential Commercial and Non-Commercial Scientific Research that includes in this contract, a request to access genetic resources and traditional knowledge and consequently Benefit-sharing agreement. It's important to highlight that according to article 41, all parties involved in the procedure of benefit-sharing can be benefited with

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	The right of access or the fee per sample collected or acquired	Not defined	Associated Traditional Knowledge and Genetic Heritage	Local Community and Government
		Advance payments			
		Single payments			
		The exploitation license fees in the event of marketing The special right to be determined			
		The funding of research in Benin			
		Joint Ventures			

Non Monetary	Not defined	Sharing the results of research and development	Not defined	Associated traditional knowledge	Local Community and Government
		Collaboration and cooperation in research and development with national research institutes			
		Participation in the development of products			
		Collaboration and cooperation in the field of education and training			
		Access to ex situ installations of biological resources and databases data			
		The transfer to Benin of knowledge and information under conditions preferential			
		Capacity building			
		Specialized and targeted training			
		Equipment and Infrastructure			
		Access to scientific information on preferential conditions			
		Contributions to development plans and economic activities in local level			
		Social recognition			
		Monitoring the development of the resource			
		Joint ownership of relevant intellectual rights			

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No sanctions in case of irregular access were identified in the norms covered by this analysis.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

Authority	Competence
Directorate General of Water, Forests and Hunting / Ministry of the Living Environment and Sustainable Development/ Direction Générale des Eaux, Forêts et Chasse/Ministère du Cadre de Vie et du Développment Durable	This Competent National Authority helps all involved on access to genetic resources and traditional knowledge in your respectives applications.

6. Websites

Benin's profile at ABS website
https://absch.cbd.int/countries/BJ

Benin's profile at CBD website
www.cbd.int/countries/?country=bj

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Benin profile. Available in: https://absch.cbd.int/countries/BJ Access on February 18, 2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Benin profile. Available in: https://www.cbd.int/countries/?country=bj Access on February 18, 2020.

REPUBLIQUE DU BENIN. **Stratégie et Plan d'Action pour la Biodiversité 2011-2020**. Ministre De L'environnement Charge De La Gestion Des Changements Climatiques, Du Reboisement Et De La Protection Des Ressources Naturelles Et Forestieres; Direction Generale Des Forets Et Des Ressources Naturelles (DGFRN). Available in: https://www.cbd.int/countries/?country=bj Access on February 18, 2020.

REPUBLIQUE DU BENIN. **Cinquieme Rapport National Sur La Mise Em Œuvre De La Convention Sur La Diversite Biologique Au Benin**. Ministre De L'environnement Charge De La Gestion Des Changements Climatiques, Du Reboisement Et De La Protection Des Ressources Naturelles Et Forestieres; Direction Generale Des Forets Et Des Ressources Naturelles (DGFRN). 2014. Available in: https://www.cbd.int/countries/?country=bj Access on February 18, 2020.

REPUBLIQUE DU BENIN. Directives Nationales Pour l'acces et le partage des avantages issus de l'utilisation des ressources genetiques et des connaissances traditionelles associees. Direction generale de eaux, forets et chasse; Direction generale de l'institut national des recherches agricoles du Benin. 2016. Available in: https://absch.cbd.int/database/record/ABSCH-MSR-BJ-240826

REPUBLIQUE DU BENIN. Décret N° 2018-405.Présidence de la Republique. 2018. Available in:https://absch.cbd.int/api/v2013/documents/02B93E5A-C873-59B4-3CC8-31753EC0464C/attachments/decret%20APA_SIGNE.pdf

Botswana[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since January 10th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, traditional knowledge associated with biological diversity is addressed by the "Industrial Property Act, 2010" standard.

1. The information hereinafter has been updated until September 02nd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge. However, the "Industrial Property Act, 2010" rule covers the issue of associated traditional knowledge.

Part I, article 2 defines traditional knowledge as the idea, knowledge, practice, use or invention, whether written or unwritten, which may be associated with biological diversity, is considered as part of culture, tradition or spiritual beliefs or values of A group of people. In this sense, according to article 5 of the Industrial Property Act, the traditional knowledge may be registered by the Registrar of Trademarks, Patents and Drawings, and the procedures and details of this registration are delimited by "Part XII - Traditional Knowledge and Handicraft".

Registration may be done by a local traditional practitioner, the representative or individual from any local community. The description of knowledge must be made clear and complete in order to allow other people to use this knowledge in order to achieve the same results as those obtained by the holder of this knowledge, as well as the community or local communities should be identified, including their geographical distribution and its intrinsic differentiating characteristics when applicable.

Access to such knowledge by third parties may be authorized by the Minister for scientific, commercial or industrial exploration, when said exploitation does not distort or offend the cultural identity of the local community and provided that there is an equitable distribution to the community of any benefits derived from the research, trade or industrial exploitation. The public interest and the expressed opinion of the traditional community that holds the knowledge will also be taken into account in granting the authorization.

Finally, it reinforces Section 127, Part XII of the Industrial Property Act, 2010 that no patent, trademark, industrial design or plant variety certificate related to the traditional knowledge referred to in that standard can not be considered valid until the local community Consent holder in writing.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, according to the Industrial Property Act, marks, patents and designs shall be registered by the Registrar, the procedures and details of this registration are delimited by "Part XII - Traditional Knowledge and Handicrafts ".

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, the benefit sharing obligation is contained in articles 124 and 125, Part XII of the Industrial Property Act, 2010, and the responsibility to share the benefits lies on the party that exploits the traditional knowledge.

3.2 What are the applicable procedures, rules and values?

( ) YES / ( ) NO / (X) NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Lump sum, royalty fee or participation in the benefits directly or indirectly derived from the exploitation of the knowledge	Not defined	Associated Traditional Knowledge	Not defined
Non Monetary	Not defined	Educational grants, medical assistance or any other benefits	Not defined	Associated Traditional Knowledge	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, one emblematic biopiracy case is the Hoodia case, involving the San people. The case took place in South Africa, where the South African Council for Scientific and Industrial Research patented Hoodia in 1997, a plant used traditionally as food and medicine, without the awareness or consent of the San People. The license was subsequently granted to Phytopharm and Unilever.

When the San people were informed about the patent, in 2001, they launched a claim against the South African Council for Scientific and Industrial Research, which led to an agreement of benefit-sharing involving Hoodia in 2003. Since then, the San Councils continue to represent San communities in Botswana, South Africa and Namibia.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Ms. Kebaabetswe Keoagile
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Department of Environmental Affairs
Ministry of Environment, Natural Resources Conservation and Tourism
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Botswana

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kebkeoagile@gov.bw
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6. Websites

ABSCH Botswana Profile
https://absch.cbd.int/countries/BW

CBD Botswana Profile
https://www.cbd.int/countries/?country=bw

Ministry of Environment, Natural Resources Conservation and Tourism
https://www.gov.bw/ministries/ministry-environment-natural-resources-conservation-and-tourism

7. References

ACCESS AND BENEFIT SHARING CLEARING HOUSE. - ABSCH. Country profiles. Botswana profile. Available in: https://absch.cbd.int/countries/BW. Access in: 02/09/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country profilmes. Botswana profile. Available in: https://www.cbd.int/countries/?country=bw. Access in: 02/09/2021.

RABITZ, Florian. Biopiracy after the Nagoya Protocol: Problem Structure, Regime Design and Implementation Challenges. Bras. Political Sci. Rev., São Paulo , v. 9, n. 2, p. 30-53, Aug. 2015 . Available from < http://dx.doi.org/10.1590/1981-38212014000200010>. Access on 02/09/ 2021.

JONAS, H; BAVIKATTE, K; SHRUMM, H. Community Protocols and Access and benefit Sharing. Asian Biotechnology and Development Review. Vol. 12, No 3, pp 49-76. 2010.
REPUBLIC OF BOTSWANA. Fifth National Report to the Convention on Biological Diversity. Department of Environmental Affairs – DEA. 2015. Available in: https://www.cbd.int/countries/?country=bw Access on 02/09/ 2021.

REPUBLIC OF BOTSWANA. Industrial Property Act, 2010 (Act No. 8 of 2010). Available in: http://www.wipo.int/wipolex/en/details.jsp?id=9602 Access on 02/09/ 2021.

REPUBLIC OF BOTSWANA. National Biodiversity Strategy and Action Plan. Department of Environmental Affairs – DEA. 2016. Available in: https://www.cbd.int/countries/?country=bw Access on 02/09/ 2021.

Burkina Faso[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Nevertheless, the following legislation have some information

1. The information hereinafter has been updated until September 13th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

about access and benefit sharing:

- Loi No. 006-2013/AN Portant Code De L'environnement Au Burkina Faso (Law N. 006-2013 Environment Code of Burkina Faso) - This law establishes the basic rules for the environment in Burkina Faso. Regarding access to genetic heritage and benefit sharing, article 8 states that local populations exercise a right to use natural resources. This right of use guarantees them, in particular, access to genetic resources as well as the sharing of benefits linked to their exploitation.

- Loi n ° 070-2015 / CNT Portant Loi D'orientation Agro-Sylvo-Pastorale, Halieutique Et Faunique Au Burkina Faso (Law n ° 070-2015 / CNT Agro-Sylvo-Pastoral, Fisheries And Fauna Guidance Law In Burkina Faso) - this law is of great importance to the theme of access and benefit sharing. Section 5 of it addresses the issue of genetic resources. In this section, article 100 emphasizes that genetic resources of plants and animals are part of the national patrimony, and confers on the State the responsibility to supervise their conservation and sustainable use. In this regard, article 101, gives the State the authority to determine the conditions of access to national genetic resources for all users and is responsible for taking the necessary measures to ensure the fair and equitable sharing of the benefits arising from their use, which shall be subject to the prior consent of the State and local communities and shall be carried out on mutually agreed terms. However, the conditions of access to national genetic resources, as well as the modalities of benefit sharing, will be set by a decree of the Council of Ministers. Lastly, article 102 indicates that the State shall ensure that Prior Informed Consent of local communities is obtained for access to the traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the use of this traditional knowledge for commercial exploitation.

- Loi n° 064-2012/AN portant régime de sécurité en matière de biotechnologie (Law n ° 064-2012 on the biotechnology safety regime) - This law applies to the development, testing, production, dissemination, storage, destruction or disposal, import, export, transboundary movement, including the transit of any genetically modified organism and any product consisting of or containing a genetically modified organism. About access and benefit sharing, article 68 establishes that genetically modified organisms developed from genetic resources taken from the national heritage are subject to regulations relating to access to genetic resources and sharing of benefits.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Although, Loi N ° 070-2015 / CNT Portant loi d'orientation agro-sylvo-pastorale, halieutique et faunique au Burkina Faso establishes in articles 101 and 102 that access to national genetic resources are subject to the prior consent of the State and local communities and are operated under mutually agreed terms. The law also states that a decree by the Council of Ministers will specify the conditions of access to national genetic resources as well as the methods of sharing the benefits resulting from the use. However, until this date the decree mentioned was not found.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, Loi N ° 070-2015 / CNT Portant loi d'orientation agro-sylvo-pastorale, halieutique et faunique au Burkina Faso provides that the prior informed consent of local communities shall be obtained with regard to access to traditional knowledge associated with genetic resources.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2. Legal information

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Nevertheless, Loi No. 006-2013/ AN Portant Code De L'environnement Au Burkina Faso, Loi N° 070-2015 / CNT Portant Loi

D'orientation Agro-Sylvo-Pastorale, Halieutique Et Faunique Au Burkina Faso and Loi n° 064-2012/AN portant régime de sécurité en matière de biotechnologie establish that the State shall ensure the fair and equitable sharing of benefits arising from the use of national genetic resources, traditional knowledge associated with genetic resources for commercial exploitation and genetically modified organisms developed from genetic resources taken from the national heritage. However, the referred laws do not provide any specific provisions on how benefit-sharing shall occur.

It should be highlighted that the National Biodiversity Strategy of Burkina Faso has established in its action No. 5 about fair benefit sharing, a regime that seeks to establish a national framework on access to genetic resources and the benefit-sharing deriving from their use. This national framework has the following tasks: i. create an institutional framework on ABS; ii. provide human and financial resources for the good operation of that framework;; iii. develop and implement a law on ABS; iv. establish an ABS focal point, including a national correspondent for the Cross-Governmental Committee.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or

public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

M. Daogo Léon Ouoba
Secretariat Permanent du Conseil National pour le Développement Durable
Ministére de l´environment de l´economie verte et du chagement climatique
01 BP 6486
Ouagadougou
Burkina Faso

ABS National Focal Point
+70 65 02 49
daogoleon@yahoo.fr

6. Websites

Country profile in the ABSCH website - Burkina Faso
https://absch.cbd.int/countries/BF

Country profile on the website of CBD - Burkina Faso
www.cbd.int/countries/?country=bf

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Burkina Faso. Available in: https://absch.cbd.int/countries/BF. Access on September 13th, 2021.

CONVENTION ON BIOLOGICAL DIVERSITY, CBD. Country profile. Burkina Faso. Available in: www.cbd.int/countries/?country=bf . Access on September 13th, 2021.

GOUVERNEMENT DU BURKINA FASO. **Cinquieme Rapport National Du Burkina Faso A La Conference Des Parties A La Convention Sur La Diversite Biologique**. Available in: https://www.cbd.int/countries/?country=bf> Access on September 13th, 2021.

GOUVERNEMENT DU BURKINA FASO. **Le Protocole De Nagoya Sur L'apa: Origines, Justification Et Enjeux**. Ministere De L'environnement Et Du Developpement Durable - Secretariat Permanent Du Conseil National Pour L'environnement Et Le Developpement Durable. Ouagadougou, 2015. Available in: http://slideplayer.fr/slide/9360368/ Access on September 13th, 2021.

GOUVERNEMENT DU BURKINA FASO. **LOI N° 070-2015 / CNT Portant Loi D'orientation Agro-Sylvo-Pastorale, Halieutique Et Faunique Au Burkina Faso**. Available at https://lavoix-dujuristebf.files.wordpress.com/2018/02/loi_070_pourtant_orientation_agro-sylvo_pastora.pdf. Access on September 13th, 2021.

GOUVERNEMENT DU BURKINA FASO. **Loi N°006-2013/AN Portant Code De L'environnement Au Burkina Faso**. Available at http://extwprlegs1.fao.org/docs/pdf/bkf124369.pdf Access on September 13th, 2021.

GOUVERNEMENT DU BURKINA FASO. **Loi n° 064-2012/AN portant régime de sécurité en matière de biotechnologie**. Available at http://extwprlegs1.fao.org/docs/pdf/bkf139471.pdf. Access on September 13th, 2021.

GOUVERNEMENT DU BURKINA FASO. **Plan D'action National 2011-2015 Du Burkina Faso Pour La Mise En Œuvre De La Convention Sur La Diversité Biologique**. Ministère De L'environnement Et Du Développement Durable - Secrétariat Permanent Du Conseil National Pour L'environnement Et Le Développement Durable. Ouagadougou, 2011. Available in: https://www.cbd.int/doc/world/bf/bf-nbsap-v2-fr.pdf. Access on September 13th, 2021.

Burundi[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since July 14, 1997.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

1. The information hereinafter has been updated until October 22nd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The ABSCH website identifies the Ministry of Waters, Environment, Regional Planning and Urbanism. as the competent institution, which is responsible for coordinating all interventions in biodiversity.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Burundi Law on Industrial Property of Jul 28, 2009 provides for protection of traditional knowledge, which includes “knowledge of the properties of biological resources as well as combinations of such resources”.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the Burundi Law on Industrial Property of Jul 28, 2009 includes procedures for registering traditional knowledge. Articles 247 to 275 set out the provisions aimed at securing the industrial property of traditional knowledge to the local indigenous communities through the registry system. According to article No. 271, the communities that have their traditional knowledge registered in the form of industrial property can license them for industrial use.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country’s territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

Authority	Competence
Ministry of Water, Environment, Spatial Planning and Urban Planning	The Ministry coordinates all interventions on biodiversity, including monitoring mechanisms for international trade and exchange of fauna and flora species and encouraging research and accompanying measures for the maintenance of biological diversity.

6. Websites

ABSCH Burundi profile
https://absch.cbd.int/countries/BI

CBD Burundi profile
www.cbd.int/countries/?country=bi

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Burundi. Available in: < https://absch.cbd.int/countries/BI>. Access on: January 16, 2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Buruindi. Available in: <www.cbd.int/countries/?country=bi> Access on: January 16, 2020.

REPUBLIQUE DU BURUNDI. **Etude Sur Le Niveau De Comprehension Des Groupes Cibles Sur Les Enjeux Du Protocole De Nagoya**. Ministere De L'eau, De L'environnement, De L'amenagement Du Territoire Et De L'urbanisme. Bujumbura, 2012. Available in: http://bi.chm-cbd.net/implementation/questions-transectorielles/acces-aux-ressources-genetiques-et-partage-des-avantages/etude-sur-le-niveau-de-comprehension-des-groupes-cibles-sur-les-enjeux-du Access on 30/10/2016.

REPUBLIQUE DU BURUNDI. **Loi n° 1/13 du 28 juillet 2009 relative à la propriété industrielle au Burundi**. Available in: http://www.wipo.int/wipolex/en/details.jsp?id=8324 Access in 30/10/2016.

REPUBLIQUE DU BURUNDI. **Loi n°1-21 du 23 juin 2014 portant adhésion par la République du Burundi au protocole de NAGOYA sur l'accès aux ressources génétiques et partage juste et équitable des avantages découlant de leur utilisation relatif à la convention sur**

la diversité biologique. Available in: http://www.ecolex.org/details/legislation/loi-n1-21-du-23-juin-2014-portant-adhesion-par-la-republique-du-burundi-au-protocole-de-nagoya-sur-lacces-aux-ressources-genetiques-et-partage-juste-et-equitable-des-avantages-decoulant-de-leur-utilisation-relatif-a-la-convention-sur-la-diversite-biologique-lex-faoc162983/?type=treaty&page=107 Access on 30/10/2016.

REPUBLIQUE DU BURUNDI. **Strategie Nationale Et Plan D'action En Matiere D'echange D'informations Sur La Biodiversite 2010-2020**. Ministere De L'eau, De L'environnement, De L'amenagement Du Territoire Et De L'urbanisme. Bujumbura, 2012. Available in: https://www.cbd.int/
countries/?country=bi Access on 30/10/2016.

REPUBLIQUE DU BURUNDI. **Stratégie Nationale et Plan d'Action sur la Biodiversité 2013-2020**. Ministere De L'eau, De L'environnement, De L'amenagement Du Territoire Et De L'urbanisme. Bujumbura, 2013. Available on: https://www.cbd.int/countries/?country=bi Access in 30/10/2016.

Cabo Verde[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since June 27th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Protocol, but has been a signatory country since September 26th, 2011.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 14 of Decree 7/2002 establishes that collection of species for research purposes shall be subject to a license to be issued by the environment

1. The information hereinafter has been updated until October 23rd, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

authority.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

Official database of Portuguese-speaking African countries
http://www.legis-palop.org/

ABSCH Cabo Verde Profile
https://absch.cbd.int/countries/CV

CBD Cabo Verde Profile
https://www.cbd.int/countries/?country=cv

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Cape Verde profile. Available at: https://absch.cbd.int/countries/CV. Access on 10/25/2020.

CABO VERDE. Decreto nº 3 de 24 de Fevereiro de 2003. Estabelece o regime jurídico dos espaços naturais, paisagens, monumentos e lugares que pela sua relevância para a biodiversidade, pelos seus recursos naturais, função ecológica, interesse socioeconômico, cultural, turístico ou estratégico, merecem uma proteção especial e integrar-se na Rede Nacional das Áreas Protegidas. **Imprensa Nacional**. Publicado no Boletim oficial dia 24 de fevereiro de 2003.

CABO VERDE. Decreto nº 7 de 30 de Dezembro de 2002. Estabelece medidas de conservação e proteção das espécies da flora e da fauna ameaçadas de extinção, enquanto componentes da biodiversidade e parte integrante do patrimônio natural de Cabo Verde. **Imprensa Nacional**. Publicado no Boletim oficial de 30 de Dezembro de 2002.

Convention on Biological Diversity. National Focal Points. Cape Verde. Available at: https://www.cbd.int/countries/nfp/?country=cv. Access on 10/25/2020.

GOVERNMENT OF CABO VERDE. **Fifth National Report on the Status of Biodiversity in Cabo Verde. National Directorate for the Environment. August, 2015**. Available at: https://www.cbd.int/countries/nfp/?country=cv Access on 09/04/2020.

GOVERNMENT OF CABO VERDE. **Resolution nº 35/2016 approving the Cape Verde National Protected Areas Strategy (ENAP)**, general policy to all National Network of Protected Areas (RNAP). I Série – nº17sup <B.O> da República de Cabo Verde de 17 de março de 2016. Available at: http://www.legis-palop.org/ Access on 09/04/2020.

Cameroon[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since January 17th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since February 28th, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has 7 IRCCs that can be found on the ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Law n° 2021/014 of July 2021 to govern Access to Genetic Resources, their derivatives,

1. The information hereinafter has been updated until September 10th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

traditional Knowledge associated with Genetic Resource and fair Equitable Sharing of the benefits arising from their utilization.

- Decision 00094/D/MINEPDED/CAB of October 24th, 2020 on organization and functioning of National Committee on Access to Genetic Resources, their derivatives, traditional Knowledge associated with Genetic Resource and fair Equitable Sharing of the benefits arising from their utilization.

- Decision 00150/D/MINEPDED/CAB of November 25th, 2020 to lay down terms and conditions governing Access to Genetic Resources, their derivatives, traditional Knowledge associated with Genetic Resource and fair Equitable Sharing of the benefits arising from their utilization.

- Law nº 96/12 of October 5th 1996 which establishes a framework for environment management.

- Law nº 94/01 of January 20th 1994 which establishes a regime for forests, faune and fisheries

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Section 33 of Law n° 2021/014 determines that the ministry in charge of environment shall be the competent institution, which is responsible for using Prior Informed Consent and ABS permits; monitoring the negotiation of MATs; ensuring the implementation of the conditions for obtaining Prior Informed Consent; granting access to genetic resources, their derivatives and/or associated traditional knowledge and coordinating the activities of the National ABS Committee.

Also, section 34 of the referred law states that a National ABS Committee shall issue technical opinions on all matters relating to Nagoya Protocol. According to article 2 of Decision 00094/D/MINEPDED/CAB, the competence of ABS Committee includes: providing opinions and technical orientations on ABS and PIC, making recommendations regarding ABS and biodiversity conservation; promoting cooperation with international ABS systems; ensuring the participation of stakeholders.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Chapter II of Law n° 2021/014, all activities relating to the use of genetic resources, their derivatives and/or associated traditional knowledge in the country must comply with the procedures described below:

1. PIC (Section 9): The applicant shall require Prior Informed Consent to the competent national authority, upon approval by the National Genetic Resources Access and Benefit Sharing Committee. It shall be valid for 1 year, renewable. According to articles 6.5 and 7 of Decision 00150/D/MINEPDED/CAB, PIC shall authorize its holder to enter into negotiations with local communities with the intention of concluding MATs.

2. MAT (Section 10): After obtaining PIC for a period of 3 years, the applicant shall conclude Mutually Agreed Terms with the community concerned by the genetic resource, its derivatives and/or associated traditional knowledge.

3. ABS Permit (Section 17): Upon presentation of PIC and MAT, the competent national authority shall issue an ABS Permit, valid for 5 years, renewable.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Notwithstanding the procedures described in item 2.3, in cases where access to associated traditional knowledge is concerned, the applicant and the holder of the associated traditional knowledge shall establish a Mutually Agreed Term, according to biocultural community protocols or the customary law applicable (Section 18 of Law n° 2021/014).

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Section 18 of Law n° 2021/014, in cases where there is a request for intellectual property involving traditional knowledge, the applicant is required to obtain consent of the indigenous or local communities owning the knowledge. Also, Section 23 of the referred law states that, in addition to the existing intellectual property system, a suitable intellectual property system for traditional knowledge owners shall be established. Both of those subjects will be stated by future legislation.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Section 12 of the referred law, sampling and exportation of biological resources shall be subject to authorizations or permits provided by the regulations in force. Section 13 of the same law states that exportation shall be subject to PIC and to the favourable opinion of the National ABS Committee.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) DSI / (X) SYNTHETIC BIOLOGY / ( ) NONE

Yes, the legislation addresses this matter on Section 7 of Law n° 2021/014 and the terminology used is synthetic biology. However, there are no specific procedures for those cases.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

According to Chapter IV of the Law n° 2021/014, benefit sharing shall be monetary or non-monetary, before, after or during the utilization of the genetic resource or the Associated Traditional Knowledge. Also, according to Section 28 (2), there are some factors that determine what should be considered to establish benefit sharing, such as the commercial use of the resources, potential market for the research findings, nature of technology used, and others.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	As defined on the Annex of Nagoya Protocol	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Community/ Government
Non Monetary	Not defined	As defined on the Annex of Nagoya Protocol	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Community/ Government

3. Benefit sharing

4.1 Is there an official inspection body? Are there any records of fines having been applied by such institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Section 49(1) of Law n° 2021/014 states that the minister in charge of environment shall impose administrative penalties in case there is a breach of an obligation of the referred law and its implementing instruments.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Law n° 2021/014 establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: 6 months to 10 years of imprisonment, de-

pending on the violation; 10 million to 100 million CFAF (approximately 17 to 180 thousand US dollars), depending on the violation.

4.3 Is there any record of emblematic biopiracy cases or disputes related to access and benefit sharing in the country?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry in charge of environment	issuing Prior Informed Consent and ABS permits; monitoring the negotiation of MATs; ensuring the implementation of the conditions for obtaining Prior Informed Consent; granting access to genetic resources, their derivatives and/or associated traditional knowledge and coordinating the activities of the National ABS Committee.

6. Websites

ABSCH Cameroon profile
https://absch.cbd.int/countries/CM

CBD Cameroon profile
https://www.cbd.int/countries/?country=cm

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Cameroon profile. Available in: https://absch.cbd.int/countries/CM Access in 23/09/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Cameroon profile. Available in: https://www.cbd.int/countries/?country=cm Access in 28/01/2020.

NCHOUTPOUEN, Chouaibou. Etude De L'etat De Lieux De La Prise En Compte De L'acces Aux Ressources Genetiques Et Le Partage Juste Et Equitable Des Avantages Decoulant De Leur Utilisation Dans Les Lois Et Texes Reglementaires Au Cameroun. Ministere De L'environnement Et De La Protection De La Nature. Republique Du Cameroun. Available in: http://www.abs-initiative.info/fileadmin//media/Events/2015/The_Echinops_ABS_Case/Rapport_Final_Etude_APA_du_Cameroun.pdf Access in 02/10/2016.

REPUBLIQUE DU CAMEROUN. Sixième Rapport National Du Cameroun A La Convention De La Diversite Biologique. Ministre de l''Environnement, de la Protection de la Nature et du Développement Durable – MINEPDED. 2019. Available in: https://chm.cbd.int/database/record?documentID=238964.

REPUBLIQUE DU CAMEROUN. Decision 00094/D/MINEPDED/CAB of October 24th, 2020 on organization and functioning of National Committee on Access to Genetic Resources, their derivatives, traditional Knowledge associated with Genetic Resource and fair Equitable Sharing of the benefits arising from their utilization. Available in: https://absch.cbd.int/countries/CM Access in: 23/09/2021.

Decision 00150/D/MINEPDED/CAB of November 25th, 2020 to lay down terms and conditions governing Access to Genetic Resources, their derivatives, traditional Knowledge associated with Genetic Resource and fair Equitable Sharing of the benefits arising from their utilization. Available in: https://absch.cbd.int/countries/CM Access in: 23/09/2021.

REPUBLIQUE DU CAMEROUN. Law n° 2021/014 of July 2021 to govern Access to Genetic Resources, their derivatives, traditional Knowledge associated with Genetic Resource and fair Equitable Sharing of the benefits arising from their utilization. Available in: https://absch.cbd.int/countries/CM Access in: 23/09/2021.

REPUBLIQUE DU CAMEROUN. Loi n° 96/12 du 5 Août 1996 portant loi-cadre relative à la gestion de l'environment. Available in: https://wipolex.wipo.int/en/legislation/details/5800 Access in: 23/09/2021.

REPUBLIQUE DU CAMEROUN. Loi n° 94/01 du 20 janvier 1994 which establishes a regime for forests, faune and fisheries. Available in: https://absch.cbd.int/api/v2013/documents/EFA8B27E-5122-A417-4757-B18BF92C2AF2/attachments/Loi_94_forestier%20et%20de%20peche.pdf. Access in: 23/09/2021.

Central African Republic[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since June 13th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 25th, 2018.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

According to the article Overview of National and Regional Measures on Access and Benefit

1. The information hereinafter has been updated until October 10th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Sharing (2014), the country is a member of COMIFAC - Commission on the Forests of Central Africa, regional organization that has developed guidelines for the implementation of access and benefit sharing policies for all its member countries, with the objective of facilitating the implementation of ABS policies that are coherent and enable cooperation between the countries of the central Africa region.

In this regard, the Environmental Code of 2008 explains in its article 37, that the protection of the country's environment must be carried out considering sustainable use of biodiversity, as well as the application of the benefit sharing system. However, no specific procedures or values were found.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. The Environmental Code of 2008 identifies the Ministry of Environment as the competent institution for the purpose of this Law. However, there is no indication of a competent authority for access and benefit sharing within the scope of the Nagoya Protocol.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 39 of the Environmental Code and the Fifth National Report in the item 6.2.4.3 explain that scientific exploration and the exploitation of biological resources must be carried out in a transparent and collaborative manner with international research institutions, local communities and non-governmental organizations.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the Environment Code of 2008 explains in its article 37, that the protection of the country's environment must be carried out considering the sustainable usage of biodiversity, as well as the genetic resources and benefit sharing system. However, no specific procedures or values were found.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.
The Environmental Code of 2008 indicates that the Ministry of Environment shall delegate the inspection bodies, which will be responsible for applying sanctions foreseen by article 117 and following.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The Environmental Code of 2008 provides for sanctions applicable in case of violation of the rules foreseen by its Chapter II. In this sense, it is determined that, in case an environmental infraction is identified, the responsible agency will notify the offender to regularize its situation. However, if the offender does not proceed to the determinations of the competent agency, the following sanctions can be applied: suspension of the functioning process of the installation where the infraction is taking place; obligation to restitute the damage caused to the public heritage; obligation to provide the expected profit as a guarantee of legal compliance, until the end of its execution; prison sentence, from 3 months to 2 years; payment of a fine from 100.000 to 5.000.000 CFA Franc.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Ms. Ricky Victoria Passineme
Directrice en matière d´Accès aux Ressources Génétiques et au Partage des Avantages
Coordinaton Nationale Biodiversité
Ministère de l´Environnement et du Développement Durable
BP 686
Bangui
Central African Republic

ABS National Focal Point
+236 75 30 19 42, +236 75 04 80 93
victorianeme72@gmail.com

6. Websites

ABSCH Central African Republic Profile
https://absch.cbd.int/countries/CF

CBD Central African Republic Profile
https://www.cbd.int/countries/?country=cf

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Central African Republic profile. Available in: https://absch.cbd.int/countries/CF> Access on 10/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Central African Republic profile. Available in: https://www.cbd.int/countries/?country=cf> Access on 10/10/2020

GOVERNMENT OF CENTRAL AFRICAN REPUBLIC. **Fourth National Report to the Convention on Biological Diversity.** Ministry of the Environment and Ecology (Ministère de l'Environment e de l'Ecologie). Available in: https://chm.cbd.int/database/record?documentID=201293 Access on 22/05/2018.

GOVERNMENT OF CENTRAL AFRICAN REPUBLIC. **Cental African Republic National Biological Diversity and Action Plan**. Ministry of Environment, Water, Forests, Hunting and Fishing (Ministère de l'Environment, dex Eaux, Forêts, Chasses et Pêches). Available in: https://chm.cbd.int/database/record?documentID=201727 Access on 22/05/2018.

Chad[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since September 5th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, Chad has been a Party to the Nagoya Protocol, by ratification, since January 9th, 2018.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation on access to genetic heritage and associated traditional knowledge has been found. However, it is important to highlight that, according to the article Overview of National and Regional Measures on Access and Benefit Sharing (2014), the country is a member of COMIFAC - Commission on the Forests of Central Africa, a regional organization that

1. The information hereinafter has been updated until November 11th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

has developed guidelines for the implementation of access and benefit sharing policies for all its member countries, with the objective to facilitate the implementation of ABS policies that are coherent and can enable the cooperation between central African countries. In addition, according to Chad's Fifth National Report (2014) to the Convention on Biological Diversity the country also has a National Biodiversity Strategy and Action Plan (2000) which highlights the importance of access and benefit-sharing as recognizes the need for national legislation regulating the matter as one of the country's goals for the next few years.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation on access to genetic heritage and associated traditional knowledge has been found. However, the website 'Centre d'échange du Tchad' indicates the Haut Comité National pour l'Environnement (HCNE) as competent on the matter: Founded by Decree N°822/PR/MET/95, it is the interministerial body responsible for guiding the government on the protection of the environment in the country, and managing biodiversity matters.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Haut Comité National pour l'Environnement	Founded by Decree N°822/PR/MET/95, it is the interministerial body responsible for guiding the government on the protection of the environment in the country, and managing biodiversity matters.

6. Websites

ABSCH Chad Profile
https://absch.cbd.int/countries/TD

CBD Chad Profile
https://www.cbd.int/countries/?country=td

Centre d'échange d'informations du Tchad
http://td.chm-cbd.net/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, ABSCH. Country profile. Chad. Available in: < https://absch.cbd.int/countries/TD>. Access in: 11/10/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, CBD. Country profile. Chad. Available in: <https://www.cbd.int/countries/?country=td> Access in: 11/10/2020.

CENTRE D'ÉCHANGE DU TCHAD. Haut Comité National pour l'Environnement (HCNE). Available at: http://td.chm-cbd.net/mise-en-oeuvre-de-la-convention/points-focaux-nationaux/comite-de-gestion/haut-comite-national-pour-l-environnement-hcne Access in: 04/15/2018.

MEDAGLIA, Jorge Cabrera; PERRON-WELCH, Frederic; PHILLIPS, Freedom-Kai. Overview of national and regional measures on access and benefit sharing: challenges and opportunities in implementing the Nagoya Protocol. CISDL Biodiversity & Biosafety Law Research Programme, 3 ed., June 25 of 2014, p. 59-61. Available at: <https://www.absfocalpoint.nl/up-

load_mm/5/f/4/008c9cc8-19f3-4926-b380-5f13fd1eb705_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf> Access in: 04/15/2020.

OLDHAM, Paul; BARNES, Colin; HALL, Stephen. Biodiversity In The Patent System:A country study of biodiversity, genetic resourcesand global patent activity for Chad. Available at: <http://www.abs-initiative.info/fileadmin//media/Knowledge_Center/Pulications/Patent_Studies/Chad_30102013.pdf>. Access in: 04/15/2020

Comoros[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 28th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country is Party to the Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the Loi Sur L'Acces Aux Ressources Genetiques et Connaissances Traditionneles de L'Union de Comores (Loi No 20-001/AU), of May 21, 2020.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

1. The information hereinafter has been updated until 4/20/2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Article 5 of Law No 20-001/AU identifies Direction Générale de l'Environnement et des Forêts (DGEF) as the competent institution, which is the only body responsible for all matters related to genetic resources in the country.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 9 of Loi Sur L'Acces Aux Ressources Genetiques et Connaissances Traditionneles de L'Union de Comores all applicants of access activities shall present the following documents: prior informed consent, mutually agreed terms, a request form.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 9 of Loi Sur L'Acces Aux Ressources Genetiques et Connaissances Traditionneles de L'Union de Comores all applicants of access activities shall present the following documents: prior informed consent, mutually agreed terms, a request form.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and it incides over access and utilization of genetic resources and associated traditional knowledge. The responsibility to share the benefits lies on the user.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Loi Sur L'Acces Aux Ressources Genetiques et Connaissances Traditionneles de L'Union de Comores (Loi No 20-001/AU), of May 21, 2020, institutes the judicial police as the official inspection body responsible for all matters related to access and benefit-sharing in the country. Nevertheless, the following institutions can act as inspection body: agents of the commissioned customs administration, sworn agents commissioned for this purpose by the administration and territorial collectivity, the sworn agents of the National Parks of the Comoros.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Law No 20-001/AU establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: I) withdrawn of the permit is when the user is not in compliance with article 10 of the Law previously mentioned; II) anyone who has committed or attempts to commit an act in violation of the relevant provisions of the ABS law shall be punished by imprisonment for at least one year and at most 5 years and a fine of 100,000 (approximately 199,90 US dollars) to 500,000 (approximately 999,50 US dollars); III)

it is punished with a fine of 100,000 (approximately 199,90 US dollars)[5] to 250,000 (approximately 499,75 US dollars) and an imprisonment of 3 less to 5 years, anyone who uses genetic resources, their derivatives or associated traditional knowledge for the purposes of scientific research, conservation and/or collection at professional title, bio-prospecting, industrial application or commercial use, without a permit provided for in article 10 above or with an authorization of the permit whose period of validity has expired or which has been withdrawn.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

Authority	Competence
Direction Générale de l'Environnement et des Forêts	Evaluate and decide on the formal request for access to genetic resources and/or associated traditional knowledge. Collect, analyze and disseminate information on access to genetic resources and associated traditional knowledge. Responsible for sensitize and orient the State actors, users, suppliers and local populations concerning their rights and obligations

6. Websites

National CHM – Comores
http://km.chm-cbd.net

ABSCH Comores Profile
https://absch.cbd.int/countries/KM

CBD Comores Profile
https://www.cbd.int/countries/?country=km

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Comoros profile. Available at: https://absch.cbd.int/countries/KM Access on 10/25/2020.

COMOROS. Interim National Report on the Convention of Biological Diversity. Published December 30th, 2017. Available at: https://absch.cbd.int/pdf/documents/absNationalReport/ABSCH-NR-KM-239087/1 Access in 10/25/2020.

5. Currency exchange rate of 10/18/2022.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Comoros profile. Available at: https://www.cbd.int/countries/?country=km Access on 10/25/2020.

RÉPUBLIQUE FÉDÉRALE ISLAMIQUE DES COMORES. 5ème Rapport National Sur La Diversité Biologique. Ministère de la production et de l'environnement, 2014. Available at: https://www.cbd.int/countries/?country=km Access in 4/20/2020.

RÉPUBLIQUE FÉDÉRALE ISLAMIQUE DES COMORES. Stratégie nationale et Plan d'Action pour la conservation de la diversité biologique. Ministère de la production et de l'environnement, 2000. Available at: https://www.cbd.int/countries/?country=km Access in 4/20/2020.

Congo[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since October 30th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since August 12th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the Interim National Report on the Implementation of Nagoya Protocol (2018), the current system of authorization for access to genetic resources is regulated by the ministry in charge of scientific research and technological inno-

1. The information hereinafter has been updated until November 22nd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

vation. Also, the exploitation or importation of genetic resources is briefly dealt by Articles 81 and 164 of the Congo Forest Code, Law No 16-2000 of 20 November 2000 (Code forestier, Loi n ° 16-2000 du 20 novembre 2000), and the National Strategy on Access to Genetic Resources and Benefit Sharing of the country (2017) states that a legislation on the matter shall be developed.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Nevertheless, article 81 of Congo Forest Code, Law No 16-2000 of 20 November 2000 (Code forestier, Loi No 16-2000 of 20 November 2000), states that the importation and exploitation of genetic material is subject to prior authorization from the minister responsible for water and forest issues and the Minister in charge of matters related to scientific research and technology.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 41 of the Law n° 05, about promotion and protection of the rights of indigenous populations (Loi n° 5 - 2011 du 25 février 2011 portant promotion et protection des droits des populations autochtones), establishes that indigenous people have the right to benefits arising from the commercial use and exploitation of their lands and natural resources.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found. Nevertheless, the Forest Code of Congo, Law No. 16-2000 of 20 November 2000 (Code forestier, Loi n ° 16-2000 of 20 November 2000) provides in article 164 that the exploitation or importation of genetic material without prior consent of the minister responsible for water and forest issues

and the minister in charge of matters related to scientific research and technology is going to incur a fine between 1,000,000 and 10,000,000 CFA francs (approximately between 499,75 and 4997,49 US dollars) and imprisonment for one to three months.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

M. Madzou Moukili
Ministère de l´Environnement, du Développement Durable et du Bassin du Congo
Tour NABEMBA - 11 ème étage
Brazzaville
Congo

ABS NFP
+242 05 525 81 51
+242 81 0330

6. Websites

National CHM – Congo
http://cg.chm-cbd.net

Congo Biodiversity Initiative
http://www.congobiodiv.org/en

ABSCH Congo Profile
https://absch.cbd.int/countries/CG

CBD Congo Profile
https://www.cbd.int/countries/?country=cg

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Congo profile. Available in: https://absch.cbd.int/countries/CG Access on 11/22/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Congo profile. Available in: https://www.cbd.int/countries/?country=cg Access on 11/22/2021.

REPUBLIQUE DU CONGO. **Cinquieme Rapport National Sur La Diversite Biologique**. Progamme Des Nations Unies Pour L'environnement. Fonds Mondial Pour L'environnement. 2014. Available in: https://www.cbd.int/countries/?country=cg Access on 11/22/2021.

REPUBLIQUE DU CONGO. **Strategie Nationale Et Plan D'actions Sur La Diversite Biologique (Revise)**. 2015. Available in: https://www.cbd.int/countries/?country=cg Access on 11/22/2021.

Côte D'Ivoire[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 27th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has 1 IRCCs that can be found on the ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The term access and benefit sharing is treated briefly in two moments of the law "Loi n° 2014-390 du 20 juin 2014 - D'Orientation sur le Développement Durable": Article 5.7. establishes the principle of fair and equitable sharing of benefits arising

1. The information hereinafter has been updated until September 9th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

from the exploitation of genetic resources, which requires the State to develop appropriate regulations on access and sharing of genetic resources, knowledge and technologies of local communities; and article 24 reinforces the State's duty to guarantee the rights of communities to genetic resources and the fair and equitable sharing of benefits arising from their exploitation.

Also, even though there is no specific legislation to regulate access to the genetic heritage and associated traditional knowledge of the country, the current legislation and article 12 of the "Loi n° 2014- 427 du 14 Juillet 2014" (Ivorian Forestry Code) establish that the State should elaborate norms to regulate this matter.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The ABSCH website and the 6th National Report indicate that The Ministry of Environment and Sustainable Development (Ministère de l'Environnement et du Développement Durable - MINEDD) is the only Competent National Authority designated as responsible for all matters related to genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Nevertheless, the 6th National Report (2019) stipulates that a draft of the decree relating to sharing of benefits arising from the use of genetic resources is operational and is currently being examined. Also, an ad hoc committee has been set up for the analysis of access permit requests.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Nevertheless, article 50 of the Ivorian Forestry Code establishes that the import or export of specimens of forest plants, seeds and

forest genetic resources, as well as the introduction of species from the sea, are subject to prior authorization by the Forestry Administration. In addition, the law sets that conditions of import, export and introduction of any specimen of plant or fauna from the sea are specified by decree of the Council of Ministers. However, the law is not clear whether this authorization is only for cases where access will occur abroad or for any commercial transaction involving export/import.

2.8. Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, Loi n° 2014-390 du 20 juin 2014 - D'Orientation sur le Développement Durable and Loi n° 2014- 427 du 14 Juillet 2014 (Ivorian Forestry Code) establish that the State should elaborate norms to regulate this matter.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Nevertheless,, the Ivorian Forestry Code sets that import or export of specimens of forest plants, seeds and forest genetic resources, as well as the introduction of species from the sea, are subject to prior authorization by the Forestry Administration, but the law is not clear whether this authorization is only for cases where access will occur abroad or for any commercial transaction involving export/import.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

In Côte d'Ivoire, the environmental inspection body is the Ministère de l'Environnement, the Salubrité Urbaine et du Développement Durable. However, according to the 6th National Report (2019) an ad hoc committee has been set up for the analysis of access permit requests.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

Authority	Competence
Ministère de l'Environnement, de la Salubrité Urbaine et du Développement Durable	Competent national body on environmental issues.

6. Websites

National CHM - Côte d'Ivoire
http://ci.chm-cbd.net

Ministère de l'Environnement, de la Salubrité Urbaine et du Développement Durable (MINEDD)
http://www.environnement.gouv.ci/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Côte d'Ivoire profile. Available in: https://absch.cbd.int/countries/CI Access on 05/03/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Côte d'Ivoire profile. Available in: https://www.cbd.int/countries/?country=ci Access on 09/09/2021.

RÉPUBLIQUE DE CÔTE D'IVOIRE. Sixième Rapport National Sur La Diversité Biologique. Ministère de l'Environnement, de la Salubrité Urbaine et du Développement Durable. Décembre 2018. Available in: https://www.cbd.int/doc/nr/nr-06/ci-nr-06-fr.pdf. Access on 09/09/2021.
RÉPUBLIQUE DE CÔTE D'IVOIRE. Loi 2014-390 du 20 juin 2014 d'orientation sur le développement durable. Available on: https://www.ecolex.org/details/legislation/loi-2014-390-du-20-juin-2014-dorientation-sur-le-developpement-durable-lex-faoc140677/ Access on 09/09/2021.

RÉPUBLIQUE DE CÔTE D'IVOIRE. Loi N°2014- 427 Du 14 Juillet 2014 Le nouveau Code forestier ivoirien. Available in: https://absch.cbd.int/api/v2013/documents/6920AC93-3BFD-FA16-5ED0-B0075ED8AC26/attachments/CODE%20FORESTIER%20ORIGINAL.pdf. Access on 09/09/2021.

RÉPUBLIQUE DE CÔTE D'IVOIRE. Strategie Et Plan D'action Pour La Diversité Biologique Nationale 2016-2020. Ministère de l'Environnement, de la Salubrité Urbaine et du Développement Durable. Available in: https://www.cbd.int/countries/?country=ci Access on 09/09/2021.

Democratic Republic of the Congo[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since March 3rd, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since May 5th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Nature Conservation Act of February 2014 (Loi N° 14/003 du 11 Février 2014, relative a la conservation de la nature) - articles of Title III, Chapters I to IV establish how the access to

1.The information hereinafter has been updated until November 22nd, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

genetic heritage and associated traditional knowledge shall happen.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. Nevertheless, on the ABSCH website the country indicates the Ministry of Environment and Sustainable Development as the competent authority. Also, the State declares that "a decree relating to the organization and functioning of the ANC has already been drawn up and validated by the parties, and is awaiting signature. According to this decree, it is the ANC that grants access to genetic resources and associated traditional knowledge, and issues the ABS permit".

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 58 of the Nature Conservation Act, all access activities in the country are subject to a permit, that its procedures shall be covered in a specific decree regarding the subject. In addition, the referred law establishes that prior informed consent and mutually agreed terms are required.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The Nature Conservation Act of January 2014 does not present a specific procedure for access to associated traditional knowledge, although article 56 mentions the need to obtain prior informed consent.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
Although there are no specific procedures for requesting patents, the aforementioned Law establishes that access to genetic resources and associated traditional knowledge imply co-property of intellectual property rights and joint venture with the provider.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
There are no specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
There is no specific procedure for shipping samples. Nonetheless, it should be remembered that in the case of export for commercial, scientific or other purposes of genetic resources without the written authorization of the competent national authority, the penalty indicated in article 81 (as described in item 4.2) is doubled.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The legislation does not foresee species that have naturally developed their distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and it incides over access, as provided in Articles 60 and 61 of the Nature Conservation Act of January 2014 (Loi Relative to the Conservation of Nature, 2014). The allocation may be in monetary or non-monetary mode (sustainable social and institutional support, as well as technology transfer). A value for monetary benefits is not defined, however, article 61 states that the State is entitled to receive 16% of the monetary benefits of access associated with the biological and genetic resources made by the local community.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The Law does not establish specific procedures for benefit sharing other than what is mentioned in 3.1 According to the Interim National Report, there will be a decree containing provisions that address this topic[5].

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Payment, royalties, fees, access rights per sample, provision of services and research funding	Not defined	Genetic Heritage/ ATK	Community/ State
Non Monetary	Not defined	Transfer of technology, sustainable institutional and social support	Not defined	Genetic Heritage/ ATK	Community/ State

5. The Access and Benefit-Sharing Clearing-House. Interim National Report on the Implementation of the Nagoya Protocol. Democratic Republic of the Congo. 28/11/2017.

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Nature Conservation Act of January 2014 (Loi Relative de la Conservation de la Nature, 2014) establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: Articles 81 and 82 indicate the imprisonment from six months to one year and a fine of one million to five million francs Congolese (498,38 to 2491,90 US dollars) or one of these penalties for those who exploit traditional knowledge or innovations associated with the genetic resources of local communities for scientific, commercial or other purposes without the prior written consent of these communities. The penalty shall be doubled in case of export of genetic resources for commercial, scientific or other purposes without the written permission of the competent national authority. In the case of access to genetic resources based on false consent, the punishment will be imprisonment of one to five years and a fine of fifty million to one hundred million Congolese francs (24919,01 to 49838,03 US dollars) or one of these penalties. The court may also order the withdrawal of the access authorization.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Environment and Sustainable Development (Ministére de l'Environnement et Développement Durable)	Responsible for granting access to genetic resources and associated traditional knowledge, and issues the ABS permit

6. Websites

Centre d'Echange d'Informations de la RD Congo Convention sur la diversité biologique
http://cd.chm-cbd.net/

ABSCH Democratic Republic of Congo Profile
https://absch.cbd.int/countries/CD

CBD Democratic Republic of Congo Profile
https://www.cbd.int/countries/?country=cd

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Democratic Republic of the Congo profile. Available in: https://absch.cbd.int/countries/CD Access on 11/23/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Democratic Republic of the Congo profile. Available in: https://www.cbd.int/countries/?country=cd Access on 11/23/2021.

DEMOCRATIC REPUBLIC OF THE CONGO. The Access and Benefit-Sharing Clearing-House. Interim National Report on the Implementation of the Nagoya Protocol. 11/23/2021..
REPUBLIQUE DEMOCRATIQUE DU CONGO. Cinquième rapport national sur la mise en œuvre de la Conservation sur la Diversité Biologique. Ministère de l'Environnement, Conservation de la Nature et Tourisme. Direction du Developpement Durable. 2014. Available in: https://www.cbd.int/countries/?country=cd Access in 11/23/2021.

REPUBLIQUE DEMOCRATIQUE DU CONGO. Loi n° 14/003 du 11 février 2014 relative à la conservation de la nature. Available in: https://www.ecolex.org/details/legislation/loi-n-14003-du-11-fevrier-2014-relative-a-la-conservation-de-la-nature-lex-faoc140376/?q=&type=legislation&xkeywords=biodiversity&xcountry=Congo%2C+Dem.+Rep.+of&xdate_min=&xdate_max= Access in 11/23/2021.

REPUBLIQUE DEMOCRATIQUE DU CONGO. Strategie Et Plan D'action Nationaux De La Biodiversite (2016-2020). Ministere De L'environnement, Conservation De La Nature Et Developpement Durable. 2016. Available in: https://www.cbd.int/countries/?country=cd Access on 11/23/2021.

Djibouti[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 30th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 1st, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Article 44 of the country's Environmental Code (Loi n ° 51 / AN /

1. The information hereinafter has been updated until October 22nd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

09 / 6ème L portant Code de l'Environnement) establishes the need for prior authorization to access genetic resources of the country, however, this same device determines that this topic shall be addressed in specific regulations.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

According to article 44 of the Environment Code of Djibouti Loi n ° 51 / AN / 09 / 6e L Portant Code de l'Environnement), the prior authorization granted by the Minister of the Environment is mandatory in cases of collection of genetic resources for commercial exploitation or scientific research.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

In the country, according to Law No. 50/AN/09/6 L on the Protection of Industrial Property, in its art. 34, the disclosure of an invention which made use of genetic, biological or traditional knowledge should be set out in detail by specifying the technical field to be used by the invention, a description of the origin of such resources or knowledge and the manner in which such resources or knowledge were obtained.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body? Are there any records of fines having been applied by such institutions?

( ) YES / (X) NO / ( ) NOT AVAILABLE

In Djibouti, the Ministère de l'Habitat, de l'Urbanisme, l'Environnement et l'Aménagement du Territoire is the environmental inspection body. However, there is no information that is the specific body to monitor access to genetic resources.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any record of emblematic biopiracy cases or disputes related to access and benefit sharing in the country?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Djibouti profile
https://absch.cbd.int/countries/QA

CBD Djibouti profile
https://www.cbd.int/countries/?country=qa

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Djibouti. Available in: <https://absch.cbd.int/countries/QA>. Accessed on 10/22/2021.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Djibouti. Available in: <https://www.cbd.int/countries/?country=qa> Accessed on 10/22/2021.

RÉPUBLIQUE DE DJIBOUTI. **5ème Rapport Convention sur la Diversité Biologique**. Ministère De L'habitat, De L'urbanisme DE L'environnement Et De L'aménagement Du Territoire.

Direction De L'amenagement Du Territoire Et De L'environnement. 2014. Available in: https://www.cbd.int/countries/?country=dj Accessed on 10/22/2021.

RÉPUBLIQUE DE DJIBOUTI. Loi n°51/AN/09/6ème L portant Code de l'Environnement. Available in: https://www.ecolex.org/details/legislation/loi-n51an096eme-l-portant-code-de-lenvironnement-lex-faoc092357/ Accessed on 10/22/2021.

RÉPUBLIQUE DE DJIBOUTI. **Stratégie Et Programme D'action National De La Diversité Biologique**. Ministère De L'habitat, De L'urbanisme DE L'envlronnement Et De L'aménagement Du Territoire. Direction De L'amenagement Du Territoire Et De L'environnement. 2006. Available in: https://www.cbd.int/countries/?country=dj Accessed on 10/22/2021.

Egypt[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since August 31st, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the Sixth National Report of the Country, there is a draft law on ABS under discussion in the Parliament, but it could not be identified by this

1. The information hereinafter has been updated until November 15th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

research.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / ( ) NO / (X) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. However, the Interim National Report on the Implementation of the Nagoya Protocol of 2018 indicates that there are competent institutions on the subject. Most of this report is in the local language, which is why it could not be analyzed by this research.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 200 of the Law 82 of 2002 on intellectual property rights, a register of intellectual property rights which includes plant genetic resources shall disclose its origin and its acquisition shall have been in accordance with Egyptian law. This also applies to traditional knowledge associated with genetic resources of plant varieties.

According to the same article, the use of genetic resources for development of new varieties shall be subject to approval of relevant competent authorities, and there shall be sharing of benefits.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Egypt Profile
https://absch.cbd.int/countries/EG

CBD Egypt Profile
https://www.cbd.int/countries/?country=eg

7. References

ACCESS AND BENEFIT-SHARING CLEARING HOUSE - ABSCH. Country Profiles. Egypt. Available in: https://absch.cbd.int/countries/EG. Access on: 11/15/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Egypt. Available in: https://www.cbd.int/countries/?country=eg. Access on: 11/15/2020.

EGYPT. Interim National Report on the Implementation of the Nagoya Protocol. The Access and Benefit Sharing Clearing House (ABSCH). 2018. Available in: https://absch.cbd.int/pdf/documents/absNationalReport/ABSCH-NR-EG-240988/1. Access on 11/15/2020.

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EGYPT. Egypt's Sixth National Report To The Convention On Biological Diversity. 2019. Available in: https://chm.cbd.int/database/record?documentID=246662 Access on 11/15/2020.
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GALAL, Salah. Farm Animal Genetic Resources in Egypt: Factsheet. Animal Production Department, Faculty of Agriculture. 2007. Available in: ftp://ftp.fao.org/docrep/fao/010/a1250e/annexes/Subregional%20reports/NearMiddleEast.pdf Access on 04/10/2016

Eritrea[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since June 19th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since June 11th, 2019.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE

1. The information hereinafter has been updated until November 11th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. Nevertheless, the Revised National Biodiversity Strategy and Action Plan for Eritrea indicates the Ministry of Land Water and Environment, Forestry and Wildlife Authority, Ministry of Agriculture, Ministry of Marine Resources, Ministry of Local Government, Ministry of National Development, Ministry of Justice, Ministry of Information, Research institutions, academia UNCBD as the institutions responsible for implementing norms related to the Nagoya Protocol.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 What are the applicable procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated .

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

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6. Websites

ABSCH Eritrea Profile
https://absch.cbd.int/countries/ER

CBD Eritrea Profile
https://www.cbd.int/countries/?country=er

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. DOMINICA. Available at: https://absch.cbd.int/countries/DM. Access on 05/11/2020.

AFREEN, Shamama; ABRAHAM, Biju Paul. **Bioprospecting: Promoting and Regulating Access to Genetic Resources and Benefit Sharing**. Indian Institute of Management Calcutta, Working paper series, nº 631, Calcuta, 2008. Available at: <https://www.iimcal.ac.in/sites/all/files/pdfs/wps-631_1.pdf> Access in: 05/11/2020.

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Available at: <http://www.lead-journal.org/content/10130.pdf> Access in: 05/06/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Dominica profile. Available at: https://www.cbd.int/countries/?country=dm. Access on 05/05/2020.

ERITREA; MINISTRY OF AGRICULTURE. **Regulations for the Issuance of Wildlife Permits**, 2006. Available at: <http://www.endangeredearth.com/wp-content/uploads/es_laws/Eritrea-Regulations-for-the-issuance-of-wildlife-permits-L.N.-No.-1122006.pdf> Access on: 05/06//2020.

ERITREA; MINISTRY OF AGRICULTURE. **Regulations for the Issuance of Forestry Permits**, 2006. Available at: <http://extwprlegs1.fao.org/docs/pdf/eri68048.pdf> Access on: 05/06/2020.

ERITREA; MINISTRY OF AGRICULTURE. The Forestry and Wildlife Conservation and Development Proclamation, 2006. Available at: <http://extwprlegs1.fao.org/docs/pdf/eri68045.pdf> Access on: 05/06/2020.

ERITREA; MINISTRY OF LAND, WATER AND ENVIRONMENT; DEPARTMENT OF ENVIRONMENT. **National Biosafety Framework for Eritrea,** 2007. Available at: <https://unep.ch/biosafety/old_site/development/Countryreports/ERNBFrep.pdf> Access on: 05/06/2020.

ERITREA; MINISTRY OF LAND, WATER AND ENVIRONMENT DEPARTMENT OF ENVIRONMENT. Revised national Biodiversity Strategy and Action Plan for Eritrea (2014-2020), 2015. Available at: <http://extwprlegs1.fao.org/docs/pdf/eri158247.pdf>. Access on: 05/06/2020.

Eswatini[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 7th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since December 20th, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

1. The information hereinafter has been updated until November 9th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The ABSCH website identifies the Eswatini Environment Authority as the competent institution, which is responsible for all genetic resources in the country.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The Interim National Report on the Implementation of the Nagoya Protocol informs that there are administrative guidelines on ABS in the country, but they could not be identified or analyzed by this study.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the Interim National Report on the Implementation of the Nagoya Protocol, benefit-sharing is addressed in the administrative guidelines on ABS in the country, but they could not be identified or analyzed by this study.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the Interim National Report on the Implementation of the Nagoya Protocol, benefit-sharing is addressed in the administrative guidelines on ABS in the country, but they could not be identified or analyzed by this study.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found. According to the Interim National Report on the Implementation of the Nagoya Protocol, the administrative guidelines were developed under the Environmental Management Act, which address measures for non compliance.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Eswatini Environment Authority	This institution is responsible for all matters of genetic resources in the country.

6. Websites

ABSCH Eswatini Profile
https://absch.cbd.int/countries/SZ

CBD Eswatini Profile
www.cbd.int/countries/?country=sz

Environment Authority
http://www.sea.org.sz/index.asp

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Swaziland profile. Available on: https://absch.cbd.int/countries/SL Access on 11/09/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Swaziland profile. Available on: https://www.cbd.int/countries/?country=sl Access on 11/09/2020.

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SWAZILAND. Interim National Report on the Implementation of the Nagoya Protocol. Ministry of Tourism and Environmental Affairs.Available on: https://absch.cbd.int/pdf/documents/absNationalReport/ABSCH-NR-SZ-239001/1 Access on 03/04/2020

Ethiopia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since July 4th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 1 IRCC for commercial purposes that is available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Ethiopia has the following laws on access to genetic heritage and associated traditional knowledge:

1. The information hereinafter has been updated until December 20th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Access to Genetic Resource and Community Knowledge, and Community Rights Proclamation n 482/2006 (Law 482/2006) - concerning the access to genetic resources and community knowledge and rights;

- Regulations on the Access to Genetic Resource and Community Knowledge, and Community Rights Proclamation n 169/2009 (Law 169/2009) - defines the powers and duties of the executive institutions within the scope of access to genetic resources and community knowledge;

- Forest Development, Conservation and Utilization Proclamation (Proclamation No. 1065/2018) - states that the Government shall allow the participation of local communities in the sharing of benefits from the forest and develop a system in order to determine benefit sharing rights of forest products;

- Proclamation To Amend The Institute Of Biodiversity Conservation And Research (Proclamation No 381/2004) - establishes that the Institute shall explore and survey the diversity and distribution of the country's plant, animal, and microbial genetic resources; collect samples for ex situ conservation and facilitate utilization of these genetic resources for research and development.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

According to Law 482/2006 Article No. 26, the competent institution for genetic resources and wild animals is the Ministry of Agriculture and Rural Development. In addition to the Ministry, article 27 of the Law 482/2006, establishes powers and duties to the Institute of Biodiversity Conservation, including: following-up and ensuring that the access is carried out in accordance with the law, collecting the benefits to be obtained from benefit-sharing arrangements and preparing model access agreements.

Also, according to the mechanism "The Access and Benefit-Sharing Clearing-House", the National Competent Authority of Ethiopia is the Ethiopian Biodiversity Institute (EBI).

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Law 482/2006, concerning access to genetic resources and community knowledge, establishes in its article 12 (1) the need to obtain a permit before the access to genetic resources can be achieved. The request must be submitted to the Institute of Biodiversity Conservation.

The procedures that describe how access requests shall be made are described under article No. 14 of the referred law. According to article 3 of law 169/2009, the application for the permit to access genetic resources or community knowledge must be submitted according to the format included under Annex I of the referred Law.

Article 15 of Law 482/2006 discusses the granting of special access permits for the purpose of development and academic research activities involving national researchers in institutions based in the country. This special case allows the Institute of Biodiversity Conservation to grant authorizations without strictly following the access procedures established by the law. In this case, the applicant shall use the access request model presented in Annex II of Law 169/2009.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Notwithstanding the procedures described in item 2.3, in cases where access to associated traditional knowledge is concerned, Law 482/2006 provides in its article 12 (1) that access to traditional knowledge is subject to prior informed consent granted by the local community. In this case, Law 169/2009 provides further specifications concerning how the prior informed consent should be submitted, informing which entities are representing the communities, among other procedures.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. In cases where patents arise from research or technological developments involving the access to genetic resources accessed, the access permit holder is required to negotiate a new agreement with the Institute of Biodiversity Conservation, according to article 17(12) of Law 482/2006. Also, article 17(13), of the referred law states that it is an obligation of the access permit holder not to apply for a patent or any other intellectual property protection over the community knowledge accessed without first obtaining explicit written consent from the Institute of Biodiversity Conservation.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. In cases where there is shipment of samples of genetic resources found in in situ or ex situ conditions in Ethiopia, the user is required to request an export authorization in accordance with article No. 11 (3) of Law 482/2006. In addition to that, article No. 12 (6) of the referred law states that the research based on the genetic resources accessed shall be carried out in Ethiopia and with the participation of Ethiopian nationals designated by the Institute, unless it is not possible.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and it comprises the utilization of their genetic resources and community knowledge. The responsibility to share the benefits lies with the applicant.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Articles 18 and 19 of Law 482/2006 regulates Benefit-Sharing under the following terms: (1) The kind and amount of the benefit to be shared by the State and local communities resulting from access to genetic resources or community knowledge shall be determined on a case-by-case basis in each specific contract to be signed; (2) The remaining portion of the monetary benefit from access to genetic resources, after deducting the share of the local community as determined pursuant to article 9, item 1 of this law, shall be allocated for conservation of biodiversity and the promotion of community knowledge (3) The sharing of non-monetary benefits from access to genetic resources among the State and the concerned local community shall be specified in each access agreement taking into account the kinds of benefits agreed to be shared with the access permit holder.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	License fee Upfront payment Milestone payment Royalty Research funding Others	Not defined	Not defined	State and local communities

Non Monetary	Not defined	Joint ownership of intellectual property; Employment opportunity; Participation of Ethiopian nationals from the Institute or the relevant institutions in the research based on the genetic resources or community knowledge accessed; Priority to supply the raw material of genetic resource required for producing products there form; Access to products and technologies developed from the use of genetic resource or community knowledge accessed; Training, both at institutional and local communities levels, to enhance local skills in genetic resources conservation, evaluation, development, propagation and use; Provision of equipment, infrastructure and technology support; Others	Not defined	Not defined	State and local communities

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Law 482/2006, in article No. 20(1), institutes the Institute of Biodiversity Conservation as the official inspection body responsible for all matters related to access and benefit-sharing in the country. In addition to that, the Ethiopian Environmental Protection Authority (EPA) has the role of protecting and monitoring environmental issues in general.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 35 of Law 482/2006 establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as:

Without prejudice to the confiscation of the genetic resource accessed, the cancellation of the access permit granted, and of the resulting civil liability, violations will be punished, depending on the gravity of the circumstance, with rigorous imprisonment of not less than 3 years and a fine of not less than 10,000 and not exceeding 30,000 Birr.

When the offense committed is in relation to genetic resources endemic to Ethiopia, the punishment shall be, depending on the circumstance, rigorous imprisonment for no less than 5 years and not exceeding 12 years, and a fine ranging from 50,000 to 100,000 Birr. Where the offenses under the referred article are committed in negligence, the penalty shall be a fine of no less than 5,000 Birr or, depending on the circumstances and gravity of the offense, simple imprisonment for no less than 3 months.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, one emblematic public dispute related to biopiracy was the case of the dispute regarding the controversial patent on Ethiopia's national cereal teff.

5. Summary - Competent Authorities

Authority	Competence
Ethiopian Biodiversity Institute (Institute of Biodiversity Conservation)	All matters related to the access to genetic resources and community knowledge

6. Websites

CBD Clearing House Mechanism of Ethiopia
http://et.chm-cbd.net

ABSCH Ethiopia's Profile
https://absch.cbd.int/en/countries/ET

CBD Ethiopia's Profile
https://www.cbd.int/countries/?country=et

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Ethiopia profile. Available in: https://absch.cbd.int/countries/ET Access on 12/20/2021..

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Ethiopia profile. Available in: https://www.cbd.int/countries/?country=et Access on 12/20/2021..

REPUBLIC OF ETHIOPIA. Access to Genetic Resources and Community Knowledge and Community Rights Proclamation (Proclamation No. 482/2006). Available in: https://absch.cbd.int/ countries/ET Access on 12/20/2021.

REPUBLIC OF ETHIOPIA. Access to Genetic Resources and Community Knowledge, and Community Rights Council of Ministers Regulation No. 169/2009. Available in: http://goalgoole.com/
regulation-no-1692009-access-to-genetic-resources-and-community-knowledge-and-community-rights-council-of-ministers-regulation/ Access on 12/20/2021.

REPUBLIC OF ETHIOPIA. Ethiopia's Fifth National Report to the Convention on Biological Diversity. Ethiopian Biodiversity Institute. 2014. Available in: https://www.cbd.int/countries/?country=et Access on 12/20/2021.

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WILHELM, Jan Philipp. Ethiopian teff: The fight against biopiracy. Available in: https://www.dw.com/en/ethiopian-teff-the-fight-against-biopiracy/a-52085081. Access on 12/20/2021.

Gabon[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since June 12th, 1997.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until November 15th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / ( ) NO / (X) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. According to the Sixth National Report on the Convention on Biological Diversity, the country has established a National Competent Authority, but no further information was found about it.

2.3. Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the Interim National Report on the Implementation of the Nagoya Protocol (2018), there are dispositions regarding sanctions on environment matters in Law 007/2014 related to the Protection of Environment and in the Forestry Code (Law 016/2001).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. One emblematic case of biopiracy relates to the patent of an isolated protein found in "brazzein/J'oublie", a berry from Gabon, which has sweetening properties. This protein was patented by an USA university and no benefit sharing to Gabon was identified.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Gabon Profile
https://absch.cbd.int/countries/GA

CBD Gabon Profile
https://www.cbd.int/countries/?country=ga

Ministère des Eaux, des Forêts, de la Mer de L'Environnement
http://www.eaux-forets.gouv.ga/

Centre d'Echange d'information du Gabon pour la biodiversité
http://ga.chm-cbd.net/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Gabon profile. Available in: https://absch.cbd.int/countries/GA Access on 11/16/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Gabon profile. Available in: https://www.cbd.int/countries/?country=ga Access on 11/16/2020.

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REPUBLIQUE GABONAISE. Second Rapport National Sur La Diversité Biologique. Ministere Des Eaux Et Forets, De La Peche, Du Reboisement Charge De L'environnement Et De La Protection De La Nature. Direction Generale De L'environnement. Observatoire National De La Biodiversite. 2004. Available on: https://www.cbd.int/countries/?country=ga Access in 05/10/2016.

REPUBLIQUE GABONAISE. Sixieme Rapport National Sur la Biodiversité. Ministere Des Eaux Et Forets, de la Mer, de l'Environment, Chargé du Plan Climat e du Plan d'Affectation des Terres. 2019. Available on: https://www.cbd.int/doc/nr/nr-06/ga-nr-06-fr.pdf. Access on 16/11/2020.

Gambia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since September 8th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

However, according to the Fifth National Report on the Convention on Biological Diversity

1. The information hereinafter has been updated until October 27th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

(2014), Gambia recognizes the need to develop a national regime on access and benefit-sharing, and since 2013 the Wildlife Conservation Bill which addresses access and benefit-sharing has been under analysis. Also, article 35 of the National Environment Act (1994) establishes the matter may be regulated in the future through a specific legal instrument.

The Sixth National Report on the Convention on Biological Diversity also stated that although the country does not have any legislation on the matter, it has developed a Roadmap on the implementation of the Nagoya Protocol. The same document establishes that policies such as the Biodiversity Wildlife Policy and National Environmental Management Act briefly address ABS.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The ABSCH website identifies the Department of Parks & Wildlife Management as the competent institution, which is responsible for all genetic resources in the country.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found. However, articles 41 and 42 of the National Environment Act (1994) provide that inspectors appointed by the National Environment Agency will have responsibility for carrying out inspections on environmental issues in general.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, it should be noted that the National Environment Act (1994), in its article 51 (concerning general offenses), provides that any natural or legal person who commits an offense under the provisions of this act or any regulations made thereunder, unless any other penalty is provided, will be liable on conviction to a fine not exceeding 3,000 Dalasi or imprisonment for not more than one year, in the case of natural persons, and a fine of not more than 20,000 Dalasi, in the case of a legal person.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

Authority	Competence
Department of Parks & Wildlife management	Responsible for all genetic resources in the country.

6. Websites

CBD Gambia Profile
https://www.cbd.int/countries/?country=gm

ABSCH Gambia Profile
https://absch.cbd.int/countries/GM

Ministry of Environment, Climate Change and Natural Resources, Department of Parks and Wildlife
http://meccnar.gm/content/department-parks-and-wildlife

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, ABSCH. Country profile. Gambia. Available in: <https://absch.cbd.int/countries/GM>. Access on:10/27/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Qatar. Available in: <https://www.cbd.int/countries/?country=gm> Access on: 10/27/2020.

MINISTRY OF MUNICIPALITY AND ENVIRONMENT, Mme. Página inicial. Available in: <http://meccnar.gm/content/department-parks-and-wildlife> Access on: 10/27/2020.

REPUBLIC OF THE GAMBIA. **National Environment Act (1994)**. Available on: http://www.ecolex.org/details/legislation/national-environment-management-act-1994-act-no-13-of-1994-lex-faoc006275/?xcountry=Gambia&type=legislation&page=2 Access on 10/27/2020.

REPUBLIC OF THE GAMBIA. **The Fifth (5th) National Report To The Convention Of Biological Diversity.** Department of Parks & Wildlife Management. Abuko, 2014. Available on: https://www.cbd.int/countries/?country=gm Access on 10/27/2020.

REPUBLIC OF THE GAMBIA. **The Sixth (6th) National Report To The Convention Of Biological Diversity**. Department of Parks & Wildlife Management. March 15, 2019 Available on: https://chm.cbd.int/database/record?documentID=243051 Access on 10/27/2020.

REPUBLIC OF THE GAMBIA. **The National Biodiversity Strategy And Action Plan (2015 – 2020)**.2015. Available in: https://www.cbd.int/countries/?country=gm Access on 10/27/2020.

Ghana[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 27th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since November 6th, 2019.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The African Union, of which Ghana is a member, elaborated a document named "AU Guidelines for the Coordinated Implementation of the Nagoya Protocol on ABS", also called "Model

1. The information hereinafter has been updated until November 9th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Law" to help its members to implement the Nagoya Protocol. However, the country still does not have a specific legislation regarding access to genetic heritage and associated traditional knowledge.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Alexander Asare
Chief Manager, Collaborative Resource Management
Resource Management Support Centre
Forestry Commission
P.O. Box 1457
Kumasi
Ghana

ABS National Focal Point
+0208149194 +0243819629
abasare99@yahoo.com

6. Websites

ABSCH Ghana Profile
https://absch.cbd.int/countries/GH

CBD Ghana Profile
https://www.cbd.int/countries/?country=gh

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Ghana Profile. Available at: https://absch.cbd.int/countries/GH Access on 11/09/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Ghana profile. Available at: https://www.cbd.int/countries/?country=gh Access on 11/09/2020.

GOVERNMENT OF GHANA. **CBD Fifth National Report**. Ministry of Environment, Science Technology and Innovation. December, 2015. Available at: https://www.cbd.int/countries/?country=gh Access on 05/15/2018.

GOVERNMENT OF GHANA. **Draft CBD Sixth National Report**. Ministry of Environment, Science Technology and Innovation. December, 2018. Available at: https://www.cbd.int/doc/nr/nr-06/gh-nr-06-en.pdf Access on 11/09/2020.

GOVERNMENT OF GHANA. **National Biodiversity Strategy for Ghana**. Ministry of Environment and Science. 2002. Available at: https://www.cbd.int/countries/?country=gh Access in 05/15/2018.

GOVERNMENT OF GHANA. **Act 575, Tradicional Medicine Practice Act, 2000**. Available at: http://laws.ghanalegal.com/acts/id/220/traditional-medicine-practice-act Access on 05/15/2018.

Guinea[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since January 5th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1. Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until November 10th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Interim National Report on the Nagoya Protocol identifies the Ministry of Environment, Waters and Forests (Ministère de l'Environnement, des Eaux et Forêts) and Observation Center of Environment Informations (Centre d'Observation et d'Informations Environnementales - COSIE) as the competent national authority.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Laye Condé
Chef Division Observation Atmosphérique et Aquatique
Centre d´Observation, de Surveillance et d´Information Environnementales (COSIE)
Ministère de l´environnement, des Eaux et Forêts (MEEF)
B.P. 761
Conakry
Guinea

ABS National Focal Point
+224 628 42 73 71, +224 624 39 74 33
layeconde.500@gmail.com
layeconde2016@yahoo.com
bahkadiatoukorka@gmail.com

6. Websites

ABSCH Guinea Profile
https://absch.cbd.int/countries/GN

CBD Guinea Profile
https://www.cbd.int/countries/?country=gn

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Guinea profile. Available in: https://absch.cbd.int/countries/GN Access on 31/07/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Guinea profile. Available in: https://www.cbd.int/countries/?country=gn Access on 31/10/2016.

RÉPUBLIQUE DE GUINÉE. **Stratégie Nationale Sur La Diversité Biologique Pour La Mise En Œuvre En Guinée Du Plan Strategique 2011 – 2020 Et Des Objectifs D'aichi.** Ministère De L'environnement, Des Eaux Et Forêts. 2016. Available in: https://www.cbd.int/countries/?country=gn Access on 05/10/2016.

RÉPUBLIQUE DE GUINÉE. **Cinquième Rapport National Sur La Mise En Œuvre De La Convention Sur La Diversité Biologique**. Ministère De L'environnement, Des Eaux Et Forêts. 2016. Available in: https://www.cbd.int/countries/?country=gn Access on 05/10/2016.

RÉPUBLIQUE DE GUINÉE. Interim National Report on the Implementation of the Nagoya Protocol. United Nations Environment. Published on March 26th, 2019.

Guinea-Bissau[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since January 25th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"4 under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

1. The information hereinafter has been updated until October 28th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

(X) YES / ( ) NO / ( ) NOT AVAILABLE
According to The Access and Benefit-Sharing Clearing-House, the competent national authority is Mr. Guilherme da Costa. There is no indication of position or competences, and the website only informs that he is the only competent authority in the country, responsible for all matters related to genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

According to the Fifth National Report to the Convention on Biological Diversity (2014), the country has the following institutions responsible for environmental inspection and control regarding biological diversity:

- Institute for Biodiversity and Protected Areas (IBAP);
- Unit for Environmental Impact Assessment (CAIA);
- State Secretariat for Environment and Sustainable Development.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Guilherme da Costa	Responsible for all genetic resources.

6. Websites

CBD Guinea-Bissau Profile
https://www.cbd.int/countries/?country=gw

ABSCH Guinea-Bissau Profile
https://absch.cbd.int/countries/GW

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, ABSCH. Country profile. Guinea-Bissau. Available in: <https://absch.cbd.int/countries/GW>. Access on: 10/28/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Guinea-Bissau. Available in: <https://www.cbd.int/countries/?country=gw> Access on: 10/28/2020.

REPUBLIC OF GUINEA-BISSAU. Fifth National Report to the Convention on Biological Diversity. Secretary Of State For Environment And Tourism. Bissau, 2014. Disponível em: https://www.cbd.int/countries/?country=gw Acesso em 18/10/2016.

REPUBLIC OF GUINEA-BISSAU. Strategy and National Action Plan for the Biodiversity 2015 – 2020. The State's General Office Of The Environment. 2015. Disponível em: https://www.cbd.int/countries/?country=gw. Acesso em 18/10/2016.

Kenya[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since October 24th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country is a Party to the Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoints:

- National Commission for Science, Technology and Innovation (NACOSTI)
- Kenya Copyright Board
- Kenya Agriculture and Livestock Research Organization (KALRO)
- Kenya Industrial Property Institute (KIPI)
- Kenya Plant Health Inspectorate Service (KEPHIS)
- Kenya Forest Service (KFS)
- National Museums of Kenya (NMK)
- Kenya Wildlife Service (KWS)

Also, according to the Sixth National Report on the Convention of Biological Diversity (2020), the country is developing additional legislation regarding ABS.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 82 IRCCs that are available on ABSCH website.

1. The information hereinafter has been updated until October 28th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Environmental Management And Coordination Act 1999
- Legal Notice No. 160 - The Environmental Management And Co-Ordination (Conservation Of Biological Diversity And Resources, Access To Genetic Resources And Benefit Sharing) Regulations, 2006
- The Wildlife Conservation and Management Act 2013
- The Seeds And Plant Varieties (Amendment) Act, 2012
- Protection of Traditional Knowledge and Cultural Expressions Act, 2016

The country also has accessory instruments to enforce the correct application of the aforementioned norms:

- The National Policy On Traditional Knowledge, Genetic Resources And Traditional Cultural Expressions, 2009.
- Kenya's Access and Benefit Sharing Toolkit for Genetic Resources and Associated Traditional Knowledge.
- The Swakopmund Protocol on the Protection of Traditional Knowledge and Expression of Folklore, 2007

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The National Competent Authority established by Kenya is the National Environment Management Authority - NEMA, created by the Environmental Management and Co-ordination Act No. 8 of 1999 (EMCA) Among its competences, article 9, item 1, establishes that this authority has the objective of supervising and coordinating all environment-related activities.

Finally, The Seeds And Plant Varieties (Amendment) Act, 2012 states a new competence for the National Center of Plant Genetic Resources, related to the protection of the ownership of indigenous seeds and plant varieties, their genetic and diverse characteristics, associated tradi-

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

tional knowledge and their use by the communities of Kenya.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Article 9 of Legal Notice No. 160 establishes that an authorization is required for accessing the genetic resources of Kenya, which must also include the payment of taxes. The authorization request must be accompanied by the Prior Informed Consent, specifically in relation to bioprospecting, The Wildlife Conservation and Management Act 2013 establishes that an authorization must be obtained from Kenya Wildlife Service.

Finally, the Kenya's Access and Benefit Sharing Toolkit for Genetic Resources and Associated Traditional Knowledge informs to those wishing to access the genetic resources of Kenya that some procedures must be carried out prior to the access, such as the identification of a local partner, the identification of the genetic resource provider, the request of a research license, the procurement of a researcher license, the procurement of prior informed consent and the signature of mutually agreed terms.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
The Protection of Traditional Knowledge and Cultural Expressions Act, published in 2016, establishes the need to require authorization to access protected traditional knowledge separately from access to genetic resources, in its article 26. Also, article 25 of the same legislation provides that there shall be benefit sharing, whether monetary or non-monetary, to be determined by a mutual agreement between the parties.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
According to article 18 of Legal Notice No. 160, a Material Transfer Agreement is required in order to transfer genetic material to outside of Kenya.

2.8. Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the legislation addresses this matter as the concept of DSI is comprised in the definition of genetic resources, which is "obtaining, possessing and using genetic resources conserved,

whether derived products, and, where applicable, intangible components, for purposes of research, bio-prospecting, conservation, industrial application or commercial use", as per Part I of the Legal Notice n. 160 (2006). The terminology used is "intangible components".

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

According to Article 20 of the Legal Notice No.160, the access permit holder is responsible for benefit sharing. The authorization holder must include in the sharing agreement both monetary and non-monetary benefits. The protection of Traditional Knowledge and Cultural Expressions Act (2016) also indicates on articles 21 and 24 that the authorization for access to traditional knowledge for commercial purposes shall contain a benefit-sharing arrangement that provides equitable monetary and non-monetary compensation to the right holders. They shall be determined by mutual agreement between the parties.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing. However, Part IV of Legal Notice No. 160 mentions monetary and non-monetary benefits, which are the same as the ones provided in the Nagoya Protocol.

The monetary benefits can be:

a. Access fees/fees per sample collected or acquired by any other means;

b. Up-front payments;

c. Milestone payment;

d. Payment of royalties;

e. License fees in case of commercialization;

f. Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;

g. Salaries and preferential terms where mutually agreed;

h. Research funding;

i. Joint ventures;

j. Joint ownership of relevant intellectual property rights.

As for non-monetary benefits, they can be:

a. Sharing of research and development results;

b. Collaboration, cooperation and contribution in scientific research and development programs, particularly biotechnological research activities whenever possible in the Part supplying the genetic resources;

c. Participation in product development;

d. Admittance to ex situ facilities of genetic resources and databases;

e. Transfer to Kenya of genetic resources of knowledge and technology under fair and most favorable terms, including concessional and preferential terms were agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;

f. Strengthening capacities for technology transfer to Kenya;

g. Institutional capacity-building;

h. Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

i. Training related to genetic resources with the full participation of Kenya and, where possible, in Kenya;

j. Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;

k. Professional and institutional relationships that can arise from access and benefit sharing agreements and subsequent collaborative activities;

l. Joint ownership of the relevant intellectual property rights.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	The same as the ones provided on Nagoya Protocol	Not defined	Genetic Heritage and Traditional Knowledge	Not defined
Non Monetary	Not defined	The same as the ones provided on Nagoya Protocol	Not defined	Genetic Heritage and Traditional Knowledge	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The National Competent Authority established by Kenya is the National Environment Management Authority - NEMA, created by the Environmental Management and Co-ordination Act No. 8 of 1999 (EMCA) Among its competences, article 9, item 1, establishes that this authority has the objective of supervising and coordinating all environment-related activities. However, there are no records of fines or sanctions applied by this institution.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The Legal Notice No. 160 establishes in its article 23 that any breach to the dispositions of this law will be considered an offense. According to article 24, the applicable penalties in that case is imprisonment for no longer than 18 months or a fine of up to 350,000 shillings (approximately 3095,98 US dollars), or both.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, there is one emblematic case of biopiracy and one public dispute. The public dispute is related to chemicals that are used to wash and fade jeans, which were patented by Genencor and use two kenyan organisms. The biopiracy case concerns the use of a bacterial strain called SE 50 to produce Acarbose, a medicine used to treat diabetes and which was patented by the pharmaceutical Bayer.

5. Summary - Competent authorities

Authority	Competence
National Environment Management Authority - NEMA	The National Competent Authority established by Kenya is the National Environment Management Authority - NEMA, created by the Environmental Management and Co-ordination Act No. 8 of 1999 (EMCA) Among its competences, article 9, item 1, establishes that this authority has the objective of supervising and coordinating all environment-related activities. However, there are no records of fines or sanctions applied by this institution.
National Center for Plant Genetic Resources.	Protection of the properties of indigenous seeds and plant varieties, their characteristics and genetic diversity, the associated traditional knowledge and their use by Kenyan communities.

6. Websites

Biodiversity Clearing House Mechanism for Kenya
http://meas.nema.go.ke/cbdchm/

ABSCH Kenya Profile
https://absch.cbd.int/en/countries/KE

CBD Kenya Profile
https://www.cbd.int/countries/?country=ke

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Kenya profile. Available in: https://absch.cbd.int/countries/KE Access on 12/15/2021.

AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION (ARIPO). Swakopmund Protocol On The Protection Of Traditional Knowledge And Expressions Of Folklore. Harare, 2010. Available in: http://www.wipo.int/edocs/trtdocs/en/ap010/trt_ap010.pdf Access on 12/15/2021.

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CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Fact-Finding Study on How Domestic Measures Address Benefit Sharing Arising From Commercial and Non-Commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequencia Information on Genetic Resources for Research and Development. CBD/DSI/AHTEG/2020/1/5. Access on 12/15/2021.

NATIONAL ENVIRONMENT MANAGEMENT AUTHORITY – NEMA. Access and Beneft Sharing From Utilization of Biological Resources & Associated Traditional Knowledge in Kenya. 2014. Available in: http://meas.nema.go.ke/abs/download/Access%20and%20Beneft%20Sharing%20brochure%20fnal.pdf Access on 12/15/2021.

REPUBLIC OF KENYA. Environmental Management and Co-ordination Act, 1999 (Cap. 387). Available in: https://www.ecolex.org/details/legislation/environmental-management-and-co-ordination-act1999cap387lexfaoc041653/?q=environmental+management&type=legislation&xcountry=Kenya&xdate_min=&xdate_max= Access in 12/15/2021.

REPUBLIC OF KENYA. Fifth National Report To The Conference Of Parties To The Convention On Biological Diversity. 2015. Available in: https://www.cbd.int/countries/?country=ke Access in 12/15/2021.

REPUBLIC OF KENYA. Seeds and Plant Varieties (Amendment) Act, 2012 (No. 53 of 2012). Available in: https://www.ecolex.org/details/legislation/seeds-and-plant-varieties-amendmentact-2012-no-53-of-2012-lex-faoc122296/?q=The+Seeds+And+Plant+Varieties+%28Amendment%29+Act%2C+2012&type=legislation&xcountry=Kenya&xdate_min=&xdate_max= Access in 12/15/2021.

REPUBLIC OF KENYA. Sixth National Report To The Conference Of Parties To The Convention On Biological Diversity. 2020. Available in: https://www.cbd.int/doc/nr/nr-06/ke-nr-06-en.pdf Access in 12/15/2021.

REPUBLIC OF KENYA. The Environmental Management And Co-Ordination (Conservation Of Biological Diversity And Resources, Access To Genetic Resources And Beneft Sharing) Regulations, 2006. Available in: https://www.ecolex.org/details/legislation/environmental-management-and-co-ordination-conservation-of-biological-diversity-and-resourcesaccesstogeneticresourcesandbeneftsharingregulations2006lnno160of2006lexfaoc071757/?q=The+Environmental+Management+And+CoOrdination+%28Conservation+Of+Biological++Diversity+And+Resources%2C+Access+To+Genetic+Resources+And+Beneft+Sharing%29+Regulations%2C+2006&type=legislation&xcountry=Kenya&xdate_min=&xdate_max=. Access in 12/15/2021.

REPUBLIC OF KENYA. The Kenya National Biodiversity Strategy And Action Plan. Ministry of Environment & Natural Resources. 2000. Available in: https://www.cbd.int/countries/?country=ke Access in 12/15/2021.

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REPUBLIC OF KENYA. Wildlife Conservation and Management Act, 2013 (No. 47 of 2013). Available in: https://www.ecolex.org/details/legislation/wildlife-conservation-and-management-act-2013-no-47-of-2013-lex-faoc134375/?q=The+Wildlife+Conservation+and+Management+Act+2013&type=legislation&xcountry=Kenya&xdate_min=&xdate_max=. Access on 12/15/2021.

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Lesotho[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since April 10th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since February 10th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in Lesotho. Nonetheless, Lesotho Environment Act 2008 establishes, in its Article 68, general provisions on access to the country's genetic resources and on the possibility of a more detailed regulation on the subject in the future. According to the Interim National

1. The information hereinafter has been updated until December 22nd, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Report on the Implementation of Nagoya Protocol (2019), the country has developed a draft Biodiversity law, but it could not be identified by this study.

The country is also a party to the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, which comprises access to traditional knowledge.

2.2. Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to the Interim National Report on the Implementation of Nagoya Protocol (2019), although the country has not yet developed specific ABS legislation, the Department of Environment requires Prior Informed Consent in order to grant permits for access to genetic resources. The procedures are based on the Environment Impact Assessment process, provided on Part V of the Environment Act 2008.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore establishes the requirement of prior authorization in articles 8.2 to 8.4, and also states that the authorization must be obtained in writing from the relevant community and must be approved by the national competent authority.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE
The Interim National Report on the Implementation of Nagoya Protocol (2019) states that the Department of Environment requires that applicants share benefits with communities in order to grant permits for access to genetic resources. Therefore, in this current procedure, benefit sharing in mandatory and the responsibility to share benefits lies on the applicant.

Also, Section 9 of the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, of which the country is a part of, provides that there shall be sharing of the benefits arising from commercial or industrial use of traditional knowledge, to be determined by mutual agreement between the parties. Those benefits may include non monetary benefits, according to the needs and preferences of the traditional communities involved.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the

Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Article 68 of the Lesotho Environment Act (2008) establishes under item 3 the applicable sanctions against violations to ABS requirements, which is a fine of up to M5,000 or imprisonment for a term not less than 2 years, or both.

Also, the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore establishes in its article 23.1 that each State shall provide for enforcement and dispute resolution mechanisms, as well as sanctions and remedies when there is a violation of the articles relating to the protection of traditional knowledge and expressions of folklore.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Lesotho Profile
https://absch.cbd.int/countries/LS

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Lesotho. Available in: <https://absch.cbd.int/countries/MU>. Access on: 12/22/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Lesotho. Available in: <https://www.cbd.int/countries/?country=ls> Access on: 12/22/2020.

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LESOTHO. **Lesotho Fourth National Report On Implementation of Convention on Biological Diversity**. Department of Environment. 2009. Available in: https://www.cbd.int/countries/?country=ls Access on 10/28/2019.

LESOTHO. **Interim National Report on the Implementation of the Nagoya Protocol**. 2019. Available in: https://absch.cbd.int/pdf/documents/absNationalReport/ABSCH-NR-LS-248560/1 Access on 12/23/2020.

LESOTHO. **Lesotho's Biological Diversity: Conservation and Sustainable Use**. National Environment Secretariat. Ministry of Environment, Gender and Youth Affairs. Maseru, 2000. Available in: https://www.cbd.int/countries/?country=ls Access on 10/28/2019.

Liberia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 6th, 2001.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since November 15th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Many documents have been found on the subject, however, the term "benefit sharing" is only associated with timber issues. On the other hand, section 86 of the Environment Protection and Management Law of Liberia states that the Environmental

1. The information hereinafter has been updated until October 29th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Protection Agency proposes a legislative initiative to address issues related to access to genetic resources in Liberia.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mrs. Frances B. Seydou
Supervisor, Environmental Unit
Department of Intersectoral Coordination
Environmental Protection Agency (EPA)
4th Street Sinkor, Tubman Boulevard
P.O. Box 4024
100-10
Monrovia
Liberia

ABS National Focal Point
+231 88 655 4295
brownefrance@yahoo.com

6. Websites

ABSCH Liberia Profile
https://absch.cbd.int/countries/LR

CBD Liberia Profile
https://absch.cbd.int/countries/LR

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Liberia. Available on: <https://absch.cbd.int/countries/LR>. Access in: 10/29/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Lesotho. Available on: <www.cbd.int/countries/?country=lr> Access in: 10/29/2020.

Libya[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since October 10th, 2001.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until November 9th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Hamzah Abdulkaber Ahmed
Environment General Authority (EGA)
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Libya

ABS National Focal Point
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6. Websites

ABSCH Libya Profile
https://absch.cbd.int/countries/LY

CBD Libya Profile
https://www.cbd.int/countries/?country=ly

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. LIBYA. Available at: https://absch.cbd.int/countries/LY. Access in: 11/09/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Libya Profile. Available at: https://www.cbd.int/countries/?country=ly Access in: 11/09/2020.

Madagascar[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since June 02nd, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

1. The information hereinafter has been updated until September 21st, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Decree nº 2017-066 about regulation of access and sharing of benefits arising from the use of genetic resources / Décret n°2017-066 du 31 Janvier 2017 portant réglementation de l'accès et du partage des avantages découlant de l'utilisation des ressources génétiques;

- Order nº 19831/2018 to the designation and functioning of the competent National authority in matters of access and sharing of benefits arising from the use of genetic resources / Arreté nº 19831/2018 Portant désignation et fonctionnement de l'autorité Nationale compétente en matière d'acces et de partage des avantages découlant de l'utilisation des ressources génétiques;

Also, before the Decree 2017-066, the Decree on the application of the Code of Protected Areas (Décret n ° 2005-13, organization de l'loi no 2001-005 portant Code de gestion des aires protégées) already provided in two articles the need to obtain an authorization for research and the establishment of an agreement to define the distribution of the scientific study, as well as the sharing of commercial benefits arising from the use of genetic resources accessed in the protected area.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to the Decree 2017-066, article 5, the competent institution is a structure within the Ministry responsible for the implementation of the Convention on Biological Diversity and the Nagoya Protocol. Also, Order nº 19831/2018 specified that Protected Areas System Directorate is responsible for the conclusion of mutually agreed terms and the Head of the Biodiversity Conservation Department gives the receipt of declaration for non-commercial research activities or, for commercial access, provides access authorization for applications after approval by the ad hoc commission.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Decree n°2017-066/2017 all access activities in the country depend on an authorization given by the Competent National Authority (CNA) that shall be requested by an Access Request Form (annexed to the Decree n°2017-066), which must include all information necessary for the CNA to make a determination on the merits of the application. After the applicant requests the authorization to access genetic resources, some documents must be provided, as so:

I. Prior informed consent (PIC) of landowners, local managers of natural resources on which the resource object of the access request is located, to be able to enter this site and carry out the resource collection;

II. Mutually Agreed Terms (MAT);

III. For a foreign applicant, a prior collaboration agreement for the project with a Malagasy public research organization.

After submitting the Access Request Form to the CNA, the authority may assist the applicant in collecting the prior informed consent (PIC) and Mutually Agreed Terms (MAT), according to Order nº 19831/2018 a technical secretariat is responsible for assisting applicants.

Also, if the object of the request is located in a land occupied or managed by private persons,

the applicant must have the prior informed consent (PIC) obtained from the natural or legal person in the power on the land to enter and collect the resources. In these cases, the consent shall be formalized, in writing, in the form of a Mutually Agreed Terms (MAT) and the document shall establish the monetary or non-monetary benefits granted in return for access to resources.

After this initial process, the CNA has 60 (sixty) days to answer this request. Nevertheless, if the CNA addresses the applicants during the assessment with questions or requests for additional information, the deadline may be extended for a reasonable response time. After this evaluation, the CNA shall deliver one of the following items to the applicant:

- The receipt of declaration for non-commercial research activities;

- Authorization of access to genetic resources for commercial purposes after a favorable technical opinion from the ad hoc commission.

According to the Decree nº 2017-066 this permit acquires the value of an international certificate according to article 17, paragraph 2 of Nagoya Protocol and is valid for one year, renewable.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The procedure is the same as the one described in item 2.3, in cases where access to associated traditional knowledge is concerned. It is necessary to have a PIC and MAT for access to Associated Traditional Knowledge. Article 14 of the Decree sets that for holders of ATK, consent is formalized in the form of a convention, which shall respect rules of customary law, values and traditional practices prescribed in the locality and must not be contrary to the law and the regulations in force. And, it must be written in a language understandable by the communities and the applicant.

Furthermore, if the traditional values and practices are already documented by a tool developed by the communities, this tool must be consulted and incorporated into the convention. Also, the agreement must specify the monetary and non-monetary benefits granted in return for access to resources. The State stresses that recognizes and protects the rights of local communities to benefit collectively from their knowledge of their natural and cultural heritage, innovations and practices acquired over generations.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis. Nevertheless, the decree establishes that research for commercial or potentially commercial purposes is only authorized if the applicant agrees to inform the National Competent Authority before making a request for intellectual property rights associated with the collected material or intellectual property related to an invention based on or associated with traditional knowledge obtained in Madagascar.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis. However, Decree nº 2017-066 establishes that the receipt of declaration for non-commercial research activities and authorization for access do not constitute export authorization. The methods of exporting genetic resources covered by this decree are regulated by other laws.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE
Yes, the Decree nº 2017-066, establishes the obligation to share benefits, as foreseen in article 2. The responsibility to share benefits, according to articles 33 and 34 of the decree, lies with who makes the access to genetic resources or associated traditional knowledge through Mutually Agreed Terms. Also, article 36 states that type and value of benefits shall be determined on a case-by-case basis and shall be shared with the State or other recipient as set forth in the written authorization for access and in the MAT.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE
According to Decree 2017-066, article 35, the Mutually Agreed Terms may include specific clauses, as a detailed description of how the resources will be used, the expected results, and the methods and amounts of funding mobilized, an evaluation of the monetary or non-monetary benefits that will result from the use of the resources and others.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	As defined on the Annex of Nagoya Protocol	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Not defined
Non Monetary	Not defined	As defined on the Annex of Nagoya Protocol	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Decree 2017-066 establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as:

In article 41, the decree establishes that any case of irregular access to genetic resource or traditional knowledge shall be suspended and withdrawn at any time by the CNA. Also, the suspension must not exceed two years. However, a permanent withdrawal of the authorization and the prohibition to carry out the same activity on the territory of Madagascar can be pronounced. These decisions must be reasonable and they are subject to an appeal to the competent authority. Still, according to article 43, any case of irregular access must be penalized according to national laws.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

Authority	Competence
Direction du Système de Aires Protégées (Protected Areas System Directorate) and Chef de Service de la Conservation de la Biodiversité (Head of the Biodiversity Conservation Department)	Protected Areas System Directorate - responsible for the conclusion of mutually agreed terms; Head of the Biodiversity Conservation Department - shall deliver receipt of declaration for non-commercial research activities or access authorization for applications for commercial access after approval by the ad hoc commission.

6. Websites

Website of Country profile of Madagascar in website of ABS
https://absch.cbd.int/countries/MG

Website of Country profile of Madagascar in website of CBD
https://absch.cbd.int/countries/GM

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Madagascar. Available in: <https://absch.cbd.int/countries/LU>. Access in: September 16th, 2021.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Madagascar. Available in: < www.cbd.int/countries/?country=lu> Access in: September 16th, 2021.

REPUBLIC OF MADAGASCAR. Décret N° 2017-066 du 30/01/2017 portant réglementation de l'accès et du partage des avantages découlant de l'utilisation des ressources génétiques. Available in:<https://absch.cbd.int/api/v2013/documents/1E13DEBB-A5F3-91A9-1CD0-D41D2B61A650/attachments/Madagascar_decret_ressources_genetiques_2017_066.pdf> Access on September 20th, 2021.

REPUBLIC OF MADAGASCAR. Arrête N° 19831/2018/MEEF Portant Designation et fonctionnement de l'autorite nationale competente en matiere d'acces et de partage des avantages decoulant de l'utilisation des ressources genetiques. Available in: < https://www.cbd.int/doc/nr/nr-06/mg-nr-06-fr.pdf> Access on September 20th, 2021.

REPUBLIC OF MADAGASCAR. **5th National Report of the Convention on Biological Diversity of Madagascar**. Ministry of Environment and Forests and National Office for the

Environment. 2014. Available in: https://www.cbd.int/countries/?country=mg Access on September 20th, 2021.

REPUBLIC OF MADAGASCAR. **Decree n ° 2005-13 organizing the application of the law nº 2001-005 bearing Code of management of the protected areas. 2005**. Available in: https://www.ecolex.org/en/details/legislation/decret-n-2005-13-organisation-lapplication-de-la-loi-no-2001-005-portant-code-de -management-of-protected-areas-lex-faoc092363 / Access on February 11, 2020.

SANBAR, Sarah. **Environmental Law in Madagascar: The Nagoya Protocol on Genetic Resource Use, Access and Beneft Sharing**. Independent Study Project (ISP) Collection. Paper 2176. 2015. Available in: http://www.digitalcollections.sit.edu/isp_collection/2176 Access on September 20th, 2021.

Malawi[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since May 3, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since November 24, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Although it is not a legislation that deals exclusively and specifically with access to genetic heritage and associated traditional knowledge, the Environment Management Act (1996) and (2017) is indicated by the country on the ABSCH website as the competent legislation on the

1. The information hereinafter has been updated until September 20th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

subject. In this sense, articles 4 and 36 of first legislation and articles 66, 67 and 68 of the recent legislation set out provisions related to genetic resources and the possibility that the subject may be further regulated in the future as to:

- Prohibit the exportation of germplasm, except in accordance with a license issued by the Minister and subject to such conditions as the Minister may impose;

- Provide for the sharing of benefits arising from the technological exploitation of germplasm originating from Malawi between the owner of the technology and the Government;

- Provide for fees payable in respect of an export license issued under subsection (2) (a) and for a charge payable for accessing germplasm.

- The authority shall protect, conserve and manage the genetic resources of the country in benefit of the people.

- The authority shall prescribe measures to:

  1. Regulate access to genetic resources by non-citizens or non-residents of Malawi

  2. Ensure that prior informed consent of communities is obtained and is an essential component for any arrangement in bio-prospecting

  3. Ensure effective equitable sharing of benefits and sustainable business mechanisms for the transfer of biotechnology

  4. Protect indigenous property rights of communities

  5. Prohibit or restrict any trade or traffic in any component of biological diversity

  6. Provide for fees payable in respect of accessing the resources and the export therefore and guidelines for reviewing of genetic materials and patenting requirements for indigenous species

  7. Regulate the collection, characterization, evaluation and documentation of plant genetic resources for food, agricultural and medicinal purposes and any other matters that the Authority may consider necessary for the sound management of the genetic resources of Malawi.

In addition, the country has two guides that do not have legal force: Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi, 2002) and Procedures and Guidelines for Conducting Research in Malawi. Malawi (Procedures and Guidelines for the Conduct of Research in Malawi, 2002).

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Although the law mentioned under item 2.1 does not indicate any institution with specific competence over access, the country's profile on the ABSCH website indicates the following competent institution (as a national competent authority on ABS): the Environmental Affairs Department, responsible for regulating the access to genetic resources and the benefit-sharing

for commercial purposes, as well as any type of export activities involving genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
In article 67 of the The Environment Management Act 2017, there is an indication of the need for prior authorization for access to genetic resources; Also, the Guide "Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi" (non-binding document) affirms, in its section D, that any research activities will require the approval of the National Research Council of Malawi (NRCM). According to information obtained from the National Focal Point, this procedure is done mainly in sectors such as Forestry, Parks and Wildlife that require authorization for access. In such cases, the provisions of the Malawi Forestry Act and the National Parks and Wildlife Act must also be observed.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for access to Associated Traditional knowledge were identified in the norms covered by this analysis.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The legislation does not establish any specific procedures for the shipment of samples; however, the Guide "Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi" (non-binding document) states, under item D, that local and foreign researchers wishing to export any genetic resources shall seek to obtain a license from the Minister of Natural Resources and Environmental Affairs.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing.

3.2 Are there any specific What are the applicable procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Environment Management Act 2017 establishes in article 104 the applicable sanction for accessing genetic resources in disagreement with the procedural rules, which is to pay a fee in value of twenty five millions kwacha (K25,000,000) and to imprisonment for twelve (12) years.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

Authority	Competence
Environmental Affairs Department	Responsible for regulating the commercial access to genetic resources, the sharing of benefits and any type of exportation of genetic resources.

6. Websites

ABSCH Malawi Profile
https://absch.cbd.int/countries/MW

CBD Malawi Profile
www.cbd.int/countries/?country=mw

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Malawi profile. Available in: https://absch.cbd.int/countries/MW Access in 12/17/2021

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Malawi profile. Available in: https://www.cbd.int/countries/?country=mw Access in 12/17/2021

GOVERNMENT OF MALAWI. Environment Management Act (No. 23 of 1996). Available in: https://absch.cbd.int/countries/MW Access in 12/17/2021

GOVERNMENT OF MALAWI. Environment Management Act (No. 19 of 2017). Available in: https://absch.cbd.int/countries/MW Access in 12/17/2021

GOVERNMENT OF MALAWI. Fifth National Report to the Convention on Biological Diversity. 2014. Available in: https://www.cbd.int/countries/?country=mw Access in 12/17/2021

GOVERNMENT OF MALAWI. National Biodiversity Strategy and Action Plan II. Ministry of Natural Resources, Energy and Mining. Available in: https://www.cbd.int/countries/?country=mw Access in 12/17/2021

GOVERNMENT OF MALAWI. Procedures and Guidelines for the Conduct of Research in Malawi. 2002. Available in: https://www.cbd.int/fnancial/bensharing/Malawi-sharing.doc Access in 12/17/2021

GOVERNMENT OF MALAWI. Procedures And Guideline For The Conduct Of Research In Malawi. Sustainable Development Network Programme – SDNP. Available in: http://www.sdnp.org. mw/nrcm/programmes/programmes.htm Access in 12/17/2021

Mali[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since June 27th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since November 29th, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the country has a draft law on the matter, which regulates access and benefit sharing arising from the utilization of genetic resources.

1. The information hereinafter has been updated until October 29th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. However, article 5 of the draft law identifies L'Autorité Nationale Competente (Competent National Authority) within the Ministère de l'Environnement, de l'Assainissement et du Développement Durable (Ministry of the Environment, Sanitation and Sustainable Development) as the competent institution.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Articles 9 and 10 of the draft law on ABS establish that access to genetic resources and associated traditional knowledge shall be subject to an authorization. The applicant shall present to the competent authority a written request containing Prior informed Consent and Mutually Agreed Terms, including provisions for sharing of benefits Then, the competent authority shall evaluate the request and issue an authorization (for utilization with commercial purposes) or a declaration receipt (for utilization with no commercial purposes), which shall function as an IRCC.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 14 of the draft law provides that in case of traditional knowledge associated with genetic resources, Prior Informed Consent shall be formalized in a Convention, which shall respect customary law, as well as traditional values and practices.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Article 31 of the draft law states that before requesting intellectual property rights regarding genetic resources or associated traditional knowledge, the user shall inform the competent national authority.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and

procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 32 of the draft law on ABS states that benefits shall be monetary or non monetary, and may be shared before, during or after the utilization of genetic resources or traditional knowledge. The value and type of benefits shall be decided on a case by case basis.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the

Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Article 40 of the draft law on ABS establishes that activities regarding access to genetic resources and associated traditional knowledge performed without authorization shall be suspended, without prejudice of criminal or customs prosecutions.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

M. Thièman Drame
Ingénieur
Direction Nationale des eaux et forêts
Ministère de l´Environnement, de l´assainissement et du développement durable
B.P. 275
Bamako
Mali

ABS National Focal Point
+223 20 23 36 95 +223 20 23 36 97
+223 20 23 36 96
vieuxthiemandrame@yahoo.fr
thiemandrame@gmail.com

6. Websites

Website of Country profile of Mali in ABS website of ABS
https://absch.cbd.int/countries/ML

Website of Country profile of Mali in CBD website
https://www.cbd.int/countries/?country=ml

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Mali. Available in: <https://absch.cbd.int/countries/ML>. Access on: 10/30/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Mali. Available in: <https://www.cbd.int/countries/?country=ml> Access on: 10/30/2020.

REPUBLIQUE DU MALI. **Strategie Nationale Et Plan D'actions Pour La Diversité Biologique, Mali**. Ministère De L'environnement De L'eau Et De L'assainissement, Direction Nationale Des Eaux Et Forêts. 2014. Available in: https://www.cbd.int/countries/?country=ml Access on October 30, 2019.

REPUBLIQUE DU MALI. **Cinquième Rapport National Sur La Mise En Œuvre De La Convention Sur La Diversité Biologique**. Ministère De L'environnement De L'eau Et De L'assainissement, Direction Nationale Des Eaux Et Forêts. 2014. Available in: https://www.cbd.int/countries/?country=ml Access on October 30, 2019.

RÉPUBLIQUE DU MALI. Avant Projet de décret sur L'Accès et du Partage des Avantages découlant de L'Utilisation des Ressources Génétiques. Available at: https://chm.cbd.int/api/v2013/documents/177A0109-89EE-1E9A-5E7E-140D6FA3211A/attachments/Avant%20projet%20de%20d%C3%A9cret%20sur%20APA%202018%20.pdf. Access in: 10/30/2020.

Mauritania[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 14th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since November 16th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoints:

- Abdarahmane O/Mohamed

General coordinator of the mobile control brigade at the Ministry of the Environment and Sustainable Development.

- Mohamed O/Babatt

Delegate of West Nouakchott for the Ministry of the Environment and Sustainable Development.

- Laghdaf O/M'Bareck

Delegate of North Nouakchott for the Environment and Sustainable Development.

- Hademine Moustapha.

Regional delegate of South Nouakchott, Ministry of the Environment and Sustainable Development.

- Ebnou O/Ahmed

Delegate of Trarza for the Ministry of the Environment and Sustainable Development.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

1. The information hereinafter has been updated until October 22nd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The ABSCH website identifies the Ministère de L'Environnement et du Développement Durable (Ministry of Environment and Sustainable Development) as the competent institution, which is responsible for all matters related to genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

tage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

Authority	Competence
Ministère de L'Environnement et du Développement Durable (Ministry of Environment and Sustainable Development)	Responsible for all matters related to genetic resources.

6. Websites

ABSCH Mauritania Profile
https://absch.cbd.int/countries/MR

CBD Mauritania Profile
https://www.cbd.int/countries/?country=mr

Ministère de L'Environnement et du Développement Durable
http://www.environnement.gov.mr/fr/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Mauritania profile. Available in: https://absch.cbd.int/countries/MRR Access on 07/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Mauritania profile. Available in: https://www.cbd.int/countries/?country=mrr Access on 07/10/2020.

RÉPUBLIQUE ISLAMIQUE DE MAURITANIE. **CDB Cinquième Rapport National sur la Biodiversité**. Ministere de L'Environnement et du Développement Durable. Coordination des Programmes Biodiversité & CITES. 2014. Available in: https://www.cbd.int/countries/?country=mr Access on 06/10/2016.

RÉPUBLIQUE ISLAMIQUE DE MAURITANIE. **Strategie et Plan S'Action National de la Biodiversité 2011 – 2020**. Ministere de L'Environnement et du Developpement Durable. Coordination des Programmes Biodiversité. Available in: https://www.cbd.int/countries/?country=mr Access on 06/10/2016.

Mauritius[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession/ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. It should be noted that the country has a legislation regarding authorization for scientific research regarding marine genetic resources, which is the Maritime

1. The information hereinafter has been updated until October 28th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Zones (Conduct of Marine Scientific Research) Regulations 2017.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Vishnou Gondeea
Permanent Secretary
Ministry of Agro Industry and Food Security
Levels 9, Renganaden Seeneevassen Building
Millard St.
Port-Louis
Mauritius

ABS National Focal Point
+230 210 2713
vgondeea@govmu.org

6. Websites

ABSCH Mauritius Profile
https://absch.cbd.int/countries/MU

CBD Mauritius Profile
https://www.cbd.int/countries/?country=mu

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Lesotho. Available in: <https://absch.cbd.int/countries/LS>. Access on: 10/28/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Mauritius. Available in: <https://www.cbd.int/countries/?country=mu> Access on: 10/28/2020.

REPUBLIC OF MAURITIUS. **Fifth National Report on the Convention on Biological Diversity**. Ministry Of Agro-Industry And Food Security. 2015. Available in: https://www.cbd.int/countries/?country=mu Access on 10/28/2020.

REPUBLIC OF MAURITIUS. **National Biodiversity Strategy and Action Plan 2017 – 2025**. Ministry of Agro Industry and Food Security. 2017. Available in: https://www.cbd.int/countries/?country=mu Access on 10/28/2020.

Morocco[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 19, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Protocol, but has been a signatory country since December 9, 2011.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, there is a law project about access to genetic resources and benefit-sharing available in ABSCH website:

- Projet de loi 56-17 sur l'accès aux ressources génétiques et le partage juste et équitable

1. The information hereinafter has been updated until October 19th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

des avantage découlant de leur utilisation (Bill 56-17 on access to genetic resources and the fair and equitable sharing of benefits arising from their use).

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address provide specific procedures for digital sequence information, or synthetic biology or similar terminologies ? If so, What is the specific terminology used in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific What are the applicable procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However,

it has a National Focal Point recognized by the Convention on Biological Diversity:

Nagoya Protocol on Access and Benefit-sharing

M. Mostafa Madbouhi
Ministère de l´Énergie, des Mines et des l´Environnement
9, Avenue Al Araar, section 16 Hay Ryad
Rabat
Morocco

CBD Primary NFP, CHM NFP, CHM Informal Advisory Committee, ABS NFP, ABS Clearing House Publishing Authority, Cartagena Protocol Primary NFP, BCH NFP
madbouhi@environnement.gov.ma
+212 5 37 57 06 02

6. Websites

Website of Country profile of Morocco in ABS website
https://absch.cbd.int/countries/MA

Website of Country profile of Morocco in CBD
www.cbd.int/countries/?country=ma

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Morocco profile. Available in: https://absch.cbd.int/countries/MA Access on February 13, 2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Morocco profile. Available in: https://www.cbd.int/countries/?country=ma Access on February 13, 2020.

ROYAUME DU MAROC. Cinquième rapport national sur la mise en œuvre de la Convention **sur la Diversité Biologique**. Global Environment Facility (Fonds pour l'environnement mondial – FEM). 2014. Available in: https://www.cbd.int/countries/?country=ma Access on February 13, 2020.

ROYAUME DU MAROC. Law **No. 2-00 on Copyright and Related Rights (promulgated by Dahir No. 1-00-20 of 9 Kaada 1420 (February 15, 2000)**). Available in: http://www.wipo.int/wipolex/en/details.jsp?id=2985 Access in February 13, 2020.

ROYAUME DU MAROC. Loi n° 34-05 modifiant et complétant la Loi n° 2-00 relative au droits **d'auteur et droits voisins (promulguée par Dahir n° 1-05-192 du 14 février 2006)**. Available in: http://www.wipo.int/wipolex/en/text.jsp?fle_id=136955 Access in February 13, 2020.

ROYAUME DU MAROC. Stratégie et Plan d'Actions National pour la Diversité Biologique du Maroc, 2016-2020. Ministre déléguée chargée de l'Environnement. Ministère de l'Énergie, des Mines, de l'Eau et de l'Environnement. 2016. Available in: https://www.cbd.int/countries/?country=-ma. Access in February 13, 2020.

ROYAUME DU MAROC. Project de loi sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation. Secrétariat d'Etat auprès du Ministre de l'Energie, des Mines et du Développement Durable, Chargé du Développement Durable. Available in: <https://absch.cbd.int/database/record/ABSCH-MSR-MA-238754>. Access in February 13, 2020.

Mozambique[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 23rd, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The country has only one specific regulation, Decree No. 19, of Aug 9, 2007, which approves the Regulation on Access and Benefit Sharing arising from Genetic Resources and Associated Traditional Knowledge.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

1. The information hereinafter has been updated until December 22nd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Article 4, item 1, of the Decree No. 19/ 2007 identifies the Minister for the Coordination of Environment Action as the competent institution, which is responsible for: granting permits for the access and shipment of components of genetic resources and associated traditional knowledge; inspecting the shipment of samples of genetic resources and associated traditional knowledge; publishing a list of facilitated exchange species; accrediting institutions as trustees; authorizing access to components of genetic resources and associated traditional knowledge that are not associated to bioprospecting, if a foreign legal person is involved; producing and periodically disseminating a list of current permits of access and shipment of samples, material transfer agreements and contracts on the use of genetic resources and benefit sharing and; approving all the complementary norms required for the implementation of the legislation.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Articles 7 to 9 of Decree No. 19/2007 establish the procedures and obligations for obtaining access to genetic resources and traditional knowledge in the country. In this sense, it is necessary to submit a prior request for the collection of samples and/or information. Only national public or private research and development institutions in the biological or related areas may be accredited for the collection, which does not mean that the participation of a foreign legal person is forbidden. In the case of international shipment of samples, the National Authority must issue a permit before the sample is transferred to another country.

According to Articles 7 to 9 of Decree No. 19/2007, all access activities in the country are subject to prior authorization and must contain Prior Informed Consent from:

- The local community involved, with the participation of the legal authority;
- The competent institution, when the process occurs in a protected area;
- The holder of the rights to land use and improvement, when access occurs in an area where such rights are applicable;
- The competent fishing or maritime authority, when access takes place in Mozambican jurisdictional waters, on the continental shelf and in the exclusive economic zone.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis. Articles 14 and 15 of Decree No. 19/2007 establish, however, that local communities that own traditional knowledge associated to genetic resources have the right to:

- Receive information about place of origin of the access to traditional knowledge in all publications, uses, activities and announcements;
- Prevent unauthorized third parties from using, conducting tests, research or exploration activities related to the associated traditional knowledge or from publishing, transmitting or retransmitting data or information that integrate or constitute an associated traditional knowledge;

- Receive benefits from the direct or indirect economic exploration of associated traditional knowledge by third parties.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 26 of Decree No. 19/2007, for registering intellectual or industrial property rights, the applicant must inform the origin of the genetic material and associated traditional knowledge, when applicable.

It must be noted that the country has an "Intellectual Property Strategy 2008 - 2018", which provides in its section 6.5.2 the need to establish an effective legal framework for the promotion and protection of genetic resources and traditional knowledge.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, Articles 11 and 12 of Decree No. 19/2007 establish specific procedures in the case of shipment of samples of the country's genetic resources and/or associated traditional knowledge. In this sense, the shipment is only authorized if related to materials in ex situ conditions and if a material transfer agreement has been signed in advance, along with the signature of a Contract of Use of Genetic Resources and Benefit Sharing, if there is interest in the commercial exploration of the product or process derived from the access.

Finally, it should be noted that the shipment of samples is a procedure used for the transfer of samples both within and outside the country. In the case of international shipments, the National Authority must issue a prior authorization.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE
The legislation does not provide specific procedures for digital sequence information, but its concept is comprised on the definition of "genetic resource", as the "information of genetic origin (...)".

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, for when its economic potential is identified in the product or process. The benefit-sharing obligation is linked to the potential for economic use of the products or processes arising from access to genetic resources and/or associated traditional knowledge, according to articles 19 to 24, of Decree No. 19/2007.

The responsibility to share the benefits lies with the beneficiary institution. Prior to the access, a Contract for the Utilization of Genetic Resources and Benefit Sharing shall be agreed, it must be approved and registered by the National Authority in order to be effective, and it shall include the minimum requirements established in article 23.

In this matter, the 6th National Report (2019) affirms that there is still no legal regime in Mozambique that effectively protects traditional knowledge.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

There is no legal definition of values, although article 21 establishes that the fair and equitable sharing of benefits can be carried in the following modalities:

- Sharing of Profits;
- Royalties payment;
- Access and transfer of technologies.
- Licensing, free of charge, of products and processes;
- Capacity-building of human resources.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Economic exploitation	Not defined	Genetic Heritage/ATK	Community
Non Monetary	Not defined	Right to intellectual property	-	Genetic Heritage/ATK	Community

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

According to article 5, c) of Decree No. 19/2007, it is the responsibility of the National Authority (Minister for the Coordination of Environment Action) to inspect any shipments of samples containing components of genetic resources and associated traditional knowledge. Apart from that, the regulation does not indicate any competent authority or institution responsible for inspecting access activities in general and more broadly.

In addition, article 27 provides for the possibility of decentralization of inspection activities, as well as for the possibility of confiscation by the competent institutions of any samples of genetic resources or any products obtained from associated traditional knowledge.

No concrete cases were found during the survey in relation to the application of fines.
Also, according to the 6th National Report (2019), there is no benefit sharing oversight, and measures to implement national legislation on ABS were ineffective, due to the lack of resources.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
The sanctions are provided for in articles 22 and 25 of Decree No. 19/2007. In this sense, the economic exploitation of products or processes derived from the access to genetic resources or associated traditional knowledge without a proper authorization, or without observing the provisions of this Decree, shall subject the offender to two alternative sanctions: the payment of a minimum compensation of 60% of the gross revenue obtained from the product's commercialization or the payment of royalties obtained from third parties by the offender, without prejudice to other applicable administrative and criminal sanctions.
In addition, the following sanctions may be applied, in the case of administrative offenses:

- Warning;
- Fine, which may vary from 100,000 MT to 1,000,000 MT in the case of a legal person, and 50,000 MT to 500,000 MT in the case of a natural person;
- Confiscation of any samples containing genetic resources components as well as any instruments used in the collection or processing of the products obtained from information on associated traditional knowledge;
- Confiscation of products derived from samples containing components of genetic resources or associated traditional knowledge;
- Withdrawal from sales of any products derived from samples containing components of genetic resources or associated traditional knowledge and their confiscation.
- Embargo of the activity;
- Partial or complete ban on the facility, activity or enterprise;
- Suspension of register, patent, license or authorization;
- Cancellation of register, patent, license or authorization;
- Loss or restriction of incentives and fiscal benefits granted by the government;

- Loss or suspension of participation in credit lines from official credit institutions;
- State intervention on the facilities;
- Prohibition to contract with the Public Administration, for a period of time of up to five years.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Coordination of Environmental Affairs	• Granting permits for the access and shipment of components of genetic resources and associated traditional knowledge; • Inspecting the shipment of samples of genetic resources and associated traditional knowledge; • Publicizing a list of facilitated exchange species; • Accrediting institutions as trustees; • Authorizing access to components of genetic resources and associated traditional knowledge, that are not associated to bioprospecting, when a foreign legal person is involved; • Producing and periodically disseminating a list of current permits of access and shipment of samples, material transfer agreements and contracts on the use of genetic resources and benefit sharing; • Approving all the complementary norms required for the implementation of the legislation.

6. Websites

No websites concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Mozambique profile. Available in: https://absch.cbd.int/countries/MZ Access on 12/22/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Mozambique profile. Available in: https://www.cbd.int/countries/?country=mz Access on 12/22/2021.

REPÚBLICA DE MOÇAMBIQUE. Decreto nº 19/2007. Available in: http://www.at.gov.mz/por/content/download/1411/10747/fle/Decreto%20n.%C2%BA%209-2008%20de%2016%20de%20Abril.pdf Access in 12/22/2021.

REPÚBLICA DE MOÇAMBIQUE. Fifth National Report on the Implementation of Convention on Biological Diversity in Mozambique. Ministry For The Coordination Of Environmental Affairs. Maputo, 2014. Available in: https://www.cbd.int/countries/?country=mz Access on 12/22/2021.

REPUBLIC OF MOZAMBIQUE. Sixth National Report on the Implementation of Convention of Biological Diversity in Mozambique. Ministry of Land, Environment and Rural Development. 2019. Available in: https://www.cbd.int/doc/nr/nr-06/mz-nr-06-en.pdf. Access on 12/22/2021.

REPÚBLICA DE MOÇAMBIQUE. National Strategy And Action Plan Of Biological Diversity Of Mozambique (2015-2035). Ministério Da Terra, Ambiente E Desenvolvimento Rural (Mitader). Maputo, 2015. Available in: https://www.cbd.int/countries/?country=mz Access on 12/22/2021.

Namibia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since August 14th, 1997.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the Access to Biological and Genetic Resources and Associated Traditional Knowledge Act 2 of 2017 regarding access and benefit-sharing.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

1. The information hereinafter has been updated until July 30th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Yes. The ABS Act 2 of 2017. identifies the Biological and Genetic Resources and Associated Traditional Knowledge Office as the competent institution, which is responsible for regulating access to biological and genetic resources and associated traditional knowledge and providing for the creation of rules, procedures and guidance in obtaining prior informed consent and mutually agreed terms with the local communities. Also, the Office is subordinate to the Ministry of Environment and Tourism and regulates all access to genetic resources and traditional knowledge.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to ABS Act 2 of 2017, all access activities in the country shall be subject to a permit, including access to biological and genetic resources in Namibia, found in both in situ or ex situ conditions or parts of such biological and genetic resources, their derivatives, products, including synthetic products, and wherever applicable, intangible components, including genetic information or gene sequences, and associated traditional knowledge.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Notwithstanding the procedures described in item 2.3, in cases where access to associated traditional knowledge is concerned, prior informed consent is required. For obtaining access to genetic resources or/and traditional knowledge, the user should notify the Office and take the necessary guidance from the Office.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / (X) NO / ( ) NOT AVAILABLE
Yes. According to the Industrial Property Act, 2012 on cases where patents arise from research or technological developments involving the access to genetic resources or traditional knowledge, the applicant is required to disclose in the application for a patent the country providing the resources or associated indigenous or traditional knowledge, from whom in the providing country they were obtained, and, as known after reasonable inquiry, the country of origin and any other information regarding the source or nature of the resources as may be prescribed.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and it shall be paid when the following happens: research and development on the biological, genetic or biochemical composition of biological and genetic resources, including through the application of biotechnology to such biological and genetic resources or their derivatives. The responsibility to share the benefits lies on the user.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Listed in article 10 2.a of the ABS Act No 2 of 2017	Not defined	Not defined	Not defined
Non Monetary	Not defined	Listed in article 10 2.a of the ABS Act No 2 of 2017	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Access to Biological and Genetic Resources and Associated Traditional Knowledge Act No 2 of 2017 institutes the Minister of Environment and Tourism as the official inspection body responsible for all matters related to access and benefit-sharing in the country.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Access to Biological and Genetic Resources and Associated Traditional Knowledge Act 2 of 2017 establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: payment to a liable not to exceed N150.000 (approximately 9578,22 US dollars) and or to the possibility the imprisonment until ten years, for all kinds of offences against the ABS rules.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. There is an emblematic case of biopiracy involving a community in Namibia. The Sans people are a traditional community in the south of the African continent. These people have had an interesting plant used as food for a thousand years and its use interested some companies from South Africa. In the 90's a group of south africans' researchers developed a substance using the traditional knowledge of the San's over the plant. After that, this group of researchers sold these products to a Pharmacal company from the U.S and turned on a warming signal on San people, who saw your traditional knowledge being taken. Although, there's no record of fines registered in the country.

5. Summary - Competent Authorities

Authority	Competence
Ministry of Environment and Tourism	It's the head of the ABS system in Namibia, with the competence to create the Office, which shall regulate and determine all rules about access to traditional knowledge and genetic resources.
Biological and Genetic Resources and Associated Traditional Knowledge Office	This office is subordinated to Minister of Environment and Tourism and has the competence to regulate access to biological and genetic resources and associated traditional knowledge; provide for the creation of rules, procedures and guidance in obtaining prior informed consent of and establishing mutually agreed terms with the local communities´; facilitate applications for access to biological and genetic resources and associated traditional knowledge, including the issuing of permits authorising access and Promote building and developing technological capacity of national and grassroots level on scientific capabilities in the fields of conservation and sustainable use of biological and genetic resources and associated traditional knowledge.

6. Websites

ABSCH Namibia's Profile
https://absch.cbd.int/countries/NA

CBD Namibia's Profile
www.cbd.int/countries/?country=na

Website of Ministry of Environment and Tourism
http://www.met.gov.na/

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Namíbia. Available in: < https://absch.cbd.int/countries/NA>. Access on: 12/22/2021.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Namíbia. Available in: <www.cbd.int/countries/?country=na> Access on: 12/22/2021.

SAN VICTORIOUS IN BIO-PIRACY CASE. Cultural Survival. 2018 Available in: https://www.culturalsurvival.org/news/san-victorious-bio-piracy-case Access in: 12/22/2021.

MINISTRY OF ENVIRONMENT AND TOURISM. Namibia Government. 2019. Available in: <http://www.met.gov.na/>. Access on: November 12/22/2021.

REPUBLIC OF NAMIBIA. Fifth National Report to the Convention on Biological Diversity (2010-2014). Ministry of Environment and Tourism; Department of Environmental Affairs. Available in: https://www.cbd.int/countries/?country=na Access on 12/22/2021.

REPUBLIC OF NAMIBIA. Namibia's Second National Biodiversity Strategy And Action Plan 2013 – 2022. Ministry of Environment and Tourism; Department of Environmental Affairs. Available in: https://www.cbd.int/countries/?country=na Access on 12/22/2021.

REPUBLIC OF NAMIBIA. Sharing the Benefts of Nature: Legitmate access to Namibia's biological and genetic resources for scientific and commercial purposes. Ministry of Environment and Tourism; Directorate of Environment, Interim Bio-prospecting Committee (IBPC). 2010. Available in: http://www.met.gov.na/policies-legislation/reports/288/ Access on 12/22/2021.

SCHRODER, Kauna; and VRANCKX, Sarah. Country Status Review Paper On Access And Benefit Sharing And Liability And Redress In Namibia. Regional Agricultural and Environmental Initiatives Network Africa. 2012. Available in: http://www.met.gov.na/policies-legislation/reports/288/ Access on 12/22/2021.

Cultural Survival. San Victorious in Bio-Piracy Case. available at: https://www.culturalsurvival.org/news/san-victorious-bio-piracy-case Access on 12/22/2021.

Niger[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since October 23rd, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The country does not have a specific law to regulate access to genetic heritage and associated traditional knowledge. However, Loi No 98- 56 of 29 December 1998 concerning the Management of Environnement, which, in article 6, states that the genetic resources to which Niger exercises sovereignty can only be accessed with prior consent, and it is incumbent upon the State to take the necessary legislative and administrative measures to ensure the fair and equitable

1. The information hereinafter has been updated until December 22nd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

sharing of benefits.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, the country does not have a specific law on access to genetic resources and associated traditional knowledge. However, Loi No 98- 56 of 29 December 1998 determines that the State shall take the necessary legislative and administrative measures to ensure fair and equitable benefit-sharing.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

M. Issaka Maman Sani
Conseiller
Division de la Diversité Biologique
Conseil National de l´Environnement pour un Développement Durable (CNEDD)
B.P. 10 193
Niamey
Niger

ABS National Focal Point
+227 96 68 01 26, +227 84 81 89 17
issaka.mamnsani@yahoo.fr

6. Websites

National CHM

http://ne.chm-cbd.net

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE - ABSCH. Country Profiles. Niger profile. Available at: https://absch.cbd.int/countries/NE Access on 12/22/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Niger profile. Available at: https://www.cbd.int/countries/?country=ne Access on 12/22/2021.

REPUBLIQUE DU NIGER. Cinquieme Rapport National Sur La Diversite Biologique. Conseil National de l'Environnement pour Développement Durable (Secretariat Executif); Fonds pour l'Environnement Mondial (FEM); Program of the United Nations for Environ- ment (UNEP). 2014. Available at: https://www.cbd.int/countries/?country=ne Access on 12/22/2021.

REPUBLIQUE DU NIGER. Loi-cadre du 29 décembre 1998 concerning the management of the environment. Available at: https://www.ecolex.org/details/legislation/loi-cadre-du-29-decembre-1998-relative-a-la-gestion-de-lenvironnement-lex-faoc019572/?type=legislation&xcountry=Niger&xkeywords=environmental+planning&page=2 Access on 12/22/2021.

REPUBLIQUE DU NIGER. Strategie Nationale Et Plan D'actions Sur La Diversite Biologique, 2ème édition. Conseil National de l'Environnement pour Développement Durable (Secretariat Executif); Fonds pour l'Environnement Mondial (FEM); Program of the United Nations for Environ- ment (UNEP). 2014. Available at: https://www.cbd.int/countries/?country=ne Access on 12/22/2021.

Nigeria[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 27, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country is a Party to the Protocol, by ratification, since September 27th, 2022.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the document "Interim National Report on the Implementation of the Nagoya Protocol", the country has a Law on the matter that is in force, in addition to having drawn up a national policy on the subject, which is in the process of be-

1. The information hereinafter has been updated until July 27th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

ing implemented. However, such norms were not identified for evaluation and inclusion of this study until the present moment.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. According to the document "Interim National Report on the Implementation of the Nagoya Protocol", the country has a competent institution on the subject. However, this institution has not been identified by this study until the present time.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the official document "Interim National Report on the Implementation of the Nagoya Protocol", prior and informed consent is a necessary condition for signing the Mutually Agreed Term. However, no regulation on the subject has been identified, thus it is not possible to detail the procedures required.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed

distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access

to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Although there's any legislation regulating access to traditional knowledge or imposing limits to them, in Nigeria there's records of Biopiracies cases. One of them is reported by Bababtunde Oni and Emeka Amechi in an article "Combating the scourge of insider biopiracy in nigeria: The law of unjust enrichment offer solution to the misappropriation of traditional knowledge on the medicinal uses of plants?" that cited two patents resulted by use of extracts of Vernonia amygdalina, an African medicinal plant popularly called Bitter leaf and widely used in Nigeria as a traditional way for the treatment of several diseases, like, diabetes and cancer.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Ahmed Labaran
Chief Scientific Officer
Federal Department of Forestry
Federal Ministry of Environment
Plot 393/394, Augustus Aikhomu Way
Utako District
Abuja
Nigeria

ABS National Focal Point
+234 806 829 1626
labaranahmed98@gmail.com

6. Websites

ABSCH Belarus Profile
https://absch.cbd.int/countries/NG

CBD Belarus Profile
www.cbd.int/countries/?country=ng

7. References

NIGERIA. **Fifth National Biodiversity Report**, 2015. Available at: <https://www.cbd.int/doc/world/ng/ng-nr-05-en.pdf> Access on September 25, 2020.

NNADOZIE, Kent, et al. **African Perspectives on Genetic Resources**: A Handbook on Laws, Policies, and Institutions, 2003. Available at: <https://www.eli.org/sites/default/files/eli-pubs/d13-17.pdf> Access in: 05/24/2018.

Rwanda[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since August 27th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since March 20th, 2012.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, Law No. 70-2013, of Sep 2, 2013, establishes the management and conservation models for the Rwandan biological diversity.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

1. The information hereinafter has been updated until July 30th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found, as, Law No. 70-2013, of Sep 2, 2013 does not indicate the competent authority.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Article 27 of law No. 70-2013, of Sep 2, 2013, all access activities in the country must comply with the procedures described below:

Partnership with local institution if foreign,: the user shall partner with a local institution, prior to beginning the research process.

Identification of the intended providers: the user shall identify the intended provider.

Application for research: the user shall apply for the permit for research with the National Commission for Science and Technology, and if in a National Park, the user shall apply for a permit before the Rwanda Development Board (RDB).

PIC and MTA: when a provider is identified, the user shall negotiate with the providers for obtaining a Prior Informed Consent and entering Mutually Agreed Terms, which will contain information about the benefit sharing.

Access permit: the user shall apply for an Access permit.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Law No. 70-2013, of September 2, 2013, which regulates Biodiversity in Rwanda, provides in its article 28 that before the permit established in article 27 of this law is granted, considerations shall be made regarding the interests of the person, community and State giving access to (1) Indigenous biological resources to which the application relates; (2) Traditional uses of indigenous biological resources; (3) Knowledge or discoveries about indigenous biological resources.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Law No. 70-2013, of Sep 2, 2013, which regulates Biodiversity in Rwanda, does not indicate any specific procedures for the patents application for research and technological developments deriving from access.

It is worth-noting that Law 31-2009, of Oct 26, 2009, of the Protection of Intellectual Property, states in its final and transitory provisions, chapter one, article 289, that the protection of rights related to the discovery of plants, genetic resources, traditional knowledge and folklore is regulated by a specific law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Law No. 70-2013, of Sep 2, 2013 does not provide for specific procedures for collection and access of exotic species. However, the Guideline and Toolkit for Access and Benefit Sharing of Traditional Knowledge Associated with Genetic Resources in Rwanda, by the Rwanda environment Management Authority states that exotic species are excluded from ABS Guidelines[5].

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The legislation does not establish procedures for shipment of samples. However, article 27 of Law No. 70-2013 requires prior authorization for the export of indigenous biological resources.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE

There are no specific procedures related to digital sequence information or synthetic biology.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The legislation does not foresee species that have naturally developed their distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Although the Law No. 70-2013, of Sep 2, 2013 does not explicitly addresses this issue, according to the aforementioned Guideline and Toolkit, benefit-sharing is mandatory[6]. The responsibility to share the benefits lies on the user, who shall include benefit sharing provisions on the MTA.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

The only article of Law No. 70-2013, of Sep 2, 2013 (which regulates Biodiversity in Rwanda) that addresses the subject of benefit sharing is article 29; without, however, establishing the relevant procedures, norms or values.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

5. RWANDA ENVIRONMENT MANAGEMENT AUTHORITY. Guideline and Toolkit for Access and Benefit Sharing of Traditional Knowledge Associated with Genetic Resources in Rwanda: Information for Providers, Users, and Regulatory Institutions. Kigali, Rwanda, 2019, p. 20.
6. RWANDA ENVIRONMENT MANAGEMENT AUTHORITY. Guideline and Toolkit for Access and Benefit Sharing of Traditional Knowledge Associated with Genetic Resources in Rwanda: Information for Providers, Users, and Regulatory Institutions. Kigali, Rwanda, 2019, p. 22.

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. Also, no concrete cases were found during the survey in relation to the application of fines.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 37 of Law No. 70-2013, of Sep 2, 2013, which regulates Biodiversity in Rwanda, establishes some administrative sanctions, which are:

- Temporary suspension of permit;
- Permit cancellation;
- Administrative fine by Ministerial order.

Also in accordance with the same article, the fine set under item 3 of the first paragraph of this article shall be deposited to the National Climate and Environment Fund (FONERWA).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Ms. Béatrice Cyiza
Environmental Audit and Monitoring Officer
Rwanda Environment Management Authority
P.O. Box 7436
Kacyiru
Kigali
Rwanda

ABS National Focal Point
+250 788525345
bcyiza@rema.gov.rw

6. Websites

ABSCH Rwanda Profile
https://absch.cbd.int/en/countries/RW

CBD Rwanda Profile
https://www.cbd.int/countries/?country=rw

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Rwanda profile. Available in: https://absch.cbd.int/countries/RW Access on 04/02/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Rwanda profile. Available in: https://www.cbd.int/countries/?country=rw Access on 04/02/2020.

REPUBLIC OF RWANDA. Fifth National Report To The Convention On Biological Diversity. Global
Environment Facility, 2014. Available in: https://www.cbd.int/countries/?country=rw> Access on 04/10/2016.

REPUBLIC OF RWANDA. Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual **Property.** Available in: http://www.wipo.int/wipolex/en/details.jsp?id=5249> Access on 04/10/2016.

REPUBLIC OF RWANDA. Loi N°70/2013 du 02/09/2013 régissant la biodiversité au Rwanda. Available in: https://www.ecolex.org/details/legislation/loi-n702013-du-02092013-regissant-la-biodiversite-au-rwanda-lex-faoc131764/?q=&type=legislation&xkeywords=biodiversity&xcountry=Rwanda&xdate_min=&xdate_max = Access in 04/10/2016.

REPUBLIC OF RWANDA. National Biodiversity Strategy And Action Plan. Global Environment Facility, 2016. Available in: https://www.cbd.int/countries/?country=rw
Access in 04/10/2016.

RWANDA ENVIRONMENT MANAGEMENT AUTHORITY. Guideline and Toolkit for Access and Benefit Sharing of Traditional Knowledge Associated with Genetic Resources in Rwanda: Information for Providers, Users, and Regulatory Institutions. Kigali, Rwanda, 2019.

Sao Tome and Principe[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 28th, 1999.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since April 10th, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

1. The information hereinafter has been updated until November 1st, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Despacho Conjunto N° 10/2017 (Joint Order N° 10/2017 of Ministry of Infrastructure, Natural Resources and Environment and Ministry of Agriculture and Rural Development) identifies the Competent National Authority for Access and Fair and Equitable Sharing of Benefits derived from the use of Genetic Resources as the competent institution for this matter on the country. This institution is responsible for developing national strategies, legislation and regulations related to benefit sharing derived from biodiversity; creating awareness for the matter; inspecting and monitoring resources derived from biodiversity; issuing reports regarding biodiversity.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Although there is no law covering ABS, according to the Interim National Report on the Implementation of the Nagoya Protocol on ABSCH website, there is an informal authorization procedure to access genetic Resources from Sao Tome and Principe through the General Direction of the Environment and Ministry of Agriculture. Also, the article “Celebrating milestones in the ratification and implementation of the Nagoya Protocol on Access and Benefit Sharing in the COMIFAC” (2020), posted in the UN Environment website, states that Sao Tome and Principe has developed and adopted ABS strategy and action plan. However, no further information was found regarding the informal procedure or the ABS policy.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.
2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Competent National Authority for Access and Fair and Equitable Sharing of Benefits derived from the use of Genetic Resources	Responsible for developing national strategies, legislation and regulations related to benefit sharing derived from biodiversity; creating awareness for the matter; inspecting and monitoring resources derived from biodiversity; issuing reports regarding biodiversity.

6. Websites

ABSCH Sao Tome and Principe Profile
https://absch.cbd.int/countries/ST

CBS Sao Tome and Principe Profile
www.cbd.int/countries/?country=st

General Directorate for the Environment of Sao Tome and Principe
http://dga.st/pt

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Samoa profile. Available in: https://absch.cbd.int/countries/WS Access on 11/01/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Samoa profile. Available in: https://www.cbd.int/countries/?country=ws Access on 11/01/2020.

REPÚBLICA DEMOCRÁTICA DE S.TOMÉ E PRÍNCIPE. **NATIONAL BIODIVERSITY STRATEGY AND ACTION PLAN 2015-2020 (NBSAP II)**. Ministério das Obras Públicas, Infraestruturas, Recursos Naturais e Meio Ambiente Direcção Geral do Ambiente. Available in: https://www.cbd.int/countries/?country=ws Access on 11/01/2020.

REPÚBLICA DEMOCRÁTICA DE S.TOMÉ E PRÍNCIPE. **V Rapport National Sur la Diversité Biologique de São Tomé et Principe**. Ministério das Obras Públicas, Infraestruturas, Recursos

Naturais e Meio Ambiente Direcção Geral do Ambiente. 2014. Available in: https://www.cbd.int/countries/?country=ws Access on 11/01/2020.

REPÚBLICA DEMOCRÁTICA DE S.TOMÉ E PRÍNCIPE. **Despacho Conjunto Nº 10/2017**. Ministério das Infraestruturas, Recursos Naturais e Ambiente e Ministério da Agricultura e Desenvolvimento Rural. 2017. Available in: https://absch.cbd.int/api/v2013/documents/1E3D-1CFB-3F8B-9DA4-3EE5-E0F4CCCA31EA/attachments/Despacho%20Conjunto%20MIRNA%20e%20MADR.pdf. Access on 11/01/2020.

UN ENVIRONMENT. Celebrating milestones in the ratification and implementation of the Nagoya Protocol on Access and Benefit Sharing in the COMIFAC. April 2020. Available at: https://www.unenvironment.org/news-and-stories/story/celebrating-milestones-ratification-and-implementation-nagoya-protocol Access on: 11/01/2020.

Senegal[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since January 15th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by ratification, since June 1st, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until November 10th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Babacar Ngor Youm
Directeur Adjoint
Direction des Parcs Nationaux
Ministère de l´Environnement et du Développement durable
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Dakar
Senegal

ABS National Focal point
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bacaryoum@yahoo.fr
youmbaba@yahoo,fr

6. Websites

ABSCH Senegal Profile
https://absch.cbd.int/countries/SN

CBD Senegal Profile
www.cbd.int/countries/?country=sn

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Senegal profile. Available on: https://absch.cbd.int/countries/SN Access on 11/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Senegal profile. Available on: https://www.cbd.int/countries/?country=sn Access on 11/10/2020.

RÉPUBLIQUE DU SÉNÉGAL. Cinquième Rapport National Sur La Mise En Œuvre De La Convention Internationale Sur La Diversité Biologique. Ministère de l'Environnement et du Développement Durable. 2014. Available on: https://www.cbd.int/countries/?country=sc Access on 07/10/2016.

RÉPUBLIQUE DU SÉNÉGAL. Stratégie Nationale & Plan National D'Actions Pour La Biodiversité. Ministère de l'Environnement et du Développement Durable. 2015. Available on: https://www.cbd.int/countries/?country=sc Access on 07/10/2016.

Seychelles[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the National Strategy and Plan of Action 2015-2020, Seychelles drafted a Bill for Access and Benefit Sharing (ABS) in 2005 (Seychelles Access to Genetic Resources and Benefit Sharing Bill, 2005), but no further developments were

1. The information hereinafter has been updated until October 30th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

found. Also, a UNDP/GEF Project has been implemented in Seychelles since 2017 in order to strengthen institutional capacities and legal frameworks to implement the Nagoya Protocol.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The ABSCH website identifies Wildlife Environment and Permit Division as the competent institution, which is responsible for all genetic resources. According to the "Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005)", by Lewis-Lettington and Dogley, the draft law for ABS (2005) states that the Competent Authority regarding access and benefit sharing shall be designated by the Minister in charge on environmental issues.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the "Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005)", by Lewis-Lettington and Dogley, the draft law for ABS (2005) states that access to genetic resources shall be subject to Prior Informed Consent from the relevant authorities and the holders of private rights involved, including holders of traditional knowledge.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the "Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005)", by Lewis-Lettington and Dogley, the draft law for ABS (2005) establishes that the applicant for intellectual property rights regarding genetic resources shall notify the Coordinating Agency, as well as disclose the origin of the genetic resources.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the "Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005)", by Lewis-Lettington and Dogley, the draft law for ABS (2005) states that genetic resources comprise its "parts and components", which include functional units of heredity and DNA sequences. No specific procedures regarding genetic resources' parts and components are established in the Bill.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the "Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005)", by Lewis-Lettington and Dogley, the draft law for ABS (2005) states that any grant of rights for the use of genetic resources in Seychelles shall be subject to benefit sharing, to be defined in regulations.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. As per the "Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005)", by Lewis-Lettington and Dogley, the draft law for ABS (2005) establishes that monetary benefits may include fees royalties or milestone payments, while non-monetary benefits shall include provision of research results, training, equipment or information contributing to the conservation and sustainable use of genetic resources of Seychelles.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found. However, according to the "Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005)", by Lewis-Lettington and Dogley, the draft law for ABS (2005) states that the Coordinating Agency, Lead Agencies and the Competent Authority shall be responsible for monitoring compliance of the act.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the "Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005)", by Lewis-Lettington and Dogley, the draft law for ABS (2005) provides that offenses shall be punished with civil and criminal prosecution. Depending on the contravention, the fines may vary from SR 5,000 to 1,000,000, and there may be imprisonment for up to 5 years, as well as damage compensation.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Wildlife Environment and Permit Division	This institution is responsible for all genetic resources in the country.

6. Websites

ABSCH Seychelles Profile
https://absch.cbd.int/countries/SC

CDB Seychelles Profile
www.cbd.int/countries/?country=sc

Seychelles Clearing House Mechanism
https://seychellesbiodiversitychm.sc/

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Seychelles profile. Available on: https://absch.cbd.int/countries/SC Access on 10/30/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Seychelles profile. Disponível em: https://www.cbd.int/countries/?country=sc Acesso em 10/30/2020.

GOVERNMENT OF SEYCHELLES. **Fifth National Report to the to the United Nations Convention on Biological Diversity**. Ministry of Environment and Energy. Victoria, 2014. Available on: https://www.cbd.int/countries/?country=sc Access on 07/10/2016.

GOVERNMENT OF SEYCHELLES. **Seychelles National Biodiversity Strategy and Action Plan 2015-2020**. Ministry of Environment and Energy. Victoria, 2014. Available on: https://www.cbd.int/countries/?country=sc Access on 07/10/2016.

LEWIS-LETTINGTON, Robert J and DOGLEY, Didier. Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005). International Plant Genetic Resources Institute. Rome, 2006. Available on https://www.bioversity-international.org/e-library/publications/detail/commentary-on-the-development-of-the-republic-of-seychelles-access-to-genetic-resources-and-benefit-sharing-bill-2005/ Access on 07/10/2016.

Sierra Leone[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since March 12th,, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since January 30th, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the Interim National Report on the implementation of

1. The information hereinafter has been updated until November 6th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

the Nagoya Protocol (2019) states that some permits to access genetic resources are issued by ad hoc mechanisms, and benefits are shared on a case by case basis.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Interim National Report on the implementation of the Nagoya Protocol (2019) identifies The Environmental Protection Agency, Sierra Leone (EPASL) as the competent institution, which is responsible for protecting all genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

Authority	Competence
The Environmental Protection Agency, Sierra Leone (EPASL)	This institution, together with National Protected Areas Authority and Ministry of Agriculture (Forestry Division) works in programmes relating to the conservation of all genetic resources in Country.

6. Websites

ABSCH Sierra Leone Profile
https://absch.cbd.int/countries/SL

CBD Sierra Leone Profile
https://www.cbd.int/countries/?country=sl

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Sierra Leone profile. Available on: https://absch.cbd.int/countries/SL Access on 11/06/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Sierra Leone profile. Available on: https://www.cbd.int/countries/?country=sl Access on 11/06/2020.

GOVERNMENT OF SIERRA LEONE. **Biodiversity: Strategic Action Plan**. Environment Protection Agency Sierra Leone. Available on: https://www.cbd.int/countries/?country=sl Access on 07/10/2016.

GOVERNMENT OF SIERRA LEONE. **Fifth National Report to the Convention on Biological Diversity**. Environment Protection Agency Sierra Leone. Available on: https://www.cbd.int/countries/?country=sl Access on 07/10/2016.

GOVERNMENT OF SIERRA LEONE. Interim National Report on the implementation of the Nagoya Protocol.Environmental Protection Agency. Available in https://absch.cbd.int/database/NR/ABSCH-NR-SL-246288. Access in 11/06/2020.

Somalia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since December 10th, 2009.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Protocol, but has been a signatory country since January 12th, 2012.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until October 12th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Ahmed Yusuf Ahmed
Director General
Directorate of Environment and Climate Change
Office of the Prime Minister
Villa Somalia
Mogadishu
Somalia

ABS National Focal Point
+252617886632
dg@environment.gov.so

6. Websites

ABSCH Somalia Profile
https://absch.cbd.int/countries/SO

CBD Somalia Profile
https://www.cbd.int/countries/?country=so

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Somalia profile. Available in: https://absch.cbd.int/countries/SO> Access on 12/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Somalia profile. Available in: https://www.cbd.int/countries/?country=so> Access on 12/10/2020.

GOVERNMENT OF SOMALIA. **The Fifth National Report on the Implementation of the Convention of Biological Diversity of Somalia**. Ministry of Fishery and Marine Resources. Available in: https://www.informea.org/en/countries/SO/legislation?page=2> Access on 24/05/2018

GOVERNMENT OF SOMALIA. **The Sixth National Report on the Implementation of the Convention of Biological Diversity of Somalia**. 2019. Available in: https://chm.cbd.int/database/record?documentID=248495lation?page=2> Access on 24/05/2018

South Africa[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since 01/31/1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since 10/12/2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoint:

- The National Department of Environment, Forestry and Fisheries

As informed on the official website of The Access and Benefit-Sharing Clearing-House Mechanism of CBD, this federal entity was designated as the National Competent Authority under the terms of article 17 of the Nagoya Protocol, being responsible for authorizing the access to genetic heritage and associated traditional knowledge, or issuing a written statement confirming that the access requirements have been accomplished. It is also in charge of:

- instructing users on the applicable procedures and requirements for obtaining prior informed consent, as well as on the signature of mutually agreed terms

- collecting or receiving relevant information related to prior informed consent and mutually agreed terms and providing such information to national authorities and to the ABS Clearing House.

Also, the National Focal Point states in the Interim National Report on the Implementation of the Nagoya Protocol that other checkpoints were established but have not been formalized through the ABS Clearing House.

- Patent office,
- Ports of Entry & Exit,
- Provincial Permit Issuing Authorities,
- National Department of Environmental Affairs

1. The information hereinafter has been updated until 11/09/2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 45 IRCCs that are available on the ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- National Environmental Management: Biodiversity Act 2004 and its amendments
- Regulations on Bioprospecting, Access and Benefit Sharing (No. R 138 of 1008) and its amendments
- Notice of Exemption In Terms of Section 86 (No. R 149 of 2008) - under the terms of article 86 of the "National Environmental Management: Biodiversity Act, 2004", establishes the resources and activities that are exempt from the obligations and dispositions of Chapter 6 "Bioprospecting, Access and Benefit-sharing" of the same 2004 Act
- Act No. 6 of 2019: Protection, Promotion, Development and Management of Indigenous Knowledge Act.
- Patents Amendment Act 2005

According to the Interim national report on the implementation of the Nagoya Protocol, Chapter 6 of NEMBA was given effect by the Regulations on Bioprospecting, Access and Benefit Sharing (BABS Regulations) on 1 April 2008, and these regulations have been amended through the years and have finally came into force only on 19 May 2015.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Access and Benefit-Sharing Clearing-House, identifies the National Department of Environmental Affairs as the only designated Competent National Institution (CNA), which is responsible for issuing Access and Benefit-Sharing related permits, as well as advising on mutually agreed terms and prior informed consent.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. All access activities in the country must comply with the procedures described below:

- For commercial activities

According to article 81 of the National Environmental Management: Biodiversity Act 2004, no person may engage in the commercialisation phase of bioprospecting before applying for a permit. Currently, the following documents are required for the application:

- Annexure 5: Application for a bioprospecting permit or biotrade permit or integrated biotrade and bioprospecting permit
- Annexure 4: non refundable fees for permit applications
- Annexure 11: Material Transfer Agreement
- Annexure 12: Benefit Sharing agreement
- Annexure 13 community resolution

- For non-commercial activities:

Article 81A of the National Environmental Management: Biodiversity Act 2004 established that no person may engage in the discovery phase of bioprospecting before notifying the minister. Currently, the following documents are required for the notification:

- Annexure 1 discovery phase notification
- Annexure 2 application for discovery phase export permit
- Annexure 4 non refundable fees for permit applications
- Annexure 11 material transfer agreement
- Annexure 12 benefit sharing agreement

Furthermore, according to article 82, applicants wishing to utilize indigenous biological resources must take consideration of their stakeholders' interests, prior to the authorization request, including those who grant access to the indigenous biological resources and indigenous communities. The prior informed consent is required at this stage, as well as the establishment of a material transfer agreement and a benefit-sharing agreement.

The exemptions of requiring the permit are described in Notice of Exemption In Terms of Section 86 (No. R 149 of 2008).

Regarding the Regulations on Bioprospecting, Access and Benefit Sharing (No. R 138 of 1008), it is important to highlight that is mandatory for the juristic person that is not registered in terms of South African law or a natural person who is not a South African citizen or permanent resident of South Africa to apply for the permit jointly with a juristic registered in terms of South African law or natural person who is a South African citizen or permanent resident of South Africa.

Finally, it is interesting to mention that, by the time of the Interim national report on the implementation of the Nagoya Protocol (published at ABS Clearing House on 01 of November of 2017, 56 permits were already issued.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Act No. 6 of 2019 on Protection, Promotion, Development and Management of Indigenous Knowledge provide on article 26 that any person who intends to use indigenous knowledge for commercial purposes must apply for a license authorizing the use of that indigenous knowledge and enter into a license agreement with the trustee of the relevant indigenous community for the use of that indigenous knowledge, as facilitated by National Indigenous Knowledge Systems Office. However, it is not clear if this procedures and complementary to the procedures for access to indigenous resources ou biological resources provided by National Environmental Management: Biodiversity Act 2004

Also, no special procedures were found in the National Environmental Management: Biodiversity Act 2004 in relation to access to associated traditional knowledge. Therefore, the procedures described at question 2.3. above must be followed. Regarding the protection of traditional knowledge, article 82 of the National Environmental Management: Biodiversity Act 2004 sets that issuing authority must take into consideration the protection of any interest of indigenous and local communities.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to the Patents Amendment Act of 2015, the applicant must provide information stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No. The definition of Indigenous biological resource, under the terms of article 80, item 2, excludes any animals, plants or exotic organisms.

2.7 Does the current legislation establish procedures for the shipment of samples?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 81 of the National Environmental Management: Biodiversity Act 2004, no person may export indigenous biological resources before applying for a permit.

Regarding bioprospecting, the procedures are described on question 2.3. above. For research other than bioprospecting, the user shall use the Annexure 3: Application for an export permit for research other than bioprospecting.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, according to the official document "Submission by the government of south africa in response to notification SCBD/NPU/DC/VN/KG/RKi/87804 in relation to a call for submission of views and information on digital sequence information on genetic resources", the following definitions provided by National Environmental Management: Biodiversity Act 2004 are linked to DSI:

- "Derivative", in relation to an animal, plant or other organism, means any part, tissue or extract of an animal, plant or other organism, whether fresh, preserved or processed, and includes any genetic material or chemical compound derived from such part, tissue or extract;

- "Genetic material", means any material of animal, plant, microbial or other biological origin containing functional units of heredity;

- "Genetic resource", includes any genetic material; or the genetic potential, characteristics or information of any species

In this sense, the Department of Environmental Affairs describes in the aforementioned that the Mutually Agreed Terms and the permit templates provide mandatory clauses which could include the utilization of the DSI on genetic resources, whether stored in the public or private databases.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and it is applicable for any future benefits that may be derived from the relevant bioprospecting (research, development, collecting, growing, processing, researching, exporting, developing and manufacturing inputs, ingredients and products using South African biodiversity). The responsibility to share the benefits lies on the applicant and the stakeholder.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. Applicants should submit the application form alongside proof of prior informed consent, the material transfer agreement and the benefit-sharing agreement made with the provider of the genetic resource or traditional knowledge to the Department of Environmental Affairs (DEA). According to article 83, (2), a benefit-sharing agreement or any amendment to such an agreement must be submitted to the Minister for approval and does not take effect unless approved by the Minister.

The payment should be made by the users to the Bioprospecting Trust Fund, but the legislation covered by this study does not establish values. The Annexure 12: Benefit-sharing Agreement

provides several examples of non-monetary, monetary, or “any kind of benefits”, but is possible for the user to choose other formats.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	All	Not defined	To be determined within the parties	Genetic Heritage/ ATK	Bioprospecting Trust Fund which will then to the providers of traditional knowledge and/or indigenous biological resources
Non Monetary	All	Not defined	To be determined within the parties	Genetic Heritage/ ATK	The providers of traditional knowledge and/or indigenous biological resources

2. Legal information

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The National Environmental Management Act (NEMA) of 2004 institutes the Environmental Management Inspectorate (EMI) as the official inspection body responsible for all matters related to access and benefit-sharing in the country.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The National Environmental Management Act (NEMA) of 2004 establishes in its article 102 the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: the payment of a fine as prescribed in terms of the Adjustment of Fines Act, 1991 and imprisonment for a period not exceeding ten years.

In addition, the Bioprospecting, Access and Benefit-Sharing Regulations, No. R. 138 of 2008 establishes in its article 20 that any person will be guilty of committing an offense if they (a) without a permit, undertake bioprospecting or export activities; (b) perform activities that differ from the permit; or (c) allow or omit breaches from another party.

Finally, Notice 447 of 2015: Amendments to the regulations on bioprospecting, access and benefit-sharing establishes some penalties in its article 42:

I. Any person who commits an offense under article 40 (which deals with the Bioprospecting

II. Trust Fund) is liable on conviction to the following penalties:

III. a) Imprisonment for a period not exceeding (10) ten years;

IV. b) Fine of up to 10 million rand; or

V. c) Both a fine and such imprisonment.

VI. (II) Any person who commits an offense involving bioprospecting or biotrading activities without an official permit issued under the terms of Chapter 7 of this Law is liable under conviction to pay a fine both under the terms of item I above or to the equivalent value of three times the commercial value of the activity executed in the offense, whichever is higher.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, one emblematic case related to biopiracy was the one involving the Hoodia cactus from the Kalahari desert and the San people of Southern Africa, in which South Africa's Council for Scientific and Industrial Research (CSIR) patented the plant without recognizing the Sans' traditional claims to both the knowledge of the plant and its uses. The CSIR was forced to negotiate with the San people's council and were able to reach an agreement in 2003 in which the traditional community would receive from 6 to 8% of the revenue from the sale of the products.

5. Summary - Competent Authorities

Authority	Competence
National Department of Environmental Affairs	The Department is the only designated competent national authority (CNA) for the country responsible for all genetic resources.

6. Websites

Biodiversity South Africa - South Africa's National Clearing-House Mechanism Training Website
https://absch.cbd.int/countries/ZA

Department of Environmental Affairs
https://www.environment.gov.za/content/home

SANBI (South African National Biodiversity Institute) _ Biodiversity for Life
http://www.sanbi.org/

7. References

The Access and Benefit-Sharing (BABS) Clearing House of the Republic of South Africa. Available at: <https://www.environment.gov.za/projectsprogrammes/bioprospectingaccess_benefit-sharing_babs_clearinghouse>. Accessed on: 07/08/2020.

South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators. Available at: <https://www.environment.gov.za/sites/default/files/legislations/bioprospecting_regulatory_framework_guideline.pdf>. Accessed on: 07/08/2020.

ACCESS AND BENEFIT SHARING - ABS: Understanding international and national laws. Available at: <http://ethicalbiotrade.org/dl/beneft-sharing/ABS_Rules_2014(2).pdf> Accessed on 31/10/2016.

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. South Africa profile. Available in: <https://absch.cbd.int/countries/ZA> Accessed on 18/10/2016.

CROUCH, Neil R., et. al. **South Africa's, bioprospecting, access and benefit-sharing legislation: current realities, future complications, and a proposed alternative**. South African Journal of Science, Science and Policy, 104, p. 355-366, September/October/2008. Available in: < https://www.cbd.int/fnancial/bensharing/southafrica-study.pdf>. Accessed on 18/10/2016.

GOVERNMENT OF SOUTH AFRICA. 2nd National Strategy and Action Plan 2015-2025 (NSAP). Department of Environmental Affairs, Republic of South Africa. Pretoria, July, 2015. Available in: <https://www.cbd.int/countries/?country=za> Accessed on 18/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Biodiversity Act nº10 of 2004 National Environmental Management**. Available in: <https://www.environment.gov.za/sites/default/fles/legislations/nema_amendment_act10.pdf> Accessed on 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **National Environmental Laws Amendment Act, 2009 No. 14 of 2009**. Available in: < https://www.environment.gov.za/sites/default/fles/legislations/nema_amendment_act14.pdf> Access on 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Notice 447 of 2015: Amendments to the regulations on bio-prospecting, access and benefit-sharing**. Available in: < https://www.environment.gov.za/sites/default/fles/legislations/nemba10of2004_babsregulations_amendments.pdf> Accessed on 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Notice 73 of 2014: Draft Amendment regulations on bio-prospecting, access and benefit-sharing**. Available at: <http://cer.org.za/wp-content/uploads/2014/02/20140217-National-Gazette-No-37331-of-17-February-2014-Volume-584.pdf> Accessed on 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Notice of Exemption In Terms of Section 86 (No. R 149 of 2008).** Available in: <http://extwprlegs1.fao.org/docs/pdf/saf85908.pdf> Accessed on 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Patents Act 57 of 1978**. Available in: < http://www.gov.za/documents/patents-act-9-apr-2015-0827> Accessed on 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Patents Amendment Act 2005**. Available in: < http://www.wipo.int/wipolex/en/text.jsp?fle_id=179614>. Accessed on 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Regulations on Bioprospecting, Access and Benefit Sharing (No. R 138 of 2008**). Available in: <http://www.ecolex.org/details/legislation/bioprospecting-access-and-beneft-sharing-regulations-2008-no-r-138-of-2008-lex-faoc085909/> Accessed on 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **South Africa's Fifth National Report To The Convention On Biological Diversity**. Republic of South Africa. March, 2014. Available in: < https://www.cbd.int/countries/?country=za> Accessed on 18/10/2016.

TSHITWAMULOMONI, Lactitia, et. al. **South Africa's Legislative Framework On Bioprospecting, Access And Beneft Sharing**. Department of Environmental Affairs. 7th Pan-African ABS Workshop, 2013. Available in: < http://www.abs-initiative.info/uploads/media/Lactitia_Tshitwamulomoni_-_DEA_-_South_Africa_s_legislative_framework.pdf>. Accessed on 18/10/2016.

UEBT - Union for Ethical BioTrade. **Access and beneft sharing - ABS: Understanding international and national laws**. Union for Ethical BioTrade, 2014. Available in: <http://ethicalbiotrade.org/dl/beneft-sharing/ABS_Rules_2014(2).pdf>. Accessed on 18/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Interim National Report on the Implementation of the Nagoya Protocol**. 2017. Available at: <https://absch.cbd.int/database/NR/ABSCH-NR-ZA-238752>. Accessed on 11/09/2020.

GOVERNMENT OF SOUTH AFRICA. **Submission by the government of South Africa in response to notification SCBD/NPU/DC/VN/KG/RKi/87804 in relation to a call for submission of views and information on digital sequence information on genetic resources**. Available at: <https://www.cbd.int/abs/DSI-views/2019/SouthAfrica-DSI.pdf>. Accessed on 11/09/2020.

South Sudan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession since May 18th, 2014.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE

1. The information hereinafter has been updated until October 12th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the bene-

fits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Nagoya Protocol on Biological Diversity

Mr. Paul L. Demetry
CBD Primary NFP, CHM, NFP
SBSTTA NFP, Resource Mobilization
FP

Mr. Kenyi Bulen Baggu
GSPC NFP

Mr. Lwanga Tiba Charles
CHM NFP

Mr. Yatta Samuel Lukou
GTI NFP

Mr. Malik Doka Morjan
Portected Areas NFP

6. Websites

ABSCH South Sudan Profile
https://absch.cbd.int/countries/SS

CBD South Sudan Profile
https://www.cbd.int/countries/?country=ss

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. South Sudan profile. Available at: https://absch.cbd.int/countries/SS> Access on 11/02/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. South Sudan profile. Available at: https://www.cbd.int/countries/?country=ss> Access on 11/02/2020.

GOVERNMENT OF SOUTH SUDAN. **The Fifth National Report to the Convention of Biological Diversity**. Ministry of Environmental. Available at: https://www.cbd.int/countries/?country=ss> Access on 24/05/2018.

Sudan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since January 28th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since December 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the Interim National Report on the Implementation

1. The information hereinafter has been updated until November 11th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

of the Nagoya Protocol (2017), the country has a draft law on ABS, but it could not be identified by this study.

Also, the ABSCH website indicates a draft Forestry Policy (2015) and a Law on National Center for Research (1995) as measures taken by the country addressing ABS, but as they are only available in local language, they could not be analyzed by this research.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country, but Sudan's ABS Procedure document (2020), published in the ABSCH website, indicates that an Interim National Committee has been receiving requests and issuing permits for access to genetic resources. The same document mentions that PIC and MAT are required, but there is no further information or contract model clauses on the subject.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

2.9. Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Sudan Profile
https://absch.cbd.int/countries/SD

CBD Sudan Profile
www.cbd.int/countries/?country=sd

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Sudan profile. Available in: https://absch.cbd.int/countries/SD Access on 11/12/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Sudan profile. Available in: https://www.cbd.int/countries/?country=sd Access on 11/12/2020.

REPUBLIC OF SUDAN. **National Biodiversity Strategy and Action Plan 2015 -2020.** Ministry of Environment, Natural Resources and Physical Development. Higher Council for Environment and Natural Resources (HCENR). 2015. Available in: https://www.cbd.int/countries/?country=sd Access on 05/10/2016.

REPUBLIC OF SUDAN. **Sudan Fifth National Report To The Convention On Biological Diversity (CBD)**. Ministry of Environment, Natural Resources and Physical Development. Higher Council for Environment and Natural Resources (HCENR). Khartoum, 2014. Available in: https://www.cbd.int/countries/?country=sd Access on 05/10/2016.

REPUBLIC OF SUDAN. **Sudan Sixth National Report To The Convention On Biological Diversity (CBD)**. 2018. Available in:https://chm.cbd.int/database/record?documentID=241358 Access on 11/12/2020.

REPUBLIC OF SUDAN. **Sudan Interim National Report on the Implementation of the Nagoya Protocol**. ABSCH. 2017. Available in:https://absch.cbd.int/pdf/documents/absNationalReport/ABSCH-NR-SD-238638/1. Access on 11/12/2020.

REPUBLIC OF SUDAN. **ABS Procedure (CBD)**. ABSCH, 2020. Available in:https://absch.cbd.int/pdf/documents/absProcedure/ABSCH-PRO-SD-250693/2 Access on 11/12/2020.

Tanzania[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since June 6h, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since April 19th, 2018.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The Environmental Management Act No. 20 of 2004 states briefly in section 66 item (1) that the Minister in charge of environment is responsible for ensuring the conservation and sustainable use of national genetic resources, as well as the fair and equita-

1. The information hereinafter has been updated until December 24th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

ble sharing of benefits.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As stated in item 2.1, the country does not have a law on access to genetic resources and associated traditional knowledge.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As stated in item 2.1, the country does not have a law on access to genetic resources and associated traditional knowledge. However, Article 188 of the Environmental Management Act No. 20 of 2004 states that anyone who markets, possesses or disturbs the habitat of a particular component of biological diversity and the procedures described in items 66, 67 and 68 commits an offense and will be penalized with a fine not exceeding 10 million shillings or imprisonment not exceeding 5 years, or both.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As stated in item 2.1, the country does not have a law on access to genetic resources and associated traditional knowledge.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Tanzania Profile
http://ne.chm-cbd.net

CBD Tanzania Profile
https://www.cbd.int/countries/?country=tz

Biodiversity Information Exchange Platform
http://tz.chm-cbd.net/biodiversity

Ministry of Natural Resources and Tourism
www.mnrt.go.tz

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE - ABSCH. Country Profiles. United Republic of Tanzania profile. Available at: https://absch.cbd.int/countries/TZ Access on 12/24/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. United Republic of Tanzania profile. Available at: https://www.cbd.int/countries/?country=tz Access on 12/24/2020.

UNITED REPUBLIC OF TANZANIA. Environmental Management Act, 2004 (No. 20 of 2004). Available at: https://www.ecolex.org/details/legislation/environmental-management-act-2004-no-20-of-2004-lex-faoc061491/?q=&type=legislation&xkeywords=biodiversity&xcountry=Tanzania%2C+Un.+Rep.+Of&xdate_min=&xdatemax= Accessed on 06/17/2016.

UNITED REPUBLIC OF TANZANIA. Fifth National Report on the Implementation of the Convention on Biological Diversity. Vice President's Office, Division of Environment. 2014. Available at: https://www.cbd.int/countries/?country=tz Access on 06/17/2016.

UNITED REPUBLIC OF TANZANIA. National Biodiversity Strategy and Action Plan (NBSAP) 2015-2020. Vice President's Office, Division of Environment. 2015. Available at: https://www.cbd.int/countries/?country=tz Access on 06/17/2016.

Togo[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by acceptance, since January 02, 2020.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by ratification, since May 05, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, LOI No. 2008-005 Portant Loi-Cadre Sur L'environnement/Law N. 2008-005 Framework Law on the Environment establishes at article 34 that the State shall take the appropriate legislative and regulatory measures to ensure equitable shar-

1. The information hereinafter has been updated until December 23rs, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

ing of the results of research on biological diversity resources, their development as well as the benefits resulting from their commercial exploitation. Also, at the ABSCH website, the country stated that “access to genetic resources is made on the basis of voluntary contracts on a case-by-case basis”.

In addition, article 70 of the Decree n° 001-2013 MERF (Arrete n° 001-2013 MERF) states that the division of Protected Areas and Wildlife is responsible for promoting the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the exploitation of genetic resources.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / (X) NO / ( ) NOT AVAILABLE
Yes. TheDecree n° 001-2013 MERF (Arrete n° 001-2013 MERF), identifies the Protected Areas and Wildlife Division of the Minister of the Environment and Forest Resources as the competent institution regarding access and benefit sharing.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biol-

ogy or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 24 of the LOI No. 2008-005 (Portant Loi-Cadre Sur L'environnement) establishes that the State shall promote the suitable administrative and legislative measures to secure an equitable sharing of the outcomes of the research on biodiversity resources, their development and the benefits arising from their commercial exploration.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In

the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No sanctions in case of irregular access were identified in the norms covered by this analysis.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

Authority	Competence
Protected Areas and Wildlife Division of the Minister of the Environment and Forest Resources	Responsible for promoting the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the exploitation of genetic resources.

6. Websites

ABSCH Togo's Profile
https://absch.cbd.int/countries/TG

CBD Togo's Profile
https://www.cbd.int/countries/?country=tg

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Togo's profile. Available in: https://absch.cbd.int/countries/TG Access on 12/23/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Togo profile. Available in https://www.cbd.int/countries/?country=tg Access on 12/23/2021.

REPUBLIQUE TOGOLAISE. Cinquieme Rapport National Sur La Diversite Biologique Du Togo **2009-2014**. Ministere De L'environnement Et Des Ressources Forestieres. 2014. Available in: https://www.cbd.int/countries/?country=tg> Access on 12/23/2021.

REPUBLIQUE TOGOLAISE. Stratégie et Plan d'Action National pour la Biodiversité du Togo **SPANB 2011-2020**. Ministere de L'environnement et des Ressources Forestieres. 2014. Available in: https://www.cbd.int/countries/?country=tg Access in 12/23/2021.

TOGO. Loi n° 2008-09 portant Code forestier. Available in: https://www.ecolex.org/details/legislation/loi-n-2008-09-portant-code-forestier-lex-faoc085011/?q=2008-09&type=legislation&xcountry=Togo&xdate_min=&xdate_max= Access on 12/23/2021.

TOGO. Loi n° 2008-005 portant loi-cadre sur l'environnement. Available in: https://www.ecolex.org/details/legislation/loi-no-2008-005-portant-loi-cadre-sur-lenvironnement-lex-faoc085010/> Access on 12/23/2021.

Tunisia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated tradition-

1. The information hereinafter has been updated until September 30th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

al knowledge in the country. However, the Sixth National Report on the Convention of Biological Diversity states that access and benefit sharing in the country is in effect and operational, according to the national legislation and the National Strategy and Action Plan about Access and Benefit Sharing.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access

to traditional knowledge?
( ) YES / (x) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol.

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Tunísia Profile
https://absch.cbd.int/countries/TN

CBD Tunísia Profile
ttps://www.cbd.int/countries/?country=tn

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Tunisia profile. Available at: <https://absch.cbd.int/countries/TN>; Access in: 12/21/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Tunisia profile. Available at: <https://www.cbd.int/countries/?country=tn>. Access in: 12/21/2020.

Uganda[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

1. The information hereinafter has been updated until October 8th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- The National Environmental Act (1995): Act for the promotion of the sustainable management of the environment, establishes an authority responsible for coordinating, monitoring and supervising that purpose; and for other incidental or environment-related subjects.

- The National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005: This law aims to describe the procedure for access to genetic resources for purposes of scientific research, commercial purposes, bio-prospecting, conservation or industrial application; to promote the sharing of benefits arising from the genetic resources; and promote the sustainable management and utilization of genetic resources, thus contributing to the conservation of Uganda's biological resources.

- Guidelines for Access to Genetic Resources and Benefit Sharing in Uganda (2007): These guidelines establish the conditions under which access to Uganda's genetic resources should be granted and the sharing of the benefits resulting from the use of genetic resources shall be considered fair and equitable.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005 identifies the National Council for Science and Technology, as the competent institution, which is responsible for all matters involving access to genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to the National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005 and Guidelines for Access to Genetic Resources and Benefit Sharing in Uganda (2007) all access activities in the country must comply with the procedures described below:

1. Prior informed consent: The Article No. 10 of the National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005 states that prior informed consent in writing with local community or owner is required; (B) carry out an environmental impact assessment, when necessary; (C) enter into a material transfer agreement; and (d) obtain the authorization of access of the competent authority in accordance with the provisions of article 19.

2. Access permission: The Item 3 of the Guidelines for Access to Genetic Resources and Benefit Sharing in Uganda (2007) states that an access permission is required for the utilization of genetic resources for research purposes, bio-prospecting, commercial purposes or export purposes. Item 3.2 deals with the exceptions (cases where prior authorization is not required).

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. As described in item 2.3 and according to article 3.5 of The Guidelines for Access to Genetic Resources Sharing and Benefit Sharing in Uganda (2007), the procedure used for access Associated Traditional Knowledge is the same used for access genetic resources.

2.5 Does the current legislation or any ongoing bills provide specific procedures for re-

questing patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis. However in Article No. 15 of the National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005 states that the material transfer agreement should contain a clause indicating that the collector must not file a patent request without the written consent of the competent authority. In addition to that, there should be a sharing of the benefits arising from intellectual property rights.In Article 20 of the referred law, it defines as one of the options for sharing benefits the joint ownership of patents and other relevant forms of intellectual property rights. Article 8 of Industrial Property law establishes that any information about the use of traditional knowledge in the product shall be disclosed.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Yes. According to article No. 14 of the National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005 the collector must not access or export genetic resources without signing a Material Transfer Agreement with the agency. The material transfer agreement shall be valid for the period of time specified in the document, and will be issued under a fee. To be sure, the material transfer agreement should not be signed before the collector obtains prior informed consent and an accessory agreement. Any person who accesses or exports or negotiates genetic resources without a material transfer agreement commits an offense.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and it comprises over access. According to the article 20 of the National Environment (Access to Genetic Resources and Benefit Sharing) Regulations,

2005 states that the benefits arising from the collection, alteration and use of genetic resources will be shared in accordance with the principle of equity and justice and on mutually agreed terms. The benefits derived from access to genetic resources under a material transfer agreement or an accessory agreement shall vary on a case by case basis and may include:

- Participation of Ugandan citizens and institutions in scientific research activities and other activities involving access to genetic resources;
- Sharing of access fees and royalties, research funds, license fees and other special fees that support biodiversity conservation;
- Payment of salaries, when mutually agreed;
- Collaboration on education and training related to genetic resources;
- Transfer of knowledge and technology in favorable terms, and, in particular, of knowledge that uses genetic resources, including biotechnology, or relevant knowledge to the conservation and sustainable use of the biological diversity;
- Access to scientific information, such as biological inventories and taxonomic studies;
- Contributions to the development of the local community;
- Benefits related to food safety;
- Joint ownership of patents and other relevant forms of intellectual property rights.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found. However the National Environment Act (1995), in its article 4, institutes the National Environmental Authority, and in its article 5, states that this authority shall have the role of monitoring and supervising activities carried out in the environmental area. Nonetheless there is no information as to whether it is the institution responsible for inspecting access to genetic resources. Indeed, no concrete cases were found during the survey in relation to the application of fines.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005 establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as:

The articles 25 to 27 of The National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005 state the competent authority, a correlative agency, the Authority or any person authorized by them, may, for the purpose of ensuring compliance with these regulations, confiscate any genetic resources collected or equipment suspected of being in violation of these regulations, or that a violation has been committed by any person.

Article 26 (1) Any person who violates rules 12 (7), 13 (4) and 17 (2) commits an offense and shall be sentenced to a fine of not less than one hundred and eighty thousand shillings and not exceeding eighteen million shillings or imprisonment not exceeding eighteen months, or both.

(2) Any person who provides false information in the application for prior informed consent, accessory agreement or material transfer agreement commits an offense and shall be sentenced to a fine of not less than thirty thousand shillings and not exceeding three million shillings or to imprisonment not exceeding three months, or both.

Article 27. The Court who condemns an individual for an offense to those Regulations may, in addition to the sentence imposed by the Court:

- Order that the genetic resources of the genetic material or their by-products be confiscated by the Government and disposed to the will of the Court;
- Make an order for the cost of disposal of such genetic resources or material or its derivatives or any other costs;
- Order that any permission granted to the collector under these regulations be canceled;
- Order the return of the genetic resources;
- Make an order for the division of benefits occurring or likely to occur from access to genetic resources.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent Authorities

Authority	Competence
Uganda National Council for Science and Technology	Responsible for the implementation of the National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005 provisions. As well as for all genetic resources

6. Websites

ABSCH Uganda Profile
https://absch.cbd.int/countries/UG

CBD Uganda Profile
www.cbd.int/countries/?country=by

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Uganda profile. Available in: https://absch.cbd.int/countries/UG Access on 21/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Uganda profile. Available in: https://www.cbd.int/countries/?country=ug Access on 21/10/2016.

REPUBLIC OF UGANDA. Guidelines for Access to Genetic Resources and Benefit Sharing in Uganda (2007). Available in: http://www.wipo.int/wipolex/en/details.jsp?id=11628 Access on 21/10/2016.

REPUBLIC OF UGANDA. National Environment Management Authority – NEMA. Fifth National Report to the Convention on Biological Diversity. Ministry of Water and Environment. Kampala, 2014. Available in: https://www.cbd.int/countries/?country=ug Access on 21/10/2016.

REPUBLIC OF UGANDA. National Environment Management Authority – NEMA. National Biodiversity Strategy and Action Plan II (2015-2025). Ministry of Water and Environment. Kampala, 2016. Available in: https://www.cbd.int/countries/?country=ug Access on 21/10/2016.

REPUBLIC OF UGANDA. The National Environment (Access to Genetic Resources and Beneft Sharing) Regulations, 2005. Available in: https://absch.cbd.int/countries/UG Access on 21/10/2016.

REPUBLIC OF UGANDA. The National Environmental Act (1995). Available in: http://www. ulii.org/ug/legislation/consolidated-act/153 Access on 21/10/2016.

Zambia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since August 18th, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

According to the Interim National Report on the Implementation of the Nagoya Protocol (2019) the country does have checkpoints, but they could not be identified by this study.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

1. The information hereinafter has been updated until October 1st, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the Law on the Protection Of Traditional Knowledge, Genetic Resources And Expressions Of Folklore Act, 2016.

It is important to highlight that the country is a Party to the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, of the African Regional Intellectual Property Organization (ARIPO), which provides rules for access to traditional knowledge of its member countries.

In addition, the country has the following rules related to the matter:

- The Patents and Companies Registration Agency Act, 2010
- National Policy on Environment (2009)
- The Patents Act, 2016
- Policies Measures and Experiences IP and Genetic Resources (WIPO), 2010
- Zambia's Constitution of 1991 with Amendments through 2016

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Article 5 of the Protection of Traditional Knowledge, Genetic Resources And Expressions of Folklore Act, 2016, identifies the following institution as competent on the matter:

- Patents and Companies Registration Agency (Agency)

It is the entity responsible for administering the provisions of this law, and the supervision and monitoring of access activities. It also prepares models of access agreement, attend providers in its needs, among other attributions regarding the effectiveness of the law.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act, 2016, determines that the access to genetic resources in the country must follow the procedures below:

1. Prior and informed consent: in its article 32, the referred law determines that access to genetic resources can only be done with prior informed consent from the provider community.

2. Permission to exploit: Part I of the law defines "exploitation" as an activity that aims to discover the existence or status of a determined genetic resource. Thus, according to art. 37, the user that intends to exploit the country's genetic resource must have a valid authorization, granted by the Agency. The application form must contain the following information: objective of the exploitation, types of genetic resources that will be exploited, where the exploitation will take place, period intended for the exploitation. These authorizations, among other forms of access authorization, will be saved in the Agency Registry, and the user must deposit a copy of the authorization document in the appropriate institution of the place where the genetic resource will be collected.

3. Access Agreement: holders of exploited genetic resources have the right to grant and sign access agreements with the users.

Moreover, article 27 of the referred law foresees that traditional communities holders of genetic resources have the following rights: exclusive right to regulate on genetic resource; inalienable right to use the genetic resource; exclusive right to receive the sharing of benefits arising from the utilization of its genetic resources; and, the right to grant and conclude the access agreements. In addition, paragraph 3 of this article foresees that the Agency will maintain a register of all agreements, authorizations, grants and licenses of access granted under the terms of this law.

Lastly, the Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act, 2016, determines in its article 3 (3), that are exempt from complying with its legal provisions: the use of Associated Traditional Knowledge or genetic resources for researches with experimental and educational purposes.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Protection Of Traditional Knowledge, Genetic Resources And Expressions Of Folklore Act, 2016, foresees in its article 18 (1) that the user of traditional knowledge must obtain the prior and informed consent, in written, of a holder or, if the holder request, of the Agency that will act on behalf of the holder.

It should be noted that according to art. 25, the authorization or license given under the legal terms to access protected traditional knowledge that is associated with genetic resources, will not imply authorization to access genetic resources derived from this traditional knowledge.

On the other hand, it is worth mentioning that Zambia is a Party to the Swakopmund Protocol, that in its Part II establishes specific procedures for the exploitation of Traditional Knowledge, such as: the right of holders of the associated traditional knowledge to grant licensing agreements for the use of TK; every authorization and license grants to use the CTA must be in writing; the authorization document must be approved by the competent authority of the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. It is one of the principles of the Protection of Traditional Knowledge, Genetic Resources And Expressions Of Folklore Act, 2016, TO prevent the granting of patents based on traditional knowledge, genetic resources and folklore expressions without the prior and informed consent of the traditional community, individual or group, as well as to give effect to the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore (of the African Regional Intellectual Property Organization - ARIPO).

Article 36, “k”, of the law foresees that:

“36. An access permit holder shall have the following obligations:

- (k) where the person seeks to acquire intellectual property rights over the genetic resource or part of the genetic resource that has been accessed, negotiate a new access agreement

with the traditional community, except where this was included in the initial access agreement;"

Article 13 (1) of this law determines that the Registry will provide a periodic publication in Journals of Intellectual Property related to Traditional Knowledge and protected genetic resources.

Regarding associated traditional knowledge and folklore expressions, the Swakopmund Protocol does not provide for a specific procedure for the request of patent, however, according to the provision of article 27.4, the ratification or accession of a country to the Protocol entices the acceptance of the Citation Agreement of the African Regional Intellectual Property Organisation – AIRPO.

In a regional scale, even though the regional policies related to intellectual property are not vast, the Common Market for Eastern and Southern Africa (COMESA) has developed a regional policy that focuses on intellectual property side by side with traditional knowledge. Currently, there is a policy elaborated by COMESA that provides for rules on intellectual property and commerce. This policy also covers the protection of traditional knowledge and intellectual property[5].

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No procedures have been found for these purposes in the analyzed legislation. However, article 32 (8) of the Protection of Traditional Knowledge, Genetic Resources And Expressions Of Folklore Act, 2016, foresees that the export of genetic resources is only allowed with an export authorization granted by the appropriate institution. Moreover, art. 68 provides rules on the inspection of genetic resources export, and other material that has incorporated traditional knowledge or genetic resources.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the legislation addresses this matter which is comprised on the definition of genetic resource, as "any genetic material of a biological resource containing genetic information having actual or potential value for humanity (...)". however, there are no specific procedures for those cases.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

5. Strengthening the Creative Industries for Development in Zambia. New York and Geneva: United Nations, 2011, p. 30

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, the Protection Of Traditional Knowledge, Genetic Resources And Expressions Of Folklore Act, 2016 establishes the obligation of benefit sharing in its articles 4 (4), "d"; 20; 27; 32 (4); 36, "m"; 41, "i"; 42; e 43.

In its article 20, the abovementioned law foresees that the holders have the right to receive the sharing of benefits arising from the utilization of its traditional knowledge and genetic resources, as established by a mutually agreed term. In case there isn't an access agreement between the parties, the benefit sharing can be determined by a Court, and, according to the provisions of art. 42, its nature and values can be determined case by case, as long as the benefits shared attend to the common interest of the holder community.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, the Protection Of Traditional Knowledge, Genetic Resources And Expressions Of Folklore Act, 2016 establishes that the sharing of benefits may be monetary or non-monetary. The latter modality can be in the form of contributions to community development, depending on the material needs and cultural preferences expressed by the traditional community. In this sense, article 43 establishes that can a part of the benefit sharing: payment of fees for licensing; payment in advance of benefit sharing; partial payment of benefit sharing; royalties; research and development funding; shared intellectual property; employment opportunities; participation of citizens of the country or national institutions designated by the Agency in the development of research using the genetic resource or TK; provide genetic resources; access to products and technologies arising from the utilization of genetic resources or traditional knowledge; training to improve local skills and knowledge on genetic resources or TK and its conservation, propagation and use; provide equipment, infrastructure and technologies; or, other forms of benefit sharing that are appropriate in relation to the accessed genetic resources and traditional knowledge.

On the other hand, article 9 of the Swakopmund Protocol foresees that holders have the right to receive the sharing of benefits arising from the utilization of its traditional knowledge and genetic resources, as established by the mutually agreed terms signed between the parties. In case there isn't an access agreement between the parties, the competent national authority should negotiate an agreement with the parties, to share the benefits, which can be non-monetary, such as contributions to the development of communities, depending on the material needs and cultural preferences expressed by the traditional community.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	License fee, upfront or mlestone payments, royalties, reseach and development funding	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Community/ Government
Non Monetary	Not defined	Joint ownership of intellectual property, employment opportunity, participation in the reseach and development, priority to supply raw materials, access to products and techologies, training, equipment, infrastructure or technological support, and any other benefits as appropriate	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Community/ Government

7. References

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 45 (1), "a", of the Protection of Traditional Knowledge, Genetic Resources And Expressions of Folklore Act, 2016, determines that the Patents and Companies Registration Agency is responsible for monitoring the execution of all access agreements through inspections, periodic reports of users, among others.

Moreover, article 12 of this Law determines that the registers of access to Associated Traditional Knowledge and Genetic Heritage in the country must remain available to the inspection of the population, and any person can require copies.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, articles 71 and 72 of the Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act, 2016. Article 71 foresees that those who perpetrate any acts listed in the subsections of the same article, commits an infraction and will be sentenced to a fine of up to 500 thousand "penalty units" or prison for a period not superior to 5 years, or both.

Article 72 foresees a general penalty, as follows:

- "Art. 72. A person who contravenes any provision of this Act where no specific penalty has been provided shall be liable, on conviction, to a fine not exceeding four hundred thousand penalty units or to imprisonment for a term not exceeding four years, or to both."

Regarding the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, its article 23.1 provides that:

- "23.1. The Contracting States shall ensure that accessible and appropriate enforcement and dispute resolution mechanisms, sanctions and remedies are available where there is a breach of the provisions relating to the protection of traditional knowledge and expressions of folklore."

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Patents and Companies Registration Agency	Responsible for administering the Protection of Traditional Knowledge, Genetic Resources And Expressions Of Folklore Act, 2016 (in accordance with art. 5, subparagraph 1 of the Law)

6. Websites

ABSCH. Zambia profile
https://absch.cbd.int/countries/ZM

CBD. Country Profiles. Zambia profile
https://www.cbd.int/countries/?country=zm

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Zambia profile. Available at: https://absch.cbd.int/countries/ZM Access on 01/10/2020.

AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION (ARIPO). Swakopmund Protocol On The Protection Of Traditional Knowledge And Expressions Of Folklore. Namibia, 2010. Available at: http://www.wipo.int/edocs/lexdocs/treaties/en/ap010/trt_ap010.pdf Access on 01/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Zambia profile. Available at: https://www.cbd.int/countries/?country=zm Access on 11/20/2016.

REPUBLIC OF ZAMBIA. Policies, Measures and Experiences regarding Intellectual Property and Genetic Resources / Intergovernmental Committee On Intellectual Property And Genetic Resources, Traditional Knowledge And Folklore. Zambia to the World Intellectual Property Organization (WIPO), 2010. Available at: http://www.wipo.int/edocs/lexdocs/laws/en/zm/zm056en.pdf Access on 11/20/2016.

REPUBLIC OF ZAMBIA. Strengthening the Creative industries For Development in Zambia. United Nations, 2011. Available at: http://www.wipo.int/edocs/lexdocs/laws/en/zm/zm054en.pdf Access on 11/20/2016.

REPUBLIC OF ZAMBIA. The Patents and Companies Registration Agency Act, 2010. Available at: http://www.wipo.int/edocs/lexdocs/laws/en/zm/zm057en.pdf Access on 11/20/2016.

REPUBLIC OF ZAMBIA. The Protection of Traditional Knowledge, Genetic Resources And Expressions Of Folklore Act, 2016. Available at: http://www.wipo.int/edocs/lexdocs/laws/en/zm/zm056en.pdf Access on 11/20/2016.

Zimbabwe[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 9th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since November 30th, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Constitution of Zimbabwe;
- Environmental Management Act;

1. The information hereinafter has been updated until October 6th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- National Environment Policy and Strategies 2009;

- Statutory Instrument 61 of 2009 (Access to Genetic Resources and Indigenous Genetic Resource-based Knowledge);

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the Environment Management Act establishes as competent authorities:

- Environmental Management Agency:

Founded by the Environmental Management Act, the body has the function of regulating, monitoring, file environmental licenses and authorizations, elaborate conservation projects and environment projects, including all matters related to access to the country's genetic resources.

- Ministry of Environment

This is the executive body responsible for regulating, monitoring and promoting environment protection, besides delegate attributions to other environmental agencies in the country. Regarding biological diversity, the body has the function of providing for fair and equitable sharing of benefits arising from the exploitation of Zimbabwe's genetic plant material, and protecting the rights of indigenous people over their properties.

Also, the ABSCH website indicates the following Competent National Authorities, in addition to the previously mentioned Environment Management Agency:

- Forestry Commission

Responsible for managing and regulating gazetted forests and forest resources in communal lands.

- National Parks and Wildlife Management Authority

Responsible for regulating and managing the parks, recreational parks, sanctuaries and safari areas.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to the Statutory Instrument 61 of 2009, prior authorization is necessary. According to the ABS procedures, published in the ABSCH website, all access activities in the country must comply with the procedures described below:

1. Application: the applicant shall apply for use of genetic resources and traditional knowledge before the Department of Environment and Natural Resources (NFP) in the Ministry of Environment, Tourism and Hospitality Industry (METHI), which will indicate the relevant local authority and communities;

2. Prior Informed Consent (PIC): the applicant shall request PIC from local authority and communities and negotiate Mutually Agreed Terms and Benefit Sharing Agreement.

3. Submission to EMA: MAT and PIC proposals shall be submitted to the Environmental Management Agency (EMA).

4. Communication to the National Focal Point (NFP): As MAT and Benefit Sharing Agreements

are done, EMA informs the NFP to issue the internationally Recognized Certificate of Compliance (IRCC).

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, according to Section 11(vii) of the Statutory Instrument 61 of 2009, intellectual property rights over genetic resources are subject to a license.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
Yes, benefit sharing is mandatory and it shall be applied over the use of genetic resources. The responsibility to share the benefits lies with the applicant.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE
Yes. The Constitution of Zimbabwe states in its article 13 that the State must guarantee to local communities the fair and equitable sharing of benefits arising from the use of its genetic heritages. This constitutional provision is reiterated by the Environmental Management Act, that in its section 117 determines that the Ministry of Environment has the function of guaranteeing the fair and equitable sharing of benefits arising from technological exploitation of national germplasm, between the holder of the technology and the Government, and protect the rights of the indigenous people over their properties related to biological diversity.

According to Section 14(5) of the Statutory Instrument 61 of 2009, the licensing authority shall ensure that the application contains the proposal of benefits that may arise from the licensed use of the genetic materials or knowledge in question.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Genetic Heritage/Associated Traditional Knowledge	Government/ Community
Non Monetary	Not defined	Not defined	Not defined	Genetic Heritage/Associated Traditional Knowledge	Government/ Community

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to Section 11(2) of the Statutory Instrument 61 of 2009, “a person who is guilty of an offense in terms of subsection (2) shall be liable to a fine not exceeding level fourteen or imprisonment for a period not exceeding twelve months or both such fine and such imprisonment”.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Environmental Management Agency	Founded by the Environmental Management Act, the body has the function of regulating, monitoring, filing environmental licenses and authorizations, elaborate conservation projects and environment projects, including all matters related to access to the country's genetic resources.
Ministry of Environment	This is an executive body responsible for regulating, monitoring and promoting environment protection, besides delegate attributions to other environmental agencies in the country.
Forestry Commission	Responsible for managing and regulating gazetted forests and forest resources in communal lands.
National Parks and Wildlife Management Authority	Responsible for regulating and managing the parks, recreational parks, sanctuaries and safari areas.

6. Websites

ABSCH Zimbabwe Profile
https://absch.cbd.int/countries/ZW

CBD Zimbabwe Profile
https://www.cbd.int/countries/?country=zw

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Zimbabwe profile. Available at: https://absch.cbd.int/countries/ZW Access on 01/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Zimbabwe profile. Available at: https://www.cbd.int/countries/?country=zw Access on 01/10/2020.

CHIBEMEME, Gladman, et al. Review of National Laws & Policies That Support or Undermine Indigenous Peoples and Local Communities. Natural Justice, 2014. Available at: <https://naturaljustice.org/wp-content/uploads/2015/09/Zimbabwe-Legal-Review.pdf> Acesso em> Access on: 11/27/2018.

ZIMBABUÉ. Zimbabwe's Fifth National Report to the Convention on Biodiversity, 2015. Available at: https://www.cbd.int/doc/world/zw/zw-nr-05-en.pdf Access in: 08/20/2018.
ZIMBABUÉ. Environmental Management Act, de 7 de abril de 2006. Available at: https://www.cbd.int/doc/measures/abs/msr-abs-zw-en.pdf Acess in: 11/27/2018.

ZIMBABUÉ. Zimbabwe's Constitution of 2013. Available at: http://extwprlegs1.fao.org/docs/pdf/zim127325.pdf Access in: 11/28/2018.



America

Antigua and Barbuda[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since March 12th, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

1. The information hereinafter has been updated until December 21st, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Environmental Protection And Management Act, 2015.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Environmental Protection and Management Act (2015), identifies the Department of Environment, Ministry of Health and the Environment as the competent institution, which is responsible for all functions regarding the aforementioned Act, including management and licensing of bioprospecting.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Environmental Protection and Management Act (2015) all access activities in the country must comply with the procedures described below:

1. Application: Fill in an application to the Department of Environment, Ministry of Health and the Environment, which shall contain information about the access, proof of payment of a fee and proof of completion of benefit sharing obligations (in advance);

2. ABS Agreement: If approved, the Department will invite the applicant to enter the Access and Benefit Sharing Agreement with the Government of Antigua and Barbuda.

3. Letter to collect : Then, the applicant shall attend to the Department to receive a letter of permission to collect, which will contain specifications of methodology, procedures and conditions for access.

4. Inspection of samples: The appropriate authority will inspect the samples collected and the Department will issue the final ABS permit, which will incorporate all the information provided during the application.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

There are no specific procedures regarding access to Associated Traditional Knowledge in the referred law.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

There are no specific procedures regarding patents. However, according to the Environmental Protection and Management Act (2015), if any provision on the environmental law regarding ABS is breached, the intellectual property certificate will be considered invalid.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The Environmental Protection and Management Act (2015) does not provide procedures regarding collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The Environmental Protection and Management Act (2015) does not establish procedures for shipment of samples. However, it provides that the Access and Benefit Sharing Agreement shall contain a limit on the sizes of the samples that the applicant may obtain and/or export.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE
The Environmental Protection and Management Act (2015) does not provide any specific procedures for digital sequence information or synthetic biology.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The Environmental Protection and Management Act (2015) does not foresee species that have naturally developed their distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE
Yes. The responsibility to share the benefits lies on the applicant, who shall present in the application the specific anticipated monetary and non-monetary benefits to be shared.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE
According to the The Environmental Protection and Management Act (2015), the application of access shall contain specific monetary and non-monetary benefits to be shared, including details about proposals for how they will be shared and with which agency institution, community or individual.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Royalties Others	Royalties amounting to 20% of the total value of the resources extracted	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Environmental Protection and Management Act (2015) institutes the Department of Environment as the official inspection body responsible for all matters related to access and benefit-sharing in the country.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Environmental Protection and Management Act (2019) establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: financial penalty, proportional do the value gained by the person or entity who accessed genetic resources or the loss in terms of biodiversity for Antigua and Barbuda, whichever is greater; written warning; confiscation of collected material and ban from access in the country. There is no indication of value.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Department of Environment, Ministry of Health and the Environment	All functions regarding the Environmental Protection and Management Act (2019), which include analysing applications for access of genetic resources and associated traditional knowledge, issuing permits, providing for the Access and Benefit Sharing Agreement and the letter to collect, other acts regarding management and licensing of bioprospecting

6. Websites

Advancing the Nagoya Protocol in Countries of the Caribbean Region
http://www.abscaribbean.com/

The Environmental Awareness Group of Antigua & Barbuda
http://www.eagantigua.org/index.html

7. References

ACCESS AND BENEFIT SHARING CLEARING HOUSE. - ABSCH. Country profiles. Antigua and Barbuda profile. Available in: https://absch.cbd.int/countries/AG. Access in: 12/22/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country profiles. Antigua and Barbuda profile. Available in: https://www.cbd.int/countries/?country=ag. Access in: 12/22/2021. .

Antigua and Barbuda. Environmental Protection and Management Act, 2019.

GOVERNMENT OF ANTIGUA AND BARBUDA. **Antigua & Barbuda National Strategic Biodiversity Action Plan (2014-2025)**. Ministry of Health and the Environment. Available in: https://www.cbd.int/countries/?country=ag Access in 12/22/2021.

GOVERNMENT OF ANTIGUA AND BARBUDA. **Fifth National Report to the Convention on Biodiversity**. Environment Division. Available in: https://www.cbd.int/countries/?country=ag Access in 12/22/2021.

Argentina[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 20, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since March 09, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, there are 46 IRCC reported on the ABSCH website, issued on May 17, 2019.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- **Federal Level:**
  - Law 24,375 of 1994 - Approves the Convention on Biological Diversity.

1. The information hereinafter has been updated until October 11th, /2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- National Decree 1,347 of 1997 - establishes the enforcement authority on biological diversity. Creates the National Advisory Commission on the Conservation and Sustainable Use of Biological Diversity within the Secretariat of Natural Resources and Sustainable Development.

- Law 27,246 - Approves the Nagoya Protocol.

- Resolution 1,659 of 2007 - Provides adjustments and guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their use. It was revoked by Resolution 226/2010.

- Resolution 226 of 2010 - Regime of access to genetic resources, which also institutes a registry of access to genetic resources. It was revoked by Resolution 410/2019.

- Resolution 81/2016 - Rules for scientific research in national parks.

- Resolution 410/2019, on prior informed consent and mutually agreed terms, and the minimum standards and procedures for granting access to genetic resources

- Provincial:

  - The list of legislations below was indicated by the Secretariat of Environment and Sustainable Development as ABS provincial rules. However, it was concluded through this study that not all of them are specific for access and benefit-sharing, nor it necessarily brings clarity on procedures and obligations for users of Argentinian biodiversity. As the purpose of this study is to describe the main guidelines on ABS of each country, only legislation at national level will be further analyzed, considering that they provide the framework for the province level laws.

  - Province of Buenos Aires - Resolution 23/2019 on access to genetic resources

  - Province of Catamarca - Resolution 309/2015 on mandatory requirements for applying for authorization to conduct research with natural or genetic resources

  - Province of Chaco - Law 5629 on Resource Management of Wildlife and Hunting

  - Province of Chubut - Law XI - 10 - Wildlife Provision

  - Province of Chubut - Resolution 48/2008 that Regulates Scientific Research Activities

  - Province of Chubut: Resolution 46/2010 that modifies Provision 48/2008

  - Province of Cordoba - Law 7343: Guiding Principles for the Preservation, Conservation, Defense and Improvement of the Environment

  - Province of Cordoba - Law 10.208: Provincial Environmental Policy

  - Province of Cordoba - Scientific collection permission and genetic resource export permit documents

- Province of Corrientes - Resolution 845/2013 on scientific collection and research
- Province of Entre Rios - Resolution 1721/2014 on access to genetic resources.
- Province of Formosa - Resolution 40/15 on access to biological resources in the jurisdiction of the Province of Formosa.
- Province of Jujuy - Resolution 15/2013 - Regime of access to the biodiversity of the Province of Jujuy.
- Province of La Pampa - Law 1,914 - environmental policy law
- Province of La Rioja - Law 7,801 - Provincial Environment Law
- Province of La Rioja - Law 4,677 - Conservation of Wildlife and Regulatory Decrees
- Province of Mendoza - Resolution 1243/2012 - Scientific Investigations in Protected Natural Areas
- Province of Misiones - Resolution 509/2007 - Access to Genetic Resources.
- Province of Misiones - Law XVI - no. 47 (Formerly Provincial Law no. 3,337 of 1996) of the Misiones Province on biodiversity.
- Province of Neuquen - Law 2503/2005 - Access to genetic and biochemical resources.
- Province of San Luis - Decree 8804 - Regulamentation of Law 851.
- Province of San Luis - Law No. IX 851 of 2013 of the San Luis Province on Access and Registry of Genetic and Biochemical Resources from the Provincial Biological Diversity;
- Province of Rio Negro - Law 2.600/93 of the Rio Negro Province on Biodiversity, Conservation and Access
- Province of Rio Negro - Decree 1135/1998 of the Rio Negro province that regulates Law 2.600/93
- Province of Salta - Resolution 91/2005: Regime for the Authorization of Scientific Studies on Land, Aquatic Fauna and Flora and/or in Protected areas in the Province of Salta
- Province of San Juan - Law 6911 - Protection and Development of Flora and Wild Fauna
- Province of San Luis - Law 851 - Access and Registration of Genetic and Biochemical Resources of the Provincial Biological Diversity
- Province of San Luis - Decree No. 8804 - Regulatory Decree of Law 851
- Province of San Luis - Resolution 03- PRN 2011 on Research Permits

- Province of Santa Cruz - Resolution 861/98 on Research Activities
- Province of Santa Fe - Guidelines for applying for access permits
- Province of Santiago Delestero - Law 6321 - General Rules and Methodology of Application for the Defense, Conservation and Improvement of the Environment and Natural Resources
- Province of Tierra del Fuego - Resolution 570/2012 on the application for access to genetic resources
- Province of Tucuman - Resolution 97/2017 - Scientific Study Activities

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. At the Federal level, the following institution was elected as Competent National Authority, responsible for all genetic resources in Argentina:

- Secretariat of Environmental Policy in Natural Resources, Ministry of Environment and Sustainable Development of the Nation

Additionally, for access to genetic resources at National Parks, the competent institution is also the Directorate of National Conservation.

At the provincial level, the Secretariat of Environment and Sustainable Development indicates the following competent institutions regarding access and benefit sharing within their territories:

- Province of Buenos Aires: Fauna and Flora Directorate, and Provincial Organism for Sustainable Development
- Province of Catamarca: Provincial Directorate of Biodiversity, Secretariat of Environment and Sustainable Development
- Province of Charco: Directorate of Fauna and Protected Natural Areas, Ministry of Production, and Ministry of Planning, Environment and Technological Innovation
- Province of Chubut: Directorate of Flora and Wildlife, Ministry of Production, and Subsecretary of Environmental Management and Sustainable Development
- Province of Cordoba: Secretariat of Environment and Climate Change, and General Directorate of Biodiversity Conservation and Natural Resources
- Province of Corrientes - Directorate of Natural Resources, Ministry of Tourism
- Province of Entrerios - Directorate of Mining, Environment and Natural Resources
- Province of Formosa - Program of Biodiversity, Protected Areas and Climate Change, of Directorate of Natural Resources and Management.
- Province of Jujuy - Directorate of Genetic Resources And Protection Of Biodiversity

- Province of La Pampa - Directorate of Natural Resources, Ministry of Production
- Province of La Rioja - General Directorate of Protected Areas and Biodiversity
- Province of Mendoza - Directorate of Renewable Natural Resources
- Province of Misiones - Directorate of Biodiversity, Ministry of Ecology and Renewable Natural Resources
- Province of Neuquen - Neuquén Applied Ecology Center (Cean), Ministry Of Security, Labor And Environment
- Province of Rio Negro - Directorate of Natural Protected Areas and Wildlife, Secretary of Environment and Sustainable Development
- Province of Salta - Biodiversity Program, Directorate of Conservation and Protected Areas
- Province of Sanjuan - Directorate of Conservation and Protected Areas, Secretariat of Environment and Sustainable Development
- Province of San Luis - Environment Program, Biodiversity Subprogram, of Ministry of Environment
- Province of Santa Cruz - General Directorate of Natural Resources, Provincial Agricultural Council
- Province of Santa Fe - Subsecretary of Natural Resources, Ministry of the Environment
- Province of Santiago Delestero - General Directorate of Forests and Fauna, Ministry of Production, Natural Resources, Forestation and Land
- Province of Tierra del Fuego - General Directorate of Protected Areas and Biodiversity, Secretariat of Environment, Sustainable Development and Climate Change
- Province of Tucuman - Directorate of Flora, Wildlife and Soil, Subsecretariat for Agricultural Affairs and Food

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. At the national level, according to Resolution 410/2019 all access activities in the country must comply with the procedures described below:

- Obtain prior informed consent (PIC) to the competent authority. Each province has its own competent authority and the documents to apply for the authorization may differ, but the formulary of application should be in accordance with Annex I of Resolution 410/2019.
- Establish and sign mutually agreed terms (MAT) between the competent authority and the applicant, which should contain the conditions to access the genetic resources, to use for commercial purposes and the fair and equitable sharing of benefits.

- Request the Certificate of Compliance.

But not all activities are covered by the Argentinian ABS framework. Article 6 establishes that the following are excluded from Resolution 410/2019:

- Human genetic resources.
- The genetic resources of domesticated or cultivated species.
- The use of biological resources that does not imply the use of their genetic and / or biochemical components. However, if biological resources are used for their genetic and / or biochemical composition, the user will be obliged to comply with the provisions of this Resolution and the Nagoya Protocol.
- Plant genetic resources that are used for food and agriculture, and that are contained in Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture.

Furthermore, article 11 provides that it is possible to request to the Competent Authority an authorization for activities conducted before this resolution entered into force, as long as it is in compliance with the minimum requirements of the aforementioned resolution.

Regarding access to genetic resources of National Parks, prior authorization has to be required in accordance with Resolution 81/2016 and its specific formulairy and procedures.

Finally, it is important to highlight that each Argentinian province has its own rules on ABS and users should seek more information on provincial procedures. As mentioned in question 2.1. above, the present study analyzed only legislation at national level.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

However, it is important to highlight that each Argentinian province has its own rules on ABS and users should seek more information on provincial procedures. As mentioned in question 2.1. above, the present study analyzed only legislation at national level.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

However, it is important to highlight that each Argentinian province has its own rules on ABS and users should seek more information on provincial procedures. As mentioned in question 2.1. above, the present study analyzed only legislation at national level.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

However, it is important to highlight that each Argentinian province has its own rules on ABS and users should seek more information on provincial procedures. As mentioned in question 2.1. above, the present study analyzed only legislation at national level.

.2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 14 of Resolution 410/2019, in case of exportation for the purpose of accessing genetic resources, it is necessary to apply for an authorization of the Competent Authority. The requirement shall be made through the formulaire of Annex VI, provided by the aforementioned rule.

Also, it is important to highlight that each Argentinian province has its own rules on ABS and users should seek more information on provincial procedures. As mentioned in question 2.1. above, the present study analyzed only legislation at national level.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies. However, it is important to highlight that each Argentinian province has its own rules on ABS and users should seek more information on provincial procedures. As mentioned in question 2.1. above, the present study analyzed only legislation at national level.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

However, it is important to highlight that each Argentinian province has its own rules on ABS and users should seek more information on provincial procedures. As mentioned in question 2.1. above, the present study analyzed only legislation at national level.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE
Yes, according to the national legislation (Resolution 410/2019 and Resolution 81/2016) benefit sharing is mandatory and the responsibility to share the benefits lies on the user.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE
No. The National ABS framework does not provide for specific procedures, rules, and values. According to article 1 of Resolution 410/2019, the benefit-sharing shall be established by the Mutually Agreed Terms.

Also, each Argentinian province has its own rules on ABS, that may differ from each other. Therefore, the user has to identify which province the genetic resource accessed comes from and be compliant with the local rule. Or, in the case of the province that does not have an ABS framework in place, it should contact the competent local authority as provided in question 2.1.

Finally, as mentioned in question 2.1. above, it is important to highlight that the present study analyzed only legislation at the national level.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Genetic Heritage	Not defined
Non Monetary	Not defined	Not defined	Not defined	Genetic Heritage	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

However, it is important to highlight that each Argentinian province has its own rules on ABS and users should seek more information on provincial procedures. As mentioned in question 2.1. above, the present study analyzed only legislation at national level.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No sanctions in case of irregular access were identified in the norms covered by this analysis.

However, it is important to highlight that each Argentinian province has its own rules on ABS and users should seek more information on provincial procedures. As mentioned in question 2.1. above, the present study analyzed only legislation at national level.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

However, it is important to highlight that each Argentinian province has its own rules on ABS and users should seek more information on provincial procedures. As mentioned in question 2.1. above, the present study analyzed only legislation at national level.

5. Summary - Competent authorities

Authority	Competence
Secretariat of Environmental Policy in Natural Resources, Ministry of Environment and Sustainable Development of the Nation	Only designated Competent National Authority for all genetic resources.

6. Websites

Website of Country profile of Argentina in website of ABS. Available in :https://absch.cbd.int/countries/AR

Website of Country profile of Argentina in website of CBD. Available in https://www.cbd.int/countries/?country=ar

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Argentina. Available in: <https://absch.cbd.int/countries/AR>. Accessed on 10/12/2019.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Argentina. Available in: <https://www.cbd.int/countries/?country=ar> Accessed on 10/12/2019.

GOBIERNO DE ARGENTINA. Decreto Nacional 1.347/97.Autoridad de aplicación de la Ley sobre Diversidad Biológica (Creación de la CONADIBIO). Available in: <http://www2.medioambiente.gov.ar/mlegal/tratados/dec1347.htm> Accessed on 10/18/2016.

GOBIERNO DE ARGENTINA. Estrategia Nacional sobre Diversidad Biológica. Resolución 91/03. Secretaria de Ambiente y Desarrollo Sustentable. Ministerio de Ambiente y Desarrollo Sustentable, Republica Argentina. Buenos Aires: Febrero, 2003. Available in: < http://www2.medioambiente.gov.ar/mlegal/biodiversidad/res91_03.htm> Accessed on 10/18/2016.

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Bahamas[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country is a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The National Biosecurity Strategy (NBS) draft provides within its content Access and Benefit Sharing and Traditional Knowledge regulations, but no further information was found on this matter. Also, the Environmental Planning and Protection Act

1. The information hereinafter has been updated until April 13th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

(2019) provides for permits regarding scientific research involving fauna and flora in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No competent authorities within the scope of access and benefit sharing as established by the Nagoya Protocol were found. However, the Bahamas has governmental agencies that are responsible for controlling the use of natural resources for the purpose of research, as follows:

- The Bahamas Environment, Science and Technology Commission

According to its official website, the Bahamas Environment, Science and Technology Commission (also known as BEST Commission) was founded in 1994, and it has the mission of managing the implementation of environment multilateral agreements and the revision of impacts and environmental control plans for the development of projects in the Bahamas. Currently, it is the main body responsible for receiving information and issuing prior authorization for the use of natural resources for academic research purposes.

- Department of Marine Resources

The Marine Resources Department has the primary mission of administering, managing and developing the fisheries sector in the Bahamas in a sustainable manner. The Department is also responsible for collecting information and providing authorization for those who intend to research on matters involving marine life.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation on access to genetic resources and associated traditional knowledge has been found. However, according to the Department of Environmental Planning and Protection, Ministry of the Environment and Housing website, Bahamas requires applications for issuing permits for academic research regarding use of natural resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7. Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation on access to genetic heritage and associated traditional knowledge has been found. However, the article "2016 Researcher Information Packet" informs that there is a need for prior authorization to export samples of species for research projects. The bodies responsible are the BEST Commission and the Ministry of Agriculture. In this case, the applicant must complete the prior authorization form, available on Best Commission website, and to inform in detail the species and the quantity that will be exported.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

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Acting Director
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Ministry of the Environment and Housing
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Ms. Janice Miller
Permanent Secretary
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6. Websites

Government of Bahamas
http://www.bahamas.gov.bs/

Department of Environmental Planning and Protection, Ministry of the Environment and Housing
http://www.best.gov.bs/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Bahamas. Available in: https://absch.cbd.int/countries/BS. Access on 03/19/2020.

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THE GOVERNMENT OF THE BAHAMAS. DEPARTMENT OF MARINE RESOURCES. Scientific Research Permit. Available at: <http://www.bahamas.gov.bs/wps/portal/public/gov/government/services/!ut/p/b1/vZPJkpswEIafZR7Ag4RYxJHFYFazG3ShWBwGbMNgY2x4-pBkDqlUZXJJo-j6p6u_6ur-SKEIlFOnyqanzsem7_PztTrgMAc0WRQbbGgs4oEeuJbr8jsYOXAPpGgC_OS-L43u9JwAssAYlAVxHQQ-RBEyO45wF1oJJdukjyza63Wz97puOuzG2jLauN3-lGNYLTgdP9c-8JmxUGt0U1qBfM9CWUaRTMOmCucjmalDVFXoyb2DSRU_dlibdWMsTjOMXrrVD0aNqnZ-zarXOALKbi3uo33UZn41A_EuSkmgneVyzvswGYyncNQSmzFJLS2TM-xd_KVj1vmuE_ReXj72_WShP_gyKFKf-2JVe6DIp3J89BH4RK6z6y9HKl1j_E_QMAZAh0D0A-gB7AMqpBLAZEE7v-vLaf-HbxXvYCtHH1jdhBO0wTAInVHV71KCjEBcq0WxfPRCGW9pRchg4hVvFfiSJCmNwB-lX-4J4OhRUoQ86MWBAA9l8DNXaPV6186IosDYCM_jMw-PtK13fRFJfXR3l5Ba8IQ4EWAOBY-joMCg6nYSp_W-kceyjaYmGYGbZHcA2Lcm-HWN6WYEVXrRk4o5NpdjuLSqvzmSKZIk503vtsc-CGl6A2_7p4PlgXhuWdcxHz_y06mnl82Xm2tNtpXKV57ZYIkU_mX35jeVjqBRhi0n3QObqNUs-n5ByGrqBexqLXbWXlueDq8JQ75doslhj94D4Rz3El6_4d2ag/dl4/d5/L2dBISEvZ0FBIS9nQSEh/> Access in: 13/04/2020.

THE OFFICE OF THE PRIME MINISTER. BAHAMAS ENVIRONMENT, SCIENCE AND TECHNOLOGY COMMISSION. Research Permits. Available at: <http://www.best.gov.bs/research-permits/> Access on: 13/04/2020.

Barbados[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since March 10, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1. Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

According to Barbados Fifth National Report to the Convention on Biological Diversity (2016), the country does not have any specific legislation regarding access to genetic heritage and associated traditional knowledge. Nonetheless the document mentions that efforts have been made towards developing an appropriate framework for the protection of Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources for Caribbean countries.

1. The information hereinafter has been updated until December 17th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. However, the official document Barbados' Fourth National Report to the Convention on Biological Diversity (2011), defines that for matters related to biodiversity and traditional knowledge, the competent institution is the Natural Heritage Department. The country's Fifth National Report to the Convention on Biological Diversity (2016) on the other hand mentions that The Intellectual Property Office has taken part in regional efforts to Establish a Caribbean Framework for the Protection of Traditional Knowledge, Folklore/Traditional Cultural Expressions and Genetic Resources.

Moreover, the National Biodiversity Strategy & Action Plan for Barbados (2002) indicates that the Ministry of Physical Development and Environment and the Ministry of Agriculture and Rural Development are the ones responsible for implementing the obligations related to the CBD.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5. Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Ms. Daphne Kellman
Permanent Secretary
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6. Websites

Government Information Service of Barbados
http://gisbarbados.gov.bb/

CBD Barbados Profile
https://www.cbd.int/countries/?country=bb

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Barbados profile. Available at: https://absch.cbd.int/countries/BB. Accessed on 12/18//2020.

GOVERNMENT OF BARBADOS. **A National Biodiversity Strategy and Action Plan for Barbados**. Available at: https://www.cbd.int/doc/world/bb/bb-nbsap-01-en.pdf. Accessed on 12/18//2020.

GOVERNMENT OF BARBADOS. **Fourth National Report of Barbados**. Available at: https://www.cbd.int/doc/world/bb/bb-nr-04-en.pdf. Accessed 31/03/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Barbados profile. Available at: https://www.cbd.int/countries/?country=bb> Access on 31/03/2020.

Caribbean Regional Framework for the Protection of Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources. Available at: <https://sustainabledevelopment.un.org/partnership/?p=7663>. Accessed on 31/03/2020.

Belize[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since March 30th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to Belize's 2016-2020 National Biodiversity Strategy and Action Plan (2016), the country does not have a legal framework or law addressing access to genetic resources or benefit sharing, but a Biosafety Policy has been developed in order to

1. The information hereinafter has been updated until October 22nd, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

cover those issues. The Sixth National Report on the Convention on Biological Diversity (2019) states that Belize has not yet established legislation on ABS.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to traditional knowledge in the country. However, in addition to being Party to the Convention on Biological Diversity, Belize is also Party to the Treaty of Chaguaramas, which establishes in its articles 58 and 66 rules on protection and recognition of Traditional Knowledge.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

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6. Websites

ABSCH Belize profile
https://absch.cbd.int/countries/BZ

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Belize. Available at: https://absch.cbd.int/countries/BZ. Accessed on 10/22/2020.

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BELIZE; Ministry of Agriculture; Forestry, Fisheries, the Environment and Sustainable Development Department. **National Biodiversity Strategy and Action Plan**, Belize, 2016. Available at: <https://www.cbd.int/doc/world/bz/bz-nbsap-v2-en.pdf> Access on: 04/02/2020.

CARIBBEAN COMMUNITY. Revised Treaty of Chaguaramas. July 4th, 2017. Available at: <https://caricom.org/documents/4906-revised_treaty-text.pdf> Access on: 04/02/2020.

Bolivia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since January 1st, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since January 4th, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Law 811 of 2016 - ratifies the Nagoya Protocol.
- Supreme Decree 24.676/1997 - Regulation on Andean Decision 391 Common Regime on

1. The information hereinafter has been updated until January 21st, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House

Access to Genetic Resources.

Colombia, Bolivia, Ecuador, Peru and Venezuela form a sub-regional organization called the Andean Community of Nations. Within the Convention on Biological Diversity, this sub-regional organization has established the following decisions to strengthen actions related to the application of the norms contained in the CBD:

- Andean Decision 391/96 – Common Regime on Access to Genetic Resources;
- Decision 423/97– Amending the Eighth Transitory Disposition of Decision 391;
- Decision 448/98 – Amending the Eighth Transitory Disposition of Decision 391;
- Decision 486/01 – Common Regime on Intellectual Property, which includes biological patents.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to the Regulation on Andean Decision 391, in its article 4, identifies the Secretariat of the Department of Natural Resources, of the Ministry of Sustainable Development and the Environment as the competent institution responsible for the regime of access to genetic resources.

Besides the Competent National Authority, the following institutions have responsibilities regarding access and benefit-sharing:

- Prefectures in Regime of Access of Genetic Resources

Responsible for receiving applications for access to genetic resources, inspecting the activities of access and issuing reports to the National Competent Authority. Also, it is responsible for promoting the development of projects that contribute to the conservation and development of genetic resources and supervising the compliance of the access Agreements.

- Body of Technical Advising (BTA)

Responsible for performing technical evaluations of the access applications and forward its opinion to the National Competent Authority, and responsible for providing the National Competent Authority with relevant information about suitability of institutions requiring access.
Furthermore, subsection XI of article 51 of Andean Decision 391establishes that each Member Countries of the Andean Community should establish a National Competent Authority and the set of directors from these National Competent Authorities shall assemble to compose the Andean Committee on Genetic Resources, described under subsection XI of article 51 of Resolution 391.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to article 18 of the Regulation on the Decision 391, the documents required to obtain prior authorization to access to Bolivian genetic resources are:

- Form for the Petition of access to genetic resources annexed to the Regulation.

- Documents that prove the legal status and legal capacity of the petitioner in accordance with the national legislation in force.

After submitting the petition, the next steps to obtain the authorization are the following, which are in compliance with the procedures prescribed by the Decision 391 of the Andean Pact:

1. Application: the applicant shall submit the request for access to the competent authority

2. Publication of Summary of the Project: the national competent authority will publish a Summary of the project of access.

3. Evaluation: a technical body will evaluate the access application.

4. Access Contract: the competent authority will accept or not the requirement and proceed to the negotiation of the Access Contract with the applicant.

5. Contract confirmation: the competent authority will publish a Resolution confirming the Access Agreement.

Also, if the access to genetic resources occurs within Protected Areas, it shall be carried out only prior to the signing of an Accessory Contract with the involved Direction of the Protected Area. The Accessory Contract will be also mandatory when the involved Protected Area constitutes a Community Land of Origin or when the peasant or indigenous communities are involved as suppliers of the intangible component associated to and, in this case, the contract shall be signed with the organization that represents the community or communities involved.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. As mentioned above, in addition to the Access Agreement, an Accessory Contract will be also mandatory when a involved Protected Area constitutes a Community Land of Origin or when the the peasant or indigenous communities are involved as suppliers of the intangible component associated to and, in this case, the contract shall be signed with the organization that represents the community or communities involved.

Regarding, Resolution 391 of the Andean Community does not include any specific or differentiated procedures for access to associated traditional knowledge, only establishing in its eighth transitional disposition that the Board of the Andean Community shall draft a proposal for the establishment of a special regime or a harmonization norm to strengthen the protection of local, Afro-American and indigenous communities' knowledge, innovations and traditional practices.

It must be highlighted that in Bolivia there are strong local and indigenous communities' organizations that take part in ABS decisions both in terms of lawmaking and deciding on access cases. At present, the indigenous social organizations are working with laws that include practical mechanisms for access to collective territories and on a concept of collective intellectual property of traditional knowledge.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 36, of the Supreme Decree No. 24,676 (Regulation on Andean Decision 391) the National Competent Authority shall negotiate with the applicant the terms of the access contract, including the conditions for determining the ownership of the intellectual property rights and the conditions for the commercialization of the results.

Furthermore, the Seventh final provision of the aforementioned Decree establishes that the Secretarial Resolution provided by article 27 that confirms the Access Contract is required in the case of protection of a right of procurer of vegetal varieties or other right of intellectual property over any product and/or live organism, developed from genetic resources.

Regarding the Andean Community, the Decision 391 establishes in its second complementary disposition that the member countries of the Andean Community should mutually acknowledge their intellectual property rights over genetic resources, by-products or synthetic products and associated intangible components, either obtained or developed through access activities. Furthermore, according to the third complementary disposition, the national competent departments dealing with intellectual property shall require the applicant to provide the registration number of the access contract and supply a copy of it as a prerequisite for granting the right to register patents.

The Andean Community also has another instrument related to this topic, Decision 486/01, which establishes the Common Intellectual Property Regime, including biological patents. In this sense, in article 3, "Genetic and Biological Heritage and Traditional Knowledge", it is established that "(...) the grant of patents relating to inventions developed on the basis of material derived from that heritage or knowledge shall be subject to that material having been acquired in accordance with international, community and national legal provisions."

Decision 486/01 also requires under article 26, items 'h', 'i' and 'j', the presentation of documents and information regarding the genetic heritage or associated traditional knowledge as a requirement for the patent approval; whereas Article 75, items 'g' and 'h', establish the cases of invalidity of patents, also in relation to the accessed genetic heritage or associated traditional knowledge.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE
Andean Resolution 391 establishes, in Article 3, the scope of the dispositions contained in this resolution. In this sense, its terms are applicable to any genetic resources originated in the member countries of the Andean Community, including its by-products and intangible components. As per the first article, the countries of origin should be understood as "countries that possess genetic resources in "in situ conditions", including those which, having been in "in situ conditions", are now in ex situ conditions". As for "in situ conditions", these are understood as "the conditions in which the genetic resources are found in their ecosystems and natural environments; in the case of domesticated or cultivated species or those having escaped domestication, in the environments where they developed their specific properties". It can be noted that on no occasion the legislation mentions explicitly native or exotic species.

On the other hand, it should be highlighted that the same article 3 adds that the scope of these legal provisions includes the genetic resources of migratory species that for natural reasons are found in the territories of the member countries of the Andean Community.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. the eight final provisions of the Supreme Decree No. 24,676 (Regulation on Andean Decision 391) establishes that the Secretarial Resolution provided by article 27 that confirms the Access Contract is a requisite for the drawing up of the Certificates of Vegetal and/or Animal Sanitation as it corresponds in case of exportation of biological resources of flora or fauna with the purpose of access to genetic resources.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE

According to the study conducted by the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources of CBD in 2020, DSI matter is addressed by the Supreme Decree 25676 when it defines “DNA” as “genetic material which contains determinant information on the hereditary transmittable characteristics for descendants. However, the study authors claim that there is not sufficient information to deepen the analysis.

Decision 391 of the Andean Community defines synthetized product and includes it as in the scope of the law. The terminology used in the Andean Community is “synthetized product”. Also, the definition of genetic resources for the purpose of Decision 391 includes any material of a biological nature that contains genetic information of actual or potential value or utility.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country’s territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The national legislation does not foresee species that have naturally developed their distinctive properties within the country’s territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and the Regulation on Decision 391 established in articles 40 and 41, that the Bolivian Government shall participate in the fair and equitable benefit-sharing resulting from the access to genetic resources originating in its territory.

Also, in case of peasant or indigenous communities suppliers of the intangible component associated with the genetic resource, they shall participate in the benefits derived from the access to the genetic resource through their representative organizations.

If the access to genetic resources occurs within Protected Areas, it shall be carried out only prior to the signing of an Accessory Contract with the involved Direction of the Protected Area. The Accessory Contract will be also mandatory when the involved Protected Area constitutes a Community Land of Origin or when the peasant or indigenous communities are involved as suppliers of the intangible component associated to and, in this case, the contract shall be signed with the organization that represents the community or communities involved.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE
Yes, as mentioned in question 2.3. and 3.3, the Access Contract is part of the procedure to obtain the authorization to access Bolivian biodiversity. Likewise, Accessory Contracts are mandatory at specific occasions, as already described in this study. Therefore, these benefits shall be distributed to promote the conservation, sustainable use and development of genetic resources in the national territory and may be consisted of:

A. The transfer of technologies and knowledge used in the investigation and/or experimentation by the Party that have accessed the resource.

B. The development of the technical and scientific capacities of national institutions.

C. The payment of royalties for the commercial use of the genetic resources, its by-products or associated intangible components.

D. Franchises granted to the country by the commercial dealers or processors of the accessed genetic resources.

E. Other benefits that may be agreed between the parties according to Decision 391, this regulation or other related dispositions.

Decision 391 of the Andean Community does not impose any specific procedures on benefit-sharing. Notwithstanding, article 2, item a, lists among the objects of the referred resolution the regulation of the access to genetic resources and its by-products in the member countries, with the objective of "establishing the conditions for just and equitable participation in the benefits of the access".

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Royalties for commercial uses and others	Not defined	Genetic Heritage/ATK	Government/ ATK provider/Direction of the Protected Area
Non Monetary	Not defined	Transfer of technology, development of technical and scientific capacities of national institutions, franchises and others	Not defined	Genetic Heritage/ATK	Government/ ATK provider/Direction of the Protected Area

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Regulations on Decision 391 institutes the following institutions:

- Prefectures in the Regime of Access of Genetic Resources are responsible for inspecting the

activities of access and supervising the compliance of the access Agreements. It is also responsible for issuing reports to the National Competent Authority concerning the inspected activities.

- The National Secretariat of Natural Resources and the Environment (National Competent Authority) is responsible for penalizing the transgressors of Decision 391 and the Regulation.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The infractions and sanctions are provided by articles 57 to 63 of Regulations on Decision 391. Some of the sanctions are:

- A written reprimand for infractions of lesser degree that are committed for the first time, with the notified individual being given a term to correct the irregularities.
- Progressive fines in case of infraction.
- Suspension of access activities and preventive or definitive seizure and immediate suspension of the access activities and the preventive or definitive seizure of the goods and/or instruments of the perpetrator.
- Revocatory of authorization and incapacitation to request new accesses.
- Resolution of the access contract.

In addition, the National Competent Authority may annul the access contract.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. One of the cases of biopiracy in the country refers to quinua, registered by US researchers in 1994. Four years later, the patent was granted to Bolivia. Another case relates to sorgo, of which its register of intellectual property was requested by a US university in 2008. No further information was found regarding the status of the patent.

As for records of application of fines, no concrete cases were found during the survey.

5. Summary - Competent authorities

Authority	Competence
Ministry of Sustainable Development and the Environment through the Secretariat of the Department of Natural Resources and the Environment (National Competent Authority)	Enforce the Regulation on the Decision 391; Create and implement national policies regarding access to genetic resources; Guarantee indigenous peoples' rights as providers; Authorize access to genetic resources; Sanction violators of the Regulation on the Decision 391; Provide for the national inventory of genetic resources of which Bolivia is the origin country.

6. Websites

Ministry of Environment and Water
http://www.mmaya.gob.bo/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. **Country Profiles. Bolívia profile**. Available in: <https://absch.cbd.int/countries> Accessed on 11/04/2016.

COMUNIDAD ANDINA. **Decisión 448 - Modificación de la Octava Disposición Transitoria de la Decisión 391: Régimen Común sobre Acceso a los Recursos Genéticos**. Available in: <http://www.wipo.int/edocs/lexdocs/laws/es/can/can015es.pdf> Accessed on 11/04/2016.

COMUNIDAD ANDINA. **Decisión 486 - Régimen Común sobre Propiedad Industrial.** Available in: < http://www.wipo.int/edocs/lexdocs/laws/es/can/can012es.pdf> Accessed on 11/04/2016.

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CONVENTION OF BIOLOGICAL DIVERSITY - CBD. **Country Profiles. Bolívia profile**. Available in: <https://www.cbd.int/countries/?country=bo> Accessed on 11/04/2016.

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GOBIERNO DE BOLIVIA. **Ley N° 530 de 23 de mayo de 2014 del patrimonio cultural boliviano**. Available in: <http://www.wipo.int/wipolex/es/text.jsp?fle_id=337062> Accessed on 11/04/2016.

GOBIERNO DE BOLIVIA. **Ley 811, de 16 de junio de 2016, que ratifica el Protocolo de Nagoya.** Available in: <https://www.ilo.org/dyn/natlex/natlex4.detail?p_lang=es&p_isn=102549> Accessed on 11/04/2016.

GOBIERNO DE BOLIVIA. **Reglamento de la Decisión 391 Régimen Común de Acceso de los Recursos Genéticos**. Available in: <http://www.wipo.int/edocs/lexdocs/laws/es/can/can011es.pdf> Accessed on 11/04/2016.

GOBIERNO DE BOLIVIA. **V Informe Nacional CDB**. Ministerio De Relaciones Exteriores y Ministerio de Medio Ambiente y Agua. 2015. Available in: <https://www.cbd.int/countries/?country=bo> Accessed on 11/04/2016.

MINISTERIO DE DESARROLLO SOSTENIBLE. **Acceso a Recursos Genéticos - La experiencia Boliviana en la aplicación de la Decisión 391: Régimen Común sobre Acceso a Recursos Genéticos**. La Paz, 2004. Gobierno de Bolivia. Viceministerio de Recursos Naturales y Medio Ambiente. Dirección General de Biodiversidad. La Paz, 2004. Available in: <http://www.bivica.org/upload/ag_recursos-geneticos.pdf> Accessed on 11/04/2016.

CONVENTION ON BIOLOGICAL DIVERSITY. **Fact-finding Study on How Domestic Measures Address Benefit-Sharing Arising From Commercial and Non-Commercial Use of Digital Sequence Information on Genetic Resources for Research and Development. Canada**, 2020. Available in: <https://www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf> Accessed 11/12/2020.

Brazil[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since May 29, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since June 02, 2021.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found for this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found for this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Brazil first established regulations regarding access and benefit-sharing in 2000, with the publication of Provisional Measure No. 2052, of June 29, 2000 (Medida Provisória n° 2.052/2000). The regulation was later replaced by Provisional Measure No. 2186-16, of August 23, 2001 (Medida Provisória n° 2.186-16/2001), which fully instituted an administrative process to authorize access to genetic heritage and promote sharing of benefits derived from access. The authorization process and benefit-sharing obligations were common to all users of the Brazilian

1. The information hereinafter has been updated until 12/12/2022.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House

genetic heritage, whatever the tier in the production chain in which the activities were carried out.

In 2015, a new law was published - Law No. 13,123 of 2015 - to facilitate access activities through a registration system, SisGen, requiring the sharing of benefits only at one level of the production chain. The law aims to reduce the regulatory burden on the ABS system and encourage better use and protection of Brazilian biodiversity.

Currently, the following regulations apply to access and benefit sharing:

- Law No. 13,123, of May 20, 2015 (Lei n° 13.123/2015), known as Brazilian Biodiversity Law.

- Decree No. 8,772, of May 11, 2016 (Decreto n° 8.772/2016), which regulates the Biodiversity Law.

CGEN INTERNAL REGULATIONS
The Genetic Heritage Management Council (CGen) is a collegiate entity of deliberative, normative, consultative and appellative nature, created by Law No. 13,123 of 2015, under the Ministry of Environment. The body coordinates the development and implementation of policies for the management of access to genetic heritage and associated traditional knowledge and benefit-sharing. Its function, composition and structure are defined according to the guidelines below.

- MINISTERIAL ORDINANCE No. 427, OF SEPTEMBER 29, 2016

- MINISTERIAL ORDINANCE No. 381, OF OCTOBER 3, 2017

- CGEN/EXECUTIVE SECRETARY ORDINANCE No. 1, OF OCTOBER 3, 2017

RESOLUTIONS
With the aim of regulating and guiding specific procedures related to access and benefit sharing, CGen has established several resolutions to, for example, provide for the change in the modality of benefit sharing after product or material notification; establish an official model for the Material Transfer Agreement (MTA) and rules for carrying out the activity; regulate cases in which the registration system is not yet prepared to receive information; and identify cases in which the user can benefit from extended deadlines for the fulfillment of obligations.

- RESOLUTION No. 2, OF OCTOBER 5, 2016

- RESOLUTION No. 3, OF AUGUST 15, 2017

- RESOLUTION No. 16, OF OCTOBER 9, 2016

- RESOLUTION No. 19, OF OCTOBER 31, 2018

- RESOLUTION No. 20, OF AUGUST 07, 2019

- RESOLUTION No. 21, OF AUGUST 07, 2019

- RESOLUTION No. 24, OF FEBRUARY 19 OF 2020

- RESOLUTION No. 26, OF AUGUST 25, 2021
- RESOLUTION No. 27, OF AUGUST 25, 2021
- RESOLUTION No. 28, OF AUGUST 25, 2021
- RESOLUTION No. 29, OF AUGUST 25, 2021

TECHNICAL ORIENTATIONS
The technical orientations are technical guidelines that aim to unify the understanding regarding methods and procedures related to specific matters, such as, for example, clarifying the application of the concept "main elements of added value to the product" exclusively for the fragrance sector. The Technical Orientations currently in force are presented below.

- TECHNICAL ORIENTATION No. 1, OF JUNE 28, 2017
- TECHNICAL ORIENTATION No. 2, OF JUNE 28, 2017
- TECHNICAL ORIENTATION No. 4, OF MAY 22, 2018
- TECHNICAL ORIENTATION No. 6, OF JUNE 20, 2018
- TECHNICAL ORIENTATION No. 8, OF SEPTEMBER 18, 2018

MINISTERIAL ORDINANCE
Ministerial Ordinances are administrative normative instruments to determine the execution of an official instruction or legal obligation. They have been published by the Brazilian Ministry of Environment, for example, to guide compliance with obligations to present benefit-sharing agreements, declare net revenue obtained from the exploitation of products arising from access to genetic heritage and regulate the process of regularizing activities, establishing timeframes and specific rules for their full compliance.

- MINISTERIAL ORDINANCE No. 378, OCTOBER 1 OF 2018
- MINISTERIAL ORDINANCE No. 143, OF MARCH 30 OF 2020
- MINISTERIAL ORDINANCE No. 199, OF ABRIL 22, 2020
- MINISTERIAL ORDINANCE No. 144, OF ABRIL 22, 2021
- LEGISLATIVE DECREE No. 136, of 2020

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The country has the following competent institutions regarding access and benefit sharing:

- **Ministry of Environment (Ministério do Meio Ambiente - MMA)**

It is the National Ministry for Environment and Legal Amazon, instituted by Law No. 8,490 of November 19, 1992. Its core mission is to plan, coordinate, supervise and control actions related to the environment. The Ministry is responsible for formulating and executing the National

Environment Policy and coordinating the integrated Policies for the Legal Amazon, aiming to improve the quality of life of the Amazonian populations. In addition, the Ministry of Environment articulates international and internal actions related to the National Environmental Policy and the National Integrated Policy for the Legal Amazon with other ministries, departments and entities of the Federal Administration. It focuses on the preservation, conservation and rational use of renewable natural resources, implementing international agreements in the areas of its competence.

- **Genetic Heritage Management Council (Conselho de Gestão do Patrimônio Genético - CGen)**

Article 6 of Law 13,123/2015 establishes, under the Ministry of the Environment, the Genetic Heritage Management Council - CGen as the competent body for ABS in Brazil, which is responsible for promoting deliberations and consultations, analyzing appeals and coordinating the development and implementation of norms to manage access to genetic heritage and associated traditional knowledge and the sharing of benefits.

The responsibilities of CGen are:

1. **To establish:** technical norms; guidelines and criteria for drafting and enforcing benefit-sharing agreements; criteria for the creation of a database to register information on genetic heritage and associated traditional knowledge; guidelines for the application of the resources destined for the National Fund for Benefit-Sharing – FNRB, related to benefit-sharing.

2. **To Monitor, in articulation with federal institutions or through partnerships with other institutions, activities of:** access and shipment of samples containing genetic heritage; and access to associated traditional knowledge.

3. **To deliberate on:** authorizations for access in Brazilian national waters, continental shelf or in the exclusive economic zone; the accreditation of national institutions that maintain ex situ collection of samples containing genetic heritage; and the accreditation of national institutions to be responsible for the creation and maintenance of the mentioned database.

4. **To certify:** regularity of access to genetic heritage or associated traditional knowledge.

5. **To register:** the receipt of notifications of finished products or reproductive material; and the submission of benefit-sharing agreements.

6. **To promote:** debates and public hearings on the topics related to Law 13,123/2015.

7. **To function:** as the higher instance of appeal to decisions related to the accreditation of institutions and acts resulting from the enforcement of the Law.

8. **To create and maintain the relevant databases for:** records of access and shipment of genetic heritage or associated traditional knowledge; authorizations of access and shipment of genetic heritage or associated traditional knowledge; material transfer agreements and legal documents; ex situ collections of genetic heritage maintained by accredited institutions; notifications on finished products or reproductive material; benefit-sharing agreements; and certificates of regular access.

9. **To notify:** federal institutions responsible for the protection of rights of indigenous popula-

tions and traditional communities of the available records of access to associated traditional knowledge.

10. To approve: its internal regulations

- **Genetic Heritage Department (Departamento de Patrimônio Genético -DPG)**

The Genetic Heritage Department, structured and instituted by Decree Nº 10.455, of August 11, 2020, is responsible for proposing and monitoring policies for the development of the economy associated with and for the management of access to genetic heritage and associated traditional knowledge, with the objective of equitably sharing the benefits arising from their use. In addition, the Department shall encourage the training and organization of agents, agencies and entities, public and private, indigenous populations, traditional communities and traditional farmers on the subject.

Other important functions of the Department are to perform the function of CGen's Executive Secretary, and to implement, maintain and operate the National System for the Management of Genetic Heritage and Associated Traditional Knowledge - SisGen.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Prior authorization to access Brazilian genetic heritage or associated traditional knowledge is not required in most cases. However, certain procedures must be observed when accessing species found in in situ conditions, including domesticated species and spontaneous populations, or kept in ex situ conditions, as long as found in in situ conditions within the national territory, on the continental shelf, on territorial waters, or in the exclusive economic zone, and associated traditional knowledge, as the case may be.

The use of the country's genetic heritage or associated traditional knowledge for research or technological development requires the registration of access or an authorization, when access occurs in specific areas (see exception below). In cases where research and development activities do not fit the exception explained below, the user may initiate them without the need for registration or prior authorization. However, the regulation provides that the achievement of certain milestones requires the fulfillment of specific obligations.

Decree 8,772/2016 establishes that the registration of access shall be prior to the following activities: a) international shipment; b) request of any intellectual property rights; c) commercialization of intermediate products; d) publication of final or partial results in scientific media or means of communication; and e) notification of finished product or reproductive material developed from the access.

Furthermore, in cases of economic exploitation of finished products or reproductive material arising from access, it is necessary to proceed with the notification of the product, which shall be made before the issuance of the first sales invoice and shall indicate the modality of benefit sharing chosen by the user. Regarding products that are notified, 90 days after the beginning of the year, users shall present the product's net revenue from the previous year, which will be used to calculate the amount due as benefit sharing.

All of the aforementioned procedures, when performed by a national individual or legal entity, must be carried out through the online government platform, SisGen. After completing the access registration or notification, the system issues an automatic registration or notification

receipt, with the exception of cases involving access to species in areas of national interest and jurisdictional waters.

Regarding institutions headquartered abroad, access registration by these institutions can only be carried out through association with a Brazilian national institution of technological and scientific research, public or private, as required by law. As for the regularization of activities carried out by foreign institutions between June 30, 2000 and November 16, 2015, the deadline is suspended until the publication of an official act by the CGen Executive Secretariat that announces the availability of a new version of SisGen that includes the implementation of functionalities for foreign users.

Exception: Article 13 of Law 13,123 establishes that some activities require prior authorization for access to genetic heritage or associated traditional knowledge, when: i) the access activity is carried out in areas indispensable to national security, subject to approval by the National Defense Council; or when access occurs in Brazilian jurisdictional waters, on the continental shelf or in the exclusive economic zone, subject to approval by the maritime authority. Differently from the access registry, the authorization is an administrative act that allows, under specific conditions, access to genetic heritage or associated traditional knowledge and the shipment of genetic heritage.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Notwithstanding the procedures described in item 2.3, according to Chapter III, of Decree 7,882/2016 (article 22 and 22-A), even when it comes to research that does not have the purpose of economic exploitation, in cases where access to associated traditional knowledge (ATK) is concerned , the following is required:

1. **To access ATK:** if the ATK is of identifiable origin, the user must request the Prior Informed Consent (PIC) with the ATK provider, respecting their traditional forms of organization. It is important to highlight that access to ATK can be sourced from primary or secondary sources (fairs, publications, inventories, films, scientific articles, registries and any other means of registry and systematization of associated traditional knowledge). The Prior Informed Consent must be obtained previously to the register at SisGen.

2. **To obtain the PIC:** The Brazilian Legislation sets out a list of specific procedures, such as the obligation to provide clarifications to the the indigenous population, traditional community or traditional farmer on:

    a. The social, cultural and environmental impacts that could follow the activity involving the access to associated traditional knowledge;

    b. The rights and responsibilities of each party in the execution of the activity and its results;

    c. The right of indigenous populations, traditional communities and traditional farmers to deny access to associated traditional knowledge.

3. **To share benefits:**

    a. if the ATK is of identifiable origin: The amount of benefit-sharing, when applicable,

whether monetary or non-monetary, must be established jointly between the indigenous populations, traditional community or traditional farmer, and the manufacturer of the finished product or reproductive material. Additionally, 0.5 % of the net revenue must be shared in favor of the National Fund for Benefit-Sharing – FNRB.

b. if the ATK is of not identifiable origin: when applicable, the benefit-sharing shall be monetary, to the value of 1% of the net revenue, in favor of the National Fund for Benefit-Sharing – FNRB.

The regulation determines that the provider of associated traditional knowledge of identifiable origin will choose the form of proof of their prior informed consent, will freely negotiate its terms and conditions, as well as those of the benefit-sharing agreement, including the modality, being guaranteed the right to refuse them.

The federal bodies and entities for the protection of rights, assistance or promotion of the activities of indigenous populations, traditional communities and traditional farmers shall, at the request of the holders, advise on activities to obtain prior informed consent and the negotiation of agreements of benefit sharing.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Before requesting any intellectual property rights, it is mandatory to register access to genetic heritage or associated traditional knowledge in SisGen. Subsequently, the applicant is obliged to present the receipt of the registration or authorization of access to the National Institute of Intellectual Property - INPI, the Brazilian federal agency responsible for executing, at the national level, the rules that regulate Industrial Property .

The economic exploitation of licensing operations, transfer or permission to use any form of intellectual property rights over a finished product, process or reproductive material arising from access to genetic heritage or associated traditional knowledge, by third parties, are exempt from the obligation to share benefits.

The obligation to register access to genetic heritage or associated traditional knowledge in SisGen prior to the application for intellectual property rights also applies to patents or rights that may be requested abroad, before foreign institutions.

For the purposes of regularizing patent applications filed with the National Institute of Industrial Property - INPI during the validity of Provisional Measure No. 2,186-16, of August 23, 2001, the applicant must present proof of registration or authorization.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding procedures for collecting and accessing exotic species related to the Brazilian ABS legislation.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Brazilian legislation requires the signature of a Material Transfer Agreement - MTA between

the institutions or natural persons involved in the shipment, according to the official model established by CGen Resolution No. 27, of August 25, 2021. This Agreement, together with the Shipment Invoice, whose model is also officially established by the Resolution, must be entered into the system when registering the shipment.

Registration must be carried out prior to each shipment to be carried out, even if referring to a species already sent in the past. Each shipment requires the completion of a unique Shipment Invoice.

After completing the shipment registration, the sample can be sent abroad and, on the way, it must be accompanied by a copy of the MTA, a copy of the Shipment Invoice and a copy of the registration receipt.

Shipments can be made from a national institution or individual to a foreign institution or to a national individual residing abroad. The transfer of samples from the recipient to third parties also requires the signature of an MTA between the new parties and the communication of the transfer to the Brazilian authorities.

The shipment is differentiated from the sending of samples abroad in Brazilian legislation. Shipment is defined as "transfer of a genetic heritage sample to an institution located abroad for the purpose of access [research or technological development], in which the responsibility for the sample is transferred to the recipient" and requires the signature of an MTA and prior registration. The sending of samples, on the other hand, is understood as "sending a sample that contains genetic heritage for the provision of services abroad as part of research or technological development in which the responsibility for the sample lies with the person who accesses it in Brazil", and requires the signature of a service provision contract and prohibits the performance of activities not established in the contract and the transfer of samples to third parties.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Brazilian legislation regulates access to genetic heritage also when obtained from in silico sources. The very concept of genetic resources in Brazil involves discussions on digital sequence information, since genetic heritage is considered to be "information of genetic origin of plant, animal, microbial species or species of another nature, including substances derived from the metabolism of these living beings".

Furthermore, in the access registration, it is required to identify the database of origin of the genetic heritage with the information contained in the deposit record, when it comes from an in silico database.

Finally, it is worth mentioning that, in case of sending samples abroad for genetic sequencing purposes, the service provision contract is not mandatory[5].

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

5 § 7° The legal instrument mentioned in § 6° will not be mandatory in cases of sending samples for genetic sequencing. Decree 8,772/2016.

Yes. Species that have developed distinctive properties within the country's territory are covered on the concept of genetic heritage, for Brazilian legislation. According to articles 1, I and 2, VVX of Law 13,123/2015, genetic heritage comprises resources "found in in situ conditions, including domesticated species and spontaneous populations, or kept in ex situ conditions, as long as found in in situ conditions within the national territory, on the continental shelf, on territorial waters, or in the exclusive economic zone". In situ conditions refer to "conditions in which genetic heritage exists within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, including those forming spontaneous populations, in the surroundings where they have naturally developed their distinctive properties".

However, the law does not define distinctive properties and how to identify them, which led to the creation of a specific Thematic Chamber on this subject under CGen with the purpose of designing a Resolution in order to address this theme.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory for as long as there is economic exploitation of the finished product or reproductive material originated from access to the genetic heritage or associated traditional knowledge. The responsibility to share benefits lies with the manufacturer of the finished product or with the producer of reproductive material, regardless of whether it is a national or a foreign company. In cases where a foreign company is responsible for sharing benefits, the importer, subsidiary, associate, affiliate, partner, or commercial representative in national territory is jointly liable for benefit-sharing.

There are several exemptions to the obligation to share benefits, such as in the case where the component of genetic heritage does not add value to the finished product; or for the intermediary links of the productive chain; for small companies in terms of Brazilian legislation, and others.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, the procedures, rules and values were established by the domestic legislation as presented below:

1. Benefit sharing may be monetary or non monetary.

2. For monetary benefit sharing, the user will share annually, and the amount will be directed towards the National Fund for Benefit-Sharing – FNRB. The amount shall correspond to 1% of the annual net revenue obtained from economic exploitation of the finished products or reproductive material arising from access to genetic heritage.

3. For non monetary benefit sharing, the user shall present a project for benefit sharing before the Ministry of Environment and sign an Agreement of Benefit-Sharing with it. The project shall be presented annually and shall follow Brazilian biodiversity Law, its Decree and regulations, and it depends on the approval of the Ministry of Environment. The amount shall correspond to 0,75% or 1% of the annual net revenue obtained from economic exploitation of finished products or reproductive material arising from access to genetic heritage, de-

pending on the modality of non monetary that has been chosen.

As per article 19 of Biodiversity Law, non monetary benefit sharing shall include a) projects for conservation or sustainable use of biodiversity, or for protection and maintenance of knowledge, innovations, or practices of indigenous peoples, traditional communities or traditional farmers; b) technology transfer; c) making the product available in public domain, unprotected by intellectual property rights or technological restrictions; d) licensing products free of charge; e) capacity building of human resources in topics related to the conservation and sustainable use of genetic heritage or associated traditional knowledge; and f) distribution of products free of charge in social programs.

Furthermore, the beneficiary is also legally established, which according to articles 50 and 51 of Decree shall be (i) conservation units; (ii) indigenous lands; (iii) remaining territories of quilombos; (iv) rural settlement of family farmers; (v) traditional territories under Decree No. 6,040, from February 7th, 2007; (vi) national public institutions of research and development; (vii) priority areas for conservation, sustainable use and benefit sharing of Brazilian biodiversity, as an act of the State Minister of Environment; (viii) activities related to traditional knowledge associated safeguard; (ix) ex situ collections maintained by accredited institutions in terms of the provisions of Section V of Chapter IV; (x) indigenous peoples, traditional communities and traditional farmers, (xi) national bodies, and (xii) public institutions running programs of social interest.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value/Amount	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Finished Product Reproductive material	to the national fund of benefit sharing (FNRB)	1% of the net revenue (or sector agreement), to be deposited in favor of FNRB. d	Genetic Heritage and Associated Traditional Knowledge	NA/ Communities
Non Monetary	Finished Product Reproductive material	Biodiversity projects, technology transfer, distribution of products, free licensing, capacity building, making a product available for public domain	0,75% or 1% of the net revenue (or sector agreement), to be deposited in favor of FNRB.	Genetic Heritage and Associated Traditional Knowledge	Ministry of Environment/ Beneficiaries under articles and 51 of Decree 8.772/2016

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 93 of Law 13,123/2015 in its Chapter II states that the following institutions are responsible for monitoring and processing infractions to the Biodiversity law: the Brazilian Institute of the Environment and Renewable Natural Resources (Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis - IBAMA); the Command of the Navy, within the scope of Brazilian jurisdictional waters; and the continental shelf and the Ministry of Agriculture, Livestock and Supply, within the scope of access to genetic heritage for agricultural activities.

Also, the official bodies defending the rights of indigenous peoples, traditional communities shall provide support to IBAMA's inspection actions when the infraction involves associated traditional knowledge.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Section III of Decree 8,772/2016 indicates the offending conducts to the Biodiversity Law, which include i) to commercialize finished product derived from access to genetic resources without prior notification; ii) to publish results of research without prior SisGen registry; iii) to refrain from doing registry of access before commercialization of intermediary product; iv) to refrain from sharing benefits; v) to refrain from indicating the origin of identifiable associated traditional knowledge; vi) to refrain from regularizing activities; as well as others provided on articles 78 to 91 of the referred Decree.

The sanctions may involve warning, apprehension of products as well as fines, which may vary from R$ 1,000.00 (one thousand Reais) to R$ 100,000.00 (one hundred thousand Reais), when the infraction is committed by a natural person; or b) from R$ 10,000.00 (ten thousand Reais) to 10,000,000.00 (ten million Reais) when the infraction is committed by a legal entity, or with its participation. The extent of the fine varies depending on the size of the companies, which is determined by the company's income, following Brazilian legislation. Also, for companies, the fines are imposed over each product and they may be increased if it is a threatened species. If a small sized company commercializes a finished product in terms of the Law without prior notification, for example, a fine from R$ 10.000,00 (ten thousand reais) and R$ 200.000,00 (two hundred thousand reais) for each product is applicable.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Since the publication of Brazil's first ABS regulation in 2000, the inspection body in Brazil, IBAMA, has been executing periodic strategic inspection operations aiming to assure the application of the legislation in place and combating infractions against the national genetic heritage and traditional knowledge. The first inspection operation 'Novos Rumos' occurred in 2010, when IBAMA inspected more than 100 companies and research institutions, leading to more than R$ 88.000.000,00 (eighty eight million reais) of fines applied to either private and academia sectors. Moreover, since 2020 two inspection operations are place named both Terra Brasilis and Arrasto, which have been inspecting companies in different sectors around Brazil, resulting in 41 fines, summing up to R$ 7.818.901,47 reais.

In terms of biopiracy cases, Brazil has many emblematic cases, such as the registration of the name and process of making "cupulate", a chocolate made from cupuaçu, by a Japanese firm. The patent was overruled years later.

5. Summary - Competent authorities

Authority	Competence
Genetic Heritage Management Council (Conselho de Gestão do Patrimônio Genético - CGEN)	Responsible for coordinating the drafting and implementation of policies for the management of access to genetic heritage and associated traditional knowledge, as well as benefit-sharing.
Ministry of Environment (Ministério do Meio Ambiente - MMA)	Responsible for planning, coordinating, supervising and controlling actions related to the environment.
Genetic Heritage Department (Departamento de Patrimônio Genético -DPG)	Responsible for proposing and monitoring policies for the development of the economy associated with and for the management of access to genetic heritage and associated traditional knowledge

6. Websites

Ministry of the Environment
MMA http://www.mma.gov.br

Brazilian Institute of the Environment and Renewable Natural Resources - Ibama
http://www.ibama.gov.br

Genetic Heritage Management Council (CGen)
http://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico

Access and Benefit-Sharing clearing-house (ABSCH)
https://absch.cbd.int/en/countries

SisGen
https://sisgen.gov.br

7 . References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Brazil profile. Available in: Access on 28/10/2022.

BRASIL. Decreto nº 7.882, de 11 de maio de 2016. Available in: http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2016/decreto/D8772.htm Access on 28/10/2022.

BRASIL. Lei nº 13.123, de 20 de maio de 2015. Available in: http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Lei/L13123.htm Acess on 28/10/2022.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Brazil profile. Available in: Access in 09/11/2017. GSS SUSTENTABILIDADE E BIOINOVAÇÃO. Lei 13.123/2015 – Lei da Biodiversidade: Acesso ao patrimônio genético, conhecimento tradicional associado e repartição de benefícios. 2ª Edição. Confederação Nacional das Indústrias – CNI. São Paulo, 2016.

Canada[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

At present there is no legal framework in Canada specifically related to ABS.

It is important to highlight that most official documents from Canada on ABS underline that, during the process of drafting a future regulation on access to genetic resources, it will be

1. The information hereinafter has been updated until September 3rd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

important to take into consideration the fact that, in the country, each province and territory has authority over the public lands within their jurisdiction and its associated natural resources, including genetic resources. These provinces and territories are also responsible for the majority of the types of property rights, including the laws that regulate access to private property. (Access to Genetic Resources and Sharing of Benefits of their use in Canada: Opportunities for a New Policy Direction. p. 11).

In addition, the National Focal Point clarifies that indigenous people who participate in self-government agreements or comprehensive land claim agreements (or other established rights) may have authority over granting access to lands and resources under their jurisdiction.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions related to access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

However, the National Focal Point of Canada warns that, although ABS issues are not provided for in current regulations, activities related to research and technological development with natural resources may have other types of legal obligations. In this regard, certain generally applicable federal, provincial and territorial laws and regulations (eg in relation to protected areas or wild animals) administer in situ access to certain biological resources and establish requirements for prior authorization. As an example, at the federal level, the Species at Risk Act (SC 2002, c 29) is in force and requires a permit for the collection or scientific study of endangered and endangered species on its list. In the territories, scientific research, including sample collection, is governed by specific legislation and requires a license, as may be noted in the following standards: Northwest Territories: Scientists Act (RSNWT 1988, c S-4); Nunavut: Scientists Act (RSNWT (Nu) 1988, and S-4); Yukon Territory: Scientists and Explorers Act (RSY 2002, c.200), among others; Manitoba Province: The Endangered Species And Ecosystems Act (C.C.S.M. c. E111).

Regarding in situ resources on indigenous lands, with respect to the various indigenous peoples of Canada (First Nations, Métis and Inuit), it is possible that certain access requires a prior consultation process. In addition, it is known that several groups have already developed codes of conduct or research protocols that relate to genetic resources in the lands they hold, as well as their traditional knowledge and cultural practices.

Finally, for access to genetic resources in ex situ collections, the National Focal Point emphasizes that the entity responsible for the management and curating of the ex situ collection often has policies in place that regulate access to the resources of these collections and, in general, require prior authorization for access.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country. However, as reported by the National Focal Point, there are several applicable procedures and guidance documents for access to the ATK:

As mentioned in 2.3, several indigenous groups have developed and continue to develop codes of conduct or research protocols related to their traditional knowledge and cultural practices. E.g. First Nations in Quebec and Labrador's Research Protocol (2014) and guidelines produced by Inuit Tapiriit Kanatami (1998, 2006). Territorial governments have also established permitting and research guidance procedures (e.g. the Yukon government's Guidebook on Scientific Research in the Yukon). In relation to Canada-wide approaches, the main funding agencies of the Government of Canada have developed the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, which includes measures and patterns of research involving indigenous communities.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the National Focal Point, federal / provincial / territorial laws regarding access to resources in certain areas generally apply if the species is native or exotic, see item 2.3.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the National Focal Point, certain federal, provincial and territorial laws govern the movement of certain materials; E.g., at the federal level, the Wild Animal and Plant Protection of International and Interprovincial Trade Act (S.C. 1992, c.52) regulates the import, export and interprovincial transport of plants and wildlife, including its parts and derivatives; and the Plant Protection Act (S.C. 1990, c.22) and the Health of Animals Act (S.C. 1990, c.21) regulate the movement of material that may affect plant and animal health.

2.8 Does the current legislation or any ongoing bills provide specific procedures for digital sequence information or synthetic biology? What is the specific terminology used in the domestic legislation?
( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to information obtained from the National Focal Point of Canada, certain laws require the allocation of non-monetary benefits in the form of information obligations (e.g., the laws of "Scientists Acts" in their respective territories). In addition, a number of applicable policies, research guidelines and codes of conduct (see items 2.3 and 2.4) establish key values related to benefit sharing, including participation, data sharing and recognition.

3.2 What are the applicable procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body? Are there any records of fines having been applied by such institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, as clarified by the National Focal Point, this does not mean that certain activities related to access with natural resourc-

es are exempt from punishment. The country has some permitting, licensing and contractual systems that control access to natural resources for research and scientific purposes at federal, provincial or territorial level (eg. the Northwest Territories Scientist Act) which contains sanctions, including the indication of the fines.

4.3 Is there any record of emblematic biopiracy cases or disputes related to access and benefit sharing in the country?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Canada Profile
https://absch.cbd.int/countries/CA

CBD Canada Profile
https://www.cbd.int/countries/?country=ca

National CHM
https://biodivcanada.chm-cbd.net/

Canadian Biodiversity Information Facility
http://www.scib.gc.ca

7. References

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Chile[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 28th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 3 of Decree with Force of Law No. 3 of March 9, 2006, which reformulates Industrial Property Law (Law 19.039), stipulates that the protection granted to industrial property rights shall respect biological and genetic heritage as well as

1. The information hereinafter has been updated until October 30th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

the national traditional knowledge. It also states that industrial property rights developed from material obtained from genetic heritage or traditional knowledge shall be acquired in accordance with the current legal system.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Nonetheless, the report "El Estado de los Recursos Genéticos Forestales en Chile" (2011) developed by FAO stated that the Government has already entered into some access and benefit sharing agreements, but there are no templates, contract models or standard definitions of benefit sharing, and each of them has been negotiated and outlined under the terms of the contract.

3.2 What are the applicable procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. An emblematic case of biopiracy involves the immunosuppression characteristics of the fungus Rapamune, collected in Isla de Pascua, which were patented by a Canadian pharmaceutical company in 1999.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol.

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Chile Profile
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CBD Chle Profile
https://www.cbd.int/countries/?country=cl

Ministry of Environment – Chile
http://www.mma.gob.cl/1257/w3-channel.html

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Colombia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 26th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Law 99 of December 22, 1993 – Colombia's General Environmental Law;
- Law 165 of November 9, 1994 – approves the Convention on Biological Diversity;

1. The information hereinafter has been updated until November 13, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Decree No. 730 of March 14, 1997 – establishes the National Competent Authority on matters of access to genetic resources;

- Decree No. 1,687 of June 27, 1997 – establishes the responsibilities of the different departments of the Ministry of Environment;

- Resolution 620 of July 7, 1997 – delegates some functions of Decision 391 of the Commission of the Cartagena Agreement, and establishes the internal procedures for processing requests for access to genetic resources and their by-products.

- Decree 309 of February 25, 2000 – regulates scientific research on biological diversity;

- Decree 3,570 of September 27, 2011 – modifies the objectives and the structure of the Ministry of Environment and Sustainable Development and integrates the Administrative Department of the Environment and Sustainable Development;

- Decree 1,375 of June 27, 2013 – regulates biological collections;

- Decree 1,376 of 2013 – regulates collection permits of wild species from the biological diversity for the purpose of non-commercial scientific research

- Resolution 1,348 of 2014 – establishes the activities that configure access to genetic resources and its by-products for the due application of Andean Decision 391 of 1996 in Colombia;

- Resolution 736 of 2015 - by which the internal working groups of the Directorate of Forests, Biodiversity and Ecosystem Services are created, their functions are determined and coordinators are appointed

- Resolution 1352, of 2017 that modifies Resolution 1348, of 2014

- Law 1955 of 2019 National Development Plan 2018-2022 “Pact for Colombia, Pact for Equity”

Colombia, Bolivia, Ecuador, Peru and Venezuela form a sub-regional organization called the Andean Community of Nations. Within the Convention on Biological Diversity, this sub-regional organization has established the following decisions to strengthen actions related to the application of the norms contained in the CBD:

- Andean Decision 391/96 – Common Regime on Access to Genetic Resources;

- Decision 423/97– Amending the Eighth Transitory Disposition of Decision 391;

- Decision 448/98 – Amending the Eighth Transitory Disposition of Decision 391;

- Decision 486/01 – Common Regime on Intellectual Property, which includes biological patents.

Regarding Decree 1076/2015 and Resolutions 620/1997,1348/2014 and 1352/2017, which so far establish the rules of access, a project of Law on Access and Benefit Sharing is under

analysis by the Ministry of Environment of Colombia being the previous resolutions and decree subject to change.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The country has the following competent institutions regarding access and benefit sharing:

- **Ministry of Environment and Sustainable Development:** only designated competent national authority (CNA) for the country. According to Law 99 of 1993 established in Article 5, item 21, the Ministry of Environment and Sustainable Development is responsible for regulating the acquisition, use, management, investigation, import, export, commerce and distribution of genetic strains and species of wild flora and fauna; responsible for regulating the import, export and commerce of the referred genetic material; to establish mechanisms and procedures of surveillance and control; and to act as necessary to reclaim the payment or acknowledgement of rights or prerogatives arising from the use of the genetic material in favor of the country.In 2011, the objectives and the structure of the Ministry of Environment and Sustainable Development were modified by Law 3,570.

Besides the Competent National Authority, the following institutions have responsibilities regarding access and benefit-sharing:

- **Office of the Vice Minister for the Environment:** Evaluates access requests in the due term; issues joint technical opinions with the legal department on the suitability or not of access requests; Coordinates, supported by the legal department, the necessary steps for negotiating the signature of access contracts; supervises and controls the fulfillment of the conditions detailed in the access contracts and in the dispositions of Decision 391, and establishes the necessary mechanisms of monitoring and evaluation.

- **Legal Department:** Receives access requests along with the relevant documents and information; Offers initial analysis of access requests to determine whether or not it is complete; Requests any missing information and documentation; Issues the order through which the access request to the genetic resources can be approved and the due procedures can be initiated.

- **Genetic Resources Group:** Elaborates policies and regulations related to the conservation and sustainable use of genetic resources; Defines technical guidelines for prevention and control of illegal access of genetic resources; organizes inventory of genetic resources and defines technical guidelines for the implementation of biosecurity measures.

Also, Law 3,570 established responsibilities related to access and benefit sharing for Sub-directorate of Education and Participation; for the Department of Green and Sustainable Businesses (the following role should be highlighted: to propose the economic calculations for the payment or acknowledgement of rights or royalties owed to the country for the use of its genetic resources, article 9, item 11); and for the Directorate of Forests, Biodiversity and Ecosystem Resources (the following role should be highlighted: to deal with procedures related to requests for access to genetic resources, accepting or denying such requests, deciding on initial appeals and approving their corresponding contracts, article 16, item 14).

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Decree 1076 of 2015 the prior authorization is mandatory, which should be outorgated in compliance with Decision 391 of the Andean Pact that prescribes the following procedures:

1. Application: the applicant shall submit the request for access to the competent authority

2. Publication of Summary of the Project: the national competent authority will publish a Summary of the project of access.

3. Evaluation: a technical body will evaluate the access application.

4. Access Contract: the competent authority will accept or not the requirement and proceed to the negotiation of the Access Contract with the applicant.

5. Contract confirmation: the competent authority will publish a Resolution confirming the Access Agreement.

It is also important to mention that Resolution 1,348 of 2014 established which activities must be considered access to genetic resources and, therefore, are within the scope of the legislation described in question 2.1 of this study. In this sense, only the following activities that are carried out with native species, in their wild forms, domesticated, cultivated or escaped from domestication, including viruses, that are in the national territory or outside of this must be compliant with Colombian ABS framework:

- The separation of the functional and non-functional units of DNA and / or RNA, in all the forms found in nature;

- The isolation of one or more molecules understood as micro and macro molecules, produced by the metabolism of an organism;

- A patent application for products or procedures obtained or developed from genetic resources or their derived products;

Although is not clear in the national legislation, the document "Acceso a Recursos Genéticos y sus Productos Derivados" provided by the Ministry of Environment that raw extracts and mixtures of molecules shall be within the scope of the national ABS framework only when a patent application is sought for products or procedures obtained or developed from genetic resources or their derived products.

Regarding activities conducted without authorization, Law 1955 of 2019 sets in its article 6 that national and international users have 2 years counted from the issuance of this Law to apply for the authorization and enter into an Access contract.

Finally, it is worth-mentioning that the document "Acceso a Recursos Genéticos y sus Productos Derivados" 313 Access Contracts was signed in 2019.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No. Resolution 391 of the Andean Community does not include any specific or differentiated procedures for access to associated traditional knowledge, only establishing in its eighth tran-

sitional disposition that the Board of the Andean Community shall draft a proposal for the establishment of a special regime or a harmonization norm to strengthen the protection of local, Afro-American and indigenous communities' knowledge, innovations and traditional practices.

As for Resolution 620 of 1997 of the Colombian Ministry of Environment, which establishes the internal procedures for processing requests for access to genetic resources and their by-products, it also does not include any specific procedures for cases of access to associated traditional knowledge.

On the other hand, Decree 309 of 2000, article 25, establishes that the approval of the research permit for scientific research on the Colombian biological diversity does not exempt its holder from requesting access to the relevant community in order to carry out research activities in indigenous lands or lands occupied by black communities.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Decision 391 establishes in its second complementary disposition that the member countries of the Andean Community should mutually acknowledge their intellectual property rights over genetic resources, by-products or synthetic products and associated intangible components, either obtained or developed through access activities. Furthermore, according to the third complementary disposition, the national competent departments dealing with intellectual property shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the right to register patents.

The Andean Community also has another instrument related to this topic, Decision 486/01, which establishes the Common Intellectual Property Regime, including biological patents. In this sense, in article 3, "Genetic and Biological Heritage and Traditional Knowledge", it is established that "(...) the grant of patents relating to inventions developed on the basis of material derived from that heritage or knowledge shall be subject to that material having been acquired in accordance with international, community and national legal provisions."

In addition, Decision 486/01 requires in Article 26, items 'h', 'i' and 'j', the presentation of documents and information regarding the genetic heritage or associated traditional knowledge as a requirement for the patent approval; whereas Article 75, items 'g' and 'h', establishes the cases of invalidity of patents, also in relation to the accessed genetic heritage or associated traditional knowledge.

Nationally, Resolution 1352, of 2017 that modifies Resolution 1348, of 2014, establish that when presenting the requirement of a patent for products derived from genetic resources or its derivatives, the applicant shall present a copy of the Agreement of Access to Genetic Resources before the competent authority, according to Andean Decision 486/01.

According to Article 1 of Resolution 620 of 1997, the Office of the Vice-Minister of Environment will maintain permanent contact with the national patent offices in order to establish a suitable information system.

Finally, it is important to note that article 2, item 3, of Resolution 1,348 of 2014 (resolution which lists the activities classified as access), establishes that access to genetic resources and its by-products will occur, among other situations, "whenever actions are carried out with the objective of requesting patents over an identified function or property of a molecule, even if it

has not been isolated or purified yet".

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No. Andean Resolution 391 establishes, in Article 3, the scope of the dispositions contained in this resolution. In this sense, its terms are applicable to any genetic resources originated in the member countries of the Andean Community, including its by-products and intangible components. As per the first article, the countries of origin should be understood as "countries that possess genetic resources in in situ conditions, including those which, having been in in situ conditions, are now in ex situ conditions", As for in situ conditions, these are understood as "the conditions in which the genetic resources are found in their ecosystems and natural environments; in the case of domesticated or cultivated species or those having escaped domestication, in the environments where they developed their specific properties". It can be noted that on no occasion the legislation mentions explicitly native or exotic species.

On the other hand, it should be highlighted that the same article 3 adds that the scope of these legal provisions includes the genetic resources of migratory species that for natural reasons are found in the territories of the member countries of the Andean Community.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, Decree 309 of 2000, chapter V, "Exportation and Importation of Species or Samples of Biological Diversity", article 18, it establishes that the holders of research permits applying for the exportation of Colombian species or biodiversity samples for research purposes shall request authorization from the Ministry of Environment, which will issue the corresponding permit or authorization required by the CITES Convention, according to each case. As per Article 200 of the same Decree, the authorization shall also be required in the case of importation of species or biodiversity samples for scientific research purposes.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE

According to the study conducted by the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources of CBD in 2020, DSI matter is addressed by Resolution 1348 (2014) when it defines ABS activities and it can be regulated through contractual provisions in access contracts.

Decision 391 of the Andean Community defines synthetized product and includes it as in the scope of the law. The terminology used in the Andean Community is "synthetized product". Also, the definition of genetic resources for the purpose of Decision 391 includes any material of a biological nature that contains genetic information of actual or potential value or utility.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The national legislation does not foresee species that have naturally developed their distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Benefit Sharing is mandatory and the responsibility to share the benefits lies on the applicant.

Decision 391 of the Andean Community does not impose any specific procedures on benefit-sharing. Notwithstanding, article 2, item a, lists among the objects of the referred resolution the regulation of the access to genetic resources and its by-products in the member countries, with the objective of "establishing the conditions for just and equitable participation in the benefits of the access".

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

There are no specific procedures about the Benefit Sharing Agreement. Law 3,570 of 2011 establishes that it is the responsibility of the Department of Green and Sustainable Businesses to propose the economic calculations for the payment or acknowledgement of rights or royalties owed to the country for the use of its genetic resources (article 9, item 11). There are specific contracts for research within the cosmetic industry.

Regulation of Andean Decision 391 states that there must be an Annex to the Agreement between the provider of the genetic resource and the applicant containing benefit sharing obligations. According to the same legislation, the Annex with the benefit sharing obligations is an essential condition for submitting the Access Agreement.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Genetic Heritage	Government
Non Monetary	Not defined	Not defined	-	Genetic Heritage	Government

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 16 of Decree 3,570 of 2011, which modifies the objectives and the structure of the Ministry of Environment and Sustainable Development and integrates the Administrative Department of the Environment and Sustainable Development, establishes that the Directorate of Forests, Biodiversity and Ecosystem Resources is responsible for "enforcing preventive and punitive sanctions on matters under their competence".

Thus, Resolution No. 620 of 1997 established that the Office of the Vice-Minister is responsible for supervising and enforcing the conditions included in access contracts and the disposi-

tions of Decision 391, as well as establishing the relevant monitoring and assessment mechanisms.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Decree 1076 of 2015 states in its article 2.2.1.6.1.3. the authorization can be suspended or revoked in case of non-compliance with the obligations provided by the authorization. Also, the sanctions described in article 85 of Law 199 of 1998 may be applicable, such as fines Daily fines up to a sum equivalent to three hundred (300) monthly minimum wages.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Environment and Sustainable Development	Authorized to supply the genetic resource and its by-products and therefore to sign or supervise the access contracts, to take the actions provided for in the Andean common regime and to ensure their performance

6. Websites

National CHM
http://co.chm-cbd.net

Ministry of Environment and Sustainable Development
https://www.minabiente.gov.co/index.php

Website of the Genetic Resources Group of the Ministry of Environment and Sustainable Development
https://www.minambiente.gov.co/index.php/component/content/article/782-plantilla-bosques-biodiversidad-y-servicios-#:~:text=En%20la%20normatividad%20Colombiana%20los,%2C%20Ley%20165%20de%201994

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GOBIERNO DE COLOMBIA. **Decreto Nº 1.376 - Reglamenta el permiso de recolección de especímenes de especies silvestres de la diversidad biológica con fines de investigación científica no comercial.** Available in: <https://www.ecolex.org/es/details/legislation/decreto-no-1376-reglamenta-el-permiso-de-recoleccion-de-especimenes-de-especies-silvestres-de-la-diversidad-biologica-con-fnes-de-investigacion-cientifca-no-comercial-lex-faoc125537/> Accessed on 11/05/2016.

GOBIERNO DE COLOMBIA. **Decreto Nº 1.687 - Se fusionan unas dependencias del Ministerio del Medio Ambiente.** Available in: <https://www.ecolex.org/details/legislation/decreto-no-1687-se-fusionan-unas-dependencias-del-ministerio-del-medio-ambiente-lex-faoc-024988/?q=Decreto+n%C2%BA+1.687+> Accessed on 11/05/2016.

GOBIERNO DE COLOMBIA. **Decreto Nº 3.570 de 2011 - Modifica los objetivos y la estructura del Ministerio de Ambiente y Desarrollo Sostenible e integra el Sector Administrativo de Ambiente y Desarrollo Sostenible.** Available in: <https://www.ecolex.org/details/legislation/decreto-no-3570-modifica-los-objetivos-y-la-estructura-del-ministerio-de-ambiente-y-desarrol-lo-sostenible-e-integra-el-sector-administrativo-de-ambiente-y-desarrollo-sostenible-lex-faoc-105546/?q=n%C2%BA+3.570+de+2011&type=legislation&xcountry=Colombia&xdate_min=&xdate_max=> Accessed on 11/05/2016.

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GOBIERNO DE COLOMBIA. **Ley Nº 165 De 1994 (Noviembre 9) por medio de la cual se aprueba el "Convenio sobre la Diversidad Biológica".** Available in: <http://www.minambiente.gov.co/images/BosquesBiodiversidadyServiciosEcosistemicos/pdf/Politica-Nacional-de-Biodiversidad/3355_ley_0165_091194.pdf> Accessed on

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GOBIERNO DE COLOMBIA. **Resolución nº 1352 de 2017, por la cual se modifica la Resolución 1348 de 2014.** Available in: <https://www.ecolex.org/details/legislation/resolucion-no-1352-modifica-la-resolucion-no-1348-que-establece-las-actividades-que-configuran-acceso-a-los-recursos-geneticos-y-sus-productos-derivados-lex-faoc175406/?q=Resolucion+1352+de+2017> Accessed on 01/24/2020.

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Costa Rica[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 24th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Law No. 7554, 1995 - Organic Law of the Environment (Ley N° 7554, 1995 - Ley Orgánica

1. The information hereinafter has been updated until December 17th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

del Ambiente);

- Law No. 7788, 1998 - Biodiversity Law (Ley N° 7788, 1998 - Ley de Biodiversidad);

- Executive Decree No. 31.514-MINAE, 2003 - General standards for Access to Genetic and Biochemical Elements and Resources of Biodiversity (Decreto Ejecutivo Nº 31.514-MINAE, 2003 - Normas generales para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad);

- Executive Decree No. 33.697-MINAE, 2007 - Regulation for Access to Genetic and Biochemical Elements and Resources of Biodiversity in ex situ conditions (Decreto Ejecutivo nº 33.697-MINAE, 2007 - Reglamento para el Acceso a los Elementos y Recursos Geneticos y Bioquimicos de la Biodiversidad en condiciones ex situ);

- Decree No. 34.433-MINAE, 2008 - Regulation to the Biodiversity Law (Decreto Nº 34.433-MINAE, 2008 - Reglamento a la Ley de Biodiversidad);

- Decree No. 34.958-MINAE-COMEX, 2008 - Regulation to Article 80 of the Biodiversity Law (Decreto n° 34.958-MINAE-COMEX, 2008 – Reglamento al Artículo 80 de la Ley de Biodiversidad);

- Law No. 8.632, 2008 - Modification of Various Articles of Law No. 7978 of Marks and Other Distinctive Signs,

- Law No. 6867 on Patents for Invention, Industrial Designs and Models of Utility, and Law No. 7788 of Biodiversity (Ley nº 8.632-MINAE, 2008 – de Modificación de Varios Artículos de la Ley Nº 7978 de Marcas y Otros Signos Distintivos, de la Ley Nº 6867 de Patentes de Invención, Dibujos y Modelos Industriales y Modelos de Utilidad, y de la Ley Nº 7788 de Biodiversidad);

- Executive Decree No. 39.341-MINAE, 2015 - Regulation for the application of administrative sanctions in matters of unauthorized access to genetic and biochemical elements and resources (Decreto Ejecutivo Nº 39.341-MINAE, 2015 - Reglamento para la aplicación de las sanciones administrativas en materia de acceso no autorizado a los elementos y recursos genéticos y bioquímicos).

- Decree Nº 40885-MINAE - Amends Decree Nº 29680-MINAE, which regulates the functioning of the National Management Commission for Biodiversity.

- Decree No. 41591 - MINAE, 2019. - Amendment to Executive Decree No. 31514 - MINAE of October 3rd 2003 and Executive Decree nº 33697 - MINAE of February 6th, 2007 (Reforma al Decreto Ejecutivo N°31514-MINAE del 3 de octubre de 2003“ Normas Generales para el acceso a los elementos y recursos genéticos y bioquímicos de la Biodiversidad” y al Decreto Ejecutivo N°33697-MINAE de 6 de febrero de 2007 “Reglamento para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad en condiciones ex situ”)

To help in understanding all these rules, a manual of April 2016 was prepared by CONAGEBIO called “Manual de Procedimientos CONAGEBIO “. Instructions to the user who wishes to access Costa Rica’s genetic resources can be found in Chapter 5 “CONAGEBIO - PRO1: Procedures for requesting permits for access to genetic elements and resources of biodiversity”

(Procedimientos para solicitar permisos para el acceso a los elementos y recursos genéticos de la biodiversidad).

Also, the country also has accessory instruments to enforce the correct application of the aforementioned norms:

- Decree No. 39.118-MINAE, 2015 - National Biodiversity Policy (Decreto Nº 39.118-MINAE, 2015 - Política Nacional de la Biodiversidad);

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The National Commission for the Management of Biodiversity (National Commission for the Management of Biodiversity) - CONAGEBIO, created by article 14 of Law N ° 7788, 1998 - Law of Biodiversity, has diverse competences in the matter of biodiversity, among them stand out:

- To formulate national policies for the conservation, ecologically sustainable use and restoration of the country's biodiversity, observing the provisions of the Convention on Biological Diversity and other related international agreements and contracts.

- To formulate and coordinate policies for access to biodiversity and associated traditional knowledge to ensure adequate technical and scientific transfer and the fair and equitable sharing of benefits.

In the same law, Article 62 establishes that the Commission will have competence to propose policies for access to genetic and biochemical resources of ex situ and in situ biodiversity and will act as mandatory consultative body in procedures for requesting protection of intellectual property rights on biodiversity.

From Decree No. 31.514-MINAE, 2003 - General rules for Access to Genetic and Biochemical Elements and Resources of Biodiversity, amended by Executive Decree No. 41.591, 2019, CONAGEBIO is renamed "Competent National Authority". In addition, Article 5 establishes the person who is on the Executive Direction of CONAGEBIO as the National Focal Point for the subject of access to genetic and biochemical resources to the Executive Secretariat of the Convention on Biological Diversity. In the same vein, the ABS-CH website informs that Ms. Angela González Grau, a member of CONAGEBIO, will represent the Competent National Authority in matters related to genetic resources, as established in the Nagoya Protocol.

Regardless of the specific Technical Office (Technical Office) of CONAGEBIO, in accordance with article 17 of Law N° 7788, 1998 - Law of Biodiversity, the following activities are within its competence:

- To process, approve, refuse and inspect the requests for access to biodiversity resources;

- To coordinate together the Areas of Conservation, the private sector, the indigenous peoples and the rural communities, the issues related to the access that deals with the law;

- To Organize and maintain updated access request registration;

- To Compile and update the regulations related to compliance with the agreements and guidelines on biodiversity.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Article 9 of Executive Decree No. 31.514 of October 3rd, 2003, all access activities in the country must comply with the procedures described below:

1. Application Form: Filling a form, which shall include, besides other requirements, proof of payment of administrative fees to CONAGEBIO.

2. PIC and MAT: Obtaining Prior Informed Consent, which shall contain Mutually Agreed Terms including information about monetary and non monetary benefits.

3. Analysis: Oficina Tecnica will issue a Resolution with technical opinion about the authorization and forward it to the Ministry of Environment, which will grant or deny the permit.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The Biodiversity Law, in Chapter V, Section III (articles 77 to 85), deals with the protection of intellectual and industrial property rights. More precisely, Article 80 indicates that both the National Seed Institute and the Registries of Intellectual Property and Industrial Property are obliged to consult the Technical Office of the Commission before granting intellectual or industrial property protection of innovations involving components of biodiversity, and always provide the certificate of origin issued by the Commission Technical Office and prior consent. Justified opposition from the Technical Office will prohibit the registration of a patent or protection of innovation.

Article 78 indicates the exceptions to patent protection:

1. Sequences of deoxyribonucleic acid, nucleotides and amino acids as found in nature or sequences of deoxyribonucleic acid, nucleotides and amino acids which do not meet the patentability requirements as set forth in Law No. 6867 of April 25, 1983, as amended.

2. Plants and animals.

3. Microorganisms as found in nature.

4. The essentially biological processes for the production of plants or animals which are not non biological and microbiological procedures.

5. Natural processes or cycles in themselves.

6. Inventions essentially derived from knowledge associated with traditional biological or cul-

tural practices in the public domain.

7. Inventions whose commercial exploitation must be avoided to protect public or moral order or to protect the health or life of humans or animals or to preserve plants or to prevent serious environmental damage.

Lastly, Article 82 of that law refers to the sui generis intellectual property rights of the community, recognizing and protecting it, under the common name of the sui generis intellectual property rights of the community, which encompasses knowledge, practices and the innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge. The right and recognition of its existence do not require a prior declaration, explicit recognition or official registration; therefore, can understand practices that in the future will acquire this category.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No, Costa Rica has no specific procedure for this purpose. However, Article 7 (17) of the Biodiversity Law indicates that an exotic species is a species of flora, fauna or microorganism whose natural geographical dispersion does not correspond to the national territory and is found in the country as a product of voluntary or non-human human activities , as well as by the activity of the species itself.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Article 6a of Executive Decree No. 31514 - MINAE of October 3rd, 2003, for the interchange and transfer of elements and genetic resources of biodiversity in situ or ex situ, the concerned parties shall enter a Material Transfer Agreement.

Also, Article 18 of Decree No. 31.514-MINAE, 2003 - General Rules for Access to Genetic and Biochemical Elements and Resources of Biodiversity covers export issues, stipulating that access authorization does not exempt compliance with other national legal obligations the export of plants, animals, seeds, micro-organisms or part of them obtained by access.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the legislation addresses this matter as this term is contained in the definition of “access to genetic resources”, according to a 2020 study from the ad hoc Technical Expert Group on Digital Sequence Information of Genetic Resources. However, there are no specific procedures for those cases.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country’s territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country’s territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and it comprises basic research, bioprospection and economic exploitation of genetic and biochemical resources . The responsibility to share the benefits lies on the applicant..

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

The fair distribution of the benefits and values denied by the use of Costa Rica's biodiversity resources is one of the objectives of Law N ° 7788, 1998 - Law of Biodiversity, according to its articles 1 and 10.

According to item 2.3. of this form, the form, content of the requests, shelf life and characteristics of the authorization for access are described in Section II "Permits for Access to the Elements of Biodiversity" of Law No. 7788, 1998 - Biodiversity Law. In this sense, Article 76 of this Section determines to the requesting party the payment up to 10% of the value of scientific research and up to 50 % of royalties to the National System of Conservation Areas, to the indigenous territory or to the private owner of the sample of the genetic resource to be accessed.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Research, Bioprospection, Economic Exploitation	Not defined	Up to 10% of scientific research and 50% of royalties	Genetic Heritage/ATK	Provider/ Government
Non Monetary	Research, Bioprospection, Economic Exploitation	Not defined	Not defined	Genetic Heritage/ATK	Provider/ Government

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The National Commission for the Management of Biodiversity (Comisión Nacional para la Gestión de la Biodiversidad) - CONAGEBIO and its Technical Office(Oficina Técnica) were created by Law N ° 7788, 1998 - Law of Biodiversity, with diverse competences in relation to biodiversity and ABS activities. However, only through Decree No. 31.514-MINAE, 2003 - General Norms for Access to Elements and Genetic and Biochemical Resources of Biodiversity, in articles 5 and 20, that the Technical Office of CONAGEBIO received new competences, among

them the responsibility to supervise requests for access to genetic and biochemical resources of biodiversity and access to the traditional knowledge associated with these resources, as well as to carry out the control and verification of the conformity of the authorizations granted and may also carry out inspections and investigations on violations of authorizations, activities irregularities and violation of prior informed consent.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The National Commission for the Management of Biodiversity (Comisión Nacional para la Gestión de la Biodiversidad) - CONAGEBIO and its Technical Office (Oficina Técnica) were created by Law N ° 7788, 1998 - Law of Biodiversity, with diverse competences in relation to biodiversity and ABS activities. However, only through Decree No. 31.514-MINAE, 2003 - General Norms for Access to Elements and Genetic and Biochemical Resources of Biodiversity, in articles 5 and 20, that the Technical Office of CONAGEBIO received new competences, among them the responsibility to supervise requests for access to genetic and biochemical resources of biodiversity and access to the traditional knowledge associated with these resources, as well as to carry out the control and verification of the conformity of the authorizations granted and may also carry out inspections and investigations on violations of authorizations, activities irregularities and violation of prior informed consent. The offenses against Costa Rica's biological diversity are provided for in the national legal system since Law No. 7554, 1995 - Organic Law of the Environment, which in article 99, item G provides for the imposition of compensatory or stabilizing obligations for the one that causes damage to the environment or biodiversity. Article 101 of this same law establishes that in this case, civil liability jointly and severally liable for natural or legal persons for damages caused to the environment or biological diversity, for violation of the legal provisions of this norm and other laws that regulate the protection of the environment and biodiversity.

Specifically regarding biodiversity, Law No. 7788, 1998 - Ley de biodiversidad, establishes in its article 112 sanctions against unauthorized access to biodiversity. Therefore, those who carry out exploration, bioprospecting or access to biodiversity without authorization or in disregard of the terms in which it was granted shall be subject to a fine of at least the equivalent of a salary provided for in article 2 of Law 7337, up to the equivalent 12 of these wages, following the same sense, Article 28 of Decree No. 31.514-MINAE, 2003 - General Rules for Access to Genetic and Biochemical Elements and Resources of Biodiversity.

The procedure for applying the sanctions above is found in Executive Decree No. 39.341-MINAE, 2015 - Regulation for the application of administrative sanctions in matters of unauthorized access to genetic and biochemical elements and resources.

Finally, it should be pointed out that non-compliance with intellectual property law devices derived from access to genetic and biochemical resources or associated traditional knowledge were also legally established. In this sense, Decree No. 34.958-MINAE-COMEX, 2008 - Regulation to Article 80 of the Law on Biodiversity determines in its article 5 that when the Technical Office becomes aware of the non-compliance with ABS standards, especially Article 80 of the Law N ° 7788, 1998, it must apply a daily fine until irregular activity ceases, in the following values:

- up to 3 months of default: one sixth of basic salary per day;
- default for 3 to 9 months: one third of basic salary per day;

- default for 9 to 12 months: half a base salary per day;
- default for more than 12 months: one basic salary per day.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Environment and Energy (Ministerio del Ambiente y Energía) - MINAE	Competent to coordinate the administrative organization in charge of the management and the conservation of the biodiversity
National Commission for the Management of Biodiversity – CONAGEBIO	It is competent to propose policies for access to genetic and biochemical elements of ex situ and in situ biodiversity. It is the competent national authority as well as the national focal point.
Technical Office CONAGEBIO	It is their responsibility to process, approve, reject and inspect requests for access to biodiversity resources; coordinate together the Conservation Areas, the private sector, indigenous peoples and rural communities, issues related to the access that the law treats; organize and maintain updated access request registration; and to compile and update the regulations regarding compliance with biodiversity agreements and guidelines.

6. Websites

National CHM
http://www.sinac.go.cr

CONAGEBIO
http://www.conagebio.go.cr/Conagebio/public/

ABSCH Costa Rica's Profile
https://absch.cbd.int/en/countries/CR

CBD Costa Rica's Profile
https://www.cbd.int/countries/?country=cr

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Costa Rica profile. Available in: https://absch.cbd.int/countries/CR Access on 12/17/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Costa Rica profile. Available in: https://www.cbd.int/countries/?country=cr Access on 12/17/2021.

CONVENTION ON BIOLOGICAL DIVERSITY. **Fact-finding Study on How Domestic Measures Address Benefit-Sharing Arising From Commercial and Non-Commercial Use of Digital Sequence Information on Genetic Resources for Research and Development**. Canada, 2020. Available in: <https://www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf> Accessed 12/17/2021.

COSTA RICA. Decreto Nº 31.514/MINAE - Normas para el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad. Available on:: http://extwprlegs1.fao.org/docs/pdf/cos65121.pdf Access in 12/17/2021.

COSTA RICA. Decreto Nº 33.106/MINAE - Crea el Programa Nacional de Corredores Biológicos: Estrategia de Conservación de la Biodiversidad. Available on: http://extwprlegs1.fao.org/docs/pdf/cos163437.pdf Access in 12/17/2021.
COSTA RICA. Decreto Nº 33.697/MINAE - Reglamento para el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad en condiciones ex situ. Available on: http://extwprlegs1.fao.org/docs/pdf/cos71597.pdf Access in 12/17/2021.

COSTA RICA. Decreto Nº 34.781/MINAE - Modifica el Decreto Nº 34.433/MINAE, Reglamento a la Ley de biodiversidad. Available in: https://www.ecolex.org/details/legislation/decreto-no-34433minae-reglamento-a-la-ley-de-biodiversidad-lex-faoc079444/?q=&type=legislation&xkeywords=biodiversity&xcountry=Costa+Rica&xdate_min=&xdate_max= Access in 12/17/2021.

COSTA RICA. Decreto Nº 39.118/MINAE - Política Nacional de la Biodiversidad. Available on: http://extwprlegs1.fao.org/docs/pdf/cos148813.pdf Access on 12/17/2021.

COSTA RICA. Decreto Nº 39.341/MINAE - Reglamento para la aplicación de las sanciones administrativas en materia de acceso no autorizado a los elementos y recursos genéticos y bioquímicos. Available on: http://extwprlegs1.fao.org/docs/pdf/cos163240.pdf Access on 12/17/2021.

COSTA RICA. Estrategia Nacional de Biodiversidad 2016 – 2025. Ministerio de Ambiente y Energía (MINAE); Comisión Nacional para la Gestión de la Biodiversidad (CONAGEBIO); Sistema Nacional de Áreas de Conservación (SINAC). 2016. Available in: https://www.cbd.int/countries/?country=cr Access on 12/17/2021.

COSTA RICA. Ley Nº 7.788 - Ley de biodiversidad. Available on: http://extwprlegs1.fao.org/docs/pdf/cos13426S.pdf Access on 12/17/2021.

COSTA RICA. V Informe Nacional al Convenio sobre Diversidad Biológica. Sistema Nacional de Áreas de Conservación (SINAC). GEF-PNUD, 192 p. San José, Costa Rica, 2014. Available in: https://www.cbd.int/countries/?country=cr Access on 12/17/2021.

COSTA RICA. Ley Nº 7.554 - Ley Orgánica del Medio Ambiente. Available in: https://www.ecolex.org/details/legislation/ley-no-7554-ley-organica-del-medio-ambiente-lex-faoc007804/?q=Ley+Org%C3%A1nica+del+Ambiente&type=legislation&xcountry=Costa+Rica&xdate_min=&xdate_max= Access in 12/17/2021.

Cuba[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification since June 06, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country is a Party to the Protocol, by accession, since December 16, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Resolution 111, 1996 - Regulates access to biological resources in Chapter II, Articles 9 to 14;

1. The information hereinafter has been updated until December 23rd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Resolution 160, 2011 - Regulations for the control and protection of species of special significance for biodiversity in the country;

- Resolution 76/2015 - rules over evaluation and approval of environmental permits for the access of natural areas;

- Law nº 81, 1997 - Environment Law;

- Decree Law No. 200, 1999, on Environmental violations;

- Decree Law No. 201, 1999, on ABS related to in situ conservation;

- Decree Law No. 290, 2011, on industrial inventions and designs;

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The country has the following competent institutions regarding access and benefit sharing:

- [Environment Office]

The Ministry of Science, Technology and Environment's Environment Office is the competent institution responsible for informing the Center of Information on Access and Benefit Sharing. The institution is also in charge of publishing ABS information.

- [Environmental Control and Inspection Office]

Also a branch of the Ministry of Science, Technology and Environment. The institution is designated as the National Authority on the matter of Access and Benefit Sharing.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, Chapter II of Resolution 111 of 1996, establishes that all access procedures must be follow the following steps:

1. Every person, natural or legal, needs prior consent granted by the Inspection and Environment Control Center to access or trade in the biological resources of Cuba's biodiversity.

2. In the case of a foreign person, natural or legal, prior consent is granted by the Minister of Science, Technology and Environment and prior consent of the Inspection and Environment Control Center.

3. The authorization form shall clearly state which biological resource will be accessed, the quantity, estimated location, estimated time to achieve this goal, and under what conditions and with what objective.

4. Once the authorization for access has been granted and, before its execution, it must be signed a written agreement between the entity concerned and the public authority setting out the obligations, specifications, limits, restrictions and mutual conditions under which the access will happen, with the purpose of ensuring adequate use of the environment and the right to the sharing of results and benefits coming from access.

5. Once the prior authorization form is approved and the agreement is signed, the environmental license will be issued, granting the right to carry out access in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, Decree Law No. 290 of 2011, in its article 26.1, provides that in order to obtain a patent, the applicant must present to the Cuban Office of Industrial Property the following documents:

1. In cases where the invention uses biological material which is not available to the public, a document proving the deposit of biological material in an institution officially recognized for purposes.

2. Copy of prior consent for access to the biological resource, granted by the competent authority.

3. Statement that biological material has not been obtained in Cuban territory, in which case it should be indicated the country of origin and its source, as well as prior consent of access.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. According to the Interim National Report on the Implementation of The Nagoya Protocol the contract shall be signed by the entity accessing genetic resources and associated traditional knowledge and the National Authority responsible for ABS norms -- in this case, the Environmental Control and Inspection Office.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. Article 12 of Resolution 111, of 1996, provides that individuals or legal persons concerned and the competent authority indicated in Article 9 shall sign mutual conditions, specifications, restrictions and limits, through which access will be granted, with the aim of always ensuring: a) the environmentally appropriate use of resources; b) the right to share in a fair and equitable manner the results and benefits arising from the commercial use and others of the country's biodiversity resources, including access to technology and its transfer in appropriate cases. The law does not provide in detail how the benefits will be distributed.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Decree No. 200 on Environmental Violations institutes in its article 16 institutes the following authorities as the official inspection bodies responsible for sanctioning irregular access to genetic resources:

(a) The head of the Environmental Inspectorate, the Provincial Heads of Inspection and the Environmental Inspectors
Ministry System.

(b) State inspectors of the State Inspection Systems of the Central State Administration Agencies, whose activity has an impact on the protection of the environment, those of the Forest Ranger Corps, Civil Defense Corps and General Customs Corps as the official inspection body responsible for all matters related to access and benefit-sharing in the country.

Furthermore, the country's Interim National Report on the Implementation of The Nagoya Protocol submitted to the Access And Benefit Sharing Clearing House Mechanism states that the Environmental Control and Inspection Office shall be considered the national authority on all matters related to ABS.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Decree No. 1999, on Environmental Violations, establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: a fine ranging from 250 to 5 000 pesos.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Environmental Control and Inspection Office	The office is responsible for granting access permits when prior informed consent has been given.

6. Websites

Instituto de Ecologia y Sistemática
http://www.ecosis.cu/

Ministry of Science, Technology and Environment
https://www.citma.gob.cu/ciencia-tecnologia-e-innovacion/

7. References

Access and Benefit Sharing Clearing House: Cuba. Available at: https://absch.cbd.int/countries/cu. Access in: 12/23/2021.

REPUBLICA DE CUBA. Decreto-ley nº 290, de Las Invenciones y Dibujos y Modelos Industriales. Gaceta Oficial de La Republica de Cuba, 16 de abril de 2012. Available at: <https://www.ecolex.org/details/legislation/decreto-ley-no-290-de-las-invenciones-y-dibujos-y-modelos-industriales-lex-faoc113255/> Access in: 12/23/2021.

REPUBLICA DE CUBA. Decreto-Ley No. 291, de Protección de las Variedades Vegetales, 20 de novembro de 2011.Available at: http://www.wipo.int/edocs/lexdocs/laws/es/cu/cu081es.pdf; Access in: 12/23/2021.

REPUBLICA DE CUBA. Ley no. 81 Del Medio Ambiente, 11 de julho de 1997. Available at: http://www.oas.org/dsd/fida/laws/legislation/cuba/cuba_81-97.pdf; Access on: 12/23/2021.

REPUBLICA DE CUBA. MINISTERIO DE CIENCIA, TECNOLOGIA Y MEDIO AMBIENTE. Resolucion nº 111/96, 14 de outubro de 1996. Available at: http://www.wipo.int/wipolex/en/details.jsp?id=12836 Access on: 12/23/2021.

REPUBLICA DE CUBA. Resolucion 34/96, Normas para la evaluación y aprobación de propuestas de ejecución de expediciones, investigaciones y visitas de carácter científico-técnico e interés ambiental. Available at: http://ex-twprlegs1.fao.org/docs/pdf/cub6772.pdf Access on: 12/23/2021..

REPUBLICA DE CUBA. Resolución nº 160/2011. Gaceta Oficial de La Republica de Cuba, 04 de agosto de 2011. Available at: http://www.orasen.cu/wp-content/uploads/2015/03/Resolucion-160-Gaceta.pdf Access on: 12/23/2021.

REPUBLICA DE CUBA. V Informe Nacional al Convenio sobre la Diversidad Biológica, 2014. Available at: https://www.biofin.org/sites/default/files/content/knowledge_products/V%20Informe%20de%20Cuba%20al%20Convenio%20sobre%20la%20diversidad%20biologica.pdf; Access on: 12/23/2021.

Dominican Republic[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 23th, 1997.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Protocol, by accession, since February 11th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoints:

- Ministry of Higher Education, Science and Technology/Ministerio Educación Superior, Ciencia y Tecnología (MESCYT)

This Ministry is responsible for monitoring and increasing transparency in access to genetic resources and traditional knowledge. Therefore, it is responsible for requesting the applicant for documents and evidence of compliance with the established regulatory framework; and suspending and filing the application in accordance with the provisions of the national legislation applicable.

- Directorate of Biodiversity - Vice-Ministry of Protected Areas and Biodiversity - Ministry of the Environment/ Dirección de Biodiversidad del Viceministerio Areas Protegidas y Biodiversidad del Ministerio de Medio Ambiente

This entity is responsible for monitoring and implementing the Nagoya Protocol, receiving applications for research and access to genetic resources and providing technical opinions.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 5 IRCCs that are available on ABSCH website.

1. The information hereinafter has been updated until March 12th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Policy of Access to Genetic Resources and Benefit-sharing (ABS)/Política de Acceso a Recursos Genèticos y Distribución de Beneficios (ABS);
- Regulation on Access to Genetic Resources and Benefit-sharing (ABS) 2018/Reglamento de Acceso a los Recursos Genéticos y Distribución de Beneficios (ABS);
- Sector Law on Biodiversity nº 333-15/Ley Sectorial de Biodiversidad nº 333-15;
- Regulation on Research in Protected Areas and Biodiversity/Reglamento de Investigacion en Areas Protegidas y Biodiversidad;
- General Law on Environment and Natural Resources (64-00) 2000 / Ley General sobre Medio Ambiente y Recurso Naturales (64-00);

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Access to Genetic Resources and Benefit-sharing Regulation (article 7) and Sectoral Law on Biodiversity nº 333-15 (article 12), identifies the Ministry of Environment and Natural Resources (Ministerio de Medio Ambiente y Recursos Naturales) and more specifically the Biodiversity Directorate as the competent institution, which is responsible for regulating the access to genetic resources, traditional knowledges and benefit-sharing.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Access to Genetic Resources and Benefit-sharing Regulation, Sectoral Law on Biodiversity nº 333-15 and Regulation on Research in Protected Areas and Biodiversity, all access activities in the country must comply with the procedures described below:

1. Research Contract: established, authorized and formalized between the Ministry of the Environment and Natural Resources and the applicant so the access done for scientific, technical or commercial research purposes can proceed. If the research is promoted by an international institution, a national institution must accompany it. The requirement must be done in the Department of Single Window Services of the Ministry of Environment and Natural Resources, indicating the purpose of the communication and attaching all the required documents.

2. Access Contract: if a genetic resource of commercial interest is detected as a result of research, an access contract must be done to comply with the benefit-sharing obligation. The contract will comprehend the conditions of access, mutually agreed terms, distribution benefits and intellectual property rights, if applicable.

3. Permits: the contract may require the presentation of permits issued by the Biodiversity Directorate or another State institution. Fees might be applied.

4. Also, Regulation on Research in Protected Areas and Biodiversity establishes that those people, natural or legal, Dominican or foreign that, who carry out research work directly or indirectly, shall request research permits.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Notwithstanding the procedures described in item 2.3, in cases where access to associated traditional knowledge is concerned, the prior informed consent is required; which is a document demonstrating that local communities have been consulted, informed and involved in the process of prior informed consent and in the establishment of mutually agreed terms, including the sharing of benefits arising from its use.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. In cases where patents arise from research or technological developments involving access to genetic resources, the applicant is required to inform the IRCC's ID number or other document proving compliance with national legislation..

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Access to Genetic Resources and Benefit-sharing Regulation, in its article 14, establishes that in the Mutually Agreed Terms there will be conditions for material transfer. Also, article 23 provides that this transfer must be authorized by the Ministry of Environment and Natural Resources.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

() YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE
Yes, according to the Access to Genetic Resources and Benefit-sharing Regulation, in its articles 10, 14 and 15, benefit sharing is mandatory and it incides over the use of genetic resources, derivatives and traditional knowledge. The responsibility to share the benefits lies on the user/applicant.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE
Yes. According to article 16 of Access to Genetic Resources and Benefit-sharing Regulation, the Access Contract shall provide for the fair and equitable participation of the Dominican State in any economic benefit, scientific, technological or any other nature that may derive from access to genetic resources or associated traditional knowledge. The determination of monetary and non-monetary benefits that may be derived from contract negotiations, shall consider the Annex to the Nagoya Protocol.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Those provided on Nagoya Protocol Annex	Not defined	Genetic Heritage/ATK	Not defined
Non Monetary	Not defined	Those provided on Nagoya	Not defined	Genetic Heritage/ATK	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Access to Genetic Resources and Benefit-sharing Regulation, in its article 7, (k), institutes the Directorate of Biodiversity of the Ministry of Environment and Natural Resources as the official inspection body responsible for all matters related to access and benefit-sharing in the country.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Access to Genetic Resources and Benefit-sharing Regulation (article 34), Law nº 64-00 (article 167), Sectoral Law on Biodiversity nº 333-15, (articles 67 to 79) and Regulations for the Investigation of Protected Areas and Biodiversity (Chapter XIV) establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as revocation of the investigation permit, suspension of activities and fines up to 3,000 (three thousand) minimum wages.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Environment and Natural Resources - Directorate of Biodiversity of Vice Ministry of Protected Areas and Biodiversity/Ministerio de Medio Ambiente y Recursos Naturales - Dirección de Biodiversidad del Viceministerio de Áreas Protegidas y Biodiversidad (-	This institution is competent for all matters involving access to genetic resources, associated traditional knowledge and benefit sharing in Country.such as defining and implementing ABS Politics, authorizing access; monitoring compliance, etc.
Mechanism of Monitoring, Inspection, Verification and Genetic Resource Coordination/Mecanismo de Monitoreo, Inspección, Verificación y Coordinación de los Recursos Genéticos	This institution is competent for verifying if the access has been carried out respecting PIC and MAT and ensuring the proper participation of local communities and equitable benefit-sharing.

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Ecuador[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Protocol, by accession, since February 11th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoints:

- National Institute of Biodiversity (Inabio)

This institution is the Verification Point for issues related to access to genetic resources for commercial purposes and it is the entity in charge of:

– Advising on the mutually agreed conditions for access to genetic resources for commercial purposes when requested by the Ministry of the Environment; and

– Planning, promoting, coordinating, executing and transferring research, science, technology and innovation processes of biodiversity and its components.

- National Service for Intellectual Rights (Senadi)

Senadi is the competent entity responsible for protecting and defending intellectual rights; organizing and managing the information on the registers of all types of intellectual property rights along with the National Information System on Science, Technology, Innovation and Ancestral Knowledge of Ecuador.

It is also the Verification Point in matters related to traditional knowledge associated with genetic resources and is responsible for:

– Ensuring the prior informed consent (addressed by Ecuadorian legislation as "Free, Prior and Informed Consent", or only "FPIC") of indigenous peoples and local communities is obtained when accessing traditional knowledge associated with genetic resources; and

– Registering the concession or refusal of the legitimate holder of the traditional knowl-

1. The information hereinafter has been updated until November 16th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

edge.

- National Customs Service of Ecuador (Senae)

Senae it is in charge of information related to the control of the entry and exit of goods, cargo units and means of transport through the borders and customs zones of the Republic; activities related to the international merchandise traffic; determine and collect the customs obligations caused by the import and export of merchandise; resolve claims, appeals, requests and inquiries; and prevent, prosecute and punish customs offenses.

- Ministry of the Environment (MAE)

This State body is responsible for the management of the strategic biodiversity sector and ensuring the sustainable management of strategic natural resources. Its Undersecretariat of Natural Heritage, through the National Biodiversity Directorate is the Verification Point in matters related to access to genetic resources for scientific and commercial research purposes and it is in charge of granting prior informed consent for access to genetic resources.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Constitution of the Republic of Ecuador, of October 20, 2008;

- Decree No. 905 - This Regulation establish complementary rules for the application of Decision 391 of the Andean Community, related to the Common Regime of Access to Genetic Resources in all the national territory;

- Agreement No. 099 of the Ministry of the Environment - Creates the Public Registry of Applications for Access to Genetic Resources, with the objective of maintaining basic information on access to genetic resources in the country of Ecuador;

- Decree No. 3,516 - Statute of Biodiversity, which establishes the conditions for the development of scientific research on the wild fauna and flora in public and private entities;

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Código Orgánico del Ambiente (Organic Code of Environment) of April 7th 2017 - Provides for Environmental law contained in the Constitution.

- Acuerdo Ministerial (Ministerial Agreement) 034, of February 4th, 2015 - Regulates the sustainable utilization of biological and genetic resources when they are used for scientific purposes only.

- Código Orgánico de la Economía Social de los Conocimientos, Creatividad e Innovación (Organic Code of Social Economy for Knowledge, Creativity and Innovation) of December 9th, 2016

- Executive Decree 1435, of June 7th, 2017 - Reglamento del Código Orgánico Economía Social de los Conocimientos (Regulation of the Organic Code of Social Economy for Knowledge, Creativity and Innovation).

- ACUERDO No. SENESCYT-2020-077 - The purpose of this Regulation is to develop, implement and facilitate adequate knowledge management, contained in the Book III of the Organic Code of the Social Economy of Knowledge, Creativity and Innovation, in relation to the acquisition, exercise and protection of intellectual rights, the rights associated with them, as well as the protection of traditional knowledge.

Ecuador, Colombia, Bolivia, Peru and Venezuela form a sub-regional organization called the Andean Community of Nations. Within the Convention on Biological Diversity, this sub-regional organization has established the following decisions to strengthen actions related to the application of the norms contained in the CBD:

- Andean Decision 391/96 – Common Regime on Access to Genetic Resources;

- Decision 423/97– Amending the Eighth Transitory Disposition of Decision 391;

- Decision 448/98 – Amending the Eighth Transitory Disposition of Decision 391;

- Decision 486/01 – Common Regime on Intellectual Property, which includes biological patents.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The country has the following competent institutions regarding access and benefit sharing:

- Ministry of Environment

This is the National Competent Authority responsible for granting access permits and for the issuance of the technical criteria and limits for the access. Its competence is shared with the Research Authority.

- Secretariat of Higher Education, Science, Technology And Research

This Secretariat is competent for granting access permits with the purpose of research.
National Intellectual Rights Service

Its competence covers all matters related to intellectual property rights, the evaluation of the

protection of traditional knowledge rights, and will act to prevent exploitation, patenting and commercialization of inventions consisting of endemic genetic resources or their derivatives. It is responsible for ensuring the enforcement of the provisions and obligations set by the Organic Code of Social Economy for Knowledge, Creativity and Innovation.

- National Institute of Biodiversity

This Institute is competent for granting access permits with the purpose of economic exploitation.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Decree 905 of 2011 the prior authorization is mandatory, which should be outorgated in compliance with Decision 391 of the Andean Pact that prescribes the following procedures:

1. Application: the applicant shall submit the request for access to the competent authority

2. Publication of Summary of the Project: the national competent authority will publish a Summary of the project of access.

3. Evaluation: a technical body will evaluate the access application.

4. Access Contract: the competent authority will accept or not the requirement and proceed to the negotiation of the Access Contract with the applicant.

5. Contract confirmation: the competent authority will publish a Resolution confirming the Access Agreement.

In case of access for scientific research without commercial exploitation purpose, article 39 sets that the competent authority must enter into a framework contract with Ecuadorian Universities, Research Centers and Researchers qualified and registered in SENESCYT, which cover the execution of research projects and conservation of access to genetic resources. The specific procedures on this matter are regulated by the Acuerdo Ministerial (Ministerial Agreement) 034, of February 4th, 2015.

Decree 905 of 2011 also established in its first article of the transitory dispositions a period to regularize the access activities carried out without authorization, which ended one year after the publication of this Decree.
Another requirement for accessing Ecuadorian genetic resources is the depositing of a duplicate of the sample collected in the National Bank of Genetic Resources (article 71 of Organic Code of Social Economy for Knowledge, Creativity and Innovation, of December 9th, 2016).

Finally, it is worth-mentioning that, according to the Sixth National Report of Ecuador, the country is planning to implement an automated system to attend access requests, with the interaction of the competent authority and their checkpoints.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Notwithstanding the procedures described in item 2.3, Decree 905 of 2011 establishes,

in its article 20, that when requesting access to an associated intangible component, the applicant must present a corresponding plan for obtaining prior informed consent from the local community that authorizes them to access the intangible component.

Articles 34 and 38 present specific procedures for the referred access, including the obligation to include the intangible component in the contract as an integral part of the annex of the contract that establishes the detailed conditions for accessing this component:

1. The definition of the mechanisms for the fair and equitable sharing of the benefits resulting from the use and distribution of the intangible component;

2. the contract must be signed by the legal representative of the local community supplying the associated traditional knowledge and by the applicant requesting access to the genetic resources;

3. the National Environmental Authority must subscribe to the Annex to the contract.

In order to protect the traditional knowledge, Ecuadorian indigenous people, traditional and local communities are encouraged to voluntarily deposit their knowledge within the mechanism of collective intellectual property rights of the National Intellectual Rights Service (SENADI). By 2019, SENADI has already registered 204 voluntary deposits of traditional knowledge associated with biological resources, traditional cultural expressions, "cosmovisión" and indigenous spirituality, benefiting 5 indigenous nationalities (Waorani, Siona, Tsa'chila, Shuar, Ai´kofan) and 6 Andean and Amazonian communities. The majority of knowledge deposited is ancestral medicine related to spirituality of such traditional communities, mostly used by women.

According to the Global ABS Community, the first Free Prior and Informed Consent (CLPI) occurred in 2019 and was granted by the indigenous community of San José de Payamino, of Kichwa nationality, to the University of Alma College, Michigan, United States of America, aiming its researchers to carry out scientific research with medicinal plants associated to San José de Payamino traditional knowledge. The Global Project ABS of PNUD-GEF, UN volunteers, SENADI, and the Ministry of Environment participated in the process of granting the consent.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Articles 332 and 402 of the Constitution of Ecuador acknowledge the right to intellectual property and prohibits any form of misappropriation of collective knowledge in the fields of science, technology and ancestral knowledge. It also prohibits the misappropriation of genetic resources contained in the biological diversity and agricultural biodiversity, and the granting of rights, including intellectual property rights, to byproducts or synthetics obtained from collective knowledge associated with national biodiversity.

In this sense, article first of the general dispositions of the Decree No. 905, sets that prior to grant any intellectual property, the National Intellectual Rights Service (SENADI) must require the register number of the Access Contract and its copy.

Article 93 of Organic Code of Social Economy for Knowledge, Creativity and Innovation (2016) establishes that the State will participate in the ownership of intellectual property rights of

products or processes derived or synthetic from national biodiversity, and according to its article 282, the following information or documents are requirements for the application for a patent:

- Inform the country from which the genetic resource or traditional knowledge were obtained;

- Inform the source, including details regarding the entity, if any, from which those resources or associated traditional knowledge were obtained;

- The applicant shall provide the International Recognized Certificate of Compliance of the respective country or other proof that the access activities are in compliance with the legislation of the provider country, including proof of lawfully obtained prior informed consent and shared benefits arising from commercial exploitation.

- The aforementioned procedures are in line with the Ecuadorian Intellectual Property Law No. 83 and the Andean Decision 391.

2.6. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Andean Resolution 391 establishes, in Article 3, the scope of the dispositions contained in this resolution. In this sense, its terms are applicable to any genetic resources originated in the member countries of the Andean Community, including its by-products and intangible components. As per the first article, the countries of origin should be understood as "countries that possess genetic resources in in situ conditions, including those which, having been in in situ conditions, are now in ex situ conditions", As for in situ conditions, these are understood as "the conditions in which the genetic resources are found in their ecosystems and natural environments; in the case of domesticated or cultivated species or those having escaped domestication, in the environments where they developed their specific properties". It can be noted that on no occasion the legislation mentions explicitly native or exotic species.

On the other hand, it should be highlighted that the same article 3 adds that the scope of these legal provisions includes the genetic resources of migratory species that for natural reasons are found in the territories of the member countries of the Andean Community.

The national regulations do not provide any specific procedures for the collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Although the legislation does not prescribe any rule regarding shipment of sample, it sets general provisions for exportation of genetic resources and its derivatives:

- Decree 905, article 33: "the entry and exit of genetic resources and their derived products in the country may only be carried out under the norms and conditions approved by the Ministry of the Environment as the National Environmental Authority, taking into account the provisions of the different international agreements of which the State is a party and are the subject of application for this regulation".

- Decree No. 3,516, article 27: the commercial exportation of wild fauna and flora species, their by-products and intangible components must be submitted to the Ministry of the En-

vironment, which will only authorize their exportation if there is proof that the species come from an authorized tenure and management center;

- Ministerial Agreement No. 034, article 16: prior to shipment of biological or genetic material or products derived from it, an approval of a Material Transfer Agreement (MTA) is required by the National Direction of Biodiversity. The MTA shall contain the register number of the Access to Genetic Resources Agreement.

- Organic Code of Social Economy for Knowledge, Creativity and Innovation (2016), article 72: establishes that the Foreign Trade Committee is in charge of creating a special and simplified system for obtaining permits for the import or export of living organisms, specimens from scientific collections whose purpose is the development of investigative processes, pedagogical research and laboratory supplies.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Ecuadorian legislation includes “genetic information” as part of the definition of genetic diversity provided by Article 6 of Decree 605. Also, a synthesized product is described as a “substance obtained through an artificial process from genetic information or other biological molecules. Includes semi-processed extracts and substances obtained through the transformation of a derived product through an artificial process (semisynthesis)”. Thus, there is evidence that DSI is within the scope of the country’s ABS legislation, although it is not expressly mentioned.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country’s territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country’s territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and the responsibility to share the benefits lies on the applicant of the access authorization.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. As clarified on question 2.3, the Access Contract is part of the process of obtaining the prior authorization and it shall be negotiated between the competent authority and the applicant. In this sense, article 26 of Decree No. 905 provide that during the negotiations of the contract it is mandatory to establish the following conditions:

- The mechanism for the benefit-sharing;

- The access and transference of the technology and biotechnology arised from the utilization

of the genetic resource;

- The payment of the economic benefits (current or potential) arised from the commercialization (national and internationally) of all products developed from the genetic resource.

- In the case of endemic species, the amount to be shared must be bigger than the amount set for species non-endemics.

- In any case, the Ecuadorian State shall participate at least in the same proportion as any natural or legal person who has obtained monetary or non-monetary benefits derived from any economic, scientific, technological or other benefit of any nature that arises from the access to genetic resources.

- It is mandatory the participation of local communities in the benefits derived from access to the genetic resource of their respective territories when those communities are providers of the intangible component associated with the genetic resource.

In reference to the third transitory disposition of Decree 905, the Ministry of the Environment, as the National Environmental Authority, shall outline the norms regulating benefit-sharing as established in article 30.

According to article 69 of Organic Code of Social Economy for Knowledge, Creativity and Innovation (2016), the Instituto Público de Investigación Científica sobre la Biodiversidad (Public Institute of Scientific Research on Biodiversity) is the competent authority to carry out procedures and negotiations regarding monetary and non-monetary benefit sharing. Article 73 of the same legislation establishes that the State is going to participate on at least the same proportion as any natural or legal person who has obtained Monetary or non-monetary benefits derived from the research, use, transfer, development and commercialization of biological or genetic material, as well as the information, products or procedures derived from it. The benefits received will be allocated in science, technology, innovation, ancestral knowledge activities, and used for conservation, restoration and repair of biodiversity, in accordance with national public policy. In cases in which the resources have been obtained from the territories of the indigenous communities, peoples and nationalities, the Afro-Ecuadorian people, the Montuvio people and their communes; the majority percentage will be allocated in those territories to the activities detailed above.

Finally, article 53 of Decreto Ejecutivo 1435 states that benefit sharing regarding scientific research may include technology transfer, and monetary benefits and it shall be destined to strengthen traditional knowledge according to SENESCYT provisions.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	At least the same proportion as any natural or legal person who has obtained monetary or non-monetary benefits from the access.	Genetic Heritage/ Associated Traditional Knowledge	Government/ Traditional community

Non Monetary	Not defined	Technology transfer and others	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Government/ Traditional community

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Decree No. 905, in its article 7, designates the Ministry of the Environment as the National Competent Authority responsible for the application of the referred regulation. Article 8 of Decree 905 establishes the attributions of the referred authority, which includes:

1. To apply administrative sanctions according to national and community legislations;

2. To coordinate activities of prevention, control and sanctions against illegal and illegitimate access to genetic resources and associated traditional knowledge with the support of other national institutions.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

According to item 2.1, the Andean Community (Colombia, Bolivia, Ecuador, Peru and Venezuela) has taken some decisions on topics covered by the Convention on Biological Diversity. In this sense, Andean Resolution 391 establishes the sanctions of fine, permanent or preventive seizure of material, permanent or temporary sealing of establishments and the disqualification of perpetrators in requesting new accesses, for cases of:

- Breach against the dispositions of this Decision;

- Transactions involving products derived or synthetized from genetic resources or intangible associated components that are not covered by the corresponding contracts, as established in this decision;

- Unauthorized access to the genetic heritage of any member country of the Andean Community.

Andean Resolution 391 does not present any indication of value for the fines.

At the national level, no sanctions in case of irregular access were identified in the norms covered by this analysis.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, in 2016 the National Intellectual Rights Service (SENADI) of Ecuador published the first national report on biopiracy. According to this document, 16 genetic resources have been accessed without Ecuadorian prior authorization, generating 128 patents over the world. Some

examples of species object of biopiracy are the Galapagos tomatillo (Solanum cheesmaniae), the Ecuadorian squash (Cucurbita ecuadorensis) and the Darwin's cotton (Gossypium darwinii), due to their resistance to pests. Also, Cosmetic and Pharmaceutical industries have accessed Galapagos brown algae (genus Ochrophyta), for skin, arthritis and obesity treatment and the black pearls (Capsicum annuum) for the conservation of stem cells.

5. Summary - Competent authorities

Authority	Competence
Ministry of Environment	This is the National Competent Authority responsible for granting access permits and for the issuance of the technical criteria and limits for the access. Its competence is shared with the Research Authority.
Secretariat of Higher Education, Science, Technology And Research	This Secretariat is competent for granting access permits with the purpose of research.
National Intellectual Rights Service	Its competence covers all matters related to intellectual property rights, the evaluation of the protection of traditional knowledge rights, and will act to prevent exploitation, patenting and commercialization of inventions consisting of endemic genetic resources or their derivatives. It is responsible for ensuring the enforcement of the provisions and obligations set by the Organic Code of Social Economy for Knowledge, Creativity and Innovation.
National Institute of Biodiversity	This Institute is competent for granting access permits with the purpose of economic exploitation.

6. Websites

No websites concerned with access and benefit-sharing were found.

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El Salvador[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 7th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, El Salvador is not a Party to the Nagoya Protocol, but has been a signatory since February 1st, 2012.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation has been identified on access to genetic heritage and associated traditional knowledge. However, the following rules regulate the subject regarding request for access to the country's biodiversity:

- Decree No. 17, General Law of Environment (2000)

1. The information hereinafter has been updated until December 21st, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Legislative Decree No. 233-98, General Environmental Law (1998)
- Decree n° 579, Law on Protected Areas (2005)
- Decree N° 844, Wildlife Conservation Law (1994), modified by Decree n°441 (2001)

2.2. Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. However, according to article 83 of Decree No. 17 of 2000, the Ministry of the Environment and Natural Resources, through an Executive Decree, shall establish the National Commission on Biological Diversity, which will have the function of managing conservation and use of the country's biological resources, in compliance with the provisions of the Convention of Biological Diversity. Until the time of this study, no evidence has been found that this institution has been created.

Moreover, article 'Acceso a los recursos genéticos y participación en los beneficios derivados de su utilización (ABS) en El Salvador' (2017), indicates that the General Office of Ecosystems and Wildlife (Dirección General de Ecosistemas y Vida Silvestre), a body linked to the Ministry of Environment and Natural Resources (MARN), is the competent body to manage and supervise access to the country's genetic resources.

2.3. Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, Decree 233 of 1998 establishes in its article 66 that the access, investigation, manipulation and exploitation of biological diversity can only be carried out after an authorization granted by the corresponding competent authority. Where necessary, local communities should be consulted through a procedure prior to the grant of the previous authorization.

The article "Access to Genetic Resources and Benefit-Sharing (ABS) in El Salvador "(2017), informs that in 2016, MARN received 20 requests for access, all of which regarding research, having as main applicants companies and universities. The article also mentions that bioprospecting activities covered the use of plant species, through extracts such as antiplasmodial, cytotoxic, with sedative and anxiolytic effects, against arthritis and fever, antiparasitic effects, insecticides and food.

2.4. Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

2.5. Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Decree No. 233 of 1998 establishes the Ministry of Environment and Natural Resources as the inspection body, and grants the National Civil Police, the Municipal Councils, the Attorney General of the Republic and the Attorney for the Defense of Human Rights, the power to inspect sites suspected of having committed an environmental infraction.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Decree No. 233 of 1998 establishes the sanctions applicable to access to genetic resources in non-compliance with the procedural rules, which are: payment of fines varying from two to one hundred times the minimum wage, equivalent to approximately US $ 610.00 to US $ 30,400.00.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
General Office of Ecosystems and Wildlife	Is the national entity officially responsible for administering and supervising the processes of access to Genetic Resources.

6. Websites

ABSCH El Salvador Profile
https://absch.cbd.int/countries/SV

CBD El Salvador Profile
https://www.cbd.int/countries/?country=sv

Ministerio de Medio Ambiente y Recursos Naturales
http://www.marn.gob.sv/

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. El Salvador Profile. Available at: <https://absch.cbd.int/countries/SV>; Access on: 12/21/2020.
CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Tunisia profile. Available at: <https://www.cbd.int/countries/?country=sv>. Access on: 12/21/2020.

EL SALVADOR. Decreto nº 233: Ley de Medio Ambiente, Maay 4 of 2018. Available at: <http://extwprlegs1.fao.org/docs/pdf/els14872.pdf> Access on: 05/14/2020.

EL SALVADOR. Decreto nº 17: Reglamento General de la Ley del Medio Ambiente, March 29 of 2000.Available at: <http://extwprlegs1.fao.org/docs/pdf/els20374.pdf> Access on: 05/14/2020.

MULLER, Manuel Ruiz. Access and Benefit-Sharing Policy and Legal Framework in Central America and the Dominican Republic, 2016. Available at: <https://absch.cbd.int/api/v2013/documents/76AAE394-EB57-FB19-64F6-F2FB9CDD07DB/attachments/ABS%20Policy%20and%20Legal%20Framework%20Central%20America%20and%20Dom.Rep_english.pdf> Access on: 05/14/2020.

GONÇALVES, Barbara. Acceso a los recursos genéticos y participación en los benefcios derivados de su utilización (ABS) en El Salvador. Deutsche gesellschaft für internationale zusammenarbeit, 2017. Available at: <http://cidoc.marn.gob.sv/documentos/acceso-a-los-recursos-geneticos-y-participacion-en-los-beneficios-derivados-de-su-utilizacion-abs-en-el-salvador/> Access on: 05/14/2020.

Equatorial Guinea[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since March 6th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. It is important to highlight that according to the article Overview of National and Regional Measures on Access and Benefit Sharing (2014), Equatorial Guinea is a member of COMIFAC - Commission on the Forests of Central Africa, a regional organization that has developed guidelines for the implementation of access and benefit sharing policies

1. The information hereinafter has been updated until November 19th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

for all its member countries, with the objective to facilitate the implementation of ABS policies that are coherent and can enable the cooperation between central African countries.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol.

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Equatorial Guinea Profile
https://absch.cbd.int/countries/GQ

CBD Equatorial Guinea Profile
https://www.cbd.int/countries/?country=gq

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Equatorial Guinea Profile. Available at: https://absch.cbd.int/countries/GQ> Access on 11/19/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Equatorial Guinea profile. Available at: https://www.cbd.int/countries/?country=gq> Access on 11/19/2020.

GOVERNMENT OF EQUATORIAL GUINEA. **CBD Strategy and Action Plan.** Ministry of Fishery and Environment. Available at: https://www.cbd.int/countries/?country=gq Access on 16/05/2018.

GOVERNMENT OF EQUATORIAL GUINEA. **CBD Fifth National Report**. Ministry of Fishery and Environment. March 2014. Available at: https://www.cbd.int/countries/?country=gq Access on 16/05/2018.

MEDAGLIA, Jorge Cabrera; PERRON-WELCH, Frederic; PHILLIPS, Freedom-Kai. Overview of national and regional measures on access and benefit sharing: challenges and opportunities in implementing the Nagoya

Protocol. CISDL **Biodiversity & Biosafety Law Research Programme,** 3 ed., June 25 of 2014, p. 59-61. Available at:<https://www.absfocalpoint.nl/upload_mm/5/f/4/008c9cc8-19f3-4926-b380-5f13fd1eb705_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf> Access on: april 27 2018.

REPÚBLICA DE GUINEA ECUATORIAL..**Sexto Informe Nacional sobre la Puesta en marcha del Convenio de las Naciones Unidas sobre la Diversidad Biológica (CBD).** Ministerio de Agricultura, Ganadería, Bosques y Medio Ambiente. March 2019. Available at: https://www.cbd.int/doc/nr/nr-06/gq-nr-06-es.pdf Access on 11/19/2020.

Grenada[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 9th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, El Salvador is not a Party to the Nagoya Protocol, but has been a signatory since February 1st, 2012.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the report Development of a Business Model for Access and Benefit Sharing in the Caribbean Region (2019), written by the Environmental Gov-

1. The information hereinafter has been updated until July 31st, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

ernance Consulting, the Environment Management Bill (2007) addresses a basic framework for ABS in the country. However, it could not be identified by this research.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the ABSCH website indicates Mrs. Merina Jessamy as the competent authority, who is responsible for all genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Mrs. Merina Jessamy Permanent Secretary Ministry of Agriculture, Lands, Forestry, Fisheries and the Environment Botanical Gardens	Responsible for all genetic resources.

6. Websites

ABSCH Grenada Profile
https://absch.cbd.int/countries/GD

CBD Grenada Profile
https://www.cbd.int/countries/?country=gd

Ministry of Agriculture, Lands, Forestry, Fisheries and the Environment
https://www.gov.gd/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Grenada Profile. Available at: https://absch.cbd.int/countries/GD. Access on 11/25/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Grenada profile. Available at: https://www.cbd.int/countries/?country=gd> Access on 11/25/2020.

GOVERNMENT OF GRENADA. **National Biodiversity Strategy and Action Plan** 2016-2020. Spencer Thomas, Ph.D. June, 2016. Available at https://www.cbd.int/countries/?country=gd Access in 15/05/2018.

GOVERNMENT OF GRENADA. **Fifth National Report to the Convention on Biodiversity.** July 2014. Available at: https://www.cbd.int/countries/?country=gd Access on 15/05/2018.

ENVIRONMENTAL GOVERNANCE CONSULTING. Development of a Business Model for Access and Benefit Sharing in the Caribbean Region, Prepared for IUCN. 2019. San Jose, Costa Rica. Available at: https://www.abscaribbean.com/sites/default/files/Business%20Model%20for%20ABS%20in%20the%20Caribbean%20Region.pdf . Access on 11/25/2020.

Guatemala[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since October 8th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 2 IRCCs that are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Nevertheless. the following documents contain some provisions regarding access and benefit-sharing:

1. The information hereinafter has been updated until December 23rd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Regulation on Research and Researchers of Biological Diversity (2020);

- Governance Agreement 171-2014 (Acuerdo Gubernativo número 1717-2014) - establishes the competent national authority;

Also, the country has other norms that contain some specification about ABS:

- Decree No. 4/89 - Law on Protected Areas

However, according to Case 2606-2016 (Resolution of Unconstitutionality before approval of the Nagoya Protocol) (Expediente 2606-2016 - Resolución de Inconstitucionalidad ante aprobación de Protocolo de Nagoya), the request by indigenous and traditional people of Guatemala that claims for the unconstitutionality of Decree 6-2014 of the Congress of the Republic of Guatemala, which approved the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of the benefits deriving from its use, was appreciated by the Constitutional Court that decreed on June 9th, 2016 the provisional suspension of this Decree. No evidence has been identified that this temporary situation has changed.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Governmental Agreement n. 171 of 2014, identifies the CONAP - Technical Council for Protected Areas (Consejo Nacional de Areas Protected) as the competent institution regarding access and benefit sharing.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Regulation on Research and Researchers of Biological Diversity (2020) all access activities in the country must comply with the procedures described below:

Researcher Registration: according to article 14 of the Regulation, any individual or legal person, national or foreign, must register as a researcher at CONAP, for which the researcher is going to be assigned a registration number. The application for registration can be made jointly or independently of the application for a research license. To register as a researcher, the natural or legal person must present the following documents:

a. Fill out the individual researcher or legal entity registration form, as the case may be (Annex 1A or 1B).

b. Letter that certifies your status as a member of a national academic institution or of the non-governmental organization or research center or other related institution (as applicable).

c. Copy of Personal Identification Document or passport.

d. Resume according to the form established by CONAP (Annex 2).

e. Payment receipt as established in the current rate published by CONAP (when applicable).

Legal persons must also present:

a. a. Copy of the testimony of the articles of incorporation.

b. b. Copy of the notarial act stating the current appointment of the legal representative and the reason for inscription in the corresponding registry.

c. Copy of the commercial patent.

d. In the case of research centers and / or units with academic purposes that by their nature do not apply with the aforementioned requirements, they must present the pertinent documentation that accredits their training and designation of the people who act on their behalf.

The accompanying documentation in the case of legal persons must be legalized by a Notary Public.
General requirements for a license application for research on biological diversity, regardless of the purpose for which the research is conducted in the country, the following documents are required:

a. a. researcher registration number with CONAP.

b. b. Fill out the research license application form depending on whether you are a national or foreign researcher (Annex 3A or 3B).

c. Research protocol according to the type of research (Annexes 4A or 4B).

d. Declaration of commitment signed by the principal investigator (Annex 5).

e. If you are a student, present a letter to a university professor who reports being the author / advisor.

f. In the case of foreign researchers without legal residence in the country:

   i. Letter of reference from the foreign institution that represents, letterhead, signed and stamped. This shall be written in Spanish.

   ii. ii. Endorsement letter from a National Academic Institution related to the research topic, when it is carried out for scientific purposes, signed by both the person in charge of the Institution and by the counterpart national researcher who will cooperate in the research (Annex 6).

   iii. iii. Letter of support from a national counterpart entity or Institution related to the research topic, when the research is for commercial purposes, signed by both the person in charge of the Institution and by the national counterpart researcher who will cooperate in the investigation (Annex 6).

g. Payment receipt as established in the current rate published by CONAP (when applicable).

In the case of requesting authorization for research within a protected area, you must also present:

h. Endorsement letter, duly letterhead, signed and stamped by the administrator or co-ad-

ministrator of the protected area where the investigation will be carried out, stating their knowledge and consent to the investigation to be carried out within the area. In the event that the investigation involves collection activities, this letter must also specify it (Annex 7).

i. If the researcher is part of the staff of the administrator or co-administrator of the protected area where the research will take place, the presentation of this letter is excepted.

In the case of requesting authorization for research in archaeological areas or sites within protected areas, you must also present:

j. Letter of endorsement from the Directorate or corresponding Unit of the Ministry of Culture and Sports (Annex 8), stating their knowledge and consent to the investigation to be carried out within the area.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol.

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

Ministerio de Ambiente y Recursos Naturales
http://www.marn.gob.gt/

ABSCH Guatemala's Profile
https://absch.cbd.int/en/countries/GT

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE - ABSCH. Country Profiles. Guatemala profile. Available at: https://absch.cbd.int/countries/GT Access on 12/22/2021.

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GOVERNMENT OF GUATEMALA. V National Report on Compliance with the Agreements on the Convention on Biological Diversity. National Council of Protected Areas - CONAP. Technical Document No. 3 - 2014. 2014. Available at: https://www.cbd.int/countries/?country=gt Access on 12/22/2021.

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Guyana[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 27th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 5 IRCCs that are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the country has the National Policy On Access to

1. The information hereinafter has been updated until December 23rd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, which was promulgated in 2007, before the country became a Party to the Nagoya Protocol. The implementation of this policy follows the draft of ABS regulations, which includes prior informed consent, benefit sharing, among others elements. This draft is currently on revision to incorporate the requirements of the Nagoya Protocol. Until the present moment, no indication that the referred law has been approved and is currently in force was found.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The National Policy On Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2007), identifies EPA - Environmental Protection Agency as the competent institution regarding all matters relates to access and benefit sharing. Other bodies, institutions and authorities may collaborate with EPA.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address authorizations in order to obtain genetic resources. Nevertheless, the National Policy On Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2007), in its article 3.2 (6), establishes that EPA shall have competence to, in accordance to the national legislation, grant access authorizations. Also, according to the Interim National Report on the Implementation of the Nagoya Protocol (2019), the Protected Areas Act (2011) requires permits for research in certain areas.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis. The Amerindian Act (2006), in its article 5.3 provides for rules on conducting a research and studies with biological diversity, natural or environment resources, or any knowledge associated thereof, in the land of local and indigenous communities, denominated by the Village Lands Law.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis. The National Policy On Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2007), in its article 5 (on collective intellectual property rights), establishes that the Amerindian traditional knowledge is considered as intellectual property and scientific knowledge, in accordance with the protection requirements provided by the legal order for traditional intellectual property.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

5. Guiana 5th National Report, 2015, p. 48

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing. Nevertheless, item 2, "e", of the National Policy On Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2007), establishes that the objective of this policy is the fair and equitable sharing of benefits arising from the utilization of genetic heritage and associated traditional knowledge.

Item 4, subsection 4, "c", of the above mentioned policy states that:

> *"What is fair and equitable sharing of benefits will be determined by all stakeholders in the ABS arrangement and by the appropriate Competent Authorities, and will be agreed through free and prior informed consent. Benefits may, for instance, include various kinds of monetary benefits, goods or equipment, information, collaborative activities, transfer of technology, training and capacity building and will be agreed through free and prior informed consent among stakeholders and Competent Authorities."*

However, no specific procedures were found.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The National Policy on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization institutes the EPA (Environmental Protection Agency) as the official inspection body responsible for all matters related to access and benefit-sharing in the country.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No sanctions in case of irregular access were identified in the norms covered by this analysis.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
EPA (Environmental Protection Agency)	National Authority responsible for all matters related to access and benefit sharing.

6. Websites

Environmental Protection Agency, Technical Secretariat, Biodiversity Research Site
http://epabiodiv.gy/rap/index.aspx

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Guyana profile. Available at: https://absch.cbd.int/countries/GY Access on: 12/232021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Guyana profile. Available at: https://www.cbd.int/countries/?country=gy Access on 12/232021.

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Haiti[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 24th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The country's National Biodiversity Strategy and Action Plan (2020) affirms that one of its goals to 2030 is to ratify the Nagoya Protocol and to establish

1. The information hereinafter has been updated until November 12th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

a legal framework regarding utilization of genetic resources and associated traditional knowledge. Also, in response to a prior version of this study, the National Focal Point informed in 2019 that the country is in process of regulating the subject.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Haiti Profile
https://absch.cbd.int/countries/HT

CBD Haiti Profile
https://www.cbd.int/countries/?country=ht

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Haiti. Available at: https://absch.cbd.int/countries/HT. Access on: 11/13/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Haiti profile. Available at: https://www.cbd.int/countries/?country=ht. Access on: 11/13/2020.

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Honduras[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since October 29th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Agreement No. 695-2016;

1. The information hereinafter has been updated until November 12th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Agreement No. 045-2011;

- Ministerial Agreement No. 706-2021 - Regulation on Access to Genetic Resources and its Derivatives and Fair and Equitable Sharing of Benefits derived from its utilization.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Ministerial Agreement No. 706-2021, identifies Natural Resources and Environment (MiAmbiente +), through the General Directorate of Biodiversity (DIBIO), which is responsible for matters of access and use of genetic resources and their derivatives and the fair and equitable sharing of benefits.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the Ministerial Agreement No. 706-2021 on the subject requires prior authorization to obtain genetic resources. According to Article 17 of the Agreement, all access activities in the country must comply with the procedures described below:

1. Application: The applicant shall present to MiAmbiente a requirement for access, including a work plan.

2. Analysis by the sectoral authority: MiAmbiente will forward the application to the sectorial authority, which will examine the application.

3. Access Agreement: The sectoral authority and the applicant shall negotiate the conditions of access.

4. (If applicable) Incorporation as an annex to the contract, the document that specifies the conditions of use of traditional knowledge of indigenous peoples and local communities.

5. Submission to MiAmbiente: The Access Agreement shall be subject to MiAmbiente for the final authorization and notification to the applicant.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Article 7 of the Agreement, when the applicant intends to use traditional knowledge associated with genetic resources, he or she shall comply with the norms regarding indigenous people, local communities and traditional knowledge, and provide for prior informed consent and a benefit sharing agreement, through their representative organizations or corresponding government structures, to enter their lands and territories and carry out related activities with access and use of biological and genetic resources or derivatives.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Article 25 of the Ministerial Agreement No. 706-2021 on ABS, as part of its regular procedures for processing invention patent applications, especially in the field of inventions in biotechnology, the General Directorate of Intellectual Property (DIGEPIH), will require

the applicant to indicate the origin of genetic resources and provide a copy of the corresponding access and use resolution issued by the Ministry of Natural Resources and Environment (MiAmbiente +), or the equivalent document of competent authorities regarding access and use of genetic resources of the countries of origin of genetic resources and derivatives, if this is the case.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. Yes, benefit sharing is mandatory and it incides over access. The responsibility to share the benefits lies with the applicant.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. According to Article 13 of the Ministerial Agreement, the Access Agreements shall contain several clauses regarding benefit sharing, such as:

a. The participation of national entities and professionals in research activities on genetic resources and its derivatives;

b. The transfer of knowledge and technologies, including biotechnologies, that are culturally, socially and environmentally healthy and safe and of special interest to Honduras;

c. The provision of information to the General Directorate of Biodiversity (DIBIO) on background, state of science or of another nature, for its dissemination and for contribute to a better knowledge of the relative situation genetic resources and their derivatives in Honduras;

d. Training of related national researchers with genetic resources and their derivatives;

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Genetic Heritage/ ATK	Government
Non Monetary	Not defined	Not defined	-	Genetic Heritage/ ATK	Government

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Yes. According to Article 09 of the Ministerial Agreement, MiAmbiente is the competent authority to determine and apply sanctions.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No sanctions in case of irregular access were identified in the norms covered by this analysis.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Secretariat of State for Energy, Natural Resources, Environment and Mines (MIAMBIENTE)	National Competent Authority for ABS

6. Websites

Secretaría de Recursos Naturales y Ambiente
http://www.miambiente.gob.hn/

CHM Honduras
http://www.chmhonduras.org/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Honduras profile. Available in: https://absch.cbd.int/countries/HN. Access on 12/24/2021.

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Jamaica[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since April 6th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The country does not have any specific legislation for access to genetic heritage and associated traditional knowledge. However, the country has the following legislations that establish rules for the use of natural resources:

1. The information hereinafter has been updated until January 4th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4.The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- The Natural Resources (National Parks) Regulations (1993)
- The Forest Act (1996)
- The Forest Regulation (2001)

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation on access to genetic heritage and associated traditional knowledge has been found. However, there are two legislations that determine the need of a prior authorization in order to use natural resources for scientific research purposes in the country, as follows:

- The Natural Resources (National Parks) Regulations (1993): determines that scientific research or collection of natural resources originated from national parks, with commercial or scientific purposes, must pay a fine and have a prior authorization, granted by the Natural Resources Conservation Authority.
- The Forest Act (1996): determines that research or the use of natural resources originating from forests must have a prior authorization, granted by the Forestry Department.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

National CHM
http://jamaicachm.org.jm/CHM/

ABSCH Jamaica Profile
https://absch.cbd.int/countries/JM

CBD Jamaica Profile
https://www.cbd.int/countries/?country=jm

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Jamaica profile. Available in: <https://absch.cbd.int/countries/JM > Access on 01/04/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Jamaica profile. Available in: <https://www.cbd.int/countries/?country=jm> Access on 01/04/2021.

JAMAICA. The Forest Regulation, August 2 of 2001. Available at: <http://extwprlegs1.fao.org/docs/pdf/jam61255.pdf> Access in: 05/21/2018.

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GOFFE, Marcus. Jamaica's Compliance with the Convention on Biological Diversity: An intellectual property assessment of the relevant laws, policies and procedures regulating access and benefit sharing with respect to genetic resources and traditional knowledge, 2010. Available at: <http://nepa.gov.jm/projects/final_reports/Biodiversity_add_on/FINAL_Report_assessment_IP.pdf> Access in: 05/21/2018.

Mexico[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December, 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since May 16th, 2012.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 8 IRCCs, for commercial and non-commercial purposes, which are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Mexico still does not have a law on access to genetic heritage and associated traditional knowledge, however there are two Federal Law Bills on Access and Utilization of Genetic Resources. The Federal Bill on Access and Utilization of Genetic Resources is currently under the

1. The information hereinafter has been updated until May 18th, 2020.
2.Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Congress of the Union, and it contains provisions to guarantee access to genetic resources and the distribution of benefits in accordance with Article 15 of the Convention on Biological Diversity.

It aims to regulate the access, use, exploitation, conservation in situ and ex situ and protection of the genetic resources, as well as the fair and equitable share of benefits arising from the exploitation and marketing of the resources. Likewise, it establishes that biological resources located in the national territory are owned by the nation and provides for the recognition of a Certificate of legal origin issued by other countries.

Below are presented some regulations related to the subject:

- Decree Nº 183 - Code for Biodiversity of the State of Mexico - deals with the use and protection of Mexican biodiversity.

- Promulgating Decree of the Nagoya Protocol concerning access to genetic resources and fair and equitable benefit sharing resulting from their utilization to the Biological Diversity Convention, adopted in Nagoya on Oct 29, 2010.

- General Law of Ecological Balance and Environmental Protection - regulates the provisions of the Constitution of the United Mexican States, which relates to the preservation and restoration of the ecological balance, as well as the protection of the environment in the country and the areas over which the country exercises its sovereignty and jurisdiction. Its provisions are of public order and local interests and aims to promote sustainable development.

- Mexican Official Norm -NOM-126-ECOL-2000 - establishes the specifications for the accomplishment of scientific activities collecting biological material from the fauna and flora and other biological resources in the national territory.

- Ley de Desarrollo Rural Sustentable - establishes the promotion of the sustainable rural development of the country.

- General Law on Sustainable Forest Development - establishes the new legal framework that regulates and promotes the integral and sustainable management of forest territories, the conservation, protection, restoration, production, management, cultivation, management and use of the country's forest ecosystems and their resources; as well as the distribution of forest competences in order to promote sustainable forest development.

- Regulation of the General Law on Sustainable Forest Development - regulates the General Law on Sustainable Forest Development within the federal sphere of competence, in terms of forest policy instruments, management and sustainable use of the country's forest ecosystems and their resources, as well as their conservation, protection and restoration.

- Internal Regulation of the Ministry of Environment and Natural Resources (November 26th, 2012): establishes competencies and internal duties of the Ministry of the Environment and Natural Resources.

- General Law on Wildlife - establishes the competencies of the federal government, state governments and municipalities regarding the conservation and sustainable use of wildlife and their habitat in the territory of the Mexican Republic.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Although there is not yet a law that directly addresses access to genetic heritage and associated traditional knowledge, the country has already indicated official institutions in the official "Access and Benefit-Sharing Clearing House" mechanism, which are:

- General Directorate for Wildlife, Under-Secretariat for Management for Environmental Protection, Secretariat for the Environment and Natural Resources (SEMARNAT) - this institution is responsible for issuing permits and other instruments for: health, capture, collection, research, exploitation, possession, management, reproduction, repopulation, import, export, release, transfer of specimens and derivatives of wildlife, species and populations at risk, including alien species.

- National Commission on Protected Natural Areas - responsible for safeguarding Protected Natural Areas (NPAs), the genetic diversity of wild species; the preservation and sustainable use of species in some risk categories. It is also responsible for promoting and developing activities for the conservation of ecosystems and their biodiversity in NPAs.

- National Commission for the Development of Indigenous Peoples - responsible for guiding, coordinating, promoting, supporting, encouraging, monitoring and evaluating programs, projects, strategies and public actions for the integral and sustainable development of indigenous peoples and communities. It is also responsible for dialogue with indigenous peoples and communities in strengthening indigenous decision-making capacities in relation to access to traditional knowledge associated with genetic resources, as provided for in Article 7 of the Nagoya Protocol.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The General Law on Sustainable Forest Development, in its Article 69, IV, provides that the Secretariat of Environment and Natural Resources is responsible for granting authorization to carry out collection and use for commercial or research purposes of genetic resources.

Regarding the scientific collection, the Official Mexican Standard NOM-126-ECOL-2000 provides in its Articles 5.1 and 5.2 that the Secretariat of Environment and Natural Resources may also grant authorization to carry out scientific collection.

Nonetheless, the Federal Bill Draft on Access and Utilization of Genetic Resources dated Apr 27, 2005 in its article 27, requires prior authorization for any project for access to genetic resources that is intended to be carried out in national territory and in areas where the nation exercises its sovereignty.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Article 39 of the Federal Bill Draft on ABS establishes that in cases of traditional knowledge involving genetic resources, there must be prior informed consent. Also, Article 87 Bis of General Law of Ecological Balance and Environmental Protection states that authorization for use of biological resources require prior informed consent of the legit owner of the local where the biological resource was encountered. Also, the same article establishes that those owners are entitled to benefit sharing.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The Federal Bill Drafton ABS on its articles 17, 23 and 30 provides that the Secretariat on Environment shall act in coordination with the Mexican Institute on Industrial Property in case of registration of intellectual property, and that the Secretariat of Environment shall be notified when the modification of genetic material may lead to intellectual property. Also, article 176 of Law on Sustainable Rural Development establishes that the Intersecretarial Commission will provide for the measures necessary for intellectual property of indigenous communities and farmers.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

() YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples containing genetic heritage were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The Federal Bill Draft on ABS establishes on its Article 69 that benefit sharing applies when there is exploitation, use, access, commercialization and transfer of intellectual property rights of genetic resources. The responsibility to share benefits lies on the applicant.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As explained under item 2.1, the country does not have any legislation on access and benefit

sharing. Nevertheless, the Federal Bill Draft on Access and Utilization of Genetic Resources, of April 27, 2005, has a chapter on benefit sharing. There is no stipulation of values, but its procedures and norms are described in the articles of chapter VIII, comprising the following

- Article 69 - Derived from the exploitation, use, access, commercialization of genetic resources and transfer of rights derived from intellectual property of the referred resources, the distribution of benefits should be fair and equitable.

- Article 70 - Due to the diversity of biotechnological products and procedures susceptible of being obtained from associated genetic resources, the sharing of benefits arising from access to genetic resources should be analyzed on a case by case basis, and determined by mutual agreement between the parties, in order to ensure it to be fair and equitable.

Although there are no specific procedures there are precedents of benefit sharing agreements[5].

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Previously defined payment, royalties (information of Draft Law)	not defined	Genetic Heritage/ATK	Provider/ Governemn
Non Monetary	Not defined	Technology transfer, development of national scientific capacity (information of Draft Law	not defined	Genetic Heritage/ATK	Provider/ Governemn

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

In Mexico, the Secretariat of Environment, Natural Resources and Fisheries is the inspection institution responsible for the environment. The Federal Bill on ABS states on its Article 83 that the referred Secretariat will sanction the infractions related to the norm.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As explained under item 2.1, the country does not have any legislation on access and benefit sharing.

However, the Federal Bill Draft on Access and Exploitation of Genetic Resources, of May 4,

5. UNITED NATIONS DEVELOPMENT PROGRAMME - UNDP, GLOBAL ENVIRONMENTAL FINANCE SUSTAINABLE DEVELOPMENT - GEF, ABS in Genetic Resources for Sustainable Development, p. 199. Available in: <https://abs-sustainabledevelopment.net/wp-content/uploads/2018/09/ABS-is-Genetic-Resources-for-Sustainable-Development-Publication.pdf> Access on 11/11/2021.

2005, on chapter III, defines the offenses, sanctions and liabilities. Article 82 of this chapter specifies, in its paragraphs, the applicable sanctions.

Article 83 provides for the sanctions, items I to III indicate that fines vary between twenty-six to fifty thousand minimum daily wage rates, and item IV indicates the withdrawal of authorizations. In the event of offense recidivism, the amount of the corresponding fine established in the sanction will be doubled, according to the provisions of the previous article, and the authorization will be canceled without prejudice to the fulfillment of the obligations arising from access that are extended through time according to article 84.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

There is a record of biopiracy regarding the genetic characteristics of a species of corn from the Mixed indigenous community in Oaxaca, Mexico[6].

5. Summary - Competent authorities

Authority	Competence
General Directorate for Wildlife, Under-Secretariat for Management for Environmental Protection, Secretariat for the Environment and Natural Resources (SEMARNAT)	responsible for issuing permits and other instruments for: health, capture, collection, research, exploitation, possession, management, reproduction, repopulation, import, export, release, transfer of specimens and derivatives of wildlife, species and populations at risk, including alien species.
National Commission on Protected Natural Areas	responsible for safeguarding Protected Natural Areas (NPAs), the genetic diversity of wild species; the preservation and sustainable use of species in some risk categories. It is also responsible for promoting and developing activities for the conservation of ecosystems and their biodiversity in NPAs.
National Commission for the Development of Indigenous Peoples	responsible for guiding, coordinating, promoting, supporting, encouraging, monitoring and evaluating programs, projects, strategies and public actions for the integral and sustainable development of indigenous peoples and communities. It is also responsible for dialogue with indigenous peoples and communities in strengthening indigenous decision-making capacities in relation to access to traditional knowledge associated with genetic resources, as provided for in Article 7 of the Nagoya Protocol.

6. EL UNIVERSAL, Indigenous Mexican corn threatened by U.S. biopiracy, 02/10/2019. Available in: <https://www.eluniversal.com.mx/english/indigenous-mexican-corn-threatened-us-biopiracy> Access on 11/11/2021.

6. Websites

Mexican Commission for the Knowledge and Use of Biodiversity
http://www.biodiversidad.gob.mx

Ministry of Environment and Natural Resources
http://www.semarnat.gob.mx/

Cámara de Diputados
http://www.diputados.gob.mx/

7. References

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CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Mexico profile. Available in: https://www.cbd.int/countries/?country=mx Access on 18/11/2016.

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GOBIERNO DE MÉXICO. Estrategia Nacional sobre Biodiversidad de México y plan de acción 2016 – 2030. Comisión Nacional para el Conocimiento y Uso de la Biodiversidad - CONABIO. México, D. F., 2016. Available in: https://www.cbd.int/countries/?country=mx Access on 18/11/2016.

GOBIERNO DEL ESTADO DE MICHOACÁN. Estrategia para la Conservación y Uso Sustentable de la Diversidad Biologica del Estado de Michoacán. Comisión Nacional para el Conocimiento y Uso de la Biodiversidad – CONABIO; Secretaria de Urbanismo y Medio Ambiente – SUMA; y Secretaria de Desarollo Agropecuario – SEDAGRO. México, D.F., 2016. Available in: https://www.cbd.int/countries/?country=mx Access on 18/11/2016.

GOBIERNO DEL ESTADO DE MORELOS. Estrategia Estatal sobre Biodiversidad de Morelos. Comisión Estatal de Agua y Medio Ambiente, Comisión Nacional para el Conocimiento y Uso de la Biodiversidad. Cuernavaca, 2003. Available in: https://www.cbd.int/countries/?country=mx
Access on 18/11/2016.

GOBIERNO DE MÉXICO. Quinto Informe Nacional de México ante el Convenio sobre la Diversidad Biológica. Comisión Nacional para el Conocimiento y Uso de la Biodiversidad (CONABIO).
2014. Available in: https://www.cbd.int/countries/?country=mx Access on 18/11/2016.

UNITED NATIONS DEVELOPMENT PROGRAMME - UNDP, GLOBAL ENVIRONMENTAL FINANCE SUSTAINABLE DEVELOPMENT - GEF, ABS in Genetic Resources for Sustainable Development, p. 199. Available in: <https://abs-sustainabledevelopment.net/wp-content/uploads/2018/09/ABS-is-Genetic-Resources-for-Sustainable-Development-Publication.pdf> Access on 11/11/2021.

Nicaragua[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 18th, 2020.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since September 10th, 2020.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country has the following laws that have provisions regarding access and benefit sharing:

1. The information hereinafter has been updated until December 24th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Law nº 807 (Law on Conservation and Sustainable Use of Biological Diversity) - Establishes rules for access to genetic heritage and associated traditional knowledge in its chapter XII;

- Presidential Decree No. 24-2019 (Regulation to Law No. 807, Law on the Conservation and Sustainable Use of Biological Diversity);

- Law No 217 - General Law on Environment and Natural Resources;

- Decree 9/96 - Regulation of the General Law of the Environment and Natural Resources;

- Penal Code, Law nº 641;

- Ministerial Resolution No.013-99, August 27, 1998.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Law No. 807 (Law of Conservation and Sustainable Use of Biological Diversity) defines in its article 11 and 12 that the Ministry of Environment and Natural Resources (MARENA) through the Directorate General of Natural Resources and Biodiversity, as the competent institution, which is responsible for, among others: (i) to supervise and inspect the holders of authorizations of access to biological diversity and genetic resources; (ii) to exercise the function of scientific entity for consultation and advice in respect of biological diversity; (iii) grant use rights such as licenses, permissions, authorizations, utilization rights and access to biological diversity resources; (iv) to credit, authorize, designate and supervise the national depositary centers for biological diversity samples; (v) promote, improve and oversee the efficient management of elements of biological diversity; (vi) provide legal assistance to providers regarding material transfer agreements; (vii) provide information to interested parties regarding prior informed consent and material transfer agreements; (viii) ensure the effective participation of interested parties in the different stages of the process of access to biodiversity, exploitation and sustainable use biological diversity; (ix) regulate fair participation and fair sharing of environmental, social and economic benefits derived from the use of biological diversity; and (x) supervise and regulate bioprospecting and access to genetic resources of biological diversity.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Law No. 807 (Law on the Conservation and Sustainable Use of Biological Diversity) establishes in its art. 57 that bioprospecting activities and access to genetic resources to be carried out within the borders of the country require prior authorization and sign an access permit agreement, which must follow the following rules:

1. Prior and informed consent: if the genetic resource is in the territory of indigenous or afro-descendants communities, the user must conduct a public consultation with the detaining community, respecting their traditional forms of organization, to obtain the letter of prior and informed consent. The authority shall verify the public consultation procedure through a public hearing, which shall convene at least 30 days in advance, so that the applicant clarifies the activity of the access, environmental impacts and objectives.

2. Request for Access: the user must submit to MARENA an access request, which must contain at minimum, the general information of the applicant (if foreign, must have a proxy), the identification of the genetic resources provider, certification of the partner national institu-

tion, the project or protocol of research, and the letter of prior and informed consent.

3. The granting of the access authorization shall observe: the strengthening of the transfer mechanisms of knowledge and technologies, including biotechnology, strengthening the capacities of indigenous and afro-descendants, local and scientific, regarding the intangible components associated with biological diversity and its by-products. MARENA has a period of 60 days to give its opinion on the request, whether favorable or not.

4. Access Agreement: it will be signed between the applicant and the State, or community that holds the genetic resource, and must contain the description of the object of the contract, rights and obligations of both parties, limits, deadlines and information on the biological component that one wishes to access, a clause for benefit sharing, the determination of ownership and possible intellectual property rights, and recognition of the country's contribution to any type of research results on the genetic resource, financial establishments or insurers that guarantee compensation for the breach of contract without prejudice to administrative, civil or criminal liability.

5. The elaboration of the agreement shall observe: the participation of at least one Nicaraguan researcher who is part of a national scientific institution, previously agreed conditions for the transfer of technology or biotechnology derived from the use of genetic resources, the agreed payment of benefits derived from the commercialization of all the products generated from the genetic resource, designation of a depositary center for the samples collected.

Furthermore, the applicant is obliged to inform and request authorization to transfer to third parties the access authorization, progress of access activities, implementation of new or future research and activities that access genetic resources, the use of new products and processes or different from the objects of access requested.

Finally, the law establishes that MARENA shall develop the 'System of Licenses and Permits for the Use of Biodiversity Resources', which was created by Resolution No.013-99, of august 27, 1998, which provides for forms and procedures for granting access authorization.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Law No. 807 (Law on the Conservation and Sustainable Use of Biological Diversity) defines in its chapter XIII that Associated Traditional Knowledge can only be carried out with the prior informed consent of the community, and the community has the right of decision.

The procedures for consultation and obtaining consent must respect the organization of the indigenous peoples, Afro-descendants and local communities. A public hearing should be held to expose the elements of access, environmental effects and actions planned to obtain the genetic material.

No other procedures or detailed information regarding prior and informed consent were found in the legislation.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 84 of Law No. 807 (Law on the Conservation and Sustainable Use of Biological Diversity) establishes that the requirements for patent applications are:

1. The applicant must present an endorsement issued by the Biodiversity Division that shows the authenticity of their studies on knowledge, practices and biological resources that implicate in the use of biological diversity.

2. In case of registration of Intellectual Property Rights granted outside the country, the competent authority shall require documentation attesting its regularity to the country of origin of the genetic resource.

Failure to comply with established obligations or disclosure of false or partly true information will result in the refusal of the request, cancellation of the registration, without prejudice to the other administrative, civil and penal sanctions.

In addition, in its article 87, Law No. 807 determines that MARENA will deal with sui generis intellectual property related to the conservation and sustainable use of biological diversity, with the objective of protecting the rights of traditional communities. The law further specifies that intellectual or industrial property rights over traditional knowledge, practices and biological resources do not prevent traditional communities from using them.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 80 of Law No. 807 (Law on the Conservation and Sustainable Use of Biological Diversity) explains that authorization for the shipment of samples will be expressly granted in the Access permits. Thus, the request must include shipping information. Article 94 classifies as very serious the act of export, import or re-export, without authorization, copies, products or derivatives of wildlife species.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the legislation addresses this matter, which comprised on the definition of bioprospecting, which is the “systematic research, classification and investigation for commercial purposes of new sources of chemical compounds, genes, proteins, microorganisms and other products with actual or potential economic value which are found in biological diversity”. However, there are no specific procedures for those cases.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country’s territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country’s territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. Law No. 807 (Law of Conservation and Sustainable Use of Biological Diversity), determines that it is the duty of the State to ensure the fair and equitable sharing of benefits arising from access and use of genetic resources, and pursue the equal opportunity between women and men in the distribution of these benefits.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing. The Law establishes that Access Permission Agreements must contain a clause for explanatory statements on the terms and conditions of the benefit sharing. However, there is no definition of values.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	not defined	Genetic Heritage/Associated Traditional Knowledge	Government/ Communities
Non Monetary	Not defined	not defined	not defined	Genetic Heritage/Associated Traditional Knowledge	Government/ Communities

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Law No. 807 (Law on the Conservation and Sustainable Use of Biological Diversity) defines in its article 11 that the Ministry of Environment and Natural Resources (MARENA), through the General Directorate of Natural Resources and Biodiversity, is the competent body to apply the rules in this norm. In addition, in its art. 12, Law No. 807 also determines that the competent body, MARENA, is responsible for supervising and inspecting the holders of permits to access the country's biological diversity.

This same Law defines in its article 92, that there should be a fine if there is an infraction.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Law No. 807 (Law on the Conservation and Sustainable Use of Biological Diversity) defines in its article 92 that actions or omissions that constitute administrative infractions, are

subject to the following sanctions: fine, cancellation of authorization or license, confiscation of products, suspension of operations and obligation to compensate for caused damages.

Furthermore, Law No. 807, establishes in its article 95, that in case of infractions considered serious, the renewals of authorizations will only be granted after proper regularization and legal compliance. It is considered as serious infractions: capture, mobilization, trade and detention of wildlife, products and by-products and genetic material without the corresponding authorization; cross-border movement of genetic or any of the components of Biological Diversity without authorization; non-compliance with the 'Veda system'[5]; perform activities not included in the authorization; carrying out activities liable to cause damage to biological diversity without the presentation of an Environmental impact study; carry out transactions over intellectual property rights related to biological diversity, that has already been granted by the competent authority, and; to extract native or endemic species of wild flora and fauna, without authorization.

In the same sense, art. 94 classifies as 'very serious' the following activities: irregular access to genetic heritage or associated traditional knowledge; non-compliance with the terms established in the access authorization; cause serious or irreversible damage to any component of biological diversity; to give false information; manipulate or alter biological research results or studies for its own benefit; falsify environmental permits and licenses; directly or indirectly introduce any invasive alien species within the limits of the Centers of Origin and Biodiversity Centers in the country; use the genetic resources and their products in the manufacture of biological weapons or practices harmful to the environment or human health; undertake scientific research or technological development activities causing serious damage to biological diversity; import, export or re-export products or derivatives of species of biological diversity without authorization.

In addition, Article 373 of the Criminal Code (Law No. 641) provides that irregular access to Genetic Resources is punishable with a prison sentence of two months to two years, and a cumulative fine of 100 to 300 days.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Directorate General for Natural Resources and Biodiversity	Responsible institution for access and benefit sharing in the country.

5. Ministerial Resolution No. 007-99, Art. 2: It is defined as 'veda', the space of time in which it is forbidden to hunt, capture, or extract from the medium an individual, part, product or derivative thereof, in order to protect the species.

6. Websites

Ministerio del Ambiente y los Recursos Naturales
http://www.marena.gob.ni/

7. References

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GOVERNMENT OF NICARAGUA. Ley No. 641, Código Penal. Available at: http://www.oas.org/juridico/spanish/mesicic3_nic_codigo_penal.pdf. Access on 12/24/2021.

GOVERNMENT OF NICARAGUA. Sistema de Licencias y Permisos para el uso de los Recursos de Biodiversidad, Resolucion Ministerial No.013-99, de 27 de agosto de 1998. Publicada en La Gaceta No.139 del 22 Julio 1999. Available at: < faolex.fao.org/docs/texts/nic67203.doc> Access in: 12/24/2021.

Panama[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since April 17th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. Article 7 of Decreto Ejecutivo No. 19 de 16 de Mayo de 2019 identifies the Ministry of Environment as the checkpoint of the country, responsible for instituting covenants and collaboration agreements with the public institutions to provide information for the users of genetic resources.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 37 IRCCs, for collection and commercial purposes, that are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

1. The information hereinafter has been updated until February 17th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Yes, the country already has the following laws regarding access and benefit-sharing:

- Decreto Ejecutivo No. 19, de 26 de marzo de 2019 (Executive Decree n 19, of March 26th 2019), which regulates access and control of use of biological and genetic resources;

- Ley 17 de 29 de junio de 2016 (Law 17 of June 29th, 2016), which establishes the protection of indigenous traditional medical knowledge and institutes mechanisms of protection of traditional knowledge through a Special System of collective intellectual property;

In addition to these legislations, the country has the following norms related to this topic:

- Executive Decree No. 12 of March 20, 2001, which regulates Law No. 20 of June 26, 2000, which provides for the Special Regime on Intellectual Property on the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and Traditional Knowledge;

- Law No. 20 of June 26, 2000, on the Special Regime of Intellectual Property on the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and Traditional Knowledge;

- Executive Decree No. 122 of December 23, 2008, which approves the National Biodiversity Policy;

- Executive Decree No. 163, of August 22, 2006, which establishes the new organizational structure and functions adopted by the National Environment Authority (ANAM);

- Law No. 41, of July 1, 1998 (General Environmental Law of the Republic of Panama);

- Resolution No. 164 of April 22, 2002, establishing the National Biodiversity Commission;

- Resolution No. AG-0208-2007, dated April 19, 2007, which forms the Genetic Resource Access Unit as the unit responsible for standardizing, regulating and controlling the access and use of genetic resources in general.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 5 of Decreto Ejecutivo No. 19 de 16 de Mayo de 2019 identifies the Ministry of Environment as the competent institution, which is responsible for issuing norms, regulations and monitoring access and use of genetic resources.

2.3. Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Article 9 of Decreto Ejecutivo No. 19 de 16 de Mayo de 2019 all access activities in the country must comply with the procedures described below:

1. Prior Informed Consent: The applicant shall request the providers their Prior Informed Consent, when applicable, before making the access.

2. Fees: The applicant shall pay the corresponding remunerative fees.

3. Application: The applicant shall present the application before Sección de Acceso a los Recursos Genéticos y Biológicos - SARGEB (Section of Access to Genetic and Biological Resources) for evaluation, in terms of Article 27 of Decreto Ejecutivo No. 19 de 16 de Mayo de 2019.

4. SARGEB Analysis: If complete, the SARGEB will evaluate and issue a resolution within 45 days.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Notwithstanding the procedures described in item 2.3, in cases where access to associated traditional knowledge is concerned, the Prior Informed Consent shall specify if the research has commercial purposes and if Mutually Agreed Terms were established (Article 19 of Decreto Ejecutivo No. 19 de 16 de Mayo de 2019).

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 21.8 of Ley 17 de 29 de junio de 2016 (Law 17 of June 29th, 2016), which establishes the protection of indigenous traditional medical knowledge, states that the requirement of patents based on knowledge, practice and innovations of indigenous people are subject to their previous informed consent and shall indicate the place of origin that was the base for the patent. Also the referred law foresees the creation of a Special System of collective intellectual property, which will provide for protection mechanisms of the traditional knowledge.

It was also noted that the country has the following regulations on intellectual property which relates to the subject:

- Executive Decree No. 12 of March 20, 2001, which regulates Law No. 20 of June 26, 2000, which provides for the Special Regime on Intellectual Property on the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and Traditional Knowledge;

- Law No. 20 of June 26, 2000, on the Special Regime of Intellectual Property on the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and Traditional Knowledge;

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Article 35 of Decreto Ejecutivo No. 19 de 16 de Mayo de 2019), in cases where there is shipment of samples with non commercial purposes, the user is required to sign a Material Transfer Agreement.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory, and the responsibility to share the benefits lies with the applicant.

Furthermore, Article 21.8 of Ley 17 de 29 de junio de 2016 (Law 17 of June 29th, 2016) states that indigenous people shall receive monetary and non monetary benefits derived from the research based on their knowledge, innovation and practice. Also, Benefit Sharing depends on the establishment of Mutually Agreed Terms, following the requirements of Article 20 of the same legislation.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, the procedures, rules and values were established by the domestic legislation as presented below:

Access to genetic heritage: According to Article 42 of Decreto Ejecutivo No. 19 de 16 de Mayo de 2019, benefit sharing agreements shall be made between the beneficiary and the Ministry of Environment, and it shall contain annual royalties of 1% of the net sales of products, while the product is in market and if it relates to a national counterpart. If it refers to a non national, the incidence is 4% over net sales. Other monetary benefits, such as initial, annual, periodic payments may be included in the agreement, as per article 42 of the same legislation.

Access to associated traditional knowledge: According to Ley 17 de 29 de junio de 2016 (Law 17 of June 29th, 2016), which establishes the protection of indigenous traditional medical knowledge, benefit sharing depends of the establishment of Mutually Agreed Terms, which shall guarantee the rights foresaw on the legislation. According to Article 25 of the same legislation, some of the non monetary benefits mentioned on the legislation are: investment of a percentage of benefits in program or projects of conservation; protection and promotion of natural resources and biodiversity of the place.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Finished products	Payment to State	At least 1% of net sales	Genetic Heritage and Associated Traditional Knowledge	Government
Non Monetary	Intellectual Property	Right of the State of Panama to grant compulsory licenses on patents of invention; participation of the State of Panama in all industrial or commercial contracts linked to the use of genetic or biological material and its derivatives	-	Genetic Heritage/ Associated Traditional Knowledge	Government

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 47 of Decreto Ejecutivo No. 19 de 16 de Mayo de 2019 institutes the Ministry of Environment as the official inspection body responsible for all matters related to access and benefit-sharing in the country. Also, Law 17 of 2016, establishes that the Advisory Commission of Indigenous Traditional Medicine will inspect the norms and commercial use of knowledge about the biological resources of indigenous territories that arise from research of bioprospection or any type of research.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Articles 46 to 49 of Decreto Ejecutivo No. 19 establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: the cancellation of access authorizations, with refraining from granting other authorizations; written warning; establishment of fine, pursuant to Article 114 of Law 41 of 1998; ineligibility for access applications; cancellation of the Resolution of the Ministry of Environment

Article 114 of Law 41 of 1998, indicated above, provides the values of fines, which will vary according to the institution that orders the payment of the fine:

- The National Environment Authority (ANAM) may impose a fine not exceeding ten million balboas (B/.10,000,000).

- The National Administrator of the Environment may apply fines of up to one million balboas

(B/.1,000,000).

- The National Environmental Council may impose fines from one million balboas (B/.1,000.001) up to ten million balboas (B / .10,000,000).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
The National Environment Authority (ANAM)	Is the Competent National Authority, with the attribution of normalizing, regulating and controlling access to and use of genetic and/or biological resources.

6. Websites

National CHM

http://www.chmpanama.gob.pa

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Panama profile. Available in: https://absch.cbd.int/countries/PA Access on 12/24/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Panama profile. Available in https://www.cbd.int/countries/?country=pa Access on 12/24/2021.

REPÚBLICA DE PANAMÁ. Decreto Ejecutivo N° 12 de 20 de marzo de 2001, por la cual se Reglamenta la Ley No. 20 de 26 de junio de 2000, del Régimen Especial de Propiedad Intelectual sobre **los Derechos Colectivos de los pueblos indígenas para la Protección y Defensa de su Identidad** Cultural y de sus conocimientos tradicionales, y se dictan otras disposiciones. Available in: http://www.wipo.int/wipolex/en/details.jsp?id=3397 Access in 12/24/2021.

REPÚBLICA DE PANAMÁ. Decreto Ejecutivo N° 12 de 20 de marzo de 2001, por la cual se Reglamenta la Ley No. 20 de 26 de junio de 2000, del Régimen Especial de Propiedad Intelectual sobre **los Derechos Colectivos de los pueblos indígenas para la Protección y Defensa de su Identidad** Cultural y de sus conocimientos tradicionales, y se dictan otras disposiciones. Available on: https://wipolex.wipo.int/en/text/179591 Access on 12/24/2021.

REPÚBLICA DE PANAMÁ. Decreto Nº 19 de 26 de marzo de 2019, por el cual se Reglamenta el Acceso y Control del uso de Recursos Biológicos en la República de Panamá y se Dictan Otras Medidas. Available on: http://www.fao.org/faolex/results/details/en/c/LEX-FAOC189937. Access on 12/24/2021.

REPÚBLICA DE PANAMÁ. Decreto Nº 163 - Organización y funciones de la Autoridad Nacional del **Ambiente (ANAM)**. Available on: https://www.ecolex.org/details/legislation/decreto-no-163-organizacion-y-funciones-de-la-autoridad-nacional-del-ambiente-anam-lex-faoc065759/?q=Decreto+No.+163+ANAM&type=legislation&xcountry=Panama&xdate_min=&xdate_max= Access in 12/24/2021.

REPÚBLICA DE PANAMÁ. Estrategia Nacional De Biodiversidad. Autoridad Nacional Del Ambiente (Anam). Panamá, 2000. Available on: https://www.cbd.int/countries/?country=pa Access on 12/24/2021.

REPÚBLICA DE PANAMÁ. Ley N° 17 del 27 de junio de 2016 que establece la protección de los conocimientos de la medicina tradicional indígena. Available at: http://extwprlegs1.fao.org/docs/pdf/pan164344.pdf. Access in 12/24/2021.

REPÚBLICA DE PANAMÁ. Ley N° 20 del 26 de junio de 2000 sobre el Régimen Especial de Propiedad Intelectual sobre los Derechos Colectivos de los Pueblos Indígenas para la Protección y **Defensa de sus Identidad Cultural y de sus Conocimientos Tradicionales**. Available on: http://www.wipo.int/wipolex/en/details.jsp?id=3400 Access in 12/24/2021.

REPÚBLICA DE PANAMÁ. Ley Nº 41 - Ley General de Ambiente. Available on: https://www.ecolex.org/details/legislation/ley-no-41-ley-general-de-ambiente-texto-refundido-lex-faoc164563/?q=Ley+-No.+41&type=legislation&xcountry=Panama&xdate_min=&xdate_max= Access in 12/24/2021.

REPÚBLICA DE PANAMÁ. Quinto Informe Nacional De Biodiversidad De Panamá Ante El Convenio Sobre Diversidad Biológica. Autoridad Nacional Del Ambiente (Anam). Panamá, 2014. Available in: https://www.cbd.int/countries/?country=pa Access on 12/24/2021.

REPÚBLICA DE PANAMÁ. Resolución Nº 164 - Crea la Comisión Nacional de Biodiversidad. Available in: https://www.ecolex.org/details/legislation/resolucion-no-164-crea-la-comision-nacional-de-biodiversidad-lex-faoc042380/?q=164+COMISION+NACIONAL+DE+BIODIVERSIDAD&type=legislation&xcountry=Panama&xdate_min=&xdate_max= Access on 12/24/2021.

REPÚBLICA DE PANAMÁ. Resolución Nº 204 - Conforma la Unidad de Acceso al Recurso Genético. Available on: https://www.ecolex.org/details/legislation/resolucion-no-204-conforma-la-unidad-de-acceso-al-recurso-genetico-lex-faoc072041/?q=AG-0208-+2007%2C&type=legislation&xcountry=Panama&xdate_min=&xdate_max= Access in 12/24/2021.

Paraguay[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since May 25th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, Law 5469 (Ley de Salud indígena) establishes in article 7 the prohibition of access without prior informed consent from indigenous people to ceremonious religious places. Also, article 6 of the same legislation states that rights, benefits and

1. The information hereinafter has been updated until December 23rd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

derivatives arising from traditional knowledge, specially the ones associated with medical and genetic resources, shall be of the indigenous people exclusive property.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. However, the National Directorate of Intellectual Property (Dirección Nacional de Propiedad Intelectual - DINAPI) has established a Directorate of Traditional Knowledge and Genetic Resources. Among its attributions, DINAPI can officially request geographical indications and designations of origin when it comes to a product that, as a result of traditional cultural processes and knowledge, is considered of national interest and therefore requires its recognition and registration.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the law 5469 in article 7 forbids the irregular access to genetic resources without specifying the procedures or to request access to genetic resources in indigenous land.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Nevertheless, article 7 of Law 5469 (Ley de Salud indígena) provides that Prior Informed Consent is required before access to genetic resources and religious ceremonies in indigenous territory, pursuant to the cultural uses of each indigenous people. Also, even though Law 5469 does not specify the procedure to access traditional knowledge from indigenous people, this law forbids any kind of irregular access to this knowledge indigenous.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information,

synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In

the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
No record of fines in the country were found. However, one emblematic case related to irregular access was when on 70's, some japaneses scientists discovered a south american plant with origin in Paraguay and Brazil, in which indigenous people from Guarani ethnicity, used to sweeten any kind of food, called stevia.With this discovery, the world market of food, principally great industrys of candy and chocolates from Europe and United States beginner to explore this plant and use it for your own formulas to make candy and chocolate without sugar.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Conventions on Biological Diversity

Sr. Lic. Rafael Cristobal Sosa Brizuela
Director General
Dirección General del Protección y Conservación de la Biodiversidad
Ministerio del Ambiente y Desarrollo Sostenible
Av. Madame Lynch 3500
Asunción
Paraguay

CBD Primary NFP, CHM NFP, SBSTTA NFP
biodiversidad@mades.gov.py
afael.sosa@ mades.gov.py

Sr. Lic. Paul Frederick Wulf Bauer Bloemeken
Ditector, Dirección de la Vida Silvestre
Dirección General del Protección y Conservación de la Biodiversidad
Ministerio del Ambiente y Desarrollo Sostenible
Av. Madame Lynch 3500
Asunción
Paraguay

CBD Secondary NFP
vidasilvestre@mades.gov.py
frederick.bauer@mades.gov.py

6. Websites

ABSCH Paraguay's Profile
https://absch.cbd.int/countries/PY

CBD Paraguay's Profile
https://www.cbd.int/countries/?country=py

Paraguay's Biodiversity
http://www.pybio.org/

7. References

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ORNELAS, Andrea. Estévia: Milagre ou pesadelo Guarani?. Swissinfo. Available in: https://www.swissinfo.ch/por/economia/o-neg%C3%B3cio-da-erva-doce-_est%C3%A9via-milagre-ou-pesadelo-guarani/42146982 Access on December 23rd, 2021.

Peru[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

- **La Comisión Nacional para la Protección al Acceso a la Diversidad Biológica Peruana y a los Conocimientos Colectivos de los Pueblos Indígenas (Comisión Nacional contra la Biopiratería)**

This is the National Commission for the Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of Indigenous Peoples (also known as the National Commission against Biopiracy), instituted by Law No. 28,216 of May 1st, 2014. Its core mission is to develop activities to identify, prevent and stop biopiracy acts in the Peruvian State. The Commission is chaired by the intellectual property authority of Peru, INDECOPI (National Institute for the Defense of Competition and Intellectual Property Protection), which is responsible for keeping a registry of any access to protected material, as well as for undertaking other activities. It was through this law that the crime of biopiracy was established, understood as the unauthorized or uncompensated for access or use of biological resources or traditional knowledge from indigenous peoples in disagreement with the principles of the CBD and the current Peruvian regulations.

- **Dirección de Invenciones y Nuevas Tecnologías (DIN) del Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual (INDECOPI)**

This is the Directorate of Inventions and New Technologies at INDECOPI. Under the aforementioned patent institution, this Directorate is the entity responsible for overseeing patent requests for inventions, utility models, industrial designs, protection certificates, collective knowledge of indigenous peoples, integrated circuits topography and licenses for the production of new plant varieties.

1. The information hereinafter has been updated until January 11th, 2022.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 53 IRCCs that are available on ABSCH website, all of them for non commercial activities.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Andean Decision 391 (1996)
- Andean Decision 486 (2000)
- Law 26,839 of July 16, 1997 – Law on the Conservation and Sustainable Use of Biological Diversity.
- Supreme Decree No. 068-2001-PCM – Regulation pursuant to the Law on the Conservation and Sustainable Use of Biological Diversity
- Law No. 27,811 of August 10, 2002 – Regime for Protecting the Collective Knowledge of Indigenous Peoples related to Biological Resources.
- Law 28,216 of April 7, 2004 – Law on the Protection of Access to Peruvian Biological Diversity and the Collective Knowledge of Indigenous Peoples
- Law 28,611 of October 15, 2005 – General Law of the Environment
- Supreme Decree No. 018-2015- MINAGRI on regulation for Forest Management
- Supreme Decree No. 019-2015-MINAGRI on regulation for Wild Fauna Management
- Supreme Decree No. 019-2021-MINAM - Regulation on Access to Genetic Resources

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Here follows a summary of institutions and their competences, according to Supreme Decree No. 019-2021-MINAM:

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- **Ministerio Del Ambiente - MINAM**

The regulatory agent on access to genetic resources is the Ministry of the Environment (MINAM). The Ministry of the Environment is the entity in charge to issue cross-sectoral provisions on matters of access to genetic resources and their derivatives and ensures compliance with public policies related to the aforementioned subject.

- **Ministerio de Agricultura y Riego - Servicio Nacional Forestal y de Fauna Silvestre (MINAGRI-SERFOR)**

According to article 12, a) of the Supreme Decree, SERFOR is the competent authority regarding genetic resources and their derivatives from the Forest and Wildlife Heritage, including the wild relatives of cultivated species; as well as the microorganisms associated with thatHeritage, which are found in the national territory, including in regional conservation areas and private conservation areas. This institution encompasses genetic resources and their derivatives contained in all or part of the specimen.

- **Instituto Nacional de Innovación Agraria (INIA)**

According to article 12, b) of the Supreme Decree, this institution is the competent authority regarding genetic resources and their derivatives of continental cultivated or domesticated species, as well as for the microorganisms associated with these, found in the national territory, including protected natural areas of national administration, regional conservation areas and conservation areas private. This competence encompasses genetic resources and their derivatives contained in all or part of the specimen.

- **El Ministerio de la Producción (PRODUCE)**

According to article 12, c) of the Supreme Decree, this institution is the competent authority regarding genetic resources and their derivatives species of marine and continental waters and their associated microorganisms, which are found in the national territory, including the natural protected areas of national administration, regional conservation areas and private conservation areas. This competence encompasses genetic resources and their derivatives contained in all or part of the specimen.

- **El Servicio Nacional de Áreas Naturales Protegidas por el Estado (SERNANP)**

According to article 12, d) of the Supreme Decree, this institution is the competent authority regarding genetic resources and their derivatives from the Forest and Wildlife Heritage and from the wild relatives of cultivated or domesticated species, which are found in the protected natural areas of national administration, as well as the microorganisms associated with them. This competence encompasses genetic resources and their derivatives contained in all or part of the specimen.

In addition, Law 27,811 establishes:

- **Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual – INDECOPI**

The Directorate of Inventions and New Technologies at the National Institute for the Defense of Competition and Intellectual Property Protection (INDECOPI) is the national competent authority responsible for judging and deciding in first instance all matters related to the protection of the collective knowledge of the Peruvian indigenous peoples, and the Special Chamber of Intellectual Property at INDECOPI must take notice and decide on all administrative appeals in the second and last instance.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authoriza-

tion in order to obtain genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, Decision 391 establishes that all access procedures must follow the following steps:

1. Submission: in order to submit the request, the requesting party shall present themselves to the National Competent Authority with all the information they have - or are in a position to obtain - regarding the relevant genetic resource and its by-products. This information must include the current and potential uses of the resource, its by-products or intangible components, their sustainability and the possible risks that may result from the access. The National Competent Authority (Ministry of the Environment) will always be a party to the access contracts. The declarations made by the requesting party in their application and in the contract, including their respective annexes, should be made in the form of an official affidavit.

2. Examination of the request by the National Competent Authority: It may be granted or denied.

3. Acceptance: immediate negotiation and signing of the access contract – which must include the competent authority in both the negotiation and the signing of the document.

4. Publication: Resolution issued by joint act and published in the country's official gazette or in a widely-read newspaper.

5. Approval: from the date of the publication, access can be considered as granted.

Article 103 of Law 28,611 establishes that in order to gain access to Peruvian genetic resources, it is necessary to have a certificate of origin of the accessed material and to officially acknowledge the communities holding the traditional knowledge.

Also, article 24 of the Supreme Decree No. 019-2021-MINAM establishes that all access procedures require the presentation of the request for access to genetic resources and their derivatives (access request), its admission, publication of the extract of the request, evaluation of the request, negotiation (if applicable), the issuance of the resolution authorizing access and signing the contract. The access request shall be admitted, evaluated, approved or denied by the competent authorities as described on item 2.2 of this form.

Moreover, article 28 of Law 26,839 establishes the State as a party to this process and shall participate in the procedures for accessing the Peruvian genetic resources.

However, generally speaking, the normative authority in matters concerning access to genetic resources is the Ministry of the Environment.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Besides the basic procedures described by Decision 391 (Submission, examination, acceptance, publication and approval), in cases where collective knowledge is concerned, the following is required:

1. Prior and informed consent of one or more communities or indigenous peoples holding the relevant collective knowledge.

2. INDECOPI will coordinate the process for developing norms concerning the rights of protection to traditional knowledge, innovations and practices of indigenous peoples associated with biological diversity.

3. Access to collective knowledge for scientific, commercial and industrial purposes must follow the prior and informed consent, as established by Article 6 of Law 27,811. As established in the same article, the responsibility for informing other indigenous peoples with the same collective knowledge falls under the group that received the request of prior informed consent.

4. The value of the benefit-sharing, as established in Article 8 of Law 27,811, specifically related to the access to collective knowledge, must not be under 10% of the gross sales resulting from the products developed from the collective knowledge, value which shall be reverted to the Fund for the Development of Indigenous Peoples. It will also be possible to increase this percentage, depending on the direct use or incorporation of the traditional knowledge to the product, or also, depending on the cost reduction such knowledge may bring to the development of the product, among other specific cases.

5. In relation to the registration of patents, Law 27,811 establishes specific procedures.

The Andean Community adopts a broader concept than that of the associated traditional knowledge, encompassing any intangible components, including all know-how, innovation, individual or collective knowledge with a real or potential value associated to the genetic resource, its by-products or containing biological resources, whether or not protected by intellectual property regimes.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Article 3 of Decision 486 establishes that patents originating from inventions created from genetic material or traditional knowledge will only be granted if the access occurred under the international, national and community legal rule, including the previously described Decision 391. Therefore, patent requests will require:

- Providing a copy of the access contract

- Providing a copy of the document that licenses or authorizes the use of the traditional knowledge

- Providing a certificate of deposit of the biological material

Besides, Law 27,811/2002, which deals with the Collective Knowledge of Indigenous Peoples Derived from Biological Resources, establishes in its complementary dispositions that this norm is independent of any other decisions from the Andean community. Also, the second complementary disposition reinforces the requirement of presenting a copy of the license agreement on the use of associated traditional knowledge, in particular when dealing with invention patents related to a product or process obtained or developed from a collective knowledge.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection

and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. In cases where there is shipment of samples, according to article 71,2 of the Supreme Decree 019-2021, the applicant is required to apply for an export permit in accordance with the provisions of the sectoral regulations of each Competent National Authority. Also, the National Superintendency of Customs and Tax Administration (SUNAT) and the Health Authority request the access contract number prior to the issuance of authorization for the export of samples or genetic material at authorized entry points in the country.

There are no express provisions on the commercialization of raw materials – which are sold by the local supplier.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the legislation addresses this matter but it does not use a specific terminology, as it is composed under the definition of genetic information.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
Yes, benefit sharing is mandatory and it comprises over access to genetic heritage or its by-products involving intangible components. The responsibility to share the benefits lies with the applicant.

3.2 Are there any specific procedures, rules and values?
(X) YES / ( ) NO / NOT AVAILABLE
Yes, the procedures, rules and values were established by the domestic legislation as presented below:

- **Access to genetic heritage:**

Decision 391 only mentions benefit-sharing once, being mandatory in the hypothesis of the access to genetic heritage or its by-products involving intangible components. In this sense, along with the Access Contract with the National Competent Authority, the parties should attach a document establishing a fair and equitable sharing of benefits deriving from the use of this component. There is no mention of payment obligations just for accessing genetic resourc-

es, or any specification of values.

Although Law 26,839 has the objective of establishing programs and action plans for the conservation of biological diversity, for the sustainable use of components and for the fair and equitable sharing of benefits deriving from their use, its contents do not make any additions to the specific legislation regulating access and benefit sharing, restricting itself to making important acknowledgements on the matter (Articles 23 and 24).

The applicable sanctions for accessing genetic resources in disagreement with the described rules are the suspension or cancelation of access authorizations, confiscation of accessed material, fine of up to 1,000 (one thousand) Tax Units (according to the UIT decree, in the Spanish-language acronym); incapacitation of the breaching party in submitting new access requests; and the cancellation of the registry of the breaching institution, with the possibility of these sanctions being applied concomitantly or not.

- **Access to associated traditional knowledge**

The value of the benefit-sharing, as established in Article 8 of Law 27,811, specifically related to the access to collective knowledge, must not be under 10% of the gross sales resulting from the products developed from the collective knowledge, value which shall be reverted to the Fund for the Development of Indigenous Peoples. It may also be possible to increase this percentage depending on the direct use or incorporation of the traditional knowledge to the product, or also, depending on the cost reduction such knowledge may bring to the development of the product, among other specific cases.

Activities in disagreement with the aforementioned rules will result in fine (of up to 150 Tax Units – UIT in the Spanish-language acronym, as established by the legislation)

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Deposit to a Fund, when Associated Traditional Knowledge is involved; Article 50 and 51 of Supreme Decree No 019-2021 MINAM.	When there is Associated Traditional Knowledge involved, benefit sharing shall be at least 10% of the sales gross value.	Genetic Heritage/ATK	/Government/ Providers
Non Monetary	Not defined	Article 49 of Supreme Decree No 019-2021 MINAM.	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 69.4 of the Supreme Decree 019-2021 establishes that the Competent National Authorities are empowered to supervise the fulfillment of the obligations contained in the authorizations and access contracts to genetic resources and their derivatives under their responsibility. They exercise the function of controlling, supervising, inspecting and sanctioning the holders of authorizations and contracts for access to genetic resources and their derivatives, exporters, importers, re-exporters, as well as others provided in the Supreme Decree No. 019-2021.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Supreme Decree No 019-2021 states that with the Competent National Authorities are empowered to impose sanctions for administrative offenses related to non-compliance with the regulation, which are contained in the Table of Classification of Infractions and Sanctions (Annex No. 5). The infractions can be minor, serious and very serious. In addition, the imposition of administrative sanctions is applied according to the seriousness of the offense and they can be: fine, final confiscation, temporary or definitive closure, disqualification of the offender from submitting new requests for access to genetic resources and their derivatives. Similarly, Law No. 27,811 establishes that activities in disagreement with the established rules will result in the application of a fine of up to 150 Tax Units – UIT. According to the table of Peruvian Tax Units, available in the National Superintendence of Customs and Tax Administration – SUNAT[5], 150 UIT is equivalent to S/. 660,000.00 Peruvian soles, which, according to the official exchange rate of the website of the Brazilian Central Bank, means a fine for irregular access in Peru is approximately $168000,00 (one hundred, sixty eight thousand dollars).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, several cases involving biopiracy in Peru were found. The Peruvian government contested patents derived from Maca, Camu camu and Sacha inchi in 2009, registered by researchers from Japan, USA and France, respectively.

It is worth noting that the Peruvian National Commission Against Biopiracy constantly monitors patent databases in order to identify irregular access to Peruvian genetic resources.

5. Summary - Competent authorities

Authority	Competence
Ministry of the Environment - MINAM	The Regulation of Access to Genetic Resources (Supreme Decree No. 019-2021-MINAM) establishes that the regulatory entity responsible for the access to genetic resources is the Ministry of the Environment (MINAM). As such, it is the regulatory agent on the matter, with competence over political, legal and administrative issues.

5. Available at: https://busquedas.elperuano.pe/normaslegales/valor-de-la-unidad-impositiva-tributaria-durante-el-ano-2021-decreto-supremo-n-392-2020-ef-1911904-3/. Access on January 11th, 2022.

Ministry of Agriculture and Irrigation – National Forestry and Wildlife Service (MINAGRI-SERFOR)	The Regulation on Access to Genetic Resources, approved by Supreme Decree No. 019-2021-MINAM, establishes in Article 12 MINAGRI as the Administration and Execution Authority (AAE) regarding genetic resources and their derivatives from the Forest and Wildlife Heritage, including the wild relatives of cultivated species; as well as the microorganisms associated with that Heritage, which are found in the national territory, including in regional conservation areas and private conservation areas. This institution encompasses genetic resources and their derivatives contained in all or part of the specimen.
National Institute of Agricultural Innovation (INIA)	The Regulation on Access to Genetic Resources, approved by Supreme Decree No. 019-2021MINAM, establishes in article 12 INIA as the Administration and Execution Authority (AAE) regarding genetic resources and their derivatives of continental cultivated or domesticated species, as well as for the microorganisms associated with these, found in the national territory, including protected natural areas of national administration, regional conservation areas and conservation areas private. This competence encompasses genetic resources and their derivatives contained in all or part of the specimen.
El Ministerio de la Producción (PRODUCE)	According to article 12, c) of the Supreme Decree, this institution is the competent authority regarding genetic resources and their derivatives species of marine and continental waters and their associated microorganisms, which are found in the national territory, including the natural protected areas of national administration, regional conservation areas and private conservation areas. This competence encompasses genetic resources and their derivatives contained in all or part of the specimen.
El Servicio Nacional de Áreas Naturales Protegidas por el Estado (SERNANP)	According to article 12, d) of the Supreme Decree, this institution is the competent authority regarding genetic resources and their derivatives from the Forest and Wildlife Heritage and from the wild relatives of cultivated or domesticated species, which are found in the protected natural areas of national administration, as well as the microorganisms associated with them. This competence encompasses genetic resources and their derivatives contained in all or part of the specimen.
National Institute for the Defense of Competition and Intellectual Property Protection - INDECOPI	According to Law 27,811, the Directorate of Inventions and New Technologies at the National Institute for the Defense of Competition and Intellectual Property Protection (INDECOPI) is the national competent authority responsible for judging and deciding in first instance all matters related to the protection of the collective knowledge of the Peruvian indigenous peoples, and the Special Chamber of Intellectual Property at INDECOPI must take notice and decide on all administrative appeals in the second and last instance.

6. Websites

Ministério del Ambiente
http://www.minam.gob.pe/

Iniciativa Andino Amazónica para la prevención de la biopiratería
http://www.biopirateria.org/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Peru's profile. Available in: https://absch.cbd.int/countries/PE Access on 01/11/2022.

ANDEAN COMUNITY. Andean Decision nº 391 Establishing the Common Regime on Access to Genetic Resources (1996). Available in: http://www.wipo.int/wipolex/en/details.jsp?id=9446 Access on 01/11/2022.

ANDEAN COMUNITY. Andean Decision nº 486 Establishing the Common Industrial Property Regime (2000). Available in http://www.wipo.int/wipolex/en/details.jsp?id=9451 Access on 01/11/2022.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Peru profile. Available in: https://www.cbd.int/countries/?country=pe Access on 01/11/2022.

MINISTERIO DEL AMBIENTE – MINAM. Política Nacional Del Perú Sobre Biodiversidad (Decreto Supremo Nº 012-2009-MINAM de 23 de Mayo de 2009). Available in http://www4.congreso.gob.pe/comisiones/1997/ambiente/DISCURSO/bio.htm Access in 01/11/2022.

REPÚBLICA DEL PERÚ. Decreto Supremo nº 029-2014 Ratifcan el Protocolo de Nagoya sobre Acceso a los Recursos Genéticos y Participación Justa y Equitativa en los Benefcios que se deriven de su utilización al Convenio sobre la Diversidad Biológica. Available in: https://absch.cbd.int/countries/PE Access on 01/11/2022.

REPÚBLICA DEL PERÚ. Decreto Supremo Nº 068/01/PCM - Reglamento de la Ley sobre conservación y aprovechamiento sostenible de la diversidad biológica. Available in: https://www.ecolex.org/es/details/legislation/decreto-supremo-no-06801pcm-reglamento-de-la-ley-sobre-conservacion-y-aprovechamiento-sostenible-de-la-diversidad-biologica-lex-faoc032237/ Access on 01/11/2022.

REPÚBLICA DEL PERÚ. Ley 28216, Ley de Protección al acceso a la diversidad biológica peruana y los conocimientos colectivos de los pueblos indígenas. Available in: https://absch.cbd.int/countries/PE Access on 01/11/2022.

REPÚBLICA DEL PERÚ. Ley N°27811, Ley que establece el Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas vinculados a los Recursos Biológicos. Available on: https://absch.cbd.int/countries/PE Access in 01/11/2022.

REPÚBLICA DEL PERÚ. Ley Nº 28.611 - Ley General del Ambiente. Available in: https://www.ecolex.org/details/legislation/ley-no-28611-ley-general-del-ambiente-lex-faoc-081742/?q=-Ley+general&type=legislation&xcountry=Peru&xdate_min=&xdate_max= Access on 01/11/2022.

REPÚBLICA DEL PERÚ. Decreto Supremo nº 019-2021-MINAN Reglamento de Acceso a los Recursos Genéticos. Available in: https://cdn.www.gob.pe/uploads/document/file/2035623/DS.%20019-2021-MINAM%20con%20anexos.pdf.pdf Access on 01/11/2022.

REPÚBLICA DEL PERÚ. V Informe Nacional Sobre La Aplicación Del Convenio Sobre La Diversidad Biológica: Perú (2010-2013). Ministerio del Ambiente. Lima, 2010. Available in: https://www.cbd.int/countries/?country=pe Access on 01/11/2022.

Biopiracy in Peru: Tracing Biopiracies, Theft, Loss & Traditional Knowledge Jodie Chapell, BSc First Class Honours, MA Submitted for the degree of Doctor of Philosophy September, 2011, Department of Sociology, Lancaster University.

Saint Lucia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The Sixth National Report on the Convention of Biological Diversity informs that there is a draft law on the subject, the "Biodiversity Conservation and Sustainable Use Bill", as well as a national ABS policy, but they could not be identified by this analysis.

1. The information hereinafter has been updated until October 10th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Conventions on Access and Benefit-sharing

Ms. Caroline Eugene
Permanent Secretary
Department of Sustainable Development
Ministry of Education, Innovation, Gender Relations and Sustainable Development
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6. Websites

ABSCH Saint Lucia Profile
https://absch.cbd.int/countries/LC

CBD Saint Lucia Profile
https://www.cbd.int/countries/?country=lc

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Saint Lucia profile. Available in: https://absch.cbd.int/countries/LC> Access in 10/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Saint Lucia profile. Available in: https://www.cbd.int/countries/?country=lc> Access in 10/10/2020

SANTA LUCIA. **Fifth National Biodiversity Report for Saint Lucia, 2014**. Available at: <https://www.cbd.int/doc/world/lc/lc-nr-05-en.pdf> Access in: 05/28/2018.

SANTA LUCIA. **Sixth National Biodiversity Report for Saint Lucia, 2019**. Available at: https://chm.cbd.int/database/record?documentID=247311 Access in: 10/10/2020.

SANTA LUCIA. National Biodiversity Strategy and Action Plan of St. Lucia Protecting the Future, 2000. Available at: <https://www.cbd.int/doc/world/lc/lc-nbsap-01-p01-en.pdf> Access in: 05/28/2018.

Saint Vincent and the Grenadines[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since September 1st, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until November 1st, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mrs. Janeel Miller-Findlay
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6. Websites

ABSCH Haiti Profile
https://absch.cbd.int/countries/HT

CBD Haiti Profile
https://www.cbd.int/countries/?country=ht

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Saint Vincent and the Grenadines profile. Available at: https://absch.cbd.int/countries/KN> Access in 11/02/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Saint Vincent and the Grenadines profile. Available at: https://www.cbd.int/countries/?country=kn> Access in 11/02/2020.

ST. VINCENT AND THE GRENADINES. **Fifth National Report To The United Nations Convention On Biological Diversity, 2015**. Available at: < https://www.cbd.int/doc/world/vc/vc-nr--05-en.pdf> Access in: 05/28/2018.

ST. VINCENT AND THE GRENADINES. **Sixth National Report To The United Nations Convention On Biological Diversity, 2019.** Available at: < https://www.cbd.int/doc/nr/nr-06/vc-nr--06-en.pdf> Access in: 11/02/2020.

ST. VINCENT AND THE GRENADINES. **National Biodiversity Strategy and Action Plan, 2014**. Available at: < https://www.cbd.int/doc/world/vc/vc-nbsap-01-en.pdf> Access in: 05/28/2018.

Suriname[1]

1. General information

(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since April 11th, 1996.
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since April 11th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until January 6th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, it is worth mentioning that the International Cooperative Biodiversity Group (ICBG), funded by the US government in 1991, has developed a 5 year project which comprised the conservation of biological diversity in different countries, including Suriname. In this scope, a bioprospecting program was implemented, which included a benefit sharing plan for the Saramaka Maroons, a traditional people living in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Conventions on Biological Diversity

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6. Websites

CBD Suriname Profile
https://www.cbd.int/countries/?country=sr

ABSCH Suriname Profile
https://absch.cbd.int/countries/SR

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Suriname profile. Available in: < https://absch.cbd.int/es/countries/SR> Access on 01/06/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Suriname profile. Available in: <https://www.cbd.int/countries/?country=sr > Access on 01/06/2021.

SURINAME. **Fifth National Report to the Convention on Biological Diversity, 2015**. Available at: <https://www.cbd.int/doc/world/sr/sr-nr-05-en.pdf> Access in: 06/04/2018.

SURINAME. **National Biodiversity Action Plan, 2013**. Available at: <https://www.cbd.int/doc/world/sr/sr-nbsap-v2-en.pdf> Access in: 06/04/2018.

Trinidad and Tobago[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since October 30th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

1. The information hereinafter has been updated until December 24th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Nagoya Protocol on Biological Diversity

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Forestry Division
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+1 868 628 5503

6. Websites

ABSCH Trinidad and Tobago Profile
https://absch.cbd.int/countries/TT

CBD Trinidad and Tobago Profile
https://www.cbd.int/countries/?country=tt

Environmental Management Authority
http://www.ema.co.tt/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Trinidad and Tobago profile. Available in: < https://absch.cbd.int/countries/TT> Access on 12/24/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Trinidad and Tobago profile. Available in: <https://www.cbd.int/countries/?country=tt > Access on 12/24/2020.

TRINIDAD AND TOBAGO. **Trinidad and Tobago's Fifth National Report to the Convention on Biological Diversity, 2016**. Available at: <https://www.cbd.int/doc/world/tt/tt-nr-05-en.pdf> Access on: 06/07/2018.

TRINIDAD AND TOBAGO. **Biodiversity Strategy and Action Plan for Trinidad and Tobago, 2017-2020.** Available at: <https://www.cbd.int/doc/world/tt/tt-nbsap-v2-en.pdf> Access on: 06/07/2018.

United States of America[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

( ) YES / (X) NO

No, the country is not a Party to the Convention on Biological Diversity.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to information obtained from the country's National Focal Point, the country has specific regulations on the access to genetic heritage in

1. The information hereinafter has been updated until September 24th, 2021.
2.Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

its national parks:

- National Park Omnibus Act of 1998 – Grants the Secretary the responsibility to manage the units of the National Park System according to the fundamental purpose of conserving their landscapes, wildlife and natural and historical landmarks, as well as promoting their sustainable use to preserve them for future generations.

- Management Policies of the National Park System 2006 – White paper of the National Park System.

- Director's Order (DO) #77-10: NPS Benefit Sharing, December 19, 2012 – Complements Management Policies NPS 2006.

- Benefits-Sharing Handbook, September 29, 2014 – Complements the Director's Order (DO) #77-10.

Furthermore, it was identified that despite not having enforced any official legislation regulating access to the national genetic heritage, national Botanical Gardens - such as the Missouri Botanical Garden and the New York Botanical Garden - have endorsed the principles related to access to genetic resources and benefit sharing. Also, there are common white papers that serve as the baseline for institutions wishing to develop institutional policies in line with the aforementioned principles.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, there are specific regulations in the national parks. In this sense, according to Management Policies 2006, section 4.2.4, any extractive use of park resources for commercial purposes is prohibited, except if expressly authorized.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to Director's Order (DO) #77-10, section 4.3.17, the research agreements signed by the national parks require the parties to notify the NPS if the inventions are subject to patent registry or if they should be

protected before being brought to public knowledge.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, §3372 of the Lacey Act (1900), amended in 2008, forbids the importation of wildlife in violation of any law or regulation of any State.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, there are specific norms applicable in case of access to the genetic resources of national parks. In this sense, in case of research developed in the national parks, Director's Order (DO) #77-10, section 4.2.1, establishes that before using the inquiry's results for commercial purposes, the party wishing to promote a commercial application of the inquiry's results must first sign a Benefit-sharing agreement with the NPS or an agreement in which the NPS waives the Benefit-Sharing.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Acess and Benefit-sharing

Mr. Patrick Reilly
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Office of Conservation and Water, Bureau of Oceans and International Environmental and Scientific Affairs
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United States of America

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6. Websites

ABSCH United States of America Profile
https://absch.cbd.int/countries/BT

CBD United States of America Profile
www.cbd.int/countries/?country=bt

Forest Legality Initiative
https://forestlegality.org/policy/us-lacey-act

United States Department of Agriculture
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/SA_Lacey_Act

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. United States of America. Available in: < https://absch.cbd.int/countries/US>. Access on: 09/24/2021.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. United States of America. Available in: < https://www.cbd.int/countries/?country=us> Access on: 09/24/2021.

UNITED STATES DEPARTMENT OF AGRICULTURE, Usda. Lacey Act, 2019. Available in: <https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/SA_Lacey_Act> Access in:24/09/2021.
FOREST LEGALITY INITIATIVE, Fli. U.S. Lacey Act, Where is it in Effect?,2019. Available in: <https://forestlegality.org/policy/us-lacey-act> Access on: 09/24/2021.

UNITED STATES GOVERNMENT. **Benefit-Sharing Handbook**. Available in: https://parkplanning.nps.gov/document.cfm?parkID=442&projectID=41624&documentID=56858 Access on 11/13/2020.

UNITED STATES GOVERNMENT. **Director's Order (DO) #77-10: NPS Benefit Sharing , 19 de dezembro de 2012**. Available in: https://www.nps.gov/policy/DOrders/DO_77-10.pdf Access on 11/13/2020.

UNITED STATES GOVERNMENT. **Management Policies of the National Park System 2006**. Available in: https://www.nps.gov/policy/mp2006.pdf Access on 11/13/2020.

UNITED STATES GOVERNMENT. **National Parks Omnibus Management Act Of 1998**. Available in: https://www.nps.gov/gis/data_standards/omnibus_management_act.html Access on 11/13/2020.

Uruguay[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 3rd, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoint:

- Dirección Nacional de la Propiedad Industrial del Ministerio Industria Energia y Mineria/ National National Directorate of Industrial Property of the Ministry of Energy, Mining and Industry:

This Ministry is responsible for inquiring patent applicants whether there was an utilization of genetic resources or derivatives in the development of the invention or procedure contained in the application. If so, they shall provide the national access permit number or the ID number of the IRCC.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 4 IRCCs that are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

1. The information hereinafter has been updated until 03/08/2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:
General Law of Environmental Protection, 2000 - Ley General de Protección del Ambiente, 2000 - IMPO
Resolution No. 291/020 about Access to genetic resources and derivatives - Resolución nº 291/020 Acceso a los recursos genéticos y derivados

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Regulation of Access to Genetic Resources and Derivatives identifies Ministry of Housing, Territorial Planning and Environment - National Directorate for Environment/Ministerio de Vivienda Ordenamiento Territorial y Medio Ambiente - Dirección Nacional de Medio Ambiente as the competent institution, which is responsible for granting access and other permits related to genetic resources and applying sanctions for those who disrespect the procedural rules.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Resolution of Access to Genetic Resources and Derivatives nº 291/2020 all access activities in the country must comply with the procedures described below:

Access permit: a) must be requested to the National Directorate for Environment prior to the access of genetic resources or traditional knowledge in Uruguay (article 2). There are exceptions when the access is required for researchers, has no commercial purpose or in case of emergency. b) The permit requirement must provide all the information established in article 4 of Regulation of Access to Genetic Resources and Derivatives, such as: precise applicants' identification; identification of genetic resources and derivatives, subject to bioprospecting, research or development; precise identification of whether the access is intended to be performed on-site or off-site; location and description of the area and influence of access; specification of collection methods and use of biological or genetic resources and derivatives; specification of whether genetic information sequences will be generated from genetic resources; natural person entitled to access genetic resources and derivatives, under the applicant's responsibility.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. In cases where patents arise from research or technological developments involving access to genetic resources, the applicant is required to inform: the use of genetic or derived resources in the development of the invention procedure; and the number of the access permit granted or the IRCC's ID number.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this
analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. In cases where there is shipment of samples, the applicant is required to present the transfer permit issued by the National Directorate for Environment and inform who will have access to the genetic resources and will be held liable for its use in contravention to the national legislation (Regulation of Access to Genetic Resources and Derivatives nº 291/2020, article 15).

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies? If so, what is the specific terminology used and procedures established in the domestic legislation?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the legislation addresses this matter and the terminology used is digital sequence information. The application of access shall include the information of whether the genetic resource has generated digital sequence information.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. Benefit sharing is mentioned in article 9 of the Resolution nº 291/2020 of Access to Genetic Resources and Derivatives and it incides over economic exploitation. The responsibility to share the benefits lies with the applicant.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address a specific procedure, rule and value about benefit sharing. The article 9 of the Regulation of Access to Genetic Resources and Derivatives nº 291/2020 only establishes that the National Directorate for Environment will analyze all the conditions with the applicant.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Regulation of Access to Genetic Resources and Derivatives institutes the National Directorat for Environment as the official inspection body responsible for all matters related to access and benefit-sharing in the country.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Regulation of Access to Genetic Resources and Derivatives establishes in articles 15 and 22 of Law 17.283 and article 6 of Law 16.112/1990 general sanctions such as warnings, confiscations, license and permit suspension and fines that can vary from 10 UR (ten resettable units) to 5000 UR (five thousand resettable units).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Housing, Territorial Planning and Environment - National Directorate for Environment/ Ministerio de Vivienda Ordenamiento Territorial y Medio Ambiente - Dirección Nacional de Medio Ambiente	This institution is competent for all matters involving access to genetic resources and benefit sharing in the Country.

6. Websites

ABSCH Uruguay Profile
https://absch.cbd.int/countries/UY

CBD Uruguay Profile
https://www.cbd.int/countries/?country=uy

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Uruguay profile. Available in: https://absch.cbd.int/countries/UY Access on 03/08/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Uruguay profile. Available in: https://www.cbd.int/countries/?country=uy Access on 03/08/2021

REPÚBLICA DEL URUGUAY. **Estrategia Nacional para la Conservación y Uso Sostenible de la Diversidad Biológica del Uruguay 2016 – 2020**. Ministerio de Vivienda, Ordenamiento Territorial y Medio Ambiente. Ministerio de Relaciones Exteriores. 2016. Available in: https://www.cbd.int/countries/?country=uy Access on 05/10/2016.

REPÚBLICA DEL URUGUAY. **Ley Nº 19.227 Protocolo de Nagoya Sobre Acceso a los Recursos Genéticos y Participación Justa y Equitativa en los Beneficios que se Deriven de su Utilización al Convenio Sobre Diversidad Biológica**. Available in: https://legislativo.parlamento.gub.uy/temporales/leytemp9534014.htm Access on 03/08/2021.

REPÚBLICA DEL URUGUAY. **V Informe Nacional a la Conferencia de las Partes del Convenio de Diversidad Biológica**. Ministerio de Vivienda, Ordenamiento Territorial y Medio Ambiente. Dirección Nacional de Medio Ambiente. 2014. Available in: https://www.cbd.int/countries/?country=uy Access on 05/10/2016.

REPÚBLICA DEL URUGUAY. Ley Nº 17.283 Ley de protección del medio ambiente. Ministerio de Vivienda, Ordenamiento Territorial y Medio Ambiente. 2019. Available on: https://absch.cbd.int/database/record/ABSCH-MSR-UY-246586. Access on 03/08/2021.

REPÚBLICA DEL URUGUAY. **Reglamento de Acceso a Recursos genéticos y derivados nº 221/2020**. Ministerio de Vivienda, Ordenamiento Territorial y Medio Ambiente. Dirección Nacional de Medio Ambiente. 2020. Available in: https://absch.cbd.int/database/record/ABSCH-MSR-UY-249189. Access on 03/08/2021.

Venezuela[1]

1. General information

(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since April 11th, 1996.
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since December 12, 1994.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since August 01, 2019.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the country already has the following laws regarding access and benefit-sharing:

1. The information hereinafter has been updated until December 24th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Law on Biological Diversity Management (Ley de Gestión de la Diversidad Biológica) of 2008, regulates access to genetic heritage and associated traditional knowledge.

- Law on Cultural Heritage of Indigenous People and Communities (Ley de Patrimonio Cultural de los Pueblos y Comunidades Indígenas) of 2009, establishes rules for access to associated traditional knowledge.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The 6th National Report to the Convention on Biological Diversity, identifies the Ministry of People's Power for Ecosocialism as the competent institution, which is responsible for coordinating the implementation of the Convention at the national level.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to the Law on Biodiversity Management (2008) all access activities in the country must comply with the procedures described below:

1. Agreement: First, according to article 95, the National Environmental Authority is the entity responsible for granting access to genetic resources, as well as its by-products and intangible components – as long as the said access does not damage biological diversity and its components. Article 98 states that access contracts shall be signed by individuals or legal persons and the National Environmental Authority. Article 99 sets forth limitations for the referred access, which are the following: genetic erosion damage provoked by any access activities; biosecurity regulations; the declaration of importance of the genetic resource or ecosystem by the National Environmental Authority; and any other limitation established by that Law.

It is important to keep in mind that, according to article 100, prior informed consent shall be requested to the National Environmental Authority should the access take place in the habitats and lands of indigenous peoples and communities. Furthermore, the agreement shall foresee fair and equitable benefit sharing arising from the access activity. Finally, the National Environmental Authority grants access to genetic resources after an analysis on the environmental and/or socio-cultural impact the referred access produces (article 105).

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Notwithstanding the procedures described in item 2.3, in cases where access to associated traditional knowledge is concerned, the following is required:

1. In cases when the access to a genetic resource in the territory of indigenous peoples and communities is requested, the Law on Biodiversity Management (2008) states that it is necessary to obtain prior and informed consent of the community in question, through a contract that should contain a benefit-sharing clause.

Article 7 of the Law on Cultural Heritage of Indigenous Peoples and Communities (Ley de Patrimonio Cultural de los Pueblos y Comunidades Indígenas) of 2009, defines that the associated traditional knowledge of indigenous peoples can not be subjected to patent registration, except by the Institute of Cultural Heritage, provided that it has a mutual agreement with the

community that holds that knowledge.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. In cases where patents arise rom research or technological developments involving the access to genetic resources/traditional knowledge, the following is required:

1. Article 91 of the Law on Biodiversity Management (Ley de Gestión de la Diversidad Biológica) of 2008 foresees the protection of the right of the author on innovations and inventions that are products of scientific activities and technologies derived from biological diversity and its components.

2. Article 92 of the Law on Biodiversity Management (Ley de Gestión de la Diversidad Biológica) of 2008, defines that every invention or innovation of scientific research activities derived from biological diversity and its components are considered public utility and, therefore, can not be patented when the investigation has been carried out within national territory.

3. Article 7 of the Law on Cultural Heritage of Indigenous Peoples and Communities (Ley de Patrimonio Cultural de los Pueblos y Comunidades Indígenas) of 2009, defines that the associated traditional knowledge of indigenous peoples can not be subjected to patent registration, except by the Institute of Cultural Heritage, provided that it has a mutual agreement with the community that holds that knowledge.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis. However, Article 109 of the Law on Biodiversity Management (Ley de Gestión de la Diversidad Biológica) of 2008 foresees that the translocation, importation, creation or cultivation of exotic species requires the prior authorization of the National Environmental Authority.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis. However, Article 109 of the Law on Biodiversity Management (Ley de Gestión de la Diversidad Biológica) states that importation and relocation demand prior authorization by the National Environmental Authority.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes.As stated in item 2.1, the Law on Biological Diversity Management (Ley de Gestión de la Diversidad Biológica) of 2008, provides in its article 100 that the Access Agreement must provide for a benefit sharing clause. The National Environmental Authority is responsible for emitting contracts whenever access to genetic resources, their derived products and tangible and intangible components is intended to take place in the habitats and lands of indigenous peoples and communities.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE
The norms covered by this analysis do not address a specific procedure, rule and value about benefit sharing. The article 9 of the Regulation of Access to Genetic Resources and Derivatives nº 291/2020 only establishes that the National Directorate for Environment will analyze all the conditions with the applicant.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Both	Not defined
Non Monetary	Not defined	Not defined	Not defined	Both	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Law on Biological Diversity Management (Ley de Gestión de la Diversidad Biológica) of 2008, foresees several infractions and respective sanctions in its articles 120 and 143, related to biodiversity and the content of this Law. As an example, find above the hypothesis of irregular activities foreseen in the Law:

Article 122 foresees that for those who signed the Access Agreement but haven't comply with its provisions, payment of fine from 2000 to 4000 Tributary Units, confiscation of products and genetic material that have been illegally used and, the revocation of the Access Agreement.

Article 135 expressly defines that those who carry out access to genetic heritage without a prior authorization or Access Agreement will be penalized with one to two years of prison, as well as payment of fine from 5000 to 10000 Tributary Units, and will remain unable to sign another Access Agreement for one year.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, one emblematic case related to biopiracy was the one involving the New Tribes Mission, in which this evangelical organization and its missionaries operated in the country by identifying potential mining sites and extracting the ancestral knowledge of indigenous peoples without any compensation or recognition.

5. Summary - Competent authorities

Authority	Competence
Biological Diversity Ministry of People's Power for Eco-socialism (MINEC)	The body is responsible for all genetic resources.It is the only designated competent national authority (CNA) for the country.

6. Websites

ABSCH Venezuela's Profiles
https://absch.cbd.int/countries/VE

CBD. Venezuela's Profiles
https://www.cbd.int/countries/?country=ve

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Venezuela profile. Available at: <https://absch.cbd.int/countries/VE> Access in 24/12/2021

GOVERNMENT OF VENEZUELA. Estrategia Nacional para la Conservación de la Diversidad Biológica 2010-2020 y su Plano de Actión Nacional. Ministerio del Poder Popular para el Ambiente. May, 2012. Available at: <https://www.cbd.int/countries/?country=ve> Access in 24/12/2021

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Venezuela profile. Available at: <https://www.cbd.int/countries/?country=ve> Access in: 24/12/2021

GOVERNMENT OF VENEZUELA. Quinto Informe Nacional de Diversidad Biológica de la República Bolivariana de Venezuela. Ministerio del Poder Popular para Ecosocialismo y Aguas. December, 2015. Available at: https://www.cbd.int/countries/?country=ve Access in 24/12/2021
GOVERNMENT OF VENEZUELA. Ley de Gestión sobre Diversidad Biológica, Gaceta Oficial 39.070 del 01/12/2008. Caracas, 2009. Available at: https://www.informea.org/sites/default/files/legislation/ven89953.pdf Access in: 24/12/2021

GOVERNMENT OF VENEZUELA. Ley de Patrimonio Cultural de los Pueblos y Comunidades Indígenas, Gaceta Oficial 39.115 del 06/02/2009. Caracas, 2009. Available at: https://www.informea.org/sites/default/files/legislation/ven86162.pdf Access in: 24/12/2021
GOVERNMENT OF VENEZUELA. Resolución N° 80 - Crea el Registro Nacional de Colecciones Biológicas. Caracas, 2009. Available at: https://www.informea.org/sites/default/files/legislation/ven92999.pdf Access in 24/12/2021

Medaglia, J. C.; Perron-Welch, F.; Phillips, F. K. - OVERVIEW OF NATIONAL AND REGIONAL MEASURES ON ACCESS AND BENEFIT SHARING. Available at: https://www.absfocalpoint.nl/upload_mm/5/f/4/008c9cc8-19f3-4926-b380-5f13fd1eb705_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf Access in: 24/12/2021



Asia

Afghanistan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since December 18th, 2002.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since September 4th, 2018.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Even though Afghanistan does not have a specific norm on access and benefit sharing, legal dispositions regarding the subject can be found in the following law:

1. The information hereinafter has been updated until March 2nd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Environment Law, 2007: article 6 (3) establishes that Islamic Republic of Afghanistan has the duty to ensure that the benefits of the use of genetic resources are shared equitably; and articles 58 to 63 regulate activities with genetic heritage of all living beings — whether in situ or ex situ —, except human beings, and their associated traditional knowledge.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the Environment Law, 2007, identifies NEPA as the competent institution. The National Environmental Protection Agency is responsible for authorizing access activities in the country. The institution is, more broadly, in charge of environmental policy-making and regulation.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to the Environment Law all access activities in the country must comply with the procedures described below:

1. Application for access: the prior authorization must be required to NEPA's and shall contain the (a) identification of and background information on the applicant; (b) description of the species or organisms to which access is sought; (c) description of intended use of genetic resources for which access is sought; and (d) payment of any prescribed fee.

- 1.2 Additional information and procedure is required for genetic resources in in-situ conditions: access to genetic resources in-situ shall be subject to an environmental impact assessment process and the following information must shall be provided: (1) identification of the site(s) in question; (2) description of proposed activities, including collection methods and volume of samples required; and (3) results of the environmental impact assessment, including conservation status of the species or organisms to which access is sought.

- 1.3 Additional information is required for genetic resources in ex-situ conditions such as: (1) identification of the institution(s) in question; and (2) attachment of a material transfer agreement.

- 1.4 Other information may be required by the NEPA.

- 1.5If the access is sought on private property or on land used by nomadic pastoralization or other communities or traditional groups, the following must be provided: (1) the consent of the owner, group or community to such access shall be required; and (2) the conditions attached to the access permit shall include provisions for equitable sharing of benefits with the owner, group or community.

2. Authorization (access permit): it will be granted if verified that the usage will not have negative impacts to the country's biodiversity; if the applicant has made full disclosure of all material information relating to the project, the parties involved and if there is a fair and equitable benefit-sharing agreement. The permit shall reflect the terms mutually agreed between the applicant and the NEPA. Also, it will include provisions guaranteeing the participation of Afghan nationals and national institutions in any research carried out with the genetic resources; requirements for technology transfer; reporting requirements; and any other conditions which the National Environmental Protection Agency may consider appropriate.

3. Certificate of Origin: issue by the NEPA for the genetic resource to which access is granted and shall be required for import and exportation.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
According to §1° of article 58 of the Environment Law, 2007, the access to associated traditional knowledge must comply with the same provisions and demands of access to genetic heritage, as provided for in articles 58 to 63 of the Law.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. In cases where there is shipment of samples, compliance with all the agreed terms set out in the access authorization and the NEPA's certification of origin of the accessed genetic resource are required. The referred document will be requested by the competent authorities in cases of import and export of the genetic material

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE
Yes, benefit sharing is present in the Environmental Law (2007) and it incides over access/use. The responsibility to share the benefits lies on the applicant/user.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE
Yes, the procedures, rules and values were established by the domestic legislation as presented below:

- Access to genetic heritage: the Environmental Law (2007) does not specify the benefit sharing procedures, but it does determine in its article 61, 1, (2), 2, (2), 4, and article 62, 1, (8) that the access authorization must foresee, as a condition, the sharing of benefits with owner, group or community located on the land where the access is sough. In addition, the benefit sharing must also be foreseen in the Mutually Agreed Terms (MAT).

- Access to associated traditional knowledge: according to §1º of article 58 of the Environment Law, 2007, the access to associated traditional knowledge must comply with the same provisions and demands of access to genetic heritage, as provided for in articles 58 to 63 of the Law.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	All	Not defined	Not defined	Not defined	Owner, group or traditional communities in which the resource is found.
Non Monetary	All	Not defined	Not defined	Not defined	Owner, group or traditional communities in which the resource is found.

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Environment Law, 2007, in its article 70, 2, institutes the NEPA (National Environment Protection Agency) as the official inspection body, being able to apply fines to those who disrespect its legal determinations.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Environment Law, 2007, in its article 70, establishes the applicable sanctions for those who disrespect the procedural rules, such as imprisonment or payment of a cash fine. In

case of fines, NEPA is responsible for deciding the values.

4.3 Is there any records of fines that have been applied, emblematic bio piracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
National Environment Protection Agency (NEPA)	Responsible for authorizing the access to genetic heritage of the country, signing the MTA and applying fines in the case of infractions against the granted authorizations.
Mr. Schah Zaman Maiwandi - Director General National Environmental Protection Agency (NEPA)	ABS National Focal Point (09/24/2018)

6. Websites

National Environmental Protection Agency
https://www.nepa.gov.af/

International Centre for Integrated Mountain Development (ICIMOD)
https://www.icimod.org/who-we-are/

National Biodiversity Strategy and Action Plan
https://www.cbd.int/doc/world/af/af-nbsap-01-en.pdf

ABSCH the Access and Benefit-Sharing Clearing-House
https://absch.cbd.int/countries/AF

7. References

ISLAMIC REPUBLIC OF AFGHANISTAN. Environmental Law, January 25, 2007. Available at: <https://www.unodc.org/res/cld/document/afg/2007/environment_law_html/Environment_Law.pdf> Access in: 03/02/2020.

MEDAGLIA, Jorge Cabrera; PERRON-WELCH, Frederic; PHILLIPS, Freedom-Kai. Overview of national and regional measures on access and benefit sharing: challenges and opportunities in implementing the Nagoya Protocol. CISDL **Biodiversity & Biosafety Law Research Programme**, 3 ed., 25 de junho de 2014, p. 59-61. Available at: <https://www.absfocalpoint.nl/upload_mm/5/f/4/008c9cc8-19f3-4926-b380-5f13fd1eb705_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf> Access in: 05/23/2020.

Armenia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by acceptance, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the following legislations provide for matters regarding authorizations for use of natural resources:

1. The information hereinafter has been updated until 03/30/2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Law on Environment and Nature Use Fee
- Law on Fauna
- Law on Flora

It is important to highlight that these laws were promulgated after Armenia became a Party to Convention on Biological Diversity, and are presented by several articles as a demonstration of effort from the country to comply with the demands of the CBD. Nevertheless, the information of the laws on the subject were difficult to access.
Furthermore, even though the country is not a Party to the Nagoya Protocol, since 2012 Armenia is among the countries that benefit from the Nagoya Protocol Implementation Fund, which has the aim of finance projects to incentive and facilitate the implementation of the Nagoya Protocol by the States.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the Law on Fauna and the Law on Flora in its articles 24 and 22, respectively, determine that the use of natural resources relative to the legislation shall be done with a license and/or a contract signed with the competent state authority when used for industrial purposes, which are defined as: collection, as well as gathering and processing of animal and plants biological activity products.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for requesting patents arising from research or technological developments involving the access were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic bio piracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Vardan Melikyan
Deputy Minister
Ministry of Environment
3rd Government Building
Republic Square
Yerevan
0010
Armenia

ABS National Focal Point
+374 11 818 510, 523
vardan.melikyan@mnp.am
interdp@mnp.am

6. Websites

Ministry of Nature protection of the Republic of Armenia
http://www.mnp.am/

Biodiversity Armenia - Armenia's National Clearing-House Mechanism Training Website
https://new-am.chm-cbd.net/en/am/home

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Armenia. Available in: https://absch.cbd.int/countries/AM. Access in 03/19/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Armenia profile. Available in: https://www.cbd.int/countries/?country=am> Access in 03/19/2020.

INTERNATIONAL PLANT GENETIC INSTITUTE. Development of a strategy on genetic resources access and benefit sharing in Armenia. **Newsletter For Europe**, N° 29, December 2004. Available in: <https://books.google.com.br/books?id=VILSqzb7GvgC&pg=PA10&lpg=PA10&dq=strategy+on+access+to+genetic+resources+and+benefit+sharing+armenia&source=bl&ots=5ff3Yu5f70&sig=fCvM__33HHe4srwbcg616fiuc0o&hl=en&sa=X&ved=0ahUKEwizpuW1oufaAhUCS5AKHU43A0IQ6AEIRDAE#v=onepage&q&f=false> Access in: 03/30/2020

ARMENIA. The law of the Republic of Armenia on nature protection and nature utilization payments, 28 December 1998. Available in: <http://www.parliament.am/legislation.php?sel=show&ID=1447&lang=eng> Access in: 03/30/2020.

ARMENIA. Law of the Republic of Armenia of June 10, 2008, on Inventions, Utility Models and Industrial Designs. Available in: <https://wipolex.wipo.int/en/text/537805>. Access in: 03/30/2020.

ARMENIA. Law on Flora of December 12, 1999. Available in: <https://www.ecolex.org/details/legislation/law-on-flora-1999-lex-faoc050260/?q=law+on+flora&xcountry=Armenia&xdate_min=&xdate_max=> Access in: 03/30/2020.

ARMENIA. Law on Fauna, 28 de novembro de 2002. Available in: < https://www.ecolex.org/details/legislation/law-on-fauna-lex-faoc050257/> Access in: 03/30/2020.

Usaid Washington & Bureau, Environment & Natural Resources Division; Chemonics International Inc. Washington, d.c. **Biodiversity Assessment for Armenia**: Task order under the biodiversity & sustainable forestry IQC, 2000. Available in: < https://webcache.googleusercontent.com/search?q=cache:1pBlH7YE0SEJ:https://rmportal.net/library/content/118_armenia/at_download/file+&cd=1&hl=pt-BR&ct=clnk&gl=br> Access in: 03/30/2020.

Azerbaijan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by approval, since November 1st, 2000.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, it is important to highlight that the country has signed a cooperation agreement with the European Union, which determines the adequacy of Azerbaijani's laws to the laws of the EU as a requisite. Therefore, through the 'Action Plan on Legal Approximation of the Legislation of the Republic of Azerbaijan with the EU Acquis', the coun-

1. The information hereinafter has been updated until 03/30/2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

try made a commitment to approximate its national environmental legislation, among others, to the EU legislation. Nonetheless, no information of whether the country has adopted ABS norms was found.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Hikmet Alizade
Deputy Director
Department of Protection of Biological Diversity and Development of Specially Protected Nature Areas
Ministry of Ecology and Natural Resources
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Baku
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ABS National Focal Point
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6. Websites

ABSCH Azerbaijan Profile
https://absch.cbd.int/countries/AZ

CBD Azerbaijan Profile
https://www.cbd.int/countries/?country=az

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Azerbaijan. Available in: https://absch.cbd.int/countries/AZ. Access in 03/19/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Azerbaijan profile. Available in: https://www.cbd.int/countries/?country=az> Access in 03/19/2020.

AZERBAIJAN. **Fifth National Report**, 2014. Available at: <https://www.cbd.int/doc/world/az/az-nr-05-en.pdf> Access in: 03/30/2020.

AZERBAIJAN. **National Strategy and Action Plan on Conservation and Sustainable Use of Biodiversity in Azerbaijan**, 2006. Available at: <https://www.cbd.int/doc/world/az/az-nbsap-v2-en.pdf> Access in: 03/30/2020.

AZERBAIJAN. **Action Plan On Legal Approximation Of The Legislation Of the Republic of Azerbaijan with the EU Acquis**: 2010-2012. Available at: <http://pao.az/en/digital-library/state-programmes-of-the-republic-of-azerbaif-the-republic-of-azerbaijan/37-action-plan-on-legal-approximation-of-the-legislation-of-the-republic-of-azerbaijan-with-eu-acquis-2010-2012/file> Access in: 03/30/2020.

Bahrain[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since November 28th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country is a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until October 22nd, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic bio piracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Ali Mansoor Abbas Abdulla
Senior Environmental Specialist
Supreme Council for Environment
P.O. Box 18233
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6. Websites

ABSCH Bahrain Profile
https://absch.cbd.int/countries/BH

CBD Bahrain Profile
https://www.cbd.int/countries/?country=bh

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Bahrein. Available at: https://absch.cbd.int/countries/BH. Accessed on 10/22/2020.

Convention on Biological Diversity. Country Profile. Bahrein Profile. Available at: https://www.cbd.int/countries/nfp/?country=bh. Accessed on 10/22/2020.

GOVERNMENT OF BAHRAIN. **Fifth National Report to the Convention on Biological Diversity.** The Supreme Council for Environment. January, 2016. Available in: https://www.cbd.int/countries/?country=bh> Access on 03/30/2020.

GOVERNMENT OF BAHRAIN. **The National Biodiversity Strategy and Action Plan.** The Supreme Council for Environment. February 04, 2016. Available in: https://www.cbd.int/countries/?country=bh Access on 03/30/2020.

Bangladesh[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since August 1st, of 1994.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Protocol, but has been a signatory country since September 6th, of 2011.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / ( ) NO / (X) NOT AVAILABLE
Yes, the country already has the following law regarding access and benefit-sharing:

- Biodiversity and Community Knowledge Protection, of 29 September of 1998: the only

1. The information hereinafter has been updated until 10/20/2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

english version found is a draft made available by the InforMEA website[5]. Thus, for the purposes of this study, the document found will not be considered as the final text promulgated by the country.

- Bangladesh Biodiversity Act, 2017 (Act. Nº II): it was not possible to access the referred law for it is only available in the Bengali language.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. Nº II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998, the version available on InforMEA states in its article 11 that the National Biodiversity Authority shall be created as a regulatory body responsible for implementing this act.

Also, according to Bangladesh's profile at Convention on Biological Diversity website, the country has constituted two committees responsible for matters related to monitoring and reviewing the implementation of the Convention on Biological Diversity: the National Technical Committee on Biodiversity and National Committee of Biosafety. However, it is not clear which committee is responsible for access and benefit-sharing.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. Nº II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998, the version available on InforMEA states on its article 13, itens 4 and 8, and article 16 that in order to have access to biological and genetic resources, and intellectual and cultural knowledge it is necessary to request authorization and Prior Informed Consent by a written application in Bangla language to the National Biodiversity Authority.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. Nº II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998, the version available on InforMEA states on its article 13, itens 4 and 8, and article 16 that in order to have access to biological and genetic resources, and intellectual and cultural knowledge it is necessary to request authorization and Prior Informed Consent by a written application in Bangla language to the National Biodiversity Authority.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological devel-

[5] InforMEA is the United Nations Information Portal on Multilateral Environmental Agreements that provides information such as treaty texts, COP decisions, national plans and reports, laws, court decisions and other informations.

opments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. N° II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998, no specific procedure for requesting patents was found on the version available on InforMEA. Nevertheless, it is important to highlight that its article 5, item 3 establishes that patenting of the life forms is illegal.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. N° II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998 (version available on InforMEA), according article 4 the definition of 'Biodiversity' or 'Biological Diversity' includes living organisms like plants, animals, fish and aquatic species and varieties and micro-organisms, found in all the ecological zones within the boundaries of Bangladesh, whether naturally occurring or modified in any manner including genetically modified, whether wild or cultivated or domesticated. Thus, it is concluded that not only native species are within the scope of this legislation.

2.7 Does the current legislation establish procedures for the shipment of samples?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. N° II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998 (version available on InforMEA), its article 28 sets that all specimens or biological and genetic resources need prior authorization before leaving Bangladesh. No other provision about shipment of samples were found.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. N° II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998, no provisions about digital sequence information were found on the version of the legislation available by InforMEA.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. N° II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998 (version available on InforMEA), according article 4 the definition of 'Biodiversity' or 'Biological Diversity' includes living organisms like plants, animals, fish and aquatic species and varieties and micro-organisms, found in all the ecological zones within the boundaries of Bangladesh, whether naturally occurring or modified in any manner including genetically modified, whether wild or cultivated or domesticated. Thus, it is concluded that not only native species are within the scope of this legislation.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. N° II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998, the version available on InforMEA states on article 16 that benefit-sharing is mandatory for those who want to have access to biological and genetic resources, and intellectual and cultural knowledge.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. N° II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998 (version available on InforMEA), according to article 7, 13 and 16, benefit sharing will be set during the prior authorization, including technology transfer and sharing of knowledge and scientific skills, and in addition at least 50 percent of the net monetary gain shall be shared with the Communities.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	50% percent of the net monetary gain	Both	Not clear
Non Monetary	Not defined	Not defined	No legislation	Both	Not clear

3. Benefit sharing

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. N° II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998 (version available on InforMEA), according to article 14 the National Biodiversity Authority have the powers to determine:

- whether any biological and genetic materials and resources and intellectual and cultural knowledges are being collected, exploited or taken out of the country without the Prior Informed Consent of the Communities, and/or being culturally abused in conflict with their local and indigenous use and practice, and/or commercially exploited against the provisions of this Act.

- whether the individual or the people involved in activities that are illegal according to this Act should be prosecuted under criminal laws or in other courts consistent with the relevant laws of the country without any prejudice of the rights of Communities to seek justice.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, it was not possible to access the referred law for it is only available in the Bengali language.

As mentioned in item 2.1, it was not possible to access the Bangladesh Biodiversity Act, 2017 (Act. N° II) for it is only available in the Bengali language.

Regarding the Biodiversity and Community Knowledge Protection, 1998 (version available on InforMEA), the penalties are the following:

- Terminate the agreement

- Written warning;

- Fines;

- Automatic cancellation/revocation of the permission for access;

- Confiscation of collected Specimen, equipment, document or any information recorded in any media;

- Perpetual ban on prospecting of biological and genetic resources in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, bio piracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
National Technical Committee on Biodiversity and National Committee of Biosafety	Ensuring, monitoring and reviewing the implementation of the Convention on Biological Diversity and the Nagoya Protocol.
National Biodiversity Authority	Regulatory body responsible for implementing the Biodiversity and Community Knowledge Protection, 1998

6. Websites

ABSCH Bangladesh Profile
https://absch.cbd.int/countries/BD

CBD Bangladesh Profile
https://www.cbd.int/countries/?country=bd

7. References

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BANGLADESH. Biodiversity and Community Knowledge Protection Act, 1998. Available at: https://www.ecolex.org/details/legislation/bangladesh-biodiversity-act-2017-act-no-ii-lex-faoc165299/Access Accessed on 10/21/2020.

CONVENTION ON BIOLOGICAL DIVERSITY. Bangladesh - Main Details. Available at: https://www.cbd.int/countries/profile/?country=bd Accessed on 10/21/2020.

Bhutan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since November 23rd, 1995.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
(X) YES / ( ) NO
Yes. The country has the following checkpoints:

- Department of Intellectual Property, Ministry of Economic Affairs.

This institution is responsible for establishing a system for mandatory disclosure of origin for intellectual property rights application which involves access to Bhutanese genetic Resources, as well as requesting the applicant to obtain a certificate of compliance in those cases.

- Bhutan Agriculture and Food Regulatory Authority, Ministry of Agriculture and Forests.

This Institution is responsible for preserving ABS obligations arising from phytosanitary applications.

- National Biodiversity Center, Ministry of Agriculture and Forests.

This Institution is responsible for issuing "National Permit equivalent to the Certificate of compliance" to a user, as well as a "Sample Transfer Certificate".

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
(X) YES / ( ) NO

1. The information hereinafter has been updated until 10/20/2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Yes, the country has issued and registered 1 IRCCs that are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the country already has the following laws regarding access and benefit-sharing:

- Biodiversity Act, 2003 - promotes and regulates the access to genetic resources and associated traditional knowledge, and promotes the fair and equitable Benefit-Sharing.

In addition to the law presented above, Bhutan has two bills:

- Access and Benefit Sharing Policy of Bhutan - this bill aims to regulate access and benefit-sharing in Bhutan, reinforcing the already existing measures provided in the Biodiversity Act of 2003.

- Biodiversity Bill of Bhutan, 2016 - this bill aims to regulate access and benefit-sharing in Bhutan, revoking the Biodiversity Act of 2003, but maintaining some regulations and establishing new ones.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Biodiversity Act 2003, chapter 6, section 51, identifies the Head of the Ministry of Agriculture of the Royal Government of Bhutan as the competent institution. According to the ABSCH website, this institution is responsible for all matters regarding genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to the Biodiversity Act of Bhutan 2003, section 5, access shall be subject to the prior informed consent of the Competent Authority. The Authorized Agency is responsible for processing the applications and monitoring the permits granted.

According to section 6, the applicant shall submit an application for access before the Authorized Agency in accordance with section 7. If the application for access complies with the requirement under section 7, the application shall be forwarded to the Competent Authority which will grant or refuse the permit.

In cases of registered ex-situ collections, the regulations of the referred Act may establish special procedures for access authorization. Requirements of the Act will be determined in a different way for non-commercial and commercial applications.

It is worth mentioning that the Act shall not apply in certain cases, such as when the biological material is used as a commodity, when the Competent Authority determines special rules, when varieties for which patent protection is available and other exemptions, as per Section 4 of Chapter 1 of the Act.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Notwithstanding the procedures described in item 2.3, in cases where access to associated traditional knowledge is concerned, the applicant shall obtain the prior informed consent of the owners of the Traditional Knowledge, as per chapter 6, section 37 to 42 of the Biodiversity Act of Bhutan 2003.

If the owners accept the application, a written authorization shall be elaborated and submitted to the comments of the Competent Authority. The competent authority has the final right to approve or deny the proposed use agreement, based on the national interest of the country (section 39). If the parts enter into an agreement, this means the prior informed consent has been given. A final copy of the agreement must be forwarded to the Competent Authority to be considered valid.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, according to section 10 of Chapter 2 of the Biodiversity Act of Bhutan (2003), benefit sharing is mandatory and the responsibility to share benefits lies on the applicant.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. According to section 10 of Chapter 2 of the Biodiversity Act of Bhutan (2003), authorization of access by the Competent Authority depends on benefit sharing requirements, which shall be included in Material Transfer Agreement or Agreement signed between the parties. The benefits shall include at least one but not be limited to the following types of benefit sharing:

- A flat fee and upfront payments.
- The sharing of the research results and relevant information.
- Royalties
- Milestones payments.
- Recognition as a partner in intellectual property ownership of products derived from the supplied material.
- Joint research activities.
- Concessionary rates or free supply of commercial products derived from the resources provided.
- Transfer of technologies.
- Training and capacity building.
- The acknowledgment of the origin of the genetic resources in any publication resulting from the research activities.
- Donation of equipment to national institutions.
- Other benefits, monetary or non-monetary

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary

Monetary	Not defined	Payments, Royalties, concessionary rates or free supply of commercial products derived from the resources provided	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Community/ Government
Non Monetary	Not defined	Sharing of research results, joint intellectual property, joint research activities, transfer or technologies, training and capacity building, acknowledgment of origin of GR, donation of equipment to national institutions	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Community/ Government

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. chapter 5, section 43 of the Biodiversity Act (2003) establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules.

In cases of collection without permit or contravention of provisions of Sections 10 or 11, or Chapter 4 of the Act, there shall be imprisonment between 1 to 3 years or fine between the equivalent of 2 to 6 years of minimum daily wage rate. In cases of collection of genetic resources in contravention with the referred act, there shall be confiscation of the genetic resources concerned.

In cases of contravention of other contraventions, there shall be imprisonment up to 3 months or fine up to 6 years of minimum daily wage rate.

4.3 Is there any record of emblematic bio piracy cases or disputes related to access and benefit sharing in the country?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of bio piracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Agriculture and Forests	Responsible for all genetics resources.

6. Websites

ABSCH Country Profile
https://absch.cbd.int/countries/BT

CBD Country Profile
www.cbd.int/countries/?country=bt

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Bhutani. Available in: < https://absch.cbd.int/countries/BT>. Access in: 10/22/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Bhutan. Available in: < www.cbd.int/countries/?country=bt> Access in: 10/22/2020.

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GOVERNMENT OF BHUTAN. **National Biodiversity Strategies And Action Plan (NBSAP)**. Ministry of Agriculture and Forests. Thimphu, 2014. Available in: https://www.cbd.int/countries/?country=bt Access in 30/10/2016.

GOVERNMENT OF BHUTAN. **The Fifth National Report.** National Environment Commission Secretariat. Thimphu. Available in: https://www.cbd.int/countries/?country=bt Access in 30/10/2016.

GOVERNMENT OF BHUTAN. **The Biodiversity Act of Bhutan.** Available in: http://www.biodiv.be/bhutan/legal-instruments/acts Access in 30/10/2016.

GOVERNMENT OF BHUTAN. **Environment Assessment Act**. Available in: http://www.biodiv.be/bhutan/legal-instruments/acts Access in 30/10/2016.

GOVERNMENT OF BHUTAN. **Biodiversity Bill of Bhutan, 2016.** Available in: http://www.nbc.gov.bt/wp-content/uploads/2016/03/Draft-Biodiversity-Bill-2016.pdf Access in 30/10/2016.

Brunei Darussalam[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since July 27, 2008.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, even though the Fifth National Report states that, after

1. The information hereinafter has been updated until October 27th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

the 2007 Amendment, the Forest Act started to emphasize the importance of biological diversity conservation, biological prospecting, access and benefit sharing, enforcement and forest protection. It does not have specific procedures for the access to genetic resources or associated traditional knowledge. it only indicates, in its article 52, that the Ministry of Development will regulate the procedures for bioprospecting and exportation of genetic material from forests, as well as the establishment of fines and royalties that will be charged.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions related with access and benefit-sharing under the terms of the Nagoya Protocol were found. Even though the law mentioned in item 2.1 is not specific on access to genetic heritage and associated traditional knowledge, it establishes rules for the use of natural resources from national forests. In this sense, according to the Forest Act, the competent institutions are:

- **Ministry of Development**

The Forest Act, in its article 52 (2), (zg), determines that the Ministry of Development is responsible for regulating procedures for bioprospecting and exportation of genetic material from forests, as well as the establishment of fines and royalties that will be charged.

- **Department of Forestry**

The Forest Act determines that the Department of Forests, represented by the Director of Forests, is responsible for granting licenses and prior authorizations for the use of natural resources from national forests, as well as the control and inspection together with the Forest Police.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, the law is not specific on access to genetic heritage and associated traditional knowledge, but establishes rules for the use of natural resources from national forests. In this sense, the Forest Act determines that researchers that use natural resources from national forests must have a license or previous authorization from the Director of Forests. However, no detailed procedures have been identified.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country..

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Development	Responsible for regulating procedures for bio prospection and exportation of genetic material.
Department of Forestry	This is the competent institution for grant of licenses and prior authorization, as well as control and inspect the use of natural resources from forests.

6. Websites

ABSCH Brunei Darussalam Profile
https://absch.cbd.int/countries/BN

CBD Brunei Darussalam Profile
https://www.cbd.int/countries/?country=bn

Forest Department
http://www.forestry.gov.bn/

Ministry of Development
http://www.mod.gov.bn/en/Theme/Home.aspx

BRUNEI DARUSSALAM. Forest Act, 7 de 1934, revised edition of 2013. Available at: <http://www.forestry.gov.bn/SiteCollectionDocuments/Forest%20Act/Forest%20Act%20Ch%2046.pdf> Access on October 27th, 2021.

BRUNEI DARUSSALAM; MINISTRY OF THE INDUSTRY AND PRIMARY RESOURCES; RESEARCH CENTER FOR BIODIVERSITY AND INNOVATION. National Biological Resources (Biodiversity) Policy and Strategic Plan of Action. Available at: <https://www.cbd.int/doc/world/bn/bn-nbsap-01-en.pdf> Access on October 27th, 2021.

BRUNEI DARUSSALAM; MINISTRY OF THE INDUSTRY AND PRIMARY RESOURCES; FOREST DEPARTMENT. The 5th National Report to the Convention on Biological Diversity. Available at: <https://www.cbd.int/doc/world/bn/bn-nr-05-en.pdf> Access on October 27th, 2021.

Cambodia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since May 10th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by ratification, since April, 19th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until October 17th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

It is important to highlight that the Sixth National Report informs that Cambodia is finalizing the Environment and Natural Resources Code that will include provisions related to ABS. Currently, the Code draft is in its 11th version, but no English version was found for the purpose of this study, nor any information regarding if the country has adopted temporary procedures while waiting for the implementation of the national ABS legislation.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The ABS Clearing-House mechanism identifies the General Secretariat of the National Council for Sustainable Development as the competent institution, which is responsible for management of all genetic resources of the country. However, according to the Interim National Report (2018), some obstacles prevent the CNA from performing its role, such as: ABS legislation is not yet developed; capacity of CNA is limited; and limit financial support and procedure to implement the protocol.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body? Are there any records of fines having been applied by such institutions?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic bio piracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, bio piracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
General Secretariat of the National Council for Sustainable Development	All subjects regarding genetic resources.

6. Websites

Camboja Clearing House Mechanism. Available in http://www.chm.gdancp-moe.org/

7. References

ACCESS AND BENEFIT-SHARING CLEARING HOUSE - ABSCH. Country Profile. Available in: https://absch.cbd.int/countries/KH. Access on 24/09/2019.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Cambodia Profile. Available in: https://www.cbd.int/countries/?country=kh. Access on 24/09/2019.

Kingdom of Cambodia. General Secretariat of the National Council for Sustainable Development/Ministry of Environment. The Sixth National Report on the Convention On Biological Diversity. Department of Biodiversity., 2019.

Kingdom of Cambodia. Interim National Report on the Implementation of the Nagoya Protocol, 2018.
KINGDOM OF CAMBODIA. National Biodiversity Strategy And Action Plan. National Council for Sustainable Development. 2016. Available in: https://www.cbd.int/countries/?country=kh Access on 03/10/2016.

KINGDOM OF CAMBODIA. The Fifth National Report To The Convention On Biological Diversity. National Biodiversity Steering Committee. 2014. Available in: https://www.cbd.int/countries/?country=kh Access on 03/10/2016.

MINISTRY OF ENVIRONMENT (MoE) OF THE KINGDOM OF CAMBODIA. Draft Environment and Natural Resources Code: 11th Draft. 2018. Available in: https://data.opendevelopmentmekong.net/en/laws_record/draft-environment-and-natural-resources-code-11th-draft Access on 17/10/2020.

COOPER, George. Review, Comments and Recommendations on the Draft Environment and Natural Resources Code (Version 11) of Cambodia. Mekong Region Land Governance (MRLG), 2019. Available in: https://www.mrlg.org/publications/review-comments-and-recommendations-on-the-draft-environment-and-natural-resources-code-version-11-of-cambodia/ Access on 17/10/2019.

China[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since September 6th, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, there are dispositions about requests of patents made with genetic resources across the patent legislation of the country, as informed in item 2.5 of

1. The information hereinafter has been updated until September 25th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

this form, as well as in the document “Measures for Examination and Approval of Entry and Exit and the Foreign Cooperative Research on the Application of Genetic Resources of Livestock and Poultry” from 2008. These Measures establish in articles 6, 7, 8, 9 and 16 that for the exportation or cooperative research on livestock and poultry included in protection lists, the presentation of the plan of benefit-sharing is a sufficient instrument. Also, the Chinese Medicine Law states some provisions about access and benefit sharing regarding this knowledge, as specified in item 2.4 of this form.

In its Interim National Report on the Implementation of the Nagoya Protocol the country informs that it is developing a specific regulation on access to genetic resources and benefit-sharing. Also, the country indicates that some laws have regulations about access and benefit sharing, such as: Husbandry Law, Seeds Law, Environmental Protection Law, Wild Animals Protection Law, Intangible Cultural Heritage Law, Law on Quarantine of Imported and Exported Animals and Plant. Nevertheless, no specific provisions were found regarding access to genetic heritage and associated traditional knowledge in the referred laws.

Also, the UNDP document ‘ABS is Genetic Resources for Sustainable Development’ states that The Ministry of Ecology and Environment of China issued a draft administrative regulation on ABS in March 2017 to request public opinion. The draft Law is only available in the local language, which is why it was not analyzed by this research.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
According to its Interim National Report, no official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. However, China is using a system of management coordinated by the Ministry of Environmental Protection while other relevant departments manage ABS-related matters in their respective areas. These departments mainly include the environment, science and technology, water resources, agriculture, forestry, customs administration, examination and quarantine, intellectual property rights administration and Chinese medicine administration.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

At present, some laws or regulations such as the Husbandry Law, the Seeds Law, the Wild Animals Protection Law and the Wild Plants Protection Regulation contain provisions that require prior informed consent in national preserved species. In special situations such as scientific research activities, collecting genetic resources of livestock and poultry, germplasm and wild animals and plants must be approved by relevant competent authorities specified in these laws and regulations.

Also , certain activities regarding genetic resources require prior authorization, such as research or transfer of livestock and poultry genetic resources overseas, as established in the Animal Husbandry Law (2005).

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE

Although there is no legislation indicating specific procedures for access to Associated Traditional Knowledge, as indicated in item 2.1, a study from the "Biodiversity & Biosafety Law Research Program", supported by the Swiss Confederation, affirms that a series of pilot projects for the intellectual property protection of associated traditional knowledge have been established, such as the Project of Protection of the Genetic Diversity of the Golden snub-nosed monkey (Rhinopithecus roxellana) in the area of the Shennongjia Forest.

Furthermore, according to the article "Key legal challenges and opportunities in the implementation of the Nagoya Protocol: The case of China", of Xiaoou Zheng, the Law on Traditional Chinese Medicine (2017) requires prior informed consent from the traditional knowledge holders, and also establishes that benefits derived from their use must be shared.

2.5. Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
According to article 26 of the Patent Law of the Republic of China, of December 27, 2008, during the process of patent request, the requesting party shall indicate in the request form the original source of direct origin of the genetic resources utilized. However, if it is not possible to indicate the origin of the genetic resources, the applicant shall justify the reasons for the absence of information. Furthermore, according to article 5, the patent rights will not be granted for products obtained through genetic resources irregularly accessed. The concept of genetic resource, for the purposes of the aforementioned Law of Patents, is included under article 26 of Implementing Regulations of the Patent Law of the People's Republic of China, of February 2010.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
There is no legislation specifying specific procedures for the shipping of samples.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the ministerial Notice on Strengthening the Management of Bio genetic Resources Utilization and Benefit Sharing in Foreign Cooperation and Exchange states that the definition of genetic resources shall include information on genetic resources.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Although there is not a specific law addressing ABS in the country, provisions of certain laws regarding genetic resources and traditional knowledge establish benefit sharing, such as the Animal Husbandry Law (2005), which requires sharing of benefits when genetic resources of livestock and poultry are exported. In this case, the responsibility to share the benefits lies with the exporter. Also, according to the article "Key legal challenges and opportunities in the implementation of the Nagoya Protocol: The case of China", of Xiaoou Zheng, the Law on Traditional Chinese Medicine (2017) establishes that benefits must be shared with the holders of traditional knowledge. There is no information about whom the responsibility to share the benefits lies with.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, in 2009, researchers from the Centre for Chinese Agricultural Policy started a project to create a national legislation on the subject. The set of bills is inspired by the current contract model adopted in Taiwan. This model requests the authorization of the party supplying the genetic resources and the establishment of a benefit-sharing agreement between the parties before issuing the access license. With this, the project establishes that the law should allow a better proportionality in the sharing of interests between suppliers and the public and private sectors

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In

the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic bio piracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, bio piracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol / Convention on Biological Diversity:

Nagoya Protocol on Access and Benefit-sharing

Ms. Xin Jing
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6. Websites

National Clearing-house Mechanism
http://english.biodiv.gov.cn/

Ministry of Environmental Protection of the People's Republic of China
http://english.mep.gov.cn/

Ministry of Agriculture of the Protection of the People's Republic of China
http://english.agri.gov.cn/

7. References

ACCESS AND BENEFIT-SHARING CLEARING HOUSE - ABSCH. Country Profiles. China. Available in: https://absch.cbd.int/countries/CN. Access on: 30/09/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. China. Available in: https://www.cbd.int/countries/?country=cn. Access on: 30/09/2021.

CHINA. China National Biodiversity Conservation Strategy and Action Plan (2011-2030). Available in: https://www.cbd.int/countries/?country=cn. Access on 30/09/2021.

CHINA. China's Fifth National Report on the Implementation of the Convention on Biological Diversity. The Ministry of Environmental Protection of China. 2014. Available in: https://www.cbd.int/countries/?country=cn. Access on 30/09/2021.

MEDAGLIA, Jorge Cabrera et al., CENTRE FOR INTERNATIONAL SUSTAINABLE DEVELOPMENT LAW – CISDL. Overview Of National And Regional Measures On Access And Beneft Sharing- Challenges And Opportunities In Implementing The Nagoya Protocol. 3th Ed. CISDL Biodiversity & Biosafety Law Research Programme and Federal Office for the Environment – FOEN (Switzerland). Available in: http://www.absfocalpoint.nl/upload_mm/5/f/4/008c9cc8-19f3-4926-b380-5f13fd1eb705_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20beneft%20sharing.pdf . Access on 03/11/2016.

People's Republic of China. Interim National Report on the Implementation of the Nagoya Protocol, 2017.

REPUBLIC OF CHINA. Implementing Regulations of the Patent Law of the People's Republic of China, of February 2010. Available in: http://www.wipo.int/edocs/lexdocs/laws/en/cn/cn078en.pdf Access on 30/09/2021.

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YICHING, Song, et al. Access and benefit sharing in participatory plant breeding in Southwest China. Farming Matters. Special Issue, April 2016. p. 18-24 ISSN: 2210-6499. Available in: https://cgspace.cgiar.org/handle/10568/73323 Access on 03/11/2016.

ZHENG, X. Key legal challenges and opportunities in the implementation of the Nagoya Protocol: The case of China. RECIEL. 2019;28:175–184. Available in: https://doi.org/10.1111/reel.12282. Access on: 26/09/2019.

East Timor[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since January 8th, 2007.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated tradition-

1. The information hereinafter has been updated until November 24th, 2021
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

al knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Timor Leste Profile
https://absch.cbd.int/countries/TL

CBD Timor Leste Profile
https://www.cbd.int/countries/?country=tl

Government of Timor-Leste
http://timor-leste.gov.tl/?p=5609&n=1

6. Websites

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Timor-Leste profile. Available at: https://absch.cbd.int/countries/TL> Access on November 24th, 2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Timor-Leste profile. Available at: https://www.cbd.int/countries/?country=tl> Access on November 24th, 2021.

GOVERNMENT OF TIMOR LESTE. **Timor-leste's Fifth National Report to the Convention on Biological Diversity**. Ministry of Commerce, Industry and Environment (MCIE). Available at: https://www.cbd.int/countries/?country=tl> Access on November 24th, 2021.

GOVERNMENT OF TIMOR LESTE. **Decree-Law No. 5 / 2011 of 9 February Environmental Licensing**. Available at: https://www.informea.org/en/legislation/decree-law-no-52011-environmental-licensing-system Access on November 24th, 2021.

India[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since May 19th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has issued and registered 2981 IRCCs that are available on ABSCH website. They include commercial and intellectual property rights authorizations.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The main laws related to this subject at national level are:

1. The information hereinafter has been updated until October 8th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Biological Diversity Act, 2002 -BDA
- Biological Diversity Rules, 2004 – BDR
- Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014
- Designation of institutions/organizations as National Repositories under Section 39 of the Biological Diversity Act, 2002
- Notification on Guidelines for International Collaborative Research Projects under Section 5 of the Biological Diversity Act, 2002
- Notification under Section 40 of the Biological Diversity Act, 2002

At state/regional level, the following rules have been identified:

- Andhra Pradesh Biological Diversity Rules, 2009
- Arunachal Pradesh (Biological Diversity) Rules, 2011
- Jharkhand Biological Diversity Rules, 2007
- Sikkim State Biological Diversity Rules, 2006
- West Bengal Biological Diversity Rules, 2005
- Meghalaya Biological Diversity Rules, 2010

To better understand these regional/state norms, the table below presents the most relevant articles in relation to the topics indicated:

Region	Definitions	Access	State Biodiversity Found	Local Biodiversity Found	Biodiversity Management Committees (BMC)
Andhra	2	16, 17 and 18	19	23	22
West Bengal	2	15, 16 and 17	18	22	21
Arunachal	2	17, 18 and 19	20	24	23
Jharkand	2	14 and 15	16	21	20
Meghalaya	2	17, 18 and 19	20	24	23
Sikkim	2	17, 18 and 19	20	24	23

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Ministry of Environment, Forest and Climate Change has designated the National Biodiversity Authority – NBA, based on Section 8 (1) of the Biological Diversity Act, 2002, to implement several dispositions of this Law and to fulfill the obligations established in Article 13 (2) of the Nagoya Protocol, assuming the role of national competent authority (according to the ABSCH website, this is the only national competent authority in the country). Therefore, this institution is responsible for regulating the activities related to access to biological resources and/or associated knowledge.

In addition, the ABSCH website reinforces that prior request must be obtained from the National Biodiversity Authority in the following situations:

Access to genetic resources or associated traditional knowledge for research, commercial exploitation, bio-survey and bio-utilization by non-Indian individuals, non-Indian residents, companies, associations or organizations registered or incorporated outside India, or registered or incorporated in India, having non-Indian participation in its share capital and/or management;

Any person or institution that seeks to apply for any Intellectual Property Rights, within or outside India, related to research or biological information obtained from India;

Any person or institution that seeks to transfer the results of any research relating to biological resources in India or obtained from India for monetary purposes;

The individuals mentioned in item 1 above who seek to transfer the biological resources or traditional knowledge to third parties.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Section 3 of the Biological Diversity Act 2002, activities seeking obtainment of biological resources occurring in India or access to associated traditional knowledge for the purpose of research or commercial utilization or bio-survey and bio-utilization carried out by non-Indian individuals, non-Indian residents, companies, associations or organizations registered or incorporated outside India, or registered or incorporated in India, having non-Indian participation in its share capital and/or management, require prior approval from the National Biodiversity Authority.

As for section 4, it establishes that activities of transfer of research results relating to biological resources in or obtained from India for non-Indian individuals, non-Indian residents, companies, associations or organizations registered or incorporated outside India, or registered or incorporated in India, having non-Indian participation in its share capital and/or management, shall obtain prior authorization from the National Biodiversity Authority.

As for intellectual property rights, the requirement of prior approval in this case is established under section 6. According to Section 19, in order to carry out the activities described above, the user shall submit an application to the National Biodiversity Authority using the forms created through the Biological Diversity Rules 2004 and proceed with the payment of the national fees. The same procedure shall apply for cases of requests for intellectual property rights arising from access activities, regardless if requested in India or outside India.

In the case of Indian citizens or companies, associations or organizations registered or incorporated in India, these only need to inform the State Biodiversity Board.

In the hypothesis of collaboration in research projects, the guidelines issued by the Notification on Guidelines for

International Collaborative Research Projects under Section 5 of the Biological Diversity Act, 2002 establish under sections 13 and 14 that the referred project shall be approved by the Ministry/Department of State or the Central Government, and a copy of that authorization shall be submitted to the National Biodiversity Authority.
It is important to highlight that the ABS norms are not applicable to certain species, according to section 40 of the Biological Diversity Act 2002, as some species are considered commodities. In this sense, some species have already been listed under the Notification under Section 40 of the Biological Diversity Act, 2002 (October 26, 2009).

Finally, the Biological Diversity Rules 2004 further details the procedures for obtaining such permits, briefly presented below:

Corresponding section in the Biological Diversity Rules, 2004	Activity	Form for requesting permit	Fee
14	Access to biological resource or traditional knowledge	Form 1	10,000 rupees
17	Transfer of research results	Form 2	5,000 rupees
18	Request for intellectual property rights	Form 3	500 rupees
19	Transfer of biological resources or accessed traditional knowledge	Form 4	10,000 rupees

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
There are no specific procedures for access to Associated Traditional Knowledge. The permits for access to associated traditional knowledge are detailed under Rule 14 of the Biological Diversity Rules 2004, and follow the same guidelines as permits for access to genetic resources.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
According to item 2.3 above, there is a requirement of obtaining prior authorization from the National Biodiversity Authority for cases of intellectual property rights, according to section 6 of the Biological Diversity Act 2002. Under section 19 of the same law, the request for permits shall be made through form III of the Biological Diversity Rules 2004 and a fee of 500 rupees shall be paid.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. As per item 2.3. above, section 4 of the Biological Diversity Act 2002 establishes that activities of transfer of research results relating to biological resources in or obtained from India

for non-Indian individuals, non-Indian residents, companies, associations or organizations registered or incorporated outside India, or registered or incorporated in India, having non-Indian participation in its share capital and/or management, shall obtain prior authorization from the National Biodiversity Authority. In this sense, the Biological Diversity Rules 2004, section 17, establishes that in the case of transfer of research results, the permit request to the National Biodiversity Authority shall be made through form II and shall include the payment of a fee of 5,000 rupees to the National Biodiversity Authority.

In relation to the transfer of accessed biological resources or traditional knowledge, the user shall use form IV and make the payment of a fee of 10,000 rupees to the National Biodiversity Authority, according to section 19 of the referred guidelines.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
Yes, benefit sharing is mandatory. The responsibility to share the benefits lies with the applicant.

3.2 Are there any specific procedures, rules and values?
(X) YES / ( ) NO / NOT AVAILABLE
Yes. The benefit-sharing requirement was established by section 6 of the Biological Diversity Act 2002. In this sense, section 21 establishes that it is the responsibility of the National Biodiversity Authority, when issuing the permits referred to by the law, to guarantee a fair and equitable sharing of benefits related to the access to genetic resources, its byproducts, innovations and practices associated with their use and application and any associated knowledge, according to mutually agreed terms. This section also defines the types of benefit-sharing that can be established, which can be in monetary or non-monetary form.

In the regulations Biological Diversity Rules 2004, section 21 is responsible for regulating the criteria for the benefit-sharing. The payment of the benefit-sharing can be made to the fund of the National Biodiversity Authority in cases where the provider of the biological resource or traditional knowledge cannot be identified. If the individuals or organizations are known, the Authority shall ensure that such individuals or organizations directly receive the agreed amount for the benefit-sharing. However, 5% of that total shall be directed to the authority or committee in view of the administrative services provided.

Also according to the regulations, the value of the benefit-sharing shall be mutually agreed between the party requesting the permit and the National Biodiversity Authority, in consultation with local entities and the beneficiaries, taking into account the parameters for access, the extension of the utilization, sustainability aspects, foreseeable impacts and the level of results expected, including measures to guarantee the conservation and sustainable use of biological diversity. Depending on each case, the National Biodiversity Authority may also determine the timeframe for the benefit-sharing: short, mid or long-term. All benefit-sharing and their applications shall be monitored by the National Biodiversity Authority. According to the 6th National Report on the Convention of Biological Diversity, 764 benefit sharing agreements on mutually agreed terms had been signed by the NBA.

The Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 determine under items 3, 4, 7, 9, 12 and 14 that the benefit-sharing may vary from 0.1% to 5% depending on the specific situations mentioned under these items. The guidelines also redefine the means of monetary and non-monetary benefit-sharing that may be adopted, according to the alternatives provided by the Nagoya Protocol.

Also, Article 14 (3) of the Guidelines provides that the amount of benefit sharing shall remain the same whether the end product contains one or more biological resources.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Research	Payment to a Fund*	case by case, agreed with the National Biodiversity Authority	Genetic Heritage/ATK	Community/ Government
	Commercialization - trader	Payment to a Fund*	If the applicant has not entered BS Agreement before access, 1% to 3% of the purchase price of the biological resources. If the applicant has concluded a BS Agreement before access, not less than 3% of purchase price.	Genetic Heritage/ATK	Community/ Government
	Commercialization manufacturer	Payment to a Fund*	If the applicant has not entered BS Agreement before access, 3 to 5% of the purchase price of the biological resources. If the applicant has concluded a BS Agreement before access,not less than 5% of purchase price.	Genetic Heritage/ATK	Community/ Government

* In case of biological resources of high economic value, upfront payment may be required

Non Monetary	Commer-cialization	Same alternatives as the ones provided in Nagoya Protocol	not defined	Genetic Heritage/ATK	Community/ Government

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No. Although the National Biodiversity Authority has been created and appointed the National Competent Authority under the terms of the Nagoya Protocol, the ABS legislation does not mention that this institution has any inspection authority.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The contraventions, offenses and penalties for irregular ABS activities are provided under sections 55 to 58 of the Biological Diversity Act 2002. In this sense, Section 55 establishes that whoever contravenes or attempts to contravene or abets the contravention of the provisions of section 3, 4 or 5, which establish the requirement of prior authorization for activities of access, remittance or patent requests, respectively, shall be punishable with imprisonment for no longer than five years, or with a fine of up to ten lakh rupees, or, where the damage caused exceeds 10 lakh rupees such a fine may commensurate with the damage caused, or both. Whoever contravenes or attempts to contravene or abets the contravention of the provisions of section 7 or any other rules established under subsection (2) of section 24 shall be punishable with imprisonment for a up to to three years, or with a fine of up to five lakh rupees, or with both.

According to section 56, if any person contravenes any direction or order provided by the Central Government, the State Government, the National Biodiversity Authority or the State Biodiversity Board for which no other punishment has been separately provided by the Biological Diversity Act 2002, shall be punished with a fine of up to one lakh rupees and, in case of a second subsequent offense, with a fine of up to two lakh rupees or, in case of repeated violation, with an additional fine which extend up to two lakh rupees every day during which the default continues.

At last, it is worth highlighting that section 57 establishes that whoever is responsible to the company that commits an offense or contravention under the aforementioned Act shall be deemed to be guilty of the offense or contravention.

4.3 Is there any records of fines that have been applied, emblematic bio piracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, several cases of bio piracy were carried out in India. One of them relates to fungicide properties of Neem, patented by a US company, even though this knowledge was traditionally widespread in India. After pressure from different groups, the patent was overturned. Another case relates to the healing properties of haldi (turmeric), also patented by US scientists in the mid 1990s. In this case, the Indian government challenged the patent, so the patent claim was rejected.

5. Summary - Competent authorities

Authority	Competence
National Biodiversity Authority – NBA	Responsible for implementing the main ABS norm in the country, the Biological Diversity Act 2002, and for regulating activities related to access to biological resources and/or associated knowledge and issue prior authorizations for access activities by foreigners, patents arising from biological resources or associated traditional knowledge, transfer of results, research and biological resources or traditional knowledge, including transfers from foreigners to third parties.
State Biodiversity Boards - SBBs	At state/subnational/province level: focused on advising state governments, under the guidelines of the Central Government, on issues related to the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the use of the biological resources. They also regulate, by issuing permits or other authorizations for commercial use, bio-survey and bio-utilization of any biological resources by Indian nationals.
Biodiversity Management Committee - BMCs	At local level: they are responsible for the promotion of conservancy, the sustainable use and documentation of biological diversity, including the preservation of habitats, conservation of terrestrial species, traditional varieties and cultures, domesticated populations and animal species and micro-organisms and the description of knowledge related to biological diversity.

6. Websites

ABSCH India Profile
https://absch.cbd.int/countries/IN

CBD India Profile
www.cbd.int/countries/?country=in

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. India profile. Available in: https://absch.cbd.int/countries/IN Access on 18/05/2020.

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CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. India profile. Available in: https://www.cbd.int/countries/?country=in Access on 18/05/2020.

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GOVERNMENT OF INDIA. **National Biodiversity Action Plan (NBAP) – Addendum 2014 to NBAP 2008.** Ministry of Environment, Forests & Climate Change. New Delhi, 2014. Available in: https://www.cbd.int/countries/?country=in Access on 06/03/2017.

GOVERNMENT OF INDIA. **Notificaiton on exemption of crops listed in the Annex-I of the ITPGRFA from the purview of the Section 3 and 4 of the Biological Diversity Act, 2002**. Available in: https://absch.cbd.int/countries/IN Access on 06/03/2017.

GOVERNMENT OF INDIA. **Notification on Guidelines for International Collaborative Research Projects under Section 5 of the Biological Diversity Act, 2002.** Available in: https://absch.cbd.int/countries/IN Acesso em 06/03/2017.

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Indonesia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since November 21st, 1994.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the country already has laws addressing access and benefit sharing, but they are only available in the local language, therefore the analysis of the legislation was limited. Thus, the laws regarding access to genetic resources and benefit sharing in Indonesia are:

1.The information hereinafter has been updated until September 29th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Law 13/2016 concerning Patents

- Regulation of Ministry Environment and Forestry No 34 /2017 (Recognition And Protection Of Local Wisdom In Management Of Natural Resources And The Environment)

In addition, the article "Implementation of Access and Benefit Sharing in Indonesia: Review and Case Studies", by Ani Mardiastuti, indicates that the Revised Law Number 5/1990 addresses the management of genetic resources. However, during this research it was not possible to find it.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Even though the analysis of the legislation was limited, the article "Implementation of Access and benefit Sharing in Indonesia: Review and Case Studies", by Ani Mardiastuti, also identifies the following competent institutions regarding access and benefit sharing:

- **Ministry of Environment and Forestry**

According to the referred article, matters related to biodiversity (including matters related to international conventions) were transferred to the Directorate of Biodiversity Conservation, under the Directorate General of Conservation of Natural Resources and Ecosystem.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the laws that address access and benefit sharing in the country are only available in local language which is why they could not be analysed by this research.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the laws are only available in the local language, therefore the analysis of the legislation was limited. However, Regulation of Ministry Environment and Forestry No 34 /2017 (Recognition And Protection Of Local Wisdom In Management Of Natural Resources And The Environment) establishes the need of Prior Informed Consent (referred as approval on the basis of Initial Information in the regulation - PADIA), which grants approval for access to Traditional Knowledge. The procedures for this approval were not identifiable in the unofficial translated version of the regulation. Also, the Regulation states that Collective Agreements between the Provider and the Local Wisdom Accessors shall be established. Local Wisdom Accessors are defined as individuals, community groups, community organizations, professional organizations, and/or business entities, both from within and outside the country, who access and/or utilize Local Wisdom that is supervised by the Indigenous Law Community or the local community.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / () NOT AVAILABLE
Yes. In cases where patents arise from research or technological developments involving the access to genetic resources and/or traditional knowledge, the applicant must clearly and correctly state the origin of the genetic resources and/or traditional knowledge in the description - this information shall be determined by an official institution recognized by the government.

Also, according to the article 26 of the Law No 13/2016, the distribution of results and/or access to the utilization of genetic resources and/or traditional knowledge shall be carried out in accordance with statutory regulations and international agreements in the field of genetic resources and traditional knowledge. Furthermore, the legislation establishes that the cancellation of a Patent based on a court decision is carried out if patents originating from genetic resources and/or traditional knowledge do not meet the provisions at Article 26 of the Law No 13/2016.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the laws that address access and benefit sharing in the country are only available in local language which is why they could not be analyzed by this research.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the laws that address access and benefit sharing in the country are only available in local language which is why they could not be analyzed by this research.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE
As mentioned in item 2.1, the laws that address access and benefit sharing in the country are only available in local language which is why they could not be analyzed by this research.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the laws that address access and benefit sharing in the country are only available in local language which is why they could not be analyzed by this research.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, the laws are only available in the local language, therefore the analysis of the legislation was limited. Nevertheless, article 24 of the Regulation of Ministry Environment and Forestry No 34 /2017 states that access to Local Wisdom/Traditional Knowledge has the right to obtain financial and non-financial benefits as determined in the collective agreement from the use of Local Wisdom in a way that it is correct, open, fair, balanced, sustainable, and respectful of the Indigenous Law Community or the local community.

3.2 Are there any specific procedures, rules and values?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the laws are only available in the local language, therefore the analysis of the legislation was limited.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the laws that address access and benefit sharing in the country are only available in local language which is why they could not be analyzed by this research.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the laws that address access and benefit sharing in the country are only available in local language which is why they could not be analyzed by this research. However, an article in the website Science about Indonesia's new biopiracy rules establishes that scientists who fail to obtain a proper permit will be blacklisted for 5 years and repeat offenders risk a $290,000 fine. Also, failure to comply with the material transfer agreement (MTA) requirements is punishable by 2 years in prison or a $145,000 fine.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, one emblematic case related to biopiracy was the Shiseido Case, in which the cosmetic company used popular Indonesian herbs that are used in a popular folk medicine ("jamu") among Indonesians.

5. Summary - Competent authorities

Authority	Competence
Ministry of Environment and Forestry	Not defined

6. Websites

Indonesia Access and Benefit Sharing Clearing House
http://abschindonesia.menlhk.go.id/pages/permen

Indonesia Biodiversity Clearing House
https://balaikliringkehati.menlhk.go.id/en/about-us/nagoya-protocol/

7. References

ACCESS AND BENEFIT-SHARING CLEARING HOUSE - ABSCH. Country Profiles. Indonesia. Available in:. https://absch.cbd.int/countries/ID. Access on: 01/10/2019.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Indonesia. Available in: https://www.cbd.int/countries/?country=id. Access on: 01/10/2019.

MARDIASTUTI, Ani. Implementation of Access and Benefit Sharing in Indonesia: Review and Case Studies. Jurnal Jurnal Manajemen Hutan Tropika, 25( ), 35. April 2019. EISSN: 2089-2063. DOI: 10.7226/jtfm. 5.1.35. ISSN: 2087-0469.

REPUBLIC OF INDONESIA. Indonesian Biodiversity Strategy and Action Plan - National Document. The National Development Planning Agency (BAPPENAS). 2003. Available in: https://www.cbd.int/countries/?country=id Access on 11/11/2016.
REPUBLIC OF INDONESIA. The Fifth National Report of Indonesia to the Convention on Biological Diversity. Ministry of Environment and Forestry of Indonesia. Deputy Minister of Environmental Degradation and Climate Change. 2014. Available in: https://www.cbd.int/countries/?country=id Access on 11/11/2016.

ROCHMYANINGSIH, Dyna. Indonesia's strict new biopiracy rules could stifle international research. July 24th, 2019. Available in: https://www.science.org/news/2019/07/indonesia-s-strict-new-biopiracy-rules-could-stifle-international-research. Access on September 29th, 2021.

Iran[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since November 4th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / ( ) NO / (X) NOT AVAILABLE
Yes, according to the FAO website, the "Law of Protection and Utilization of the Country's Genetic Resources" (2018) addresses the sustainable use of Iran genetic resources, including traditional knowledge, medical genetic resources and authorization requirements from the

1. The information hereinafter has been updated until August 19, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Ministry of Agriculture and the Department of the Environment. However, as it is only available in the local language, it could not be analyzed by this research. Also, there is no information of whether the legislation is in effect and if it covers benefit sharing in the scope of CBD or Nagoya Protocol.

Furthermore, about traditional knowledge, the country has the Regulation on the National Document on Medical Plants and Traditional Medicine (2013), which comprises sustainable use of natural resources and guidelines for development of medicinal plants and traditional medicine. This legislation is also only available in local language and it could not be analyzed by this study to check if it provides ABS procedures regarding access to traditional knowledge related to genetic resources.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the law that addresses access and benefit sharing in the country is only available in local language which is why it could not be analyzed by this research.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the law that addresses access and benefit sharing in the country is only available in local language which is why it could not be analyzed by this research.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the law that addresses access and benefit sharing in the country is only available in local language which is why it could not be analyzed by this research.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the law that addresses access and benefit sharing in the country is only available in local language which is why it could not be analyzed by this research.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the law that addresses access and benefit sharing in the country is only available in local language which is why it could not be analysed by this research.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the law that addresses access and benefit sharing in the country is only available in local language which is why it could not be analyzed by this research.

2.8. Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / ( ) NO / (X) NOT AVAILABLE

As mentioned in item 2.1, the law that addresses access and benefit sharing in the country is only available in local language which is why it could not be analyzed by this research.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the law that addresses access and benefit sharing in the country is only available in local language which is why it could not be analyzed by this research.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the law that addresses access and benefit sharing in the country is only available in local language which is why it could not be analyzed by this research.

3.2 Are there any specific procedures, rules and values?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the law that addresses access and benefit sharing in the country is only available in local language which is why it could not be analyzed by this research.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not available	Not available	Not available	Not available	Not available
Non Monetary	Not available	Not available	Not available	Not available	Not available

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the law that addresses access and benefit sharing in the country is only available in local language which is why it could not be analyzed by this research.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Dr. Eskandar Zand
Advisor to Minister of Jihad Agriculture
Ministry of Jihad Agriculture
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6. Websites

ABSCH Iran Profile
https://absch.cbd.int/countries/IR

CBD Iran Profile
https://www.cbd.int/countries/?country=ir

Environment Department
https://biodiversity.doe.ir/Portal/Home/default.aspx

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Iran Profile. Available at: https://absch.cbd.int/countries/IR> Access on 19/08/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Iran profile. Available at: https://www.cbd.int/countries/?country=ir. Accessed on 19/08/2020.

FAOLEX DATABASE. Iran - Islamic Republic of. Law of Protection and Utilization of the Country's Genetic Resources. Available in: http://www.fao.org/faolex/results/details/en/c/LEX-FAOC182127/. Accessed on 11/16/2020.

GOVERNMENT OF IRAN. **Revised National Biodiversity Strategies and Action Plan (NBSAP2) 2016-2030**. Department of Environment. 2016. Available at: https://www.cbd.int/countries/?country=ir Access on 16/05/2018.

GOVERNMENT OF IRAN. **The Fifth National Report to the Convention on Biological Diversity**. April, 2015. Available at: https://www.cbd.int/countries/?country=ir Access on 16/05/2018.

GOVERNMENT OF IRAN. **The Sixth National Report to the Convention on Biological Diversity.** July, 2020. Available at: https://chm.cbd.int/database/record?documentID=251196 Access on 19/08/2018.

Iraq[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since October 26th, 2009.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the article Overview of National and Regional Measures on Access and Benefit Sharing (2014), the country is elaborating a draft law

1.The information hereinafter has been updated until October 28th, 2020
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

on the subject.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Jasim Abdulazeez Humadi
Deputy Minister of Environmental Affairs
Ministry of Health and Environment
P.O. Box 10062
Baghdad
Iraq

ABS National Focal Point
moen_iraq@yahoo.com
moen.iraq@gmail.com

6. Websites

ABSCH Iraq Profile
https://absch.cbd.int/countries/IQ

CBD Iraq Profile
https://www.cbd.int/countries/default.shtml?country=iq

Ministry of Environment
http://www.moen.gov.iq/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Iraq Profile. Available at: https://absch.cbd.int/countries/IQ> Access on 10/28/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Iraq profile. Available at: https://www.cbd.int/countries/default.shtml?country=iq. Accessed on 10/28/2020.

IRAQ. **Fifth National Report to the Convention on Biological Diversity,** 2014. Disponível em: < https://www.cbd.int/doc/world/iq/iq-nr-05-en.pdf> Access on: 10/28/2020.

IRAQ. **Iraq's National Biodiversity Strategy and Action Plan:** 2015-2020. Disponível em: < https://www.cbd.int/doc/world/iq/iq-nbsap-01-en.pdf> 10/28/2020.

MEDAGLIA, Jorge Cabrera; PERRON-WELCH, Frederic; PHILLIPS, Freedom-Kai.

Overview of national and regional measures on access and benefit sharing: Challenges and opportunities in implementing the Nagoya Protocol. CISDL Biodiversity & Biosafety Law Research Programme, 3 ed., 2014. Disponível em:< https://www.absfocalpoint.nl/upload_mm/5/f/4/008c9cc8-19f3-4926-b380-5f13fd1eb705_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf> Acesso em: 10/28/2020.

Israel[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since November 5th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until October 13th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body? Are there any records of fines having been applied by such institutions?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any record of emblematic biopiracy cases or disputes related to access and benefit sharing in the country?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Dr. Simon Nemtzov
Head of International Relations
Israel Nature and Parks Authority
3 Am Ve´Olamo St.
Jerusalem
9546303
Israel

ABS National Focal Point
+972 58 5063118
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6. Websites

Ministry of Foreign Affairs
http://mfa.gov.il/

Ministry of Environment and Protection
http://www.sviva.gov.il/English/env_topics/InternationalCooperation/IntlConventions/Pages/CBD.aspx

7. References

ACCESS AND BENEFIT-SHARING CLEARING HOUSE - ABSCH. Country Profiles. Israel. Available in: https://absch.cbd.int/countries/IL. Access on: 10/13/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Israel. Available in: https://www.cbd.int/countries/nfp/?country=il. Access on: 10/13/2020.

STATE OF ISRAEL. Fifth National Report to the United Nations Convention on Biological Diversity. Ministry of Environmental Protection. 2016. Available in: https://www.cbd.int/countries/?country=il. Access on: 11/08/2016.

STATE OF ISRAEL. Israel's National Biodiversity Plan. Ministry of Environmental Protection. 2010. Available in: https://www.cbd.int/countries/?country=il Access on: 11/08/2016.

Japan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since December 29, 1993.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since August 20, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
(X) YES / ( ) NO
Yes. The country has one checkpoint, which is the Ministry of Environment, responsible for access and genetic resources. It shall provide information related to the utilization of genetic resources.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has 5 checkpoint communiqués that are available on ABSCH website.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The website of the Japanese Ministry of the Environment affirms

1. The information hereinafter has been updated until September 29th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

that there are no official regulations or procedures on prior informed consent and, therefore, there is no requirement of prior informed consent in order to gain access to the Japanese genetic heritage. The Ministry has not clarified whether there are any norms or bills related to access and benefit sharing as dealt with in the Nagoya Protocol and in the Convention on Biological Diversity.

Although there is no legislation on the subject, several Ministries of Japan JBA have developed Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2017). These Guidelines clarify the procedures and frequently asked questions on obtaining access to genetic resources in countries that are parties to the CBD. There are no specifications on national access, as the guide is restricted to the text of the CBD, the Bonn Guidelines and the Nagoya Protocol. In this sense, item 1 of the framework of the guide reinforces the sovereignty of countries which are a party to the CBD and acknowledges that the internal rules of countries that already have domestic legislation and regulatory procedures on the subject shall prevail.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. It should be highlighted that the Ministry of the Environment is clear in instructing potential users of the Japanese biodiversity that there is no need for obtaining prior informed consent before the access. No other authorization requirements are specified.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.. It should be highlighted that the Ministry of the Environment is clear in instructing potential users of the Japanese biodiversity that there is no need for obtaining prior informed consent before the access.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The Guidelines on ABS (2017) specifically state that they do not apply to information concerning genetic resources, such as nucleic acid base sequenced or to synthetic nucleic acids.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, chapter 3 of the Guidelines on ABS Users in Japan (2017) encourages that providers of genetic resources existing in Japan which seek benefit sharing conclude a contract ensuring fair and equitable sharing of benefits. Also, the same chapter states that the person who utilizes genetic resources shall comply with the regulation of the provider country and is encouraged to conclude a contract ensuring fair and equitable sharing of benefits.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Japan Profile
https://absch.cbd.int/countries/JP

CBD Japan Profile
https://www.cbd.int/countries/?country=jp

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Japan. Available in: <https://absch.cbd.int/countries/JP >. Access on: 09/29/2021.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Japan. Available in: <https://www.cbd.int/countries/?country=jp> Access on: 09/29/2021.

GOVERNMENT OF JAPAN. Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (2017). Available in: https://absch.cbd.int/database/record/ABSCH-MSR-JP-238074. Access on 09/20/2021.

Kazakhstan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since December 5th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since September 15th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country, but the Environmental Code (2007) provides for permits related to

1. The information hereinafter has been updated until November 20th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

natural resources.

According to the UNDP 2018 report “ABS is Genetic Resources for Sustainable Development”, the inspectorate of the protected areas under the Committee of Forestry and Wildlife has been issuing bioprospecting permits following the Bioprospecting, Access and Benefit Sharing Regulations, which came into force in 2007. However, those regulations could not be identified by this analysis. According to the same report, the country has been revising its legislation in order to cover ABS obligations under the Nagoya Protocol.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, as per the UNDP 2018 report “ABS is Genetic Resources for Sustainable Development”, the inspectorate of the protected areas under the Committee of Forestry and Wildlife has been issuing permits for bioprospection.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the Order of the Minister of Justice No. 89 of February 24, 2012, on the implementation of intellectual property rights, there shall be disclosure of origin in case of biotechnological products.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
According to the official government website, the Committee of Forestry and Wildlife, of the Ministry of Agriculture is the environmental inspection institution with supervisory functions regarding use of wildlife. However, there is no information as to whether it is the institution responsible for inspecting access to genetic resources.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Kairat Ustemirov
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Committee of Forestry and Fauna
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6. Websites

ABSCH Kazakhstan Profile
https://absch.cbd.int/countries/KZ

CBD Kazakhstan Profile
https://www.cbd.int/countries/?country=kz

Forestry and Wildlife Committee of the Ministry of Ecology, Geology and Natural Resources
https://www.gov.kz/memleket/entities/forest/about?lang=en

7. References

ACCESS AND BENEFIT-SHARING CLEARING HOUSE - ABSCH. Country Profiles. Kazakhstan. Available in: https://absch.cbd.int/countries/KZ. Access in: 11/20/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Kazakhstan. Available in: https://www.cbd.int/countries/?country=kz. Access in: 11/20/2020.

REPUBLIC OF KAZAKHSTAN Interim National Report on the Implementation of the Nagoya Protocol, 2018. Available at: https://absch.cbd.int/pdf/documents/absNationalReport/ABSCH-NR-KZ-239922/1 Access on 11/20/2020.

REPUBLIC OF KAZAKHSTAN. The Sixth National Report on Biological Diversity in the Republic of Kazakhstan. Astana, 2018. Available at: https://chm.cbd.int/database/record?documentID=242894 Access on 11/20/2020.

REPUBLIC OF KAZAKHSTAN. National Strategy And Action Plan On Conservation And Sustainable Use Of Biological Diversity In The Republic Of Kazakhstan. Ministry Of Natural Resources And Protection Of Environment Of The Republic Of Kazakhstan. Kokshetau, 1999. Available in:https://www.cbd.int/countries/?country=kz Access on 18/10/2016.

REPUBLIC OF KAZAKHSTAN. Order of the Minister of Justice of the Republic of Kazakhstan No. 89 of February 24, 2012, on Approval of the Rules on Drafting and Examination of Applications for Certain Types of Industrial Property Rights, Recording of Registration Information in the State Registers of Industrial Property of the Republic of Kazakhstan, and Issuance of Title of Protection; and on Amendments to the Order of Acting Minister of Justice of the Republic of Kazakhstan No. 136 of 23 April 2010, on Certain Issues of Legal Protection of Industrial Property (as amended up to Order of the Minister of Justice No. 364 of June 30, 2015). 2012. Available at: https://wipolex.wipo.int/en/legislation/details/16109 Access on 11/20/2020.

UNECE - United Nations Economic Commission for Europe. Environmental Performance Reviews. Kazakhstan. Third Review. ECE/CEP/185. Geneva, 2019.

UNDP. - United Nations Development Programme. ABS is Genetic Resources for Sustainable Development. New York, 2018. Available at: https://abs-sustainabledevelopment.net/resource/abs-is-genetic-resources-for-sustainable-development/ Access on 11/20/2020.

Kuwait[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since October 31st, 2002.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since August 31st, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has 5 checkpoint communiqués that are available on ABSCH website.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until October 29th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8. Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or

public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol

Nagoya Protocol on Access and Benefit-sharing

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CBD Kuwait Profile
https://www.cbd.int/countries/?country=kw

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, ABSCH. Country profile. Japan. Available in: <https://absch.cbd.int/countries/KW>. Access on: 10/29/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Japan. Available in: <https://www.cbd.int/countries/?country=kw> Access in: 10/29/2020.

STATE OF KUWAIT. **Fifth National Report on the implementation of the Convention on Biological Diversity**. Environment Public Authority - EPA. 2014. Available at: https://www.cbd.int/countries/?country=kw Access on 10/29/2020.

STATE OF KUWAIT. **Patent Law No. 71 of 2013**. Available at: http://www.wipo.int/wipolex/en/details.jsp?id=15423 Access on 10/29/2020.

STATE OF KUWAIT. **The National Biodiversity Strategy For The State Of Kuwait.** Environment Public Authority - EPA; International Union for Conservation of Nature - IUCN; and United Nations Development Program - UNDP. 2010. Available at: https://www.cbd.int/countries/?country=kw Access on 10/29/2020.

Kyrgyzstan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since November 4th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since September 13th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
The 5th and 6th National Reports on Biodiversity Conservation in Kyrgyzstan state that the country is in the process of drafting legislation on access to genetic resources. While the rules are not formulated, access to the country's genetic resources is under the responsibility of the State Agency on Environment Protection and Forestry (SAEPF). Additionally, the need to cre-

1. The information hereinafter has been updated until February 10 th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

ate a National Coordination Center was indicated in the Interim National Report on the Implementation of the Nagoya Protocol, but no measures to implement the SAEPF Protocol have yet been taken.

On the other hand, the country has the following laws regarding traditional knowledge:

- Law No. 116 “On the Protection of Traditional Knowledge” (2007)
- Law No. 178 amending Law No. 116 “On protection of traditional knowledge”
- Order No. 154 of February 29, 2012 - Rules on the Drafting, Filing and Examination of Applications Traditional Knowledge
- Order of the Government of the Kyrgyz Republic in Compliance with the Law “On Protection of Traditional Knowledge”
- Regulations of Fees for the “Registration and the Right to Use Traditional Knowledge”

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Law No. 166, “On the Protection of Traditional Knowledge” (2007) provides that the Authorized State Body competent to deal with matters of traditional knowledge shall be the same body responsible for intellectual property. Regarding genetic resources, Kyrgyzstan’s 5th National Report on Biodiversity Conservation states that access to genetic resources is under the responsibility of the State Agency on Environment Protection and Forestry (SAEPF), which assesses and grants authorizations for these cases. The State Agency on Environment Protection and Forestry (SAEPF) is also the National Focal Point established in the country for matters related to the Nagoya Protocol.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
According to item 2.1, the country does not have specific legislation on access to genetic resources. On the other hand, Kyrgyzstan’s Sixth and Fifth National Reports on Biodiversity Conservation state that access to the country’s genetic resources should be done with authorization and analysis from the State Agency on Environment Protection and Forestry (SAEPF).

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As explained in item 2.1, the country’s only legislation regarding associated traditional knowledge is Law No. 166 “On the Protection of Traditional Knowledge” from 2007 and its complementary regulations. Article 14 of this standard states that traditional knowledge may be used by people who do not hold this knowledge as long as it is established an agreement with the holder of the traditional knowledge previously registered with the Authorized State Body. This agreement shall provide for the conditions of use, period and payments due, and shall be registered in the Authorized State Body as well.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Law No. 166 “On the Protection of Traditional Knowledge”, 2007 defines in article 8 the conditions for patents originating from traditional knowledge. The origin and the source of knowledge should be indicated.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country’s territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country’s territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
Yes, sharing of benefits in the case of access to traditional knowledge is covered by Articles 14 and 16 of Law No. 166 “On the Protection of Traditional Knowledge” (2007). The responsibility to share the benefits lies with the applicant. There is no stipulation of value, as this and other issues shall be mutually agreed on by the user and the traditional knowledge holder. These articles also provide for the establishment of a Fund for the conservation and development of local communities, which may receive part of the proceedings of agreements between users and holders of traditional knowledge, at a minimum percentage of 20%.

3.2 Are there any specific procedures, rules and values?
(X) YES / ( ) NO / NOT AVAILABLE
About access to traditional knowledge, Law No. 166 “On the Protection of Traditional Knowledge” (2007) states that an agreement between the parties must be established and later registered in the Authorized Body. Also, a fee must be paid, and the benefits shall be deposited in favor of a local community or State Fund.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Deposit to a local community or local fund	Minimum of 20%	Associated Traditional Knowledge	Government/ Provider
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
There is no indication of sanctions in the analyzed legislation. Article 17 of Law No. 166 "On the Protection of Traditional Knowledge", 2007, solely determines that the use of traditional knowledge in commercial production without the conclusion of agreements with its holders will be considered as illegal use of traditional knowledge.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Authorized State Body responsible for intellectual property	Law No. 166, "On the Protection of Traditional Knowledge" (2007) provides that the Authorized State Body competent to deal with matters of traditional knowledge shall be the same body responsible for intellectual property.
State Agency on Environment Protection and Forestry (SAEPF)	State Agency on Environment Protection and Forestry (SAEPF) Regarding genetic resources, Kyrgyzstan's 5th National Report on Bio-diversity Conservation states that access to genetic resources is under the responsibility of the State Agency on Environment Protection and Forestry (SAEPF).

The country also has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Ms. Bermet Omurova
Deputy Head
International Cooperation Department
State Agency on Environment Protection and Forestry (SAEPF)
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ABS National Focal Point
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+996 312 54 50 91
bemamo@mail.ru
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min-eco@elcat.kg

6. Websites

ABSCH Kyrgyzstan Profile
https://absch.cbd.int/countries/KG

CBD Kyrgyzstan Profile
https://www.cbd.int/countries/?country=kg

BIOFIN Kyrgyz Republic Profile
https://www.kg.undp.org/content/kyrgyzstan/en/home/projects/biofin-swiss-2.html

7. References

ACCESS AND BENEFIT-SHARING CLEARING HOUSE - ABSCH. Country Profile. Available in: https://absch.cbd.int/countries/KG. Access on 23/10/2019.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Kyrgyzstan Profile. Available in: https://www.cbd.int/countries/?country=kg. Access on 23/10/2019.

KYRGYZSTAN. Biodiversity conservation priorities of the Kyrgyz Republic till 2024. Available in: https://www.cbd.int/countries/?country=kg Access on 21/11/2016.

KYRGYZSTAN. Fifth National Report On Conservation Of Biodiversity Of The Kyrgyz Republic. State Agency On Environment Protection and Forestry under The Government Of The Kyrgyz Republic; Global Environment Facility; United Nations Environment Programme. Bishkek, 2013. Available on: https://www.cbd.int/countries/?country=kg Access on 21/11/2016.

KYRGYZSTAN. Law nº 166 On the Protection of Traditional Knowledge, 2007. Available in: http://www.wipo.int/wipolex/en/details.jsp?id=5571 Access on 21/11/2016.

KYRGYZSTAN. Law No. 178 amending Law No. 116 “On protection of traditional knowledge”. Available in: https://www.ecolex.org/details/legislation/law-no-178-amending-law-no-116-on-protection-of-traditional-knowledge-lex-faoc161200/?q=178&type=legislation&xcountry=Kyrgyzstan&xdate_min=&xdate_max= Access on 21/11/2016.

KYRGYZSTAN. Order No. 154 of February 29, 2012 - Rules on the Drafting, Filing and Examination of Applications Traditional Knowledge. Available in: http://www.wipo.int/wipolex/en/details.jsp?id=11555 Access on 21/11/2016.

KYRGYZSTAN. Order of the Government of the Kyrghyz Republic in Compliance with the Law ‘On Protection of Traditional Knowledge’. Available in: http://www.wipo.int/wipolex/en/details.jsp?id=11577 Access on 21/11/2016.

KYRGYZSTAN. Regulations on Fees for the Registration and the Right to Use Traditional Knowledge. Available in: http://www.wipo.int/wipolex/en/details.jsp?id=11541 Access on 21/11/2016.

Lao People's Democratic Republic[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since December 19th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has issued and registered 16 IRCCs that are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the Biotechnology Safety Law (2014) states that access

1. The information hereinafter has been updated until October 17th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

to genetic resources shall be made sustainably and benefits shall be shared.

Also, the country developed in 2013 a document entitled "Lao National Framework on the Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization", which contained drafts of a Government Policy in ABS, including a draft ABS legislation covering procedures for access to genetic resources, benefit sharing, technology transfer and compliance. Furthermore, a study of the United Nations Conference on Trade and Development (UNCTAD) regarding Guidelines and Model Clauses on Access and Benefit Sharing and Biotrade in the country (2019) stated that while the draft regulatory regime has not yet been implemented, the Biotechnology and Ecology Institute created an informal administrative procedure to handle requests for access to genetic resources on a case by case basis, which was not identified by this study.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The ABSCH website identifies the Biotechnology and Ecology Institute as the competent institution.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 7 of the draft law on ABS, all access activities in the country must comply with the procedures described below:

1. Application: the applicant shall present an application before the Competent National Authority requiring Prior Informed Consent for utilization of genetic resources or associated traditional knowledge.

2. Authorization: the National Competent Authority shall accept or reject the application by a written decision.

3. Mutually Agreed Terms (MAT): the parties shall establish MAT and notify the Access and Benefit Sharing Clearing House.

While this rules are not yet in place, the draft Guidelines and Model Clauses on Access and Benefit Sharing and Biotrade in the country (2019) developed by the UNCTAD, provide for model contractual clauses to be presented before the Biotechnology and Ecology Institute of the Ministry of Science and Technology, which shall follow a case by case procedure.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Notwithstanding the procedures described in item 2.3, in cases where access to associated traditional knowledge is concerned, article 7.6 of the draft law on ABS states that the Competent National Authorities shall establish criteria and processes for obtaining prior informed consent and involvement of indigenous and local communities. Also, article 9 of the draft law establishes that indigenous and local communities customary laws shall be considered.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The draft legislation foresees species that have developed distinctive properties within the country's territory on the definition of "in situ conservation" and "in situ conditions".

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
Yes, according to articles 22 and 24 of the Biotechnology Safety Law (2014), benefit sharing is mandatory. According to article 12 of the draft law on ABS, the responsibility to share the benefits arising from the utilization, application and commercialization of genetic resources lies on the applicant.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
The norms covered by this analysis do not address procedures, rules and values about benefit sharing, as the legislation in force, Biotechnology Safety Law (2014), only provides that access to genetic resources shall be made sustainably and benefits shall be shared. However, article 12 of the draft law on ABS states that benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex to the Nagoya Protocol.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Article 66 of the Biotechnology Safety Law (2014), which briefly addresses ABS, institutes the Inspection Agency for Biotechnology Safety as the official inspection body responsible for monitoring all activities related to administration, including research, development, services and usage of biotechnologies and GMOs.

As per the draft law on ABS, no official inspection bodies concerned with access and benefit-sharing were found, but its articles 20 to 23 establish provisions regarding monitoring and law enforcements.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Article 70 of the Biotechnology Safety Law (2014), which briefly addresses ABS, establishes the applicable sanctions disagreement with the procedural rules, such as reprimands, warnings, fines and compensation. Article 73.2 of the referred legislation states that people who cause negative impacts or damages to biodiversity shall be fined.

As per the draft law on ABS, no sanctions in case of irregular access were identified in the norms covered by this analysis.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Institute of Biotechnology and Ecology	All matters regarding genetic resources.

6. Websites

ABSCH CountryProfile
https://absch.cbd.int/countries/LA

CBD Country Profile
www.cbd.int/countries/?country=la

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, ABSCH. Country profile. Lao People's Democratic Republic. Available in: <https://absch.cbd.int/countries/LA>. Access on 01/24/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Lao People's Democratic Republic. Available in: < https://www.cbd.int/countries/?country=la> Access on 24/01/2020.

LAO PEOPLE'S DEMOCRATIC REPUBLIC.Biotechnology Safety Law. 2014. Available at: <https://data.opendevelopmentmekong.net/dataset/fe7b85c4-19f4-4bc4-a2a3-dc-fa286439d4/resource/595b7fe3-0e98-40bf-8499-71c6dc6c44d2/download/biotechnolo-gy-safety-law.pdf>. Access on 10/17/2020.

LAO PEOPLE'S DEMOCRATIC REPUBLIC. **Fifth National Report To The United Nations Convention On Biological Diversity**. Ministry of Natural Resources and the Environment (MoNRE) and Technical support: IUCN - Vientiane, Lao PDR. 2016. Available in: https://www.cbd.int/countries/?country=la Access on 01/24/2020 .

LAO PEOPLE'S DEMOCRATIC REPUBLIC. **National Biodiversity Strategy and Action Plan 2016 – 2025**. Ministry of Natural Resources and the Environment (MoNRE) Vientiane, Lao PDR. 2016. Available in: https://www.cbd.int/countries/?country=la Access on 01/24/2020.

LAO PEOPLE'S DEMOCRATIC REPUBLIC. **NBSAP Assessment - An Assessment of Lao PDR's National Biodiversity Strategy to 2020 and Action Plan to 2010**. Ministry of Natural Resources and the Environment (MoNRE) and Technical support: IUCN - Vientiane, Lao PDR. 2016. Available in: https://www.cbd.int/countries/?country=la Access on 01/24/2020.

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Lebanon[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since March 15, 1995.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by ratification, since January 11th, 2018.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / ( ) NO / (X) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country, once it is only available in the local language and an English version was not found by the time of this study, thus prejudicing the conclusion of the present

1. The information hereinafter has been updated until August 20th, 2020
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

study.

Nevertheless, the official website 'Le Centre d'échange d'information de la Convention sur la diversité biologique' and FAO Website indicate that the country has the following law on biodiversity and access "Law for the Protection of the Environment (Law 444, 8/8/2002)".
Also, the National Focal Point informed that there is a draft law regarding Access and Benefit Sharing, which has already been submitted to the Council of Ministers, and awaits transfer to the Parliament. However, as the referred draft law is not public, it was not possible to analyze it.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4. Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Lebanon Profile
https://absch.cbd.int/countries/LB

CBD Lebanon Profile
https://www.cbd.int/countries/?country=lb

Ministry of Environment
http://www.moe.gov.lb/

Le Centre d'échange d'information de la Convention sur la diversité biologique
http://www.archives.biodiv.be/liban/biodiversite-au-liban

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Lebanon Profile. Available at: https://absch.cbd.int/countries/LB> Access on 19/08/2018.

CHALAK, Lamis. Proposed Regulations on Access and Benefit-sharing for biological and genetic Resources of Lebanon. In: COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE. Proceedings of the International Workshop on Access and Benefit-sharing for Genetic Resources for Food and Agriculture. Preliminary version.CGRFA/WG-PGR-9/18/Inf.12 Rev.1. July 2018.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Lebanon profile. Available at: https://www.cbd.int/countries/?country=lb> Access on 19/08/2018.

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LEBANON. Sixth National Report of Lebanon: To the Convention on Biological Diversity, 2019. Available at: https://www.cbd.int/doc/nr/nr-06/lb-nr-06-en.pdf Access in: 20/08/2020.

YOUNG, Tomme. Covering ABS: Addressing the need for Sectorial, Geographical, Legal and International Integrattion in the ABS Regime. Papers and Studies of The ABS Project, IUCN, Gland, Switzerland, 2009.

REPUBLIC OF LEBANON. Le Centre d'échange d'information de la Convention sur la diversité biologique: Environmental Legislation. Available at: http://www.biodiv.be/liban/implementation/national-legislation-and-policies/environmental-legislation Access in: 08/20/2018.

Malaysia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since September 22nd, 1994

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since February 3rd, 2019.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
(X) YES / ( ) NO
Yes. The country has the following checkpoints communiqués:

- **Intellectual Property Corporation of Malaysia;**

The Intellectual Property Corporation of Malaysia (MyIPO) oversees and administers Malaysia's IP system. MyIPO administers and enforces Intellectual Property Legislation namely the Trademarks Act 2019, the Patents Act 1983, the Copyright Act 1987, the Industrial Designs Act 1996, the Layout Designs of Integrated Circuits Act 2000, Geographical Indications Act 2000 and subsidiary regulations

- **The National Pharmaceutical Regulatory Agency;**

The National Pharmaceutical Regulatory Agency (NPRA), formerly known as the National Pharmaceutical Control Bureau (NPCB), was set up in October 1978 under the quality control activity of Pharmacy and Supply Programme. This institution was established to implement quality control on pharmaceutical products. The infrastructure and facilities were designed to meet the requirements for testing and quality control activities. In 1985, NPRA was given the task of ensuring the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme.

- Any public research institution, university public higher education institution or other public institution funding research and development activity in relation to a biological resource or traditional knowledge associated with a biological resource as may be determined by the National Competent Authority.

1. The information hereinafter has been updated until October, 22nd, 2019.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the country already has the following laws regarding access and benefit-sharing:

- Act 795 - Access to Biological Resources and Benefit Sharing (2017);

- Access to biological Resources and Benefit Sharing Regulations (2020);

Also, according to the Malaysian Access and Benefit-sharing Clearing House, the states across the South the China Sea of Peninsular Malaysia, the state of Sabah and Sarawak, has its own system in accessing its biological resources, which are regulated by the following laws:
Sabah Biodiversity Enactment 2000
Sarawak Biodiversity Ordinance 1997

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The ABS Act (2017) identifies the following competent institutions regarding access and benefit sharing:

- Regional Competent Authorities

Those are responsible for dealing with the application for access to biological resources and associated traditional knowledge, as well as benefit sharing within its jurisdiction; preparing annual reports about permits granted. There is an annex to Act 795 which contains the regional competent authorities in each Malaysian state.

- Secretary General of the Ministry responsible for natural resources and environment

It is responsible for coordinating the implementation of the Act; determining the fees applicable; communicating with other countries and organizations regarding ABS; promoting awareness and training about ABS; receiving and approving permits of access; establishing measures for monitoring and tracking biological resources; and supporting customary laws and practices of indigenous and local communities.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to ABS Act (2017), all access activities in the country must comply with the procedures described below:

1. Application for permit for commercial or potential commercial purpose: according to section 12 of Act 795, any person who intends to access a biological resource or traditional knowledge associated with a biological resource including through an authorized intermediary for commercial or potential commercial purposes shall apply for a permit to the relevant Competent Authority in the form of the First Schedule annexed in the Regulations of Act 795 (2020), which shall be accompanied by payment of the prescribed fee (RM500 for local applicant or US$500 for foreign applicant).

2. Application for permit for non-commercial purpose: according to section 15 of the Act 795, any person who intends to access a biological resource or traditional knowledge associated with a biological resource, including through an authorized intermediary for non-commercial purpose shall apply for a permit to the relevant Competent Authority in the form of the First Schedule, annexed in the Regulations of Act 795 (2020), which shall be accompanied with a copy of a statutory declaration duly completed as specified in the Second Schedule of Act 795 and payment of the prescribed fee (RM100 for local applicant or US$100 for foreign applicant). Also, section 15 of the Act 795 states that the application shall be in collaboration with a public higher education institution, public research institution or a Government agency from Malaysia, unless the relevant Competent Authority is satisfied that the applicant is a non-profit organization based or registered in Malaysia, local researchers are involved in the activity or if a program for capacity building is included in the activity.

3. Prior Informed Consent (PIC): The PIC shall be obtained from a benefit sharing agreement settle with the representative or organisation responsible, if there is not, with the holders of the traditional knowledge associated with a biological resource within the indigenous community and local community or with the Federal Government or State Authority, as the case may be. It is necessary to obtain the PIC if the access to the biological resource occurs on land to which such indigenous community and local community have a right, as established by law, or if the traditional knowledge associated with a biological resource is held by such indigenous community and local community. Also, it shall be obtained in accordance with customary laws and practices, protocols and procedures of indigenous community and local community, as the case may be.

4. Benefit Sharing Agreement: It is only necessary for applicants that require access to a biological resource or traditional knowledge associated with a biological resource, for commercial or potential commercial purposes. The agreement shall be based upon mutually agreed terms and provide for fair and equitable benefit sharing. Alsom The benefits derived from the access shall be deposited into a fund established by the Federal or State government.

Permit is not required in the following cases: research for non-commercial purposes under the authority of a research institution or public higher education institution, or government agency within Malaysia; exchange of biological resources for non-commercial purposes under the authority of a research institution or public higher education institution, or government agency within Malaysia; access from a permit holder for the purpose of carrying out or continuing any research for non-commercial purpose.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access

to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to Act 795 (2017), all access activities in the country must comply with the procedures described below:

5. Obtain Prior Informed Consent (PIC): If the biological resource is located in indigenous lands or it is associated with traditional knowledge, PIC is required. It shall be obtained in accordance with customary laws and practices of indigenous and local communities.

6. Benefit Sharing Agreement: If the biological resource is located in indigenous lands or it is associated with traditional knowledge, Benefit Sharing Agreement is required. The benefits derived from the access shall be deposited into a fund established by the Federal or State government.

7. Application: There must be an application to the Competent Authority, which will evaluate the requirements and authorize (or deny) the access of biological resources.

Permit is not required in the following cases: research for non-commercial purposes under the authority of a research institution or public higher education institution, or government agency within Malaysia; exchange of biological resources for non-commercial purposes under the authority of a research institution or public higher education institution, or government agency within Malaysia; access from a permit holder for the purpose of carrying out or continuing any research for non-commercial purpose.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to Act 795 (2017), any person that applies for a patent shall notify the National Competent Authority relating to ABS within 30 days from the date of the application.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The legislation does not foresee procedures for collection or access to exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
The ABS Act (2017) foresees that transfer of biological resources require prior approval of the competent authority. In addition, when the approval is given by the Competent Authority for the transfer, it shall be subject to such conditions as may be prescribed and the transferee shall be required to apply for a permit under the terms of the Act, unless otherwise decided by the Competent Authority.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
(X) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE
Yes, the ABS Act (2017) addresses this matter since “information” is comprehended on the concept of biological resources. However, there are no specific procedures for those cases.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The legislation does not foresee procedures for species that have naturally developed their distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
Yes. Any applicant for access to genetic resources or associated traditional knowledge, for commercial or potential commercial purposes, shall make a benefit-sharing agreement with the resource provider. The responsibility lies within the applicant.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
The ABS Act (2017) does not provide specific procedures about benefit sharing. The Act establishes that the benefit sharing agreement shall be based upon mutually agreed terms, which shall be and must be fair and equitable. Also, when the resource provider is not the State, it may require monetary benefits derived from the benefit sharing agreement, which shall be deposited into a fund that is going to be used for the conservation of biodiversity, sustainable use of its components in the country and for other incidental expenses.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Deposit into a fund	Not defined	Not defined	Not defined
Non Monetary	Not defined	as established in section 9. 2, (b) of Regulations of the ABS Act (2020)	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Section 8 of the ABS Act (2017) institutes the National and Regional Competent Authorities as the official inspection bodies responsible for all matters related to access and benefit-sharing in the country.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The ABS Act (2017) establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: fine up to 500,000.00 (five hundred thousand) ringgit for individuals, which is equivalent to approximately 119,200 US dollars; imprisonment for up to 10 (ten) years); fine up to 5,000,000.00 (five million) ringgit for companies, which is equivalent to approximately 1,192,000 US dollars.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Regional Competent Authorities	Deals with the application for access to biological resources and associated traditional knowledge, as well as benefit sharing within its jurisdiction; preparing annual reports about permits granted.
National Competent Authority	Coordinate the implementation of the Act; determining the fees applicable; communicating with other countries and organizations regarding ABS; promoting awareness and training about ABS; receiving and approving permits of access; establishing measures for monitoring and tracking biological resources; and supporting customary laws and practices of indigenous and local communities.

6. Websites

ABSCH Malaysia's profile
https://absch.cbd.int/countries/my

CBD Malaysia's Profile
https://www.cbd.int/countries/?country=my

Malaysia's ABS Clearing House
https://myabs.gov.my/

Malaysia Biodiversity Information System
https://www.mybis.gov.my/one

7. References

ACCESS AND BENEFIT-SHARING CLEARING HOUSE - ABSCH. Country Profiles. Malaysia. Available in: https://absch.cbd.int/countries/MY. Access on: 11/10/2019.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Malaysia. Available in: https://www.cbd.int/countries/?country=my. Access on: 11/10/2019.

GOVERNMENT OF MALAYSIA. Act 795. Laws of Malaysia. Access to Biological Resources and Benefit Sharing Act, October 17th 2017 (publication). Available in: http://extwprlegs1.fao.org/docs/pdf/mal176890.pdf. Access on 23/04/2020.

GOVERNMENT OF MALAYSIA. Fifth National Report to the Convention on Biological Diversity. Ministry of Natural Resources and Environment, Biodiversity and Forestry Management Division. Putrajaya, 2014. Available in: https://www.cbd.int/countries/?country=my Access on 16/10/2016.

GOVERNMENT OF MALAYSIA. Final Draft Access to Biological Resources and Benefit Sharing Bill Now Online for Views and Inputs. Ministry of Natural Resources and Environment, 2013. Available in: http://www.tfbc.frim.gov.my/Press%20Release.pdf Access on 16/10/2016.

GOVERNMENT OF MALAYSIA. National Policy on Biological Diversity 2016-2025. Ministry of Natural Resources and Environment, Biodiversity and Forestry Management Division. Putrajaya, 2016. Available in: https://www.cbd.int/countries/?country=my Access on 16/10/2016.

Maldives[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since September 29th, 2019.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated tradition-

1. The information hereinafter has been updated until December 23rd, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

al knowledge in the country. The Sixth National Report on the Convention on Biological Diversity (2019) states that there is a legal instrument on ABS under development. Also, the same document mentions that the current legislation regarding marine research covers some aspects of research involving marine biodiversity.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Maldives Profile
https://absch.cbd.int/countries/MV

CBD Maldives Profile
https://www.cbd.int/countries/?country=mv

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Maldives profile. Available in: https://absch.cbd.int/countries/MV.Access on 10/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Maldives profile. Available in: https://www.cbd.int/countries/nfp/?country=mv. Access on 10/10/2020.

MALDIVES; MINISTRY OF PLANNING HUMAN RESOURCES AND ENVIRONMENT; ZUHAIR, Muhamed. **Access and Benefit Sharing in Maldives**. Available at: <http://www.biodiversitya-sia.org/books/abs/Chapter%208.pdf> Access on: 05/22/2018.

MALDIVES; MINISTRY OF ENVIRONMENT AND ENERGY. **National Biodiversity Strategy and Action Plan**, 2015. Available at: < https://www.cbd.int/doc/world/mv/mv-nbsap-v2-en.pdf> Access on: 05/22/2018.

MALDIVES. **Sixth National Report on the Convention on Biological Diversity**, 2019. Available at:https://chm.cbd.int/database/record?documentID=247054. Access on 12/23/2020.

Mongolia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated tradition-

1. The information hereinafter has been updated until November 9th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

al knowledge in the country. However, the Environmental Protection Law of Mongolia of March 30, 1995, as amended on November 18, 2005, establishes that in reference to environmental protection, the central state administrative body responsible for matters of nature and environment shall have the right in plenary to provide citizens, business entities and organizations with environmental information to support the fair sharing of benefits arising from the use of traditional knowledge, new discoveries and daily practices for the sustainable use of biological or genetic resources.

Also, the Interim National Report on the Implementation of the Nagoya Protocol (2017) states that a draft law on ABS has been under development under the Ministry of Environment and Tourism.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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Director
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6. Websites

ABSCH Mongolia Profile
https://absch.cbd.int/countries/MN

CBD Mongolia Profile
https://www.cbd.int/countries/?country=mn

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, ABSCH. Country profile. Mongolia. Available in: <https://absch.cbd.int/countries/MN>. Access on: 11/09/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, CBD. Country profile. Mongolia. Available in: <https://www.cbd.int/countries/?country=mn> Access on: 11/09/2020.

MONGOLIA. **Convention on Biological Diversity: The 5th National Report of Mongolia**. Ministry of Environment and Green Development; Steppe Forward Programme, Biology Department, National University of Mongolia – NUM. Ulaanbaatar, 2014. Available in: https://www.cbd.int/countries/?country=md Access on 11/09/2020.

MONGOLIA. Interim National Report on the Implementation of the Nagoya Protocol. Ministry of Environment and Tourism. 2017. Available in: Access on 11/09/2020.

MONGOLIA. **National Biodiversity Program (2015-2025)**. Cabinet Secretariat of the Government of Mongolia; Ministry Of Environment, Green Development And Tourism; and WWF Mongolia. 2015. Available in: https://www.cbd.int/countries/?country=md Access on 11/09/2020.

Myanmar[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since February 23rd,1995.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The country has been a part of an ABS Project funded by the

1. The information hereinafter has been updated until October 18th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Global Environment Facility (GEF) in order to implement the Nagoya Protocol, which includes the elaboration of a legal framework in the subject. At the time of this study, no specific legislation on the matter was found.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Country Profile
https://absch.cbd.int/countries/MM

CBD Country Profile
https://www.cbd.int/countries/nfp/?country=mm

Myanmar Clearing House Mechanism
http://www.myanmarchm.gov.mm/en_US/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, ABSCH. Country profile. Myanmar. Available in: <https://absch.cbd.int/countries/MM>. Access on: 10/17/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Myanmar. Available in: <https://www.cbd.int/countries/nfp/?country=mm> Access on: 10/17/2020.

REPUBLIC OF THE UNION OF MYANMAR. **Fifth National Report to the Convention on Biological Diversity**. Ministry of Environmental Conservation and Forestry. Nay Pyi Taw, 2014. Available in: https://www.cbd.int/countries/?country=mm Access on 10/17/2020.

REPUBLIC OF THE UNION OF MYANMAR. **National Biodiversity Strategy and Action Plan 2015-2020**. Ministry of Environmental Conservation and Forestry; Forest Department. 2015. Available in: https://www.cbd.int/countries/?country=mm Access on 10/17/2020.

Nepal[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since February 21, 1994.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since March 28, 2019.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until October 19th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Article 51 g (1) of the Constitution of Nepal states that the sustainable use of natural resources and the equitable distribution of benefits shall be pursued by environmental policies in the country. However, according to the Sixth National Report on the Convention on Biological Diversity (2019), the country is in the process of making a new law to regulate access and benefit sharing. As per the referred report, the draft law, named Access to Genetic Resources and Benefit Sharing Bill, covers access to genetic resources, traditional knowledge, institutional mechanisms and benefit sharing process. However, until the moment of this study, no evidence of the promulgation of the draft law was found.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or

public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol

Nagoya Protocol on Access and Benefit-sharing

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Chief, Environment and Biodiversity Division
Ministry of Forests and Envionment
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6. Websites

ABSCH Nepal Profile
https://absch.cbd.int/countries/NP

CBD Nepal Profile
https://www.cbd.int/countries/?country=np

Ministry of Forests and Environment
http://www.mope.gov.np/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, ABSCH. Country profile. Nepal. Available in: <https://absch.cbd.int/countries/NP>. Access in: 10/17/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, CBD. Country profile. Nepal. Available in: <https://www.cbd.int/countries/nfp/?country=np> Access in: 10/17/2020.

ICIMOD. **Access and Benefit Sharing from Genetic Resources**, 2008. Available at: < http://www.icimod.org/?q=2236> Access in: September 28, 2020.

ICIMOD. **Access and Benefit Sharing Between Nepal and India**, February 26 of 2016. Available at: <http://www.icimod.org/?q=21598> Access in: September 28, 2020.

NEPAL. Constitution of Nepal. 2015. Available at: https://www.constituteproject.org/constitution/Nepal_2015.pdf. Access in: 10/20/2020.

NEPAL; Ministry of Forests and Soil Conservation. **Fifth National Report on the Convention on Biological Diversity,** 2014. Available at: <https://www.cbd.int/doc/world/np/np-nr-05-en.pdf> Access in:September 28, 2020.

NEPAL. **Sixth National Report to the Convention on Biological Diversity**. Ministry of Forest and Environment 2019. Available in: https://chm.cbd.int/database/record?documentID=241425 Access on 10/17/2020.

North Korea[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by approval, since January 24th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since December 30th, 2019.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
According to the Fifth National Report on the Convention on Biological Diversity, protection of traditional knowledge associated with genetic resources is addressed in the Patent Law, Inven-

1. The information hereinafter has been updated until October 27th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

tion Law and Agriculture Law. However, no specific provisions on the subject were found in the referred laws.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9. Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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National Coordinating Committee for Environment
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6. Websites

ABSCH North Korea Profile
https://absch.cbd.int/countries/KP

CBD North Korea Profile
https://www.cbd.int/countries/?country=kp

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, ABSCH. Country profile. Democratic People's Republic of Korea. Available in: <https://absch.cbd.int/countries/KP>. Access on: 10/27/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, CBD. Country profile. Democratic People's Republic of Korea. Available in: <https://www.cbd.int/countries/nfp/?country=kp> Access on: 10/27/2020.

DPR KOREA. **5th National Report on Biodiversity of DPR Korea**. Available at: <https://www.cbd.int/doc/world/kp/kp-nr-05-en.pdf> Access on: 4/22/2020.

DPR KOREA. **Invention Law**, 11 de março de 1999. Available at : <http://www.wipo.int/wipolex/en/text.jsp?file_id=228072> Access on: 4/22/2020.

DPR KOREA. **Copyright Law**, February 1st 2006. Available at: < http://www.wipo.int/wipolex/en/text.jsp?file_id=226324> Access on: 4/22/2020.

Oman[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since May 9th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since September 21st, 2020.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated tradition-

1.The information hereinafter has been updated until November 6th. 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

al knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Oman Profile
https://absch.cbd.int/countries/OM

CDB Oman Profile
https://www.cbd.int/countries/?country=om

6. Websites

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Oman profile. Available at: https://absch.cbd.int/countries/OM> Access on 11/06/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Oman profile. Available at: https://www.cbd.int/countries/?country=om> Access on 11/06/2020.

GOVERNMENT OF OMAN. Fifth National Report Of Oman: Convention on Biological. Available at: https://chm.cbd.int/database/record?documentID=204829. Access on 11/06/2020.

GOVERNMENT OF OMAN. Royal Decree No. 114/2001 issuing the Law on Conservation of

the Environment and Preservation of Pollution. Available at: http://www.vertic.org/media/National%20Legislation/Oman/OM_Law_Conservation_Environment_114-2001.pdf. Access on 11/06/2020.

GOVERNMENT OF OMAN. National Biodiversity Strategy and Action Plan. Ministry of Regional Municipalities, Environment and Water Resources. Available at: https://chm.cbd.int/database/record?documentID=201633. Access on 11/06/2020.

Pakistan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since October 24th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since February 21st, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the Sixth National Report to the Con-

1. The information here has been updated until October 20 of 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

vention on Biological Diversity, the country already has a draft ABS legislation, which encompasses access to genetic resources and their derivatives, traditional knowledge and equitable sharing of benefits. The draft law was not identified by this research.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, one emblematic case related to biopiracy was the patent of the Basmati rice by a US company in 1997, which conferred the company several rights including the exclusive use of the term “Basmati”. The Basmati rice originates from Pakistan and India and constitutes an import-

ant resource to those countries. After the Indian Government formally challenged the patent, the company which patented the Basmati rice voluntarily withdrew it.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Naeem Ashraf Raja
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Biodiversity Directorate
Ministry of Climate Change
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6. Websites

ABSCH Country Profile
https://absch.cbd.int/countries/PK

CBD Country Profile
:https://www.cbd.int/countries/?country=pk

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Pakistan. Available in: < https://absch.cbd.int/countries/PK>. Access on: 11/06/2019.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Pakistan. Available in: <https://www.cbd.int/countries/?country=pk> Access on: 11/06/2019.

GOVERNMENT OF PAKISTAN. **Biodiversity Action Plan Pakistan**. IUCN/WWF. World Bank/ GEF. 1999. Available in: https://www.cbd.int/countries/?country=pk Access on 11/06/2019.

GOVERNMENT OF PAKISTAN. **Fifth National Report: Progress on CBD Strategic Plan 2010-2020 and Aichi Biodiversity Targets**. Climate Change Division. 2014. Available in: https://www.cbd.int/countries/?country=pk Access on 11/06/2019.

GOVERNMENT OF PAKISTAN. **Sixth National Report to the United Nations Convention on Biological Diversity. Ministry of Climate Change. 2019**. Available on: https://www.cbd.int/doc/nr/nr-06/pk-nr-06-en.pdf. Access on 10/20/2020.

Palestine[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since April 2nd, 2015.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until October 28th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH State of Palestine Profile
https://absch.cbd.int/countries/PS

CBD State of Palestine Profile
https://www.cbd.int/countries/?country=ps

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. State of Palestine profile. Available in: https://absch.cbd.int/countries/PS Access on 10/29/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. State of Palestine profile. Available in: https://www.cbd.int/countries/?country=ps Access on 10/29/2020.

STATE OF PALESTINE. **Fifth National Report to The Convention On Biological Diversity**, 2015. Available at:< https://www.cbd.int/doc/world/ps/ps-nr-05-en.pdf> Access on: 05/11/2018.

Philippines[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since January 6th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since December 28th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the country already has the following laws regarding access and benefit-sharing:

1. The information hereinafter has been updated until December 22nd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Joint Administrative Order No. 1, de 2005: Guidelines for Bioprospecting Activities in the Philippines;

- Implementing Rules and Regulations of Republic Act No. 10055 (Joint Administrative Order No. 02-2010);

- Executive Order No. 247 of May 18, 1995, prescribing Guidelines and establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes; and for other Purposes;

- Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources, Department Administrative Order No. 96-20

- The Indigenous Peoples Rights Act of 1997 (Republic Act No. 8371): recognizes, protects and promotes the rights of indigenous communities, creating a national commission of indigenous people, establishing mechanisms for execution, fund raising, and others.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Executive Order nº 247, of May 18, 1995, identifies the following institutions as competent:

- **Department of Environment and Natural Resources (DENR)**

In its preamble, the law indicates that this is the main governmental body responsible for the conservation, management, development and sustainable use of the environment and natural resources in the country.

- **Inter-Agency Committee on Biological and Genetic Resources**

It is the regulatory body that has the functions of guarantee for the legal compliance, deliberate about requirements of the Research Agreement and recommend for the approval of the responsible body.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Joint DENR-DA-PCSD-NCIP Administrative Order No. 1, of 2005, determines that in order to carry out bioprospecting in the country, the user must obtain a prior authorization, which is named Bioprospection Undertaken. This document is granted by the competent authority through a requirement of the user that has to present a certificate of prior and informed consent and Research Agreement, which are described below:

- **Prior and Informed Consent**

The user of genetic resource must obtain prior and informed consent from the providers of the involved resources, in accordance with the provisions of Chapter V of the law, including the Indigenous People, the Protected Areas Management Counsel, the Local Government Unit, the particulars and other bodies that might have special jurisdiction over specific areas, according to existing laws. The procedures are, as follows:

1. Notification: the user must notify the provider of the genetic resource through an Intention Letter, indicating its intention to conduct bioprospecting inside the limits of its particular area. The Intention Letter must be sent with a copy of the research project, which must con-

tain the complete description of the activities to be carried out.

2. Consultation: the user must require the holders of the genetic resource to hold a community assembly. Before the assembly, enough copies of the research project must be provided to the community, in a language that is known to them.

3. Grant of a Consentient Certificate: the certificate will be signed by the President of the Protected Area Management Board (PAMB) or Punong Barangay, only upon authority granted through an appropriate Resolution, which must be passed within 30 days after the assembly consultation that has a favorable answer.

- **Research Agreement**

The Executive Order nº 247 determines, in its sections 3 and 4, that the researches with genetic resources must be made through the submission of a Research Agreement, which must contain the following information: the research objective, the funding source, duration of time, the biological and genetic materials used, as well as the quantity.

The Research Agreement must be adequate in accordance with the purpose of the research. Thus, if the research is academic, the applicant must present an Academic Research Agreement, and if the research has commercial purposes, the applicant must present a Commercial Research Agreement.

It falls within the scope of academic research, universities and Philippine academic institutions duly recognized, in addition to governmental agencies in the country. As for the commercial research, it includes natural persons and corporations, including international and foreigners institutions.

The proposed research model can be found attached to the Department Administrative Order No. 96-20.

Moreover, every document necessary to the concession of authorization are delivered to the user through a request to any of the competent agencies indicated in section 7 of this Law. Therefore, once the user has this information, it must present a form and further mandatory documents, plus payment of $500 pesos (equivalent to approximately $10 dollars) to the Protected Areas and Wildlife Bureau (PAWB), Palawan Council for Sustainable Development (PCSD) and/or Bureau of Fisheries and Aquatic Resources (BFAR), which will issue the BU within 30 days.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were found. Nevertheless, the Department Administrative Order No. 96-20 determines, in its section 5, that the access to Associated Traditional Knowledge can only be made through prior and informed consent, which must follow the procedures for access to genetic resources, as described in item 2.3.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

According to Section 5 of Joint DENR-DA-PCSD-NCIP Administrative Order No. 1, of 2005, the relevant applications for intellectual property rights shall mention the country of origin of the biological resource used. Also, the Joint IPOPHL-NCIP Administrative Order No. 01, 2016 (Rules and Regulations on Intellectual Property Rights Application and Registration Protecting the Indigenous Knowledge Systems and Practices of the Indigenous Peoples and Indigenous Cultural Communities) aims to provide a harmonized rules and regulations of the Intellectual Property Office of the Philippines (IPOPHL) and the National Commission on Indigenous Peoples (NCIP) to protect the intellectual creations including the Indigenous Knowledge Systems and Practices (IKSP), which includes the knowledge associated with genetic resources of the indigenous peoples and indigenous cultural communities.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis. However, Section 2 of the Joint DENR-DA-PCSD-NCIP Administrative Order No. 1, de 2005 states that exotic species are included in the scope of the legislation. However, no specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis. Nevertheless, the Joint DENR-DA-PCSD-NCIP Administrative Order No. 1, of 2005, establishes in its section 4 the objectives of the law, which includes creating an effective model of Material Transfer Agreement (MTA), which is provided in Annex II of the referred legislation. According to the document of Annex II, the MTA is part of the Bioprospection Undertaken, in other words, it must be required and granted with the BU. However, the legislation does not detail any further procedures for the shipment of samples.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
Yes, benefit sharing is mandatory and it incides over the utilization of biological resources for

bioprospecting purposes. The responsibility to share the benefits lies on the user.

3.2 Are there any specific procedures, rules and values?
(X) YES / ( ) NO / NOT AVAILABLE
The Joint DENR-DA-PCSD-NCIP Administrative Order No. 1, of 2005, foresees, in its section 14, guidelines for the benefit sharing, which are: the providers must designate representatives, which will have the power of decision in the benefit sharing negotiations with the users. If there is more than one group of providers, which group will have its own representative, and the negotiation can be individual or collective. Moreover, the legislation also foresees that the payment of the benefit sharing must be shared in the following manner:

The Bioprospecting Fee: with a minimum value of US$3.000,00 per BU and, not exceeding three times this value, the bioprospecting fee must be paid to the Philippine State, through the DENR, DA or PCSD.

Upfront payments: with a value of $1.000,00 per collection, upfront payments must be made to the providers. These payments are considered as advance royalties.

Royalties: with a minimum value of 2% of the gross revenue of the sales of the product made from genetic material, the royalties must be paid annually to the Philippine State, which will receive 25% of the value, and the providers, which will receive the remaining earnings, as long as the product continues to be marketed.

Moreover, in its section 17, the law indicates non-monetary modalities of benefit sharing: equipment for monitoring biodiversity, equipment and provender for conservation activities, technology transfer, professional training, infrastructure for management of conservation areas, health programs, and other forms of support to conservation of biodiversity.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Fees, Upfront Payments, Royalties	Fee: US$3.000,00 per Bioprospecting Undertaken; Upfront Payment:$1.000,00 per collection; Royalties:2% of the gross revenue of the sales of the product	Genetic Heritage/ ATK	Fees to government; Upfront Payment to providers; Royalties shared 25% to government and 75% to providers

Non Monetary	Not defined	Equipment for monitoring biodiversity, equipment and provender for conservation activities, technology transfer, professional training, infrastructure for management of conservation areas, health programs, and other forms of support to conservation of biodiversity.	Not defined	Genetic Heritage/ ATK	Government/ Provider

4. Sanctions

4.1 Is there an official inspection body?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Executive Order nº 247 of May 18, 1995, determines in its section 8, that The Protected Areas and Wildlife Bureau is the main responsible body for monitoring the compliance of the terms set out in the Research Agreement. In addition, the Executive Order nº 247 indicates in its section 7, that the Inter-Agency Committee on Biological and Genetic Resources has the duty to guarantee legal compliance.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Joint DENR-DA-PCSD-NCIP Administrative Order No. 1, of 2005, foresees that the irregular access will result in the automatic cancellation or revocation of the agreement between the parties. Moreover, in 2010, the Supreme Court of Philippines, approved the Rules of Procedures for Environmental Cases, a set of rules that cover civil and criminal cases that involve the environment and violation of environmental laws. However, there are no specific legal provisions on irregular access. Therefore, unlawful acts are judged by common laws, and the sanctions are provided for in laws of pecuniary order, administrative sanctions and even the possibility of prison sentence. In the case of a fine, there is no indication of values in the law.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, one emblematic case related to biopiracy was the development of a painkiller derived from

the Philippine sea snail by a US company. Another case relates to the patent by a US company of a medicine for diabetes derived from Talong and Ampalaya.

5. Summary - Competent authorities

Authority	Competence
Department of Environment and Natural Resources	Responsible for the access to genetic heritage in the Republic of Philippines.
Inter-Agency Committee on Biological and Genetic Resources	It is the regulatory body that has the functions of guarantee for the legal compliance, deliberate about requirements of the Research Agreement and recommend for the approval of the responsible body.

6. Websites

National Clearing-house Mechanism
http://www.chm.ph/

Department of Environment and Natural Resources
http://www.denr.gov.ph/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Philippines profile.Available at: https://absch.cbd.int/countries/PH Access on 12/22/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Philippines profile. Available at: https://www.cbd.int/countries/?country=ph Access on 12/22/2021.

BENGWAYAN, Michael. Companies Rush to Patent Wildlife of The Philippines. Eurasia Review. March 5, 2019. Available at: <https://www.eurasiareview.com/05032019-companies-rush-to-patent-wildlife-of-the-philippines-oped/>. Access on 28/07/2020.

REPUBLIC OF THE PHILIPPINES. Executive Order No. 247 of May 18, 1995, prescribing Guidelines and establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes; and for other Purposes. Available at: http://www.wipo.int/wipolex/en/text.jsp?file_id=225249 Access on 12/22/2021.

REPUBLIC OF THE PHILIPPINES. Implementing Rules and Regulations of Republic Act No. 10055 (Joint Administrative Order No. 02-2010). Available at: http://www.wipo.int/wipolex/en/text.jsp?file_id=225395 Access in 12/22/2021.

REPUBLIC OF THE PHILIPPINES. Joint DENR-DA-PCSD-NCIP Administrative Order No. 01, Series of 2005, Guidelines for Bioprospecting Activities in the Philippines. Available at: http://www.wipo.int/wipolex/en/text.jsp?file_id=414693 Access on 12/22/2021.

REPUBLIC OF THE PHILIPPINES. Philippine Biodiversity Strategy and Action Plan 2015-2028. Department of Environment and Natural Resources (DENR); Biodiversity Management Bureau. Available at: https://www.cbd.int/countries/?country=ph Access on 12/22/2021.

REPUBLIC OF THE PHILIPPINES. Philippine Biodiversity Strategy and Action Plan 2015-2028. Executive Order No. 247 of May 18, 1995, prescribing Guidelines and establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-Products and Derivatives, for Scientific and Commercial Purposes; and for other Purposes. Available at: http://www.wipo.int/wipolex/en/text.jsp?file_id=225249 Access on 12/22/2021.

REPUBLIC OF THE PHILIPPINES. The Fifth National Report To The Convention On Biological Diversity Republic Of The Philippines 2014. Department of Environment and Natural Resources Biodiversity Management Bureau (formerly Protected Areas and Wildlife Bureau); and Ateneo School of Government. Available at: https://www.cbd.int/countries/?country=ph Access on 12/22/2021.

REPUBLIC OF THE PHILIPPINES. Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources, Administrative Order No. 96-20. Available at: http://www.wipo.int/wipolex/en/text.jsp?file_id=179607 Access on 12/22/2021.

Qatar[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since November 19, 1996.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since January 25, 2019.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
(X) YES / ( ) NO
Yes. According to the ABSCH website, the Agricultural Research Department - Genetic Resources Department is the officially indicated checkpoint.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
(X) YES / ( ) NO
Yes. The Ministry of Municipality and Environment is the recognized checkpoint communiqué.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated tradition-

1. The information hereinafter has been updated until December 17th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

al knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The website of ABSCH, identifies the Ministry of Municipality and Environment as the competent institution, which is responsible for all genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresees species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Municipality and Environment	According to the website of ABSCH, the Ministry of Municipality and Environment has the competence about all cases with use of genetic resources or access to genetic resources.

6. Websites

ABSCH Qatar Profile
https://absch.cbd.int/countries/QA

CBD Qatar Profile
www.cbd.int/countries/?country=qa

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Qatar. Available in: <https://absch.cbd.int/countries/QA>. Access on: September 26, 2019.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Qatar. Available in: <https://www.cbd.int/countries/?country=qa> Access in: September 26, 2019.

MINISTRY OF MUNICIPALITY AND ENVIRONMENT, Mme. Página inicial. Available in: <http://www.mme.gov.qa/cui/index.dox?siteID=2> Access on: September 26, 2019.

STATE OF QATAR. **Protected Area Action Plan 2008-2013**. Supreme Council for Environment and Natural Reserves (SCENR). Department of Wildlife Conservation. Doha, 2007. Available on: https://www.cbd.int/countries/?country=qa Access on September 26, 2019.

STATE OF QATAR. **Qatar National Biodiversity Strategy and Action Plan 2015-2025**. Ministry of Environment, 2014. Available in: https://www.cbd.int/countries/?country=qa Access on September 26, 2019

Saudi Arabia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since January 1st, 2002.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
(X) YES / ( ) NO
Yes. According to the ABSCH website, the Agricultural Research Department - Genetic Resources Department is the officially indicated checkpoint.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The official document "The National Strategy for Conservation of Biodiversity in the Kingdom of Saudi Arabia (2005)", indicates in its chapter four that Saudi Arabia has a strategy to regu-

1. The information hereinafter has been updated until March 23, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

late the access and benefit sharing in the country. However, the country's last official reports to the CBD are only available in Arabic and therefore could not be analysed by this study. Furthermore, according to the National Report of Parties On the Implementation of the Convention on the Conservation of Migratory Species of Wild Animals, the country has developed a draft of a National Strategy on Access and Benefit- sharing in Relation to Genetic Resources. The document, nonetheless, could not be found in its entirety. Thus, until the present moment, no legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge. However, The official document The National Strategy for Conservation of Biodiversity in the Kingdom of Saudi Arabia (2005) identifies the following institutions as competent to legislate and elaborate public policies on the matter:

- The National Committee on Biodiversity,
- The Ministry of Agriculture,
- The National Commission for Wildlife Conservation and Development,
- The National Committee for Biological Diversity,
- King Abdulaziz City for Science and Technology,
- Ministry of Commerce and Industry, Food and Medicine Commission,
- Ministry of Defense and Aviation (Military Survey),
- Ministry of Higher Education (Saudi Universities).

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has National Focal Points recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Yousef S. Al-Hafedh
Chairman, National Committee on Biosafety, Director, Center of Excellence for Wildlife Research
King Abdulaziz City for Science and Technology
P.O. Box 6086
1144
Riyadh
Saudi Arabia

ABS National Focal Point
+966 14 81 36 04
+966 14 81 38 11
yhafedh@kacst.edu.sa

6. Websites

Saudi Wildlife Authority
https://www.swa.gov.sa/en/

ABSCH Saudi Arabia Profile
https://absch.cbd.int/countries/SA

CBD Saudi Arabia Profile
https://absch.cbd.int/countries/SA

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. SAUDI ARABIA. Available at: https://absch.cbd.int/countries/SA. Access on 03/26/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Venezuela profile. Available in: https://www.cbd.int/countries/?country=sa Access at: 03/26/2020.

GOVERNMENT OF SAUDI ARABIA. **Environmental Act**. Available at: http://extwprlegs1.fao.org/docs/pdf/sau138926.pdf. Access on 03/26/2020.

National Commission for Wildlife Conservation and Development of Saudi Arabia. **The National Strategy for Conservation of Biodiversity in the Kingdom of Saudi Arabia**. Available at: https://www.cbd.int/doc/world/sa/sa-nbsap-01-en.pdf. Access on 03/26/2020.

Singapore[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since March 20th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until January 4th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to the ABSCH website, the competent authority on matters related to biodiversity is the National Parks Board Singapore, which was founded by the National Parks Board Act (Chapter 19BA). According to article 6 of this Act, the National Parks Board Singapore is responsible for protecting and preserving the country's biodiversity within national parks. It is worth mentioning that this Law does not provide for specific regulations on access and benefit sharing.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the official website of the National Parks Board, any non-scientific research using genetic material in the country requires prior authorization. In this sense, the applicant must comply with the following procedures:

1. Access the Biodiversity and Environment Database System (https://biome.nparks.gov.sg) to register;

2. After creating the register, fill out the online form containing information from the person responsible for the research, the signature of all members, the species used and the place of access.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and

procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the

case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
National Parks Board Singapore	Control, administration and managing of the national parks; protect and preserve the country's biodiversity within national parks; provide and control installations suitable for study and researches with biodiversity in the country, as well as incentive and promote these studies and researches, among others.

6. Websites

ABSCH Singapore Profile
https://absch.cbd.int/countries/SG

CBD Singapore Profile
https://www.cbd.int/countries/?country=sg

Biodiversity and Environment Database System
https://biome.nparks.gov.sg/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Singapore profile. Available in: https://absch.cbd.int/countries/SG> Access on 10/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Singapore profile. Available in: https://www.cbd.int/countries/?country=sg> Access on 10/10/2020

ASEAN. The ASEAN Framework Agreement on Access to Biological and Genetic Resources, February 24 of 2000. Available at: <http://www.mabs.jp/countries/others/pdf/321e.pdf> Access on: 05/30/2018.

NATIONAL PARKS BOARD; BIOME. Research Permit Application User Guide, 2017. Available at: < https://www.nparks.gov.sg/-/media/nparks-real-content/biodiversity/resources-research-permit/research-permit-application-user-guidde.pdf> Access on: 05/30/2018.

MEDAGLIA, Jorge Cabrera; PERRON-WELCH, Frederic; PHILLIPS, Freedom-Kai. **Overview of national and regional measures on access and benefit sharing: Challenges and opportunities in implementing the Nagoya Protocol**. CISDL Biodiversity & Biosafety Law Research Programme, 3 ed., 2014. Available at: <https://www.absfocalpoint.nl/upload_mm/5/f/4/008c9cc8-19f3-4926-b380-5f13fd1eb705_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf> Access in: 05/24/2018.

SINGAPORE. **5th National Report to the Convention on Biological Diversity**, 2015. Available at: < https://www.cbd.int/doc/world/sg/sg-nr-05-en.pdf> Access on: 05/30/2018.

SINGAPORE. **National Parks Board Act (Chapter 198A)**, of July 1st of 1996. Available at: < http://extwprlegs1.fao.org/docs/pdf/sin88112.pdf> Access on: 11/21/2018.

South Korea[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since January 1st, 1995.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by ratification, since August 17th, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
(X) YES / ( ) NO
Yes. The country has the following checkpoints:

- **Ministry of Environment**

The Ministry of Environment has jurisdiction over biological resources in the field of wildlife in accordance with the Wildlife Protection and Management Act and biological resources in accordance with the Act on the Conservation and Use of Biological Diversity.

- **Ministry of Science, Information and Communications Technology**

The Ministry of Science, Information and Communications Technology has jurisdiction over biological research resources pursuant to the Act on the Acquisition, Management, and Utilization of Biological Research Resources.

- **Ministry of Agriculture, Food and Rural Affairs**

The Ministry of Agriculture, Food and Rural Affairs has jurisdiction over agricultural bio-resources pursuant to the Act on the Conservation, Management, and Use of Agricultural Bio-Resources.

- **Ministry of Health and Welfare**

The Ministry of Health and Welfare has jurisdiction over pathogen resources pursuant to the Act on the Promotion of Collection, Management and Utilization of Pathogen Resources.

- **Ministry of Oceans and Fisheries**

The Ministry of Oceans and Fisheries has jurisdiction over marine and fisheries bio-resources pursuant to the Act on Securing, Management, Use, etc. of Marine Biological Resources.

- **Ministry of Trade, Industry and Energy**

1. The information hereinafter has been updated until October, 1st, 2019.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

The Ministry of Trade, Industry and Energy has jurisdiction over

According to the Guide on Act on Access to and Utilization of Genetic Resources and Benefit-Sharing in the Republic of South Korea, the referred National Checkpoints address procedural compliance that include investigation, recommendations and review of the compliance reports and relevant matters.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
(X) YES / ( ) NO
Yes, there are 36 IRCC reported on the ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the country already has the following laws regarding access and benefit-sharing:

- Act on the Conservation and Use of Biological Diversity (2012)
- The Act on Access to and Utilization of Genetic Resources and Benefit-Sharing (2017)
- Enforcement Decree of the Act of Access to and Utilization of Genetic Resources and Benefit-Sharing (2018)
- Enforcement Rule of the Act of Access to and Utilization of Genetic Resources and Benefit-Sharing (2018)
- Public Notice on Exemptions from Reporting Access to Domestic Genetic Resource(s), No. 2018-149 (2018)

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The country has the following competent institutions regarding access and benefit sharing:

- Ministry of Environment
- Ministry of Science, Information and Communications Technology

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Ministry of Agriculture, Food and Rural Affairs
- Ministry of Health and Welfare
- Ministry of Oceans and Fisheries

Each Competent Authority has jurisdiction over its fields of knowledge, which coincides with the National Focal Points'. Also, according to the Article 8 (2) of the referred Act and Article 3 of the referred Enforcement Decree, each Competent Authority shall process reports and reports on changes; prohibit or restrict access to and utilization of domestic genetic resource(s); support the fair and equitable sharing of benefits arising from domestic genetic resource(s); investigate and manage the status of utilization of domestic genetic resource(s); and investigate and manage benefit sharing and mutually agreed terms.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No. The current legislation does not foresee the need for prior authorization in order to obtain genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No. The current legislation does not provide specific procedures for access to Associated Traditional Knowledge. The concept of "access" in the legislation includes both genetic resources and associated traditional knowledge, as stated on Article 2(3) of the Act on Access to and Utilization of Genetic Resources and Benefit-Sharing: "the term 'access' means acquiring specimen or substance of a genetic resource; or collecting genetic resources and information regarding traditional knowledge associated with genetic resources (hereinafter referred to as 'genetic resource(s)')".

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No. The Act on Access to and Utilization of Genetic Resources and Benefit-Sharing does not provide specific procedures for requesting patents arising from research or technological development involving the access. Also, the referred Law does not apply to genetic resource(s) granted rights.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No, the legislation that addresses Access and Benefit-Sharing does not provide procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The shipment of samples is covered by the Act on The Conservation and Use of Biological Diversity, of 2012 (amended by Act No. 12459, Mar. 18, 2014), article 11; but the legal instrument only regulates the shipment of biological resources understood to require a high level of

protection. The shipment of such materials requires official authorization.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE
No, the legislation that addresses Access and Benefit-Sharing does not provide procedures for digital sequence information or synthetic biology.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No, the legislation that addresses Access and Benefit-Sharing does not foresee species that have naturally developed their distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / ( )NOT AVAILABLE
Yes, Benefit-Sharing is mandatory. The responsibility to share the benefits lies with the person who intends to access the genetic resources, who must present information concerning the method of Benefit-Sharing

3.2 Are there any specific procedures, rules and values?
( ) YES / ( ) NO / (X) NOT AVAILABLE
The legislation available only states that providers and users of genetic resource(s) shall agree to share the benefits of domestic genetic resource(s) fairly and equitably.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Both the National Focal Points and Competent Authorities are responsible for monitoring the compliance with the legislation. However, no records of fines have been found by this research.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Act on Access to and utilization of Genetic Resources and Benefit-Sharing establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules. The applicable fine for failing to file reports may vary from 5 million won (approximately 4,169.10 US dollars) to 10 million won (approximately 8,312.80 US dollars).

If there is access or utilization of genetic resources which are under prohibition or restriction, the sanction applicable is imprisonment with labor for up to 3 years or fine under 30 million won, which is equivalent to approximately 25,016.55 US dollars. Also, the genetic resource shall be confiscated, and if not possible, an amount equivalent to its price must be paid.

As per item 2.1, the Act on The Conservation and Use of Biological Diversity, of 2012 (amended by Act No. 12459, Mar. 18, 2014), provides in its article 35 that any person who transports biological resources whose exportation require official authorization without obtaining such approval may be liable to imprisonment for no longer than 2 years or a fine not exceeding 20 million won.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of environment	Liaising with the secretariat of the Convention on Biological Diversity; Procedural activities regarding: Biological resources in the field of wildlife pursuant to the Wildlife Protection and management Act, and biological resources pursuant to the Act on the Conservation and use of Biological Diversity
Ministry of Science, Information and Communications Technology	Procedural activities regarding: Biological research resources pursuant to the Act on the Acquisition, Management, and Utilization of Biological Research Resources
Ministry of Agriculture, Food and Rural Affairs	Procedural activities regarding: Agricultural bio-resources pursuant to the Act on the Conservation, Management, and Use of Agricultural Bio-Resources
Ministry of Health and Welfare	Procedural activities regarding: Pathogen resources pursuant to the Act on the Promotion of Collection, Management and Utilization of Pathogen Resources

Ministry of Oceans and Fisheries	Procedural activities regarding: Marine and fisheries bio-resources pursuant to the Act on Securing, Management, Use, etc. of Marine Biological Resources

6. Websites

ABS Genetic Resources Information Center
https://www.abs.go.kr/absch-en/main.do

CBD-Clearing House Mechanism Korea
http://www.cbd-chm.go.kr/eng/main/main.do

Ministry of Environment
http://eng.me.go.kr/eng/web/main.do

7. References

ACCESS AND BENEFIT-SHARING CLEARING HOUSE - ABSCH. Country Profiles. Republic of Korea. Available in: https://absch.cbd.int/countries/KR. Access on: 01/10/2019.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Republic of Korea. Available in: https://www.cbd.int/countries/?country=kr. Access on: 01/10/2019.

Genetic Resources Information Center and Ministry of Environment. A Guide to Act on Access to and Utilization of Genetic Resources and Benefit-Sharing in the Republic of Korea. July, 2018.

REPUBLIC OF KOREA. Act on Conservation and Utilization of Biodiversity (Act No. 11257 of February 1, 2012, as amended up to Act No. 12459 of March 18, 2014). Available in: http://www.wipo.int/wipolex/en/details.jsp?id=15653 Access on 18/10/2016.

REPUBLIC OF KOREA. Korea's National Biodiversity Strategy 2014-2018. Ministry of Environment of the Republic of Korea. Sejong Special Self-Governing City, 2014. Available in: https://www.cbd.int/countries/?country=kr Access on 18/10/2016.

REPUBLIC OF KOREA. The Fifth National Report to the Convention on Biological Diversity. Ministry of Environment of the Republic of Korea. Sejong Special Self-Governing City, 2014 Available in: https://www.cbd.int/countries/?country=kr Access on 18/10/2016.

Sri Lanka[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since June 21st, 1994.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

In 2015, the Fifth National Report (2015) informed that no specific legislation on access to ge-

1. The information hereinafter has been updated until October 18th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

netic heritage and associated traditional knowledge was developed yet. The last report submitted on June 26th , 2019, the Sixth National Report, clarifies that:

- a National Policy on access to Biological Resources and Benefit Sharing and a commercial and non-commercial Material Transfer Agreements have been drafted by the Ministry of Mahaweli Development and Environment (MoMD&E)

- a National ABS Policy and Plant Breeders' Rights Act have been proposed

In this sense, the National Policy on Access to Biological Resources, Sustainable use and Benefit Sharing, available online establishes the principles and objectives of the country for access and benefit-sharing. Thus, it determines that future ABS standards should ensure, as a minimum, fair and equitable sharing of benefits, that the access will be made through prior and informed consent and mutually agreed terms, monitoring access to genetic heritage and associated traditional knowledge in the country, among others.

Also, the country has established the National Policy and Strategies on Traditional Knowledge and Practices related to Biodiversity. According to its article 7, benefits derived from the usage of traditional knowledge and practices should be shared in a fair and equitable manner, but there are no other provisions regarding ABS specifically.

Also, it is worth mentioning that the country has a Code of Ethics for Research on Biological Diversity, 2013, which includes provisions on access to genetic resources.

Lastly, Sri Lanka, in cooperation with WIPO, developed in 2009 the "A legal framework for the protection of traditional knowledge in Sri Lanka", which defines the legal scope for protection of traditional knowledge in the country. According to article 52, the provisions therein relating to the protection of traditional knowledge shall not be understood as a permit access to or use of associated biological resources.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. Although there is no specific legislation on access and benefit-sharing (ABS), the document "A legal framework for the protection of traditional knowledge in Sri Lanka" states in its Article 4 that the responsible for administering the provisions of this law is the General Director of Intellectual Property (Director) and the Minister responsible for matters relating to Intellectual Property shall advise the Director on the matter.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The draft of National Policy on Access to Biological Resources, Sustainable use and Benefit Sharing establishes that access to genetic heritage and traditional knowledge should be made subject to prior informed consent and the execution of Mutually Agreed Terms and the article 7 sets that the development of the adequate legal framework is a strategy for the policy implementation.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
The “Legal Framework for the Protection of Traditional Knowledge in Sri Lanka” states in article 16 that the access to Associated Traditional Knowledge can only be carried out with prior and informed consent of the providers of this knowledge. Here are other procedures provided by this law:

1. The access to associated traditional knowledge carried out by a foreign individual or institution must be done in collaboration with citizens of the country or national institutions that do not have the participation of foreigners.

2. The person who is naturalized from Sri Lanka or national institutions will be responsible for sending the form requesting access to the Director.

3. An access concession contract shall be signed with the National Government, represented by the Director, the provider and the user. The contract must contain, at least: name, address and other information of the user, description of the TK to be accessed, the benefits belonging to the holder of the TK, the amount to be paid to the Traditional Knowledge Fund, restrictions on the use of TK, among others.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country’s territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
Yes, although the ABS rules and benefit sharing mechanisms are yet to be settled. Nevertheless, The "Legal Framework for the Protection of Traditional Knowledge in Sri Lanka" establishes that benefit sharing is mandatory for access to traditional knowledge.

3.2 Are there any specific procedures, rules and values?
(X) YES / ( ) NO / NOT AVAILABLE
The "Legal Framework for the Protection of Traditional Knowledge in Sri Lanka" establishes in its article 20 that the contract for concession of access must have a benefit sharing clause, which cannot be less than 0,5% of the profits originated from the commercialization of products developed from access to traditional knowledge, and must be paid to the Traditional Knowledge Fund. In addition, article 21 of the same law provides that holders of Associated Traditional Knowledge shall have the right to non-monetary benefits, such as access to research results, among others.

Regarding the draft of the National Policy on Access to Biological Resources, Sustainable use and Benefit Sharing, article 7 establishes that a benefit sharing mechanism based on realistic guidelines will be developed to enable fair and equitable benefits from providing 'Access' to the country's biological material.

Ultimately, the article 7 of National Policy and Strategies on Traditional Knowledge and Practices related to Biodiversity sets that benefits derived from the usage of traditional knowledge and practices should be shared in a fair and equitable manner, but there are no other provisions regarding ABS specifically.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Deposit into a Fund	0,5% of the profits originated from the commercialization	Associated Traditional Knowledge	Community/ Government
Non Monetary	Not defined	-	-	-	-

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
The "A legal framework for the protection of traditional knowledge in Sri Lanka" establishes in its article 42, the sanctions applicable to any person who does not obey its legal provisions, which are: sentence of imprisonment and / or fine payment of up to 5 (five) million Rs.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, Sri Lanka has been reportedly a victim of biopiracy over the last years, with an increase due to the biotechnology progress. A emblematic case occurred in 1993 when 12 medicinal plants, such às Nutmeg (Sadikka), Masakka, Nigella sativa or Black Cumin (Kaluduru), Sida alnifolia (Heenbabila), Weniwalgata and Clove (Karabu Nati), etc were patented in Japan under the title of 'Preventive for dental caries'.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. A.H.S. Wijesinghe
Secretary
Ministry of Environment and Wildlife Resources
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biodiversitysl@gmail.com

6. Websites

ABSCH Sri Lanka Profile
https://absch.cbd.int/countries/LK

CBD Sri Lanka Profile
https://www.cbd.int/countries/?country=lk

Sri Lanka Biodiversity CHM
http://lk.chm-cbd.net/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles.Sri Lanka profile.
Available in: < https://absch.cbd.int/countries/LK> Access on 24/09/2020.

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MINISTRY OF ENVIRONMENT & WILDLIFE RESOURCES. National Policy on Access to Biological Material and Fair and Equitable Benefit Sharing. Available at: http://www.env.gov.lk/web/images/pdf/2020/abs%20policy%20english.pdf Accessd on Accessed on 10/18/2020.

MINISTRY OF ENVIRONMENT & WILDLIFE RESOURCES. Draft National Policy and Strategies on Traditional Knowledge and Practices related to Biodiversity. Available at: http://www.env.gov.lk/web/images/pdf/2020/tk%20policy%20english.pdf Accessed on 10/18/2020.

FERNANDOPULLE, Sheain. Sri Lanka affected by bio piracy menace: Repercussions of advances in biotechnology. Daily Mirror, December 6th, 2017. Available at: http://www.dailymirror.lk/News-Features/Sri-Lanka-affected-by-bio-piracy-menace/131-141649 Accessed on 10/18/2020.

SRI LANKA. Sixth National Report to the Convention on Biological Diversity, 2019. Available at: https://chm.cbd.int/database/record?documentID=246651 Accessed on 10/18/2020.

Syrian Arab Republic[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since April 3rd, 1996.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / ( ) NO / (X) NOT AVAILABLE
According to the bibliography consulted, the country has a norm on access and benefit sharing, namely Act No. 20 on the Protection and Exchange of Plant Genetic Resources (2003), but as it

1. The information hereinafter has been updated until October 24th, 2019.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

was only available in local language, it could not be analyzed by this study.

The literature states that the current legislation covers issues such as protection and facilitation of access to plant genetic resources, fair and equitable benefit sharing on the use of plant genetic resources, among other issues. However, Act No. 20 on the Protection and Exchange of Plant Genetic Resources (2003) regulates only access to plant genetic resources, and other issues, such as traditional knowledge, are not included.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / ( ) NO / (X) NOT AVAILABLE
The country profile on the ABSCH website indicates the following competent national authorities:

- Syrian Society for Conservation of Wildlife (SSCW): responsible for issues related to traditional uses of local communities related to biodiversity.
- Ministry of State for Environment Affairs (MOEN): responsible for all issues related to genetic resources.
- General Commission for Scientific Research in Agriculture (GCSAR): responsible for information on the genetic resources of the country's flora and fauna.
- Atomic Energy Commission (AEC): responsible for information on genetic resources of flora.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the legislation found is only available in local language, which is why it could not be analyzed by this study.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the legislation found is only available in local language, which is why it could not be analyzed by this study.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the legislation found is only available in local language, which is why it could not be analyzed by this study.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the legislation found is only available in local language, which is why it could not be analyzed by this study.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / ( ) NO / (X) NOT AVAILABLE

As mentioned in item 2.1, the legislation found is only available in local language, which is why it could not be analyzed by this study.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the legislation found is only available in local language, which is why it could not be analyzed by this study.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the legislation found is only available in local language, which is why it could not be analyzed by this study.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, the legislation found is only available in local language, which is why it could not be analyzed by this study.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, the legislation found is only available in local language, which is why it could not be analyzed by this study.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not available	Not available	Not available	Not available	Not available
Non Monetary	Not available	Not available	Not available	Not available	Not available

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / ( ) NO / (X) NOT AVAILABLE

As mentioned in item 2.1, the legislation found is only available in local language, which is why it could not be analyzed by this study.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the legislation found is only available in local language, which is why it could not be analyzed by this study.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / ( ) NO / (X) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry Of State for Environment Affairs (MOEN)	Responsible for all matters relating to genetic resources
Syrian Society for Conservation of Wildlife (SSCW)	Responsible for issues related to traditional uses of local communities related to biodiversity
General Commission for Scientific Agricultural Researches (GCSAR)	Responsible for information on genetic resources of the flora and fauna of the country.
Atomic Energy Commission (AEC)	Responsible for information on flora genetic resources.

6. Websites

ABSCH Syrian Arab Republic Profile
https://absch.cbd.int/countries/SY

CBD Syrian Arab Republic Profile
https://www.cbd.int/countries/?country=sy

ACCESS AND BENEFIT-SHARING CLEARING HOUSE - ABSCH. Country Profiles. Syrian Arab Republic. Available in: https://absch.cbd.int/countries/SY. Access on: 11/09/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Syrian Arab Republic. Available in: https://www.cbd.int/countries/?country=sy. Access on: 11/09/2020.

MEDAGLIA, Jorge Cabrera; PERRON-WELCH, Frederic; and PHILLIPS, Freedom-Kai. Overview Of National And Regional Measures On Access And Benefit Sharing: Challenges And Opportunities In Implementing The Nagoya Protocol. Third Ed. CISDL Biodiversity & Biosafety Law Research Programme. 125 pgs. Montreal, 2014. Available in: http://www.fkphillips.com/?page_id=39 Access on 08/11/2016.

SYRIAN ARAB REPUBLIC. Strategy and Action Plan - Syrian Arab Republic. Ministry of State for Environmental Affairs. Available in: https://www.cbd.int/countries/?country=sy Access on 08/11/2016.

SYRIAN ARAB REPUBLIC. The Fifth National Report to the Convention on Biological Diversity. Ministry of Local Administration and Environment. Available in: https://www.cbd.int/countries/?country=sy Access on 08/11/2016.

Tajikistan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since January 27th, 1998.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the Fifth National Report on Preservation of Biodi-

1. The information hereinafter has been updated until November 10th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

versity of the Republic of Tajikistan (2014), the Law "On Genetic Resources of Plants (August 1st, 2012, No. 892)" addresses collection, research and use of plant genetic resources, but it is not clear of whether it covers prior authorizations for the use of genetic resources or benefit sharing. As it is only available in the local language, it could not be analysed by this study. Also, according to the Sixth National Report for the Convention on Biological Diversity (2019), a draft law regarding access to genetic resources and equitable sharing of benefits has been under development in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The ABSCH website identifies the National Biodiversity and Biosafety Center as the competent institution, which is responsible for all genetic resources in the country.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally

developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access

to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
National Biodiversity and Biosafety Center	According to the ABSCH website, the National Biodiversity and Biosafety Center is responsible for all genetic resources.

6. Websites

ABSCH Tajikistan Profile
https://absch.cbd.int/countries/TJ

CBD Tajikistan Profile
https://www.cbd.int/countries/?country=tj

National Biodiversity and Biosafety Center
http://www.biodiv.tj/en/index

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Tajikistan. Available in: < https://absch.cbd.int/countries/TJ>. Access on: 11/10/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Tajikistan. Available in: <https://www.cbd.int/countries/?country=tj> Access on: 11/10/2020.

REPUBLIC OF TAJIKISTAN. **Fifth National Report On Preservation Of Biodiversity Of The Republic Of Tajikistan**. National Center on Biodiversity and Biosafety of the Republic of Tajikistan (NCBB). 2014. Available in: https://www.cbd.int/countries/?country=tj Access on 11/10/2020.

REPUBLIC OF TAJIKISTAN. **Interim National Report on the Implementation of the Nagoya Protocol.** National Center on Biodiversity and Biosafety of the Republic of Tajikistan (NCBB). 2019. Available in: https://absch.cbd.int/pdf/documents/absNationalReport/ABSCH-NR-TJ-246305/1 Access on 11/10/2020.

REPUBLIC OF TAJIKISTAN. **Sixth National Report for the Convention on Biological Diversity**. National Center on Biodiversity and Biosafety of the Republic of Tajikistan (NCBB). 2019. Available in: https://chm.cbd.int/database/record?documentID=247273 Access on 11/10/2020.
REPUBLIC OF TAJIKISTAN. National Strategy and Action Plan for Biodiversity Conservation Until 2020. Global Ecological Fund (GEF). 2016. Available in: https://www.cbd.int/countries/?country=tj Access on 11/10/2020.

REPUBLIC OF TAJIKISTAN. **Law No. 892 "On collection, conservation and rational management of genetic resources of cultivated plants"**. Available in: https://www.ecolex.org/details/legislation/law-no-892-on-collection-conservation-and-rational-management-of-genetic-resources-of-cultivated-plants-lex-faoc117782/?q=892&type=legislation&xcountry=Tajikistan&xdate_min=&xdate_max= Access on 11/10/2020.

Thailand[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since January 29th, 2004.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the legislation addressing ABS is the Regulations on Criteria and Procedures for Access to Biological Resources and Sharing of Benefits (2011), by the National Committee on the Conservation and Sustainable Use of Biodiversity's. However, it was not possible to analyze the document, once it is only available in the local language and an English version was not found

1. The information hereinafter has been updated until October 17th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

by the time of this study, thus prejudicing the conclusion of the present study.

Nevertheless, according to the Access and Benefit-Sharing report issued by Office of Natural Resources and Environmental Policy and Planning of Kingdom of Thailand in 2014, it is known that the law constitutes a framework for agencies to institute their own criteria and regulations on ABS which, by that time, 11 organizations reportedly had developed ABS regulations, such as the Department of National Parks, Wildlife and Plants and BIOTEC. Also, it is informed by the report that is mandatory for foreigners that are interested to conduct research, collect specimens and other genetic materials and /or access traditional knowledge in Thailand to comply with National Research Council of Thailand Regulation and seek for permission mentioned at Foreign Researchers to Conduct Research in Thailand B.E. 2550 (1982).

Also, other regulations regarding plant protection, traditional knowledge and patents are indicated as ABS related rules, such as:

- Plant Varieties Protection Act (1999);
- Protection and Promotion of Thai Traditional Medicinal Knowledge Act BE 2542 (1999);
- Patent Act (2017);
- Community Forest Act B.E. 2562 (2019);
- Wildlife Conservation and Protection of Act B.E. 2562 (2019);

Regulations on the Conservation and Utilization of Biodiversity by the Office of the Prime Minister's.

The last regulation mentioned above was not found for the purpose of this study.

Lastly, it is important to note that there are draft bills under discussion: the draft Biodiversity Act ("Draft BD Act") was open to public hearing until 4 May 2020, and the draft of the Patent Act amendment was approved by the Cabinet on 29 January 2019 but has not entered into force yet.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, the ABS legislation is only available in the local language and therefore it could not be analyzed by this study. However, according to The Access and Benefit-Sharing Clearing House website, the country has not established a Competent National Authority in reference to Article 13, paragraph 2 of Nagoya Protocol.

Regarding the ABS related rules:

- Ministry of Natural Resources and Environment, Office of Natural Resources and Environmental Policy and Planning: main actor responsible to coordinate biodiversity related issues with other actors and institutions.
- Department of Agriculture: competent authority established by Plant Varieties Protection Act (1999) for access to plant varieties described therein;

- Department for Development of Thai Traditional and Alternative Medicine: competent authority designed by Protection and Promotion of Thai Traditional Medicinal Knowledge Act BE 2542 (1999) for access activities described therein;

- Department of National Park, Wildlife and Plant Conservation: competent authority for access to genetic resources, biological resources and traditional knowledge in protected areas;

- National Center for Genetic Engineering and Biotechnology (BIOTEC): competent authority for research and development activities with biological materials in BIOTEC culture collection; and

- Provincial Community Forest Committee: competent authority to grant permission for access to community forests.

Also, local authorities may be consulted once agencies can institute their own criteria and regulations on ABS as stated in question 2.1 above.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, the ABS main legislation is only available in the local language and therefore it could not be analyzed by this study. However, it is known from the publication by the Office of Natural Resources and Environmental Policy and Planning that the authorization must be required for the state agency with jurisdiction over the biological resource involved and according to the ABS report issued by the Thai Government in 2014, all access activities in the country must comply with the procedures described below:

1. Application: The applicant shall submit a form as described by NCBD (National Committee on Conservation and Utilization of Biological Diversity) to the applicable government agency, which will analyze it within 90 days.

2. License: The applicable government agency shall issue the license document and notify the applicant.

3. Submission of project: The applicant shall submit the project plan within 30 days from the date of notification

4. ABS Agreement: The government agency may enter an ABS agreement with the licensee, for commercial or non-commercial purposes.

5. Monitoring and Control: The government agency shall monitor the access of the genetic resource and issue periodic reports.

Also, the Plant Varieties Protection Act BE 2542 (1999) requires an authorization for collection of plant varieties for development, education, experiment or research for commercial interest, which shall be made to the Department of Agriculture.

Regarding Thai Traditional Medicine and formulas, the Protection and Promotion of Thai Traditional Medical Knowledge Act BE 2542 (1999) states that production, research or development of drugs that involve traditional Thai drugs for commercial benefits are subject to

registration and permission. The same legislation provides that research and exportation of controlled herbs for commercial purposes depends on a license from the licensing authority.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned on question 2.3., the Protection and Promotion of Thai Traditional Medical Knowledge Act BE 2542 (1999) states that production, research or development of drugs that involve traditional Thai drugs for commercial benefits are subject to registration and permission. The same legislation provides that research and exportation of controlled herbs for commercial purposes depends on a license from the licensing authority.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Draft Amendment to the The Patent Act, issued in 2019, includes a section regarding ABS, in which the applicant must declare the source of origin of the genetic resource or traditional knowledge associated with the genetic resource. Also, the applicant must submit the request for authorization of access when applying for a patent. The draft states that those actions are subject to criminal punishment.

Also, the Protection and Promotion of Thai Traditional Medical Knowledge Act BE 2542 (1999) states that traditional Thai drugs may be registered for protection of intellectual property rights[5].

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the ABS legislation is only available in the local language and therefore it could not be analyzed by this study.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the ABS legislation is only available in the local language and therefore it could not be analyzed by this study.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the ABS legislation is only available in the local language and therefore it could not be analyzed by this study.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, the ABS legislation is only available in the local language and

5. UNCTAD. The Convention on Biodiversity and the Nagoya Protocol: Intellectual Property Implications, A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property. United Nations Publications, 2014. Annex I, p. 175.

therefore it could not be analyzed by this study.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

As mentioned in item 2.1, the ABS legislation is only available in the local language and therefore it could not be analyzed by this study. However, it is known that benefit-sharing it is mandatory as the following:

- the Plant Varieties Protection Act BE 2542 (1999) in Section 52, requires a benefit-sharing agreement for the situations provided in it;
- The Protection and Promotion of Thai Traditional Medical Knowledge Act BE 2542 (1999) establishes that the applicant shall "forward their application to obtain benefits", but there are no other specifications.

Considering that state agencies are responsible to create their own ABS rules, it is necessary to contact the local competent authority to seek for deeper information.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, the ABS Act establishes a framework for agencies to institute their own criteria and regulations on ABS, so there are no general procedures to be followed, as it will depend on the type of the resource involved in the access.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, the ABS legislation is only available in the local language and therefore it could not be analyzed by this study. Nevertheless, the Access and Benefit-Sharing report issued by Office of Natural Resources and Environmental Policy and Planning of Kingdom of Thailand in 2014, states that each Government agency which issues license documents related to ABS have the duty to inspect, monitor and control the activities of the licensee to

guarantee that the agreement has been strictly followed. Reports of the results of access activities are mandatory.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Section 88 of the Community Forest Act (2019) establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: In case a biological resource leaves community forests without a permission or notification, the offender shall be liable to an administrative fine not exceeding three hundred thousand baht (approximately 8.867,87 US dollars) or, if the use of biological resources for research purposes are used for commercial benefits, the offender shall be liable to an administrative fine not exceeding six hundred thousand baht (approximately 17.735,74 US dollars).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, there are several records of Biopiracy in Thailand. One of them was related to Jasmine Rice, in which a USA company claimed intellectual property in 1998. In response, Thailand Deputy Agriculture Minister launched a protest at the World Trade Organization[6]. Other case of biopiracy in Thailand was the US patenting of a protein of the Thai bitter gourd, found to be useful against HIV infection[7].

5. Summary - Competent authorities

Authority	Competence
Ministry of Natural Resources and Environment Office of Natural Resources and Environmental Policy and Planning	Main actor responsible to coordinate biodiversity related issues with other actors and institutions.
Department of Agriculture	Competent authority established by Plant Varieties Protection Act (1999) for access to plant varieties described therein, such as general domestic plant varieties, wild plant varieties or any part of such plant varieties, for the purpose of variety development, education, experiment or research for commercial interest, a study, an experiment or research of or into a general for a non-commercial.

6. p. 19.
7. KHOR, Martin. Why we must fight biopiracy. Sci Dev Net. 23/08/02. Available in: <https://bit.ly/37fqEMR>. Access in: 21/01/2020.

Department for Development of Thai Traditional and Alternative Medicine	Competent authority designed by Protection and Promotion of Thai Traditional Medicinal Knowledge Act BE 2542 (1999) or access to national recipe of Thai traditional medicine and other activities described therein;
Department of National Park, Wildlife and Plant Conservation	Responsible for access to genetic resources, biological resources and traditional knowledge in protected areas.
National Center for Genetic Engineering and Biotechnology (BIOTEC)	Responsible for research and development activities with biological materials in BIOTEC culture collection.
Provincial Community Forest Committee	competent authority to grant permission for access to community forests
Local authorities	Local authorities may be consulted once agencies can institute their own criteria and regulations on ABS as stated in question 2.1 above.

6. Websites

No websites concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

7. References

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CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country profiles. Thailand profile. Available in: https://www.cbd.int/countries/?country=th. Access on: 05/10/2021.

THAILAND. Access and Benefit-Sharing. Ministry of Natural Resources and Environment. Biological Diversity Division., p. 17

THAILAND. **Thailand's Sixth National Report on the Implementation of the Convention on Biological Diversity**. June 2019.

UNCTAD. **The Convention on Biodiversity and the Nagoya Protocol: Intellectual Property Implications, A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property**. United Nations Publications, 2014.

Union for Ethical BioTrade (UEBT). **ABS in Thailand**. June 2019. Available in: https://www.ethicalbiotrade.org/resource-pages/abs-in-thailand Acessed on 05/10/2021.

OFFICE OF NATURAL RESOURCES AND ENVIRONMENTAL POLICY AND PLANNING. Access and Benefit-Sharing. Ministry of Natural Resources and Environment. 28 pages. Bangkok, 2014. Available in: http://chm-thai.onep.go.th/chm/ABS/Documents/Nagoya/ACCESS%20Eng.pdf Access on 05/10/2021.

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SUJINTAYA, Say; MUNGKARNDEE, Radeemada; and MAHIPANT, Gumpanat. **Thailand Releases Draft Biodiversity Act**. Global Compliance News, February 14, 2019. Available in: https://globalcompliancenews.com/thailand-releases-draft-biodiversity-act-20190212/ Acessed on 17/10/2020.

SUJINTAYA, Say; MUNGKARNDEE, Radeemada; and PONGPATTANAPUN, Peeriya. **Draft Biodiversity Act: ABS and Biosafety**. Lexology, July 14, 2020. Available in: https://www.lexology.com/library/detail.aspx?g=767d7504-faae-42d1-b0e1-a4b7854b296c Acessed on 17/10/2020.

Turkey[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since May 15, 1997.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, there are some dispositions regarding ABS on the country's Regulation on the Implementation of the Industrial Property Law (2017).

1. The information hereinafter has been updated until September 29th, 2021
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 74, “h” of Regulation on the Implementation of the Industrial Property Law (2017) states that the geographical origin of a genetic resource shall be mentioned on the application for an invention. Also, article 100, “i” of the same law states that the source of traditional knowledge associated to genetic resources shall also be mentioned in cases of patent applications.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresees species that have naturally developed their distinctive properties within the country’s territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, one emblematic case related to biopiracy concerning Turkey purple carrot, in which an american company is claiming plant variety rights.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Turkey Profile
https://absch.cbd.int/countries/TR

CBD Turkey Profile
https://www.cbd.int/countries/nfp/?country=tr

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Turkey. Available in: < https://absch.cbd.int/countries/TR>. Access on: 09/20/2021.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Turkey. Available in: <https://www.cbd.int/countries/nfp/?country=tr>. Access in: 09/20/2021

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REPUBLIC OF TURKEY. **UN Convention on Biological Diversity Sixth National Report, 2019**. Ministry of Agriculture and Forestry. Available in: https://www.cbd.int/doc/nr/nr-06/tr-nr-06-en.pdf. Access on: 09/20/2021

REPUBLIC OF TURKEY. **Regulation on the Implementation of Industrial Property Law (as amended by Regulation published in the Official Gazette No. 30223 of October 27, 2017)**. Available on: https://wipolex.wipo.int/en/legislation/details/17697 . Access on: 09/20/2021

Turkmenistan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since December 17th, 2020.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since February 2nd, 2021.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated tradition-

1. The information hereinafter has been updated until October 12th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

al knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Nagoya Protocol on Biological Diversity

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6. Websites

ABSCH Turkmenistan Profile
https://absch.cbd.int/countries/TM

CDB Turkmenistan Profile
https://www.cbd.int/countries/?country=tm

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Turkmenistan profile. Available at: https://absch.cbd.int/countries/TM> Access on 12/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Turkmenistan profile. Available at: https://www.cbd.int/countries/?country=tm> Access on 12/10/2020.

GOVERNMENT OF TURKMENISTAN. **Turkmenistan Third National Report**. Ministry of Nature Protection of Turkmenistan. Ashgabat, 2006. Available at: https://www.cbd.int/countries/?country=tl> Access on 25/05/2018.

Unite Arab Emirates[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since May 10th, 2000.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since December 11th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated tradition-

1. The information hereinafter has been updated until October 27th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

al knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3. Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have naturally developed their distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

CBD United Arab Emirates Profile
https://www.cbd.int/countries/?country=ae

ABSCH United Arab Emirates Profile
https://absch.cbd.int/countries/AE

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. United Arab Emirates.. Available in: <https://absch.cbd.int/countries/AE>. Access on: 10/27/2020.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. United Arab Emirates. Available in: <https://www.cbd.int/countries/?country=ae> Access on: 10/27/2020.

UNITED ARAB EMIRATES. **5th National Report.** Ministry of Environment & Water. Available in: https://www.cbd.int/countries/?country=eg Access on 04/10/2016.

UNITED ARAB EMIRATES. **National Biodiversity Strategy 2014-2021**. Ministry of Environment & Water. Available in: https://www.cbd.int/countries/?country=eg Access on 04/10/2016.

Uzbekistan[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by accession, since October 17th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE

1. The information hereinafter has been updated until November 9th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the bene-

fits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Uktam Utaev
Deputy Chairman
State Committee for Ecology and Environmental Protection
2A Tuytepa Street
Tashkent
100047
Uzbekistan

ABS National Focal Point
+99871 207 0770 ext 1039
uktam.utaev@eco.gov.uz

6. Websites

ABSCH Uzbekistan profile
https://absch.cbd.int/countries/UZ

CBD Uzbekistan profile
https://www.cbd.int/countries/?country=uz>

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Uzbekistan profile. Available at: https://absch.cbd.int/countries/UZ. Access on 08/27/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Uzbekistan profile. Available at: https://www.cbd.int/countries/?country=uz> Access on 08/27/2020.

GOVERNMENT OF UZBEKISTAN. Biodiversity Conservation. National Strategy and Action Plan. Tashkent. Available at: https://www.cbd.int/countries/?country=uz. Access on 08/27/2020.

Viet Nam[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since February 14th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
(X) YES / ( ) NO
Yes, the country has issued and registered 36 IRCCs that are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the country already has the following laws regarding access and benefit-sharing:

- Biodiversity Law, 2008 (Law No. 20/2008/QH12)

1. The information hereinafter has been updated until October 21st, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Decree on Detailed Regulations and Guidelines for Implementation of Some Articles of the Law on Biodiversity (Decree No. 65/2010/ND-CP)

- Decree on the Management of Access to genetic resources and the sharing of benefits arising from their utilization.(Decree 59/2017/ND-CP)

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to Article 6 of Decree on the Management of ABS, the country has the following competent institutions regarding access and benefit sharing:

- Ministry of Natural Resources and Environment

Responsible for licenses for access to genetic resources of agricultural crop varieties, livestock, aquatic species and forest seedlings.

- Ministry of Agriculture and Rural Development

Responsible for licenses for access to genetic resources for matters other than the competence of the Ministry of Natural Resources and Environment.

Furthermore, article 55 of the Biodiversity Law, 2008, establishes that genetic resources in the country shall be managed by Conservation management units, heads of biodiversity facilities, organizations, families and individuals and popular committees, accordingly.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 8 of Decree on Management of ABS and article 57 of Biodiversity Law 2008, all access activities in the country must comply with the procedures described below:

1. Registration of access to genetic resources with the Competent National Authority.

2. Negotiation of a written agreement with the provider of the genetic resources, containing benefit sharing provisions.

3. Request the Commune-level People's Committee to certify the contract.

4. Submission of the dossier requesting a license to access genetic resources to the Competent National Authority.

Each step of the procedure is further detailed on articles 8 to 20 of the referred Decree.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis. Article 64 of the Biodiversity Law, 2008 defines the Ministry of Science and Technology as the primary responsible, in the joint coordination of ministries and relevant ministerial agencies, on the procedures for registering copyright of the traditional knowledge associated with genetic resources.

2.5 Does the current legislation or any ongoing bills provide specific procedures for re-

questing patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 14.3 of the Decree on Management of ABS, in cases where patents arise from research or technological developments involving the access to genetic resources and its derivatives, the registration shall clearly state their source of origin. Also, Circular No. 01/2007/TT-BKHCN of February 14, 2007, provides for additional requirements when inventions include biotechnology or biological materials.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis. However, Biodiversity Law 2008 defines in Article 60, item 1, "b", that it is the right of the organization or individual who has been granted a license to access genetic resources to remove genetic resources from the territory of VietNam, except from those on the list of species banned from exporting.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
Yes, benefit sharing is mandatory and it incides over utilization of genetic resources. The responsibility to share the benefits lies on the user.

3.2 Are there any specific procedures, rules and values?
(X) YES / ( ) NO / NOT AVAILABLE
Yes, article 4, item 4 of the Biodiversity Law, 2008 states that those who exploit or use biodiversity must share the benefits derived from this exploration or use with the appropriate parties, thus ensuring harmony between the interests of States, organizations and individuals.

Also, article 56 of the same legislation stipulates that organizations, families and individuals designated to manage genetic resources shall have the right to receive benefits shared by organizations or individuals who have accessed the genetic resource and the obligation to conclude contracts on access to genetic resources and sharing of benefits with holders of access licenses.

The requirements of the contracts on access to genetic resources and benefit sharing are contained in Article 58. Among them is the need for the contract signed to pass through the certification of the People's Committee and the mandatory clause of benefit sharing, including the distribution of intellectual property rights derived from inventions based on access to genetic resources or traditional knowledge.

According to article 61, beneficiaries of benefit sharing may be (a) the State; (b) organizations, families and individuals designated to manage genetic resources; (c) organizations and individuals licensed to access genetic resources and other related persons as described in the licenses.

Types of benefits are defined on articles 21 to 23 of Decree on Management on ABS and they include but are not limited to those provided on the Annex of Nagoya Protocol.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Fees, Royalties, License fees, lump sum payments	not less than 1% if the total annual revenue of the product generated from the utilization of genetic resources	Genetic Heritage/ Associated Traditional Knowledge	Community/ Government
Non Monetary	Not defined	Sharing of research results, right to be involved in collaboration the research, technology transfer, training and capacity building, joint intellectual property, and others.	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Community/ Government

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No sanctions in case of irregular access were identified in the norms covered by this analysis. The Biodiversity Law, 2008 only prohibits in its article 7, item 8, illegal access of genetic resources of species listed as threatened of great importance and rare priority for legal protection.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Natural Resources and Environment	Responsible for licenses for access to genetic resources of agricultural crop varieties, livestock, aquatic species and forest seedlings.
Ministry of Agriculture and Rural Development	Responsible for licenses for access to genetic resources for matters other than the competence of the Ministry of Natural Resources and Environment.

6. Websites

Viet Nam Biodiversity
https://vietnamabs.gov.vn/en/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Viet Nam profile. Available in: https://absch.cbd.int/countries/VN Access on 10/21/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Viet Nam profile. Available in: https://www.cbd.int/countries/?country=vn Access on 10/21/2020.

VIETNAM. **Biodiversity Law (2008)**. Available in: https://absch.cbd.int/countries/VN Access on 17/06/2016.

VIETNAM. **Decree No. 651 2010 ND·CP of June 11, 2010**. Available in: http://extwprlegs1.fao.org/docs/pdf/vie98415.pdf Access on 17/06/2016.

VIETNAM. **Decree On The Management Of Access To Genetic Resources And The Sharing of Benefits Arising From Their Utilization**. Available in: https://absch.cbd.int/countries/VN Access on 17/06/2016.

VIETNAM. **Vietnam National Biodiversity Strategy to 2020, vision to 2030**. Ministry Of Natural Resources And Environment. Available in: https://www.cbd.int/countries/?country=vn Access on 17/06/2016.

VIETNAM. **Vietnam's Fifth National Report To The United Nations Convention On Biological Diversity Reporting period: 2009–2013**. Ministry Of Natural Resources And Environment. Hanoi, 2014. Available in: https://www.cbd.int/countries/?country=vn Access on 17/06/2016.

Yemen[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?
(X) YES / ( ) NO
Yes, the country has been a Party to the Convention, by ratification, since May 21st, 1996.

1.2 Is the country a Party to the Nagoya Protocol?
( ) YES / (X) NO
No, the country is not a Party to the Protocol, but has been a signatory country since February 2nd, 2011.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?
( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?
( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated tradition-

1. The information hereinafter has been updated until November 9th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

al knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, bio piracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Ms. Ammar Al-Aulaqi
Chairman
Environment Protection Authority (EPA)
Yemen

ABS National Focal Point
ammar.aluqi@gmail.com
info@epa-ye.org

6. Websites

ABSCH Yemen Profile
https://absch.cbd.int/countries/YE

CBD Yemen Profile
https://www.cbd.int/countries/?country=ye

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Yemen Profile. Available in: < https://absch.cbd.int/countries/YE> Access on 08/17/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Yemen profile. Available in: https://www.cbd.int/countries/?country=ye> Access on 08/17/2020.

GOVERNMENT OF YEMEN. Fifth National Report to the Convention on Biological Diversity (2010-2014). Available in: https://www.cbd.int/doc/world/ye/ye-nr-05-en.pdf. Access on 08/17/2020.

GOVERNMENT OF YEMEN. National Biodiversity Strategy and Action Plan II
achieving a resilient, productive and sustainable socio- ecosystem by 2050. Ministry of Water and Environment. 2017. Available in: https://www.cbd.int/countries/?country=ye Access on 08/17/2020.



Europe

Albania[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since April 5th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / ( ) NO / (X) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Law No. 9,587 of July 20, 2006, on biodiversity protection: establishes detailed procedures and obligations related to access and benefit-sharing. However, Law 37 of 2013 changed

1. The information hereinafter has been updated until November 23rd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

some dispositions of the aforementioned law. In relation to ABS, it changed article 49 of the referred law, related to the value of the fines.

According to the UNDP website, additional amendments regarding ABS were made on the law on national biodiversity (Law No. 9,587 of July 20, 2006) in 2020, but the amended version could not be found by this study.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The ABCSH website identifies the General Directorate of Environmental Policies and Development as the competent institution, which is responsible for all matters related to genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to article 41 of Law No. 9,587 of July 20, 2006, the activities that explore or use the biological diversity of Albania require a license. Also, item 3 of the aforementioned article, the approval of such a license depends on the user of biodiversity obtaining prior consent from the government or the owner of the assets, and on the establishment of a benefit-sharing agreement. In addition, item 5 also provides specific requirements in the case of foreign companies.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

Although there are no specific procedures, article 45 reinforces the necessity of prior informed consent and the right of communities to obtain benefit from the commercial or non-commercial use of their knowledge and practices.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. In cases where there is shipment of samples, the user is required to set a material transfer agreement, as mentioned under item 4 of article 41 of Law No. 9,587 (July 20, 2006),

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE
Yes, benefit sharing is mandatory, as set out in article 42, item 2, d) and article 43, item 2, c) of Law No. 9,587 (July 20, 2006). However, the referred law does not provide any specific provisions on how benefit-sharing shall occur.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE
The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to article 2, item 2, of, which altered article 49 of Law 9,587 of July 20, 2006 (on biodiversity protection), the following institutions are responsible for inspections on biodiversity-related issues in the country: the State Police, the Forest Service Police, and the Institutes responsible for Plant Protection, Protected Areas, Fisheries and Zootechnical Services.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Law No 37 of 2013 changed some dispositions of law 9,587 of 2006, including the sanctions related to the value of fines. Thus, according to the new text given by article 4 of law 37 of 2013, some infractions will result in

the imposition of a fine from 300,000 to 500,000 Leke (2781,00 to 4634,99 US dollars), while others will have values from 10,000 to 300,000 Leke (92,70 to 2781,00 US dollars).

The same article also presents a new text establishing the possibility of application of other sanctions like the cancellation of the environmental license and the partial or complete suspension of the user's activities. And, in addition, article 3 of law 37 of 2013 establishes that for the violations defined under chapter IV, V and VI of Law 9,587, besides the application of fines and accessory sanctions in all cases, the penalty applied will also be accompanied by the apprehension of the biological material and the tools employed in carrying out the illegal activities.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
General Directorate of Environmental Policies and Development	Responsible for all genetic resources. Only designated competent national authority (CNA) for the country.

6. Websites

ABSCH Albania's Profile
https://absch.cbd.int/countries/AL

CBD Albania's Profile
https://www.cbd.int/countries/?country=al

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Albania profile. Available in: < https://absch.cbd.int/countries/AL > Access on November 23rd, 2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Albania profile. Available in: <https://www.cbd.int/countries/?country=al > Access on November 23rd, 2021.

GOVERNMENT OF ALBANIA. Document of Strategic Policies for the Protection of Biodiversity in Albania. Government of Albania (GoA). Tirana, December, 2015. Available in: <https://www.cbd.int/countries/?country=al > Access on November 23rd, 2021.

GOVERNMENT OF ALBANIA. Fifth National Report Of Albania To The United Nations Convention On Biological Diversity (CDB). Albania. May, 2014. Available in <https://www.cbd.int/countries/?country=al > Access on November 23rd, 2021.

GOVERNMENT OF ALBANIA. Sixth National Report Of Albania To The United Nations Convention On Biological Diversity (CDB). Albania. May, 2019. Access on November 23rd, 2021.

GOVERNMENT OF ALBANIA. Interim National Report on the Implementation of the Nagoya Protocol. Published in 6th of November 2017. Access on November 23rd, 2021.

GOVERNMENT OF ALBANIA. Law No. 9587 of 2006 on Biodiversity Protection. Available in: <http://www.ecolex.org/details/legislation/law-no-9587-on-biodiversity-protection-lex-faoc067304/ > Access on November 23rd, 2021.

GOVERNMENT OF ALBANIA. Law No. 37/2013 For Some Changes And Additions To Law No. 9587, 2006 "On Protecting Biodiversity". Available in: < http://faolex.fao.org/docs/texts/alb132097.doc> Access on November 23rd, 2021.

GOVERNMENT OF ALBANIA. Law No 113/2012 on the Accession. Available in: <https://absch.cbd.int/database/record/ABSCH-MSR-AL-207101> Access on November 23rd, 2021.

UNDP. Parliament approves UNDP-backed biodiversity law to meet obligations arising from Nagoya Protocol. Posted on May 10, 2020. Available at:https://www.al.undp.org/content/albania/en/home/presscenter/articles/2019/parliament-approves-undp-backed-biodiversity-law-to-meet-obligat.html. Access on: November 23rd, 2021.

Andorra[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since May 5th, 2015.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

1. The information hereinafter has been updated until March 20, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

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Mrs. Silvia Ferrer
Director
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6. Websites

ABSCH Andorra Profile
https://absch.cbd.int/countries/AD

CBD Andorra Profile
https://www.cbd.int/countries/?country=ad

Environment and Sustainability
https://www.mediambient.ad/biodiversitat

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Andorra. Available in: *https://absch.cbd.int/countries/AD*. Access on 03/19/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Andorra profile. Available in: *https://www.cbd.int/countries/?country=ad*> Access on 03/19/2020.

GOVERNMENT OF ANDORRA. **Estratègia Nacional de la Biodivesitat D'Andorra (ENBA)**. Available in: *https://www.mediambient.ad/images/stories/biodiversitat/ENPA_Biodiversitat_Cat.pdf*. Access on 03/19/2020.

GOVERNMENT OF ANDORRA. **Rapport National sur la Diversité Biologique em Andorre**. Available in: *https://chm.cbd.int/pdf/documents/nationalReport6/241228/1* Access on 03/19/2020

Austria[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 16th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 18th, 2018.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has one checkpoint which is available on the ABSCH website:

- Federal Minister for Climate Action, Environment, Energy, Mobility, Innovation and Technology

This institution is responsible for all matters related to genetic resources.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has one law regarding access and benefit-sharing, which is the Federal Law Gazette I

1. The information hereinafter has been updated until July 20th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

No. 36/2019, which regulates the implementation of obligations from the Nagoya Protocol and the implementation of Regulation (EU) No. 511/2014.

As a regional organization, the European Union – of which Austria is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2. Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Federal Law Gazette I No. 36/2019 identifies the Federal Minister for Climate Action, Environment, Energy, Mobility, Innovation and Technology as the competent institution, which is responsible for matters relating to implementation of Nagoya Protocol and EU Regulations on the matter.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address authorizations in order to obtain genetic resources.
EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Federal Law Gazette I No. 36/2019 institutes the district administrative authority (criminal authority) to conduct the criminal proceedings for sanctions of the conducts provided in this legislation.

Also, in Austria, the Ministry of Environment (Umweltbundesamt) is the government authority responsible for environmental protection and control. However, there is no information as to whether it is the institution responsible for inspecting access to genetic resources.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Federal Law Gazette I No. 36/2019 establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules of the Regulation (EU) No. 511/2014, such as: not providing information to subsequent users; not keeping information for 20 years after the permit expires, not providing declarations and others. Those violations shall be punished with a fine up to EUR 50,000.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Federal Minister for Climate Action, Environment, Energy, Mobility, Innovation and Technology as the competent institution	Responsible for matters relating to implementation of Nagoya Protocol and EU Regulations on the matter

6. Websites

National CHM
http://at.chm-cbd.net

The Austrian Clearing-House Mechanism
https://www.biologischevielfalt.at

Austria Biodiversity website
https://www.biodiv-abs.at/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Austria profile. Available in: *https://absch.cbd.int/countries/AT* Access on 10/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profles. Austria profle. Available in: *https://www.cbd.int/countries/?country=at* Access on 10/10/2020.

GOVERNMENT OF AUSTRIA. Fifth National Report Of Austria: Convention on Biological Diversity. Umweltbundesamt (Environmental Protection Agency). Vienna, 2014. Available in: *https:// www.cbd.int/countries/?country=at* Access on 04/11/2016.

GOVERNMENT OF AUSTRIA. Sixth National Report Of Austria: Convention on Biological Diversity. Federal Ministry Republic of Austria, Sustainability and Tourism. Vienna, 2018. Available in: *https://www.cbd.int/doc/nr/nr-06/at-nr-06-en.pdf.* Access on 10/10/2020.

GOVERNMENT OF AUSTRIA. Biodiversity Strategy Austria 2020+. Federal Ministry of Agriculture, Forestry, Environment and Water Management. Vienna, December, 2014 Available in: < *https://www.cbd.int/countries/?country=at*> Access on 04/11/2016.

GOVERNMENT OF AUSTRIA. Federal Law Gazette I No. 36/2019. Issued May 22nd, 2019. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-AT-247052* Access on 10/10/2020.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: *https://absch.cbd.int/database/record/ABSCHMSR-DE-204508* Access on 04/11/2016.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Councilon the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefts Arising from their Utilisation in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR--DE-208044* Access on 04/11/2016.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefts Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/ record/ABSCH-MSR-DE-201808* .Access on 04/11/2016.

Belarus[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The National Coordination Centre for Access to Genetic Resources and Benefit-Sharing is the official checkpoint, responsible for requesting to the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus a prior informed consent and written evidence that access requirements have been met.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 10 IRCCs that are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated tradition-

1. The information hereinafter has been updated until August 3rd, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

al knowledge in the country. Although the country does not have any specific laws regulating the access to genetic resources and associated traditional knowledge, Belarus has the following norms related to the matter:

- Presidential Decree No. 235, of May 22, 2014, of the Republic of Belarus, concerning the access of the Republic of Belarus to the Nagoya Protocol;

- Resolution 2358 - XII of 1993 of the Republic of Belarus, which ratifies the Convention on Biological Diversity;

- Resolution No. 70, of Oct 27, 2014, from the National Academy of Sciences of Belarus, which provides for the approval of the regulations of the National Coordination Centre for Genetic Resources Access and Benefit Sharing, and Regulations for the Checkpoint for Monitoring the Utilization of Genetic Resources.

- Resolution No. 933, of Oct 2014, from the Council of Ministers of the Republic of Belarus, concerning the establishment of the National Coordination Centre for Genetic Resources Access and Benefit Sharing (Resolution of the Council of Ministers of the Republic of Belarus "On Establishment of the National Coordination Centre on Access to Genetic Resources and Benefit-Sharing" of October 1st, 2014, N933)

It should be noted that, according to the National Focal Point, the country's law states that the Nagoya Protocol itself is recognized as a law until a national law on access to genetic resources and benefit sharing is developed and adopted.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The country has the following competent institutions regarding access and benefit sharing:

- **National Coordination Center for Access to Genetic Resources and Benefit Sharing**

This is the National Coordination Center for Access to Genetic Resources and Benefit Sharing , established in 2014 by the Resolution of the Council of Ministers of the Republic of Belarus of October 1, 2014 No 933. Among various responsibilities one of the responsibilities of this NCA is to analyze and systematize all relevant information about access genetic resources and benefit sharing and perform functions of the Checkpoint for monitoring the utilization of the genetic resources.

- **Ministry of Natural Resources and Environmental Protection**

This institution is responsible for the implementation of the Nagoya Protocol in the Republic of Belarus.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, as clarified by the National Focal Point, the lack of ABS standards does not prevent natural resource activities from complying with legislation related to the protection of natural resources: Law on the Environmental Protection No. 1982-XII of November 26, 1992, Law on Plant World and Law on Animal.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Resolution No. 933, of Oct 2014, from the Council of Ministers of the Republic of Belarus, concerning the establishment of the National Coordination Centre for Access to Genetic Resources and Benefit Sharing, states, in its article 2, that one of the main objectives of the Center consists in determining the conditions of access to the country's genetic resources, including in the sharing of benefits arising from the use of such resources.In the absence of a national legislation, and considering that it is the responsibility of the Center to determine the conditions for the sharing of benefits resulting from

the use of the genetic resources, there is no specification of values, procedures and norms.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The National Coordination Centre for Access to Genetic Resources and Benefit Sharing has the function to enforce the Nagoya Protocol in the Republic of Belarus through the appropriate measures of monitoring and increased transparency concerning the use of genetic resources.

According to Resolution 933, of October 2014, from the Council of Ministers of the Republic of Belarus, it is the responsibility of this Center to request the users of genetic heritage to provide information about the use of genetic heritage and compliance with the terms of the Nagoya Protocol, and it may take effective regulation measures on issues related to the non-compliance with the said terms, including in the case of non-compliance with benefit sharing requirements.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
National Coordination Centre for Access to Genetic Resources and Benefit Sharing	This is the National Coordination Centre for Access to Genetic Resources and Benefit Sharing , established in 2014 by the Resolution of the Council of Ministers of the Republic of Belarus of October 1, 2014 No 933. Among various responsibilities one of the responsibilities of this NCA is to analyse and systematize all relevant information about access genetic resources and benefit sharing and perform functions of the Checkpoint for monitoring the utilization of the genetic resources.
Ministry of Natural Resources and Environmental Protection	This institution is responsible for the implementation of the Nagoya Protocol in the Republic of Belarus.

6. Websites

ABSCH Belarus Profile
https://absch.cbd.int/countries/BY

CBD Belarus Profile
www.cbd.int/countries/?country=by

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Belarus profile. Available in: https://absch.cbd.int/countries/BY Access on August 20, 2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Belarus profile. Available in: https://www.cbd.int/countries/?country=by Access on August 19, 2020.

REPUBLIC OF BELARUS. National Action Plan for the Conservation and Sustainable Use of Biological Diversity for 2016-2020 and on amendments to the Resolution of the Council of Ministers of the Republic of Belarus -1707 dated November, 19, 2010. Government of Belarus. Minsk. 2015. Available in: https://www.cbd.int/countries/?country=by Access on August 21, 2020.

REPUBLIC OF BELARUS. Fifth National Report. Government of Belarus. Minsk, 2015. Available in: ttps://www.cbd.int/countries/?country=by Access on August 20, 2020.

REPUBLIC OF BELARUS. Decree of the President of the Republic of Belarus "On Accession of the Republic of Belarus to the International Treaty". Available in: https://absch.cbd.int/database/record/ABSCH-MSR-BY-204260 Access on August 20, 2020.

REPUBLIC OF BELARUS. Decree of the President of the Republic of Belarus “On Accession of the Republic of Belarus to the International Treaty”. Available in: https://absch.cbd.int/database/ record/ABSCH-MSR-BY-201806 Access on August 20, 2020.

REPUBLIC OF BELARUS. National Coordination Centre on Access to Genetic Resources Issues and Beneft Sharing (ABS NCC). Available in: https://absch.cbd.int/database/record/ABSCHMSR-BY-202255 Access on 30/10/2016.

REPUBLIC OF BELARUS. Resolution of the Council of Ministers of the Republic of Belarus “On Establishment of the National Coordination Centre on Access to Genetic Resources and 465 Beneft-Sharing” of 1 October 2014, N933. Available in: https://absch.cbd.int/database/record/ABSCH-MSR-BY-202243 Access on August 21, 2020.

REPUBLIC OF BELARUS. Resolution of the Presidium of the National Academy of Sciences of Belarus of 27 October, 2014- 70 “On Approval of the Regulations for the National Coordination Centre on Access to Genetic Resources and Beneft-Sharing and Regulations for the Checkpoint of Monitoring the Utilization of Genetic Resources”. Available in: https://absch.cbd.int/database/record/ABSCH-MSR-BY-202445 Access on August 21, 2020.

Belgium[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 20th, 1997.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since November 7th, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

Yes, the checkpoint is the Agency Nature & Forests, responsible for receiving due diligence declarations in the Flemish Regional of Belgium.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge at national level. However, the country already has the following laws regarding

1 The information hereinafter has been updated until August 4th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

access and benefit-sharing at sub-national level:

Walloon Region - Décret relatif à l'accès aux ressources génétiques et au partage juste et équitable des avantages découlant de leur utilisation (Decree relating to genetic resources and benefit sharing arising from their utilization), of May 20th, 2020.

Flanders Region - Decreet betreffende de toegang tot genetische rijkdommen en de eerlijke en billijke verdeling van voordelen die voortvloeien uit hun gebruik (Decree relating to genetic resources and benefit sharing arising from their utilization), of March 22nd, 2019.

As a regional organization, the European Union – of which Belgium is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No official national competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

At the Walloon Region, the Direction générale opérationnelle de l'Agriculture, des Ressources naturelles et de l'Environnement (General Operation Direction of Agriculture, Natural Resources and Environment) is the Competent Authority for the Nagoya Protocol.

In the Flanders Region, the Natuurinspectie/Nature inspection of the "Agentschap Natuur en Bos/ Agency Nature & Forests" is the Competent Authority for the Nagoya Protocol.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

At the sub-national level, article 6 of Decree on Access and Benefit Sharing of the Walloon region establishes that an authorization is necessary for physical access to genetic resources and associated traditional knowledge. The user shall enter an agreement with the administration and consult with the providers, when appropriate. The referred agreement shall provide for monetary and non monetary benefits, which vary depending on if the utilization is for commercial or non commercial purposes.

Also, article 5 of the same Decree states that there shall be notification of utilization of genetic resources and associated traditional knowledge to the Administration in the following cases:

1. If the utilization is for non commercial purposes, when there is publication of results from the utilization;

2. If the utilization is for commercial purposes, when there is a patent arising from the utilization; commercialization and sale or transfer of results.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

At sub-national level, according to Article 5(a) of the Decree on ABS in the Walloon region, when the user obtains a patent derived from access to genetic resources or associated traditional knowledge, he/she shall notify the administration, which shall inform the ABSCH Clearing-House.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

At sub-national level, the Decree on ABS of the Walloon region states that benefit sharing is mandatory and it incides over utilization of genetic resources. The responsibility to share the benefits lies on the user.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be composed by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

At sub-national level, according to article 7 of the Decree on ABS of the Walloon region, the user shall enter a benefit sharing agreement with the administration. The monetary benefits shall be up to 1% of the profits generated each year of marketing, and they shall be directed to the conservation of biodiversity. The types of benefit sharing are available in Annex 1 and 2 of the legislation, and they depend on if the utilization is for commercial or non commercial purposes.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

At the Walloon Region, the Direction générale opérationnelle de l'Agriculture, des Ressources

naturelles et de l'Environnement (General Operation Direction of Agriculture, Natural Resources and Environment) is the inspection body for the Nagoya Protocol.

In the Flanders Region, the Natuurinspectie/Nature inspection of the "Agentschap Natuur en Bos/ Agency Nature & Forests" is the inspection body for the Nagoya Protocol.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

According to Article 3 of Regulation 511/2014 of the European Union, "illegally acquired genetic resources" are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations ("user conformity" and "monitoring of user conformity", respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Direction générale opérationnelle de l'Agriculture, des Ressources naturelles et de l'Environnement - General Operation Direction of Agriculture, Natural Resources and Environment (Walloon Region)	All matters related to Nagoya Protocol
Natuurinspectie/Nature inspection of the "Agentschap Natuur en Bos/ Agency Nature & Forests (Flanders Region)	All matters related to Nagoya Protocol

6. Websites

National CHM
http://www.biodiv.be

CBD Belarus Profile
www.cbd.int/countries/?country=by

Royal Belgian Institute of Natural Sciences
http://www.naturalsciences.be

Ministry of Foreign Affairs, Foreign Trade and Development
http://diplomatie.belgium.be/en/policy/

Belgian Development Cooperation Agency
http://www.btcctb.org/?sLangCode=EN

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Belgium profile. Available in: https://absch.cbd.int/countries/BE Access on 10/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Belgium profile. Available in: https://www.cbd.int/countries/?country=be Access on 10/10/2020.

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BELGIUM. 20 May 2020. Walloon Decree on access to genetic resources and the just and equitable sharing of benefits resulting from their utilisation. 2020.

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EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: https://absch.cbd.int/database/record/ABSCH-MSRDE-204508 Access on 04/11/2016.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: https://absch.cbd.int/database/record/ABSCH-MSR--DE-208044 Access in 04/11/2016.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808 Access on 11/11/2016 Access on 04/11/2016.

GOVERNMENT OF BELGIUM. Biodiversity 2020, Update of Belgium's National Strategy. Interministerial Conference for the Environment. Brussels, November, 2013 Available in: < https://www.cbd.int/countries/?country=at> Access on 04/11/2016.

GOVERNMENT OF BELGIUM. Fifth National Report of Belgium to the Convention on Biological Diversity. Brussels, 2014. Available in: https://www.cbd.int/countries/?country=at Access on 04/11/2016.

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Bosnia and Herzegovina[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since November 24th, 2002.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol. Nonetheless, governmental efforts have been made towards the accession and implementation of the Protocol. According to the Sixth National Report submitted to the Convention on Biological Diversity, the United Nations Environment Programme's office in Bosnia and Herzegovina has implemented the "Global Support for the Ratification and Entry into Force of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in BiH" in 2014 aiming to facilitate the country's accession to the Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

1. The information hereinafter has been updated until October 23rd, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mrs./Dr. Senka Barudanovic
SBSTTA Chair
Faculty of Science
University of Sarajevo
Zmaja od Bosne 33-35
71 000
Sarajevo
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ABS National Focal Point
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sbarudanovic@gmail.com

6. Websites

ABSCH Bosnia and Herzegovina Profile
https://absch.cbd.int/countries/BA

CBD Bosnia and Herzegovina Profile
https://www.cbd.int/countries/?country=ba

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Bosnia and Herzegovina. Available at: *https://absch.cbd.int/countries/BA*. Access on 10/23/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Barbados profile. Available at: *https://www.cbd.int/countries/?country=ba>* Access on 10/23/2020.

GOVERNMENT OF BOSNIA AND HERZEGOVINA. **Strategy and Action Plan for Protection of Biological Diversity in Bosnia and Herzegovina**. Ministry of Foreign and Trade Relations of Bosnia and Herzegovina. Available at: *https://www.cbd.int/doc/world/ba/ba-nbsap-v2-en.pdf*. Access on 02/04/2020.

Government of Bosnia and Herzegovina. **Sixth National Report to the United Nations Convention on Biological Diversity of Bosnia and Herzegovina**. Available at: *https://chm.cbd.int/database/record?documentID=246864*. Access in 02/04/2020.

Bulgaria[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, Bulgaria has been a Party to the Convention on Biological Diversity, by ratification, since July 16th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, Bulgaria has been a Party to the Nagoya Protocol, by ratification, since November 9th, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The Ministry of Environment and Water of Bulgaria is the checkpoint in the country, responsible for developing and implementing all environmental protection policies.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 3 IRCCs that are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

1. The information hereinafter has been updated until September 30th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 66 of the Biological Diversity Act - BDA established some provisions on the subject.

Paragraphs II and VI of article 66 state that the access to the country's genetic resources and its intellectual property rights must be carried out according to the specific legislation, to be established by the Council of Ministers of the country. Paragraphs III and V, however, make it clear that the access to genetic resources by other States, as well as the utilization of the resources by third parties, require the establishment of mutually agreed terms concerning the benefit-sharing and prior informed consent.

As a regional organization, the European Union – of which Bulgaria is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2. Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Biological Diversity Act, identifies Minister of Environment and Water as the competent institution, which is responsible, according to article 115, to give consent for access to genetic resources of the natural resources and monitor, within its jurisdiction, the fulfillment of compliance obligations of the users of genetic resources according to Regulation (EU) No. 511/2014 of the European Parliament and the Council.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country. Although the country does not have any specific legislation on access and benefit sharing, and the Council of Ministers is the entity responsible for creating norms to regulate the subject, the Bulgarian Biological Diversity Act (2000) provides in its article 66, paragraphs III and V, that the access to genetic resources by other States, as well as the utilization of the resources by third parties, require the establishment of mutually agreed terms concerning the benefit sharing and prior informed consent.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country and according with the National Focal Point, it was confirmed that there is no specific legal provision in the existing legislation and there is also no provision for amendment of the Bulgarian Patents and Utility Models Registration Act to include issues related to ABS. However, it should be noted that the Bulgarian Patents and Utility Models Registration Act is the relevant national legislation.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and

other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. and according with the National Focal Point, the existing legislation does not regulate ABS issues in the case of exotic species and the future regulation on ABS also does not provide special procedures for collecting and accessing exotic species.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the Bulgarian Biological Diversity Act (2000) provides in its article 66, paragraphs III and V, that the access to genetic resources by other States, as well as the utilization of the resources by third parties, require the establishment of mutually agreed terms concerning the benefit sharing and prior informed consent. There is no indication of the values - however, paragraph III includes a non-exhaustive list of requirements that the agreement must have:

- Indication of the natural place of origin of the material;
- Commitment of the user State to share the results of the research and technologies obtained, related or derived from the referred resources;
- Receipt of part of the resources obtained from the utilization of the material, as well as of the results or studies targeted for commercial purposes;
- Joint participation in scientific studies.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, as mentioned in item 3.1, BDA establishes a requirement for MTA concerning Benefit sharing and Prior informed consent, but there are no specific rules and values.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Biological Diversity Act institutes the Ministry of Environment and Water as the official inspection body responsible for all matters related to access and benefit-sharing in the country. According to the National Focal Point, this information is described in article 115, paragraph 1 (18) and article 118, paragraph 4 (1 and 2), Biological Diversity Act - BDA.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to the Bulgarian National Focal Point, the rules and sanctions provided for in art. 11 of Regulation 511/2014 (EU) are set out in Articles 127a and 128a of the Biological Diversity Act. Those articles establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as:

Violation of the Articles 75 (1); 76 (4); 92 (1); and 94 (1), fines of BER 500 to BER 30 000 are foreseen, depending on whether they are natural persons, legal entities or individual traders. It is important to highlight that, according to article 3 of Regulation 511/2014 of the European Union, “illegally acquired genetic resources” are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries should establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”, respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Environment and Water of Bulgaria	This institution is responsible in Bulgaria for developing and implementing all environmental protection policies

6. Websites

ABSCH Bulgaria Profile
https://absch.cbd.int/countries/BG

CBD Bulgaria Profile
www.cbd.int/countries/?country=bg

7. References

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Councilon the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-208044* Accessed on 10/27/2021

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefts Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808* Accessed on 10/27/2021

REPUBLIC OF BULGARIA. Biological Diversity Act 2002. Available in: *http://www.wipo.int/edocs/lexdocs/laws/en/bg/bg038en.pdf* Accessed on 10/27/2021.

REPUBLIC OF BULGARIA. Fifth National Report 2009 – 2013 - Convention On Biological Diversity. Ministry Of Environment And Water. Sofa, 2008. Available in: *https://www.cbd.int/countries/?country=bg* Access on 18/11/2016.

Croatia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since January 5th, 1997.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since December 1st, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

1. The information hereinafter has been updated until August 4th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the country already has the following laws regarding access and benefit-sharing:

- Nature Protection Act (2013) Reg. No.: 71-05-03/1-13-2, in articles 88 to 98, addresses access to genetic resources in the country.

- OG 14/2019, Act on Amendments to the Act on the Implementation on Regulation (EU) n 511/2014 on measures for users.

As a regional organization, the European Union – of which Croatia is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Ministry of Environment and Nature Protection is responsible for the implementation of the Nagoya Protocol, for approving permits of access to genetic resources and for other functions resulting from the access, while also having competence to sign benefit-sharing agreements with the users (art. 93 of the Nature Protection Act (2013)). Article 89, item 2 of the Nature Protection Act (2013) establishes that the permits for accessing genetic resources shall be requested from the Ministry (defined in Article 11 of the said Act as the central government institution responsible for nature protection), which shall act in cooperation with other central government institutions.

Article 89, item 4 of the Nature Protection Act (2003) No. 01-081-03-3243/2 provides that the conditions and methods for extracting genetic material from nature shall be determined by the Ministry in a regulation approved by the Ministry responsible for agriculture and forestry.

According to the ABSCH website, the Ministry of Environment and Nature Protection is responsible for:

- The implementation of the Nagoya Protocol.
- Issuing permits for access to the genetic resources of in situ native wildlife species;
- Establishing requirements to ensure the sharing of benefits arising from the utilization of genetic material;
- Authority to negotiate and sign contracts with potential users;
- Responsible for receiving information on the transfer of genetic material to third parties;
- This Ministry shall be one of the checkpoints under the terms of article 17 of the Nagoya Protocol.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Nature Protection Act (2013) Reg. No.: 71-05-03/1-13-2 establishes the need for an authorization to access the genetic resources in its articles 89 to 93.

It must be noted that Article 89, paragraphs (3) and (4) stipulate that any natural or legal person may conduct research on genetic material of wild native species that are not strictly protected by the aforementioned Act without commercial objectives (Article 89, paragraph 3). Paragraph 4 of article 89 provides that, if the natural or legal person referred to in paragraph 3 identifies the possibility of commercial use of the genetic material, they shall immediately obtain the permission referred to in paragraph 2 of Article 89.

According to article 91, the referred authorization shall provide the necessary conditions for the future sharing of benefits, and can be valid for up to 5 years.

Also, article 98 states that all other requirements on access, issuing of permits, conditions for the transfer of genetic material and benefit sharing must be regulated by the Government.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encour-

aged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

Although it is clear that the transfer of genetic material should be monitored and reported to the Ministry, according to Articles 89 and 92 of the Nature Protection Act (2013), article 98 states that the form of this procedure shall be regulated by the Government.

2.8 Does the current legislation or any ongoing bills address digital sequence information,

synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. Article 88, paragraph 1, of the Nature Protection Act (2013) provides that the conservation of genetic diversity shall be conducted in accordance with the principles of sustainable development and the fair distribution of the benefits arising from the use of genetic resources.

In this sense, Article 91, paragraph 4 of the referred act establishes that the permission to access genetic resources shall also establish the conditions agreed for the fair distribution of the benefits arising from the use of genetic resources. Article 93 stipulates that the user and the ministry shall enter into an agreement in which the conditions for the fair distribution of benefits are determined in further detail.

On the other hand, as already mentioned in the previous question, Article 98 stipulates that

the detailed content of the conditions for access and fair distribution of benefits arising from the use of genetic resources shall be determined by the government through specific regulations.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 s there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found. According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 228, item 1 of the Nature Protection Act (2013) establishes that a fine to the amount of 25,000 to 200,000 HRK shall be imposed on any person who:

- access and utilize genetic material from native wildlife species (in situ) without permission or in disagreement with the permit referred to in article 89, paragraph 2 of this Act (Article 89, paragraph 2);
- fails to comply with the requirements for access and/or use of genetic material from native wildlife species described in the regulation referred to in article 98 of this Act (Article 89, paragraph 2);
- fails to obtain the permission referred to in article 89, paragraph 2 of this Act, if, while

conducting non-commercial research with genetic material from native wildlife species not strictly protected by this Act, they identify the possibility of commercial use of the genetic material (Article 89, Paragraph 4);

- Access or utilize genetic material from native wildlife species from ex situ sources without permission or in disagreement with the permit referred to in article 96, paragraph 1 of this Act (Article 96, paragraph 1);

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Environmental and Nature Protection	Implementation of the Nagoya Protocol. Issuing of permits for access to the genetic resources of native wildlife species located in situ; Establishing requirements to ensure the sharing of benefits arising from the utilization of genetic material; Authority to negotiate and sign contracts with potential users; Responsible for receiving information on the transfer of genetic material to third parties; This Ministry shall be one of the checkpoints under the terms of article 17.º of the Nagoya Protocol.

6. Websites

ABSCH Croatia Profile
https://absch.cbd.int/countries/HR

CBD Croatia Profile
https://www.cbd.int/countries/?country=hr

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Croatia profile. Available in: *https://absch.cbd.int/countries/HR* Accessed on 10/27/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Croatia profile. Available in: *ttps://www.cbd.int/countries/?country=hr* Accessed on 10/27/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available at: *https: ttps://absch.cbd.int/database/record/ABSCHMSR-DE-204508* Accessed on 10/27/2021.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefts Arising from their Utilisation in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR--DE-208044* Accessed on 10/27/2021

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefts Arising from their Utilization in the ion. Available in: *https://absch.cbd.int/database/ record/ABSCH-MSR-DE-201808* Access on 11/11/2016.

REPUBLIC OF CROATIA. Nature Protection Act (Offcial Gazette No 80/2013). Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-HR-206385* Access on 18/10/2016.

REPUBLIC OF CROATIA. Strategy And Action Plan For The Protection Of Biological And Landscape Diversity Of The Republic Of Croatia. Available in: *https://www.cbd.int/countries/?country=hr* Access on 18/10/2016.

Cyprus[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since October 8th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Protocol, but has been a signatory country since December 12th, 2011.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / ( ) NO / (X) NOT AVAILABLE

According to the information provided by the National Focal Point, with the objective to comply

1. The information hereinafter has been updated until July 28th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

with the determinations of the Regulation (EU) 511/2014, the country has published the law The Compliance Measures of Users under the Nagoya Protocol on Access to Genetic Resources and the Law and Equal Allocation of the Benefits arising from their Use in the Union Act of 2018 (Law 49 (I) / 2018). However, it was not possible to analyze the referred law,as it was only available in local language.

As a regional organization, the European Union – of which Cyprus is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / ( ) NO / (X) NOT AVAILABLE

According to the country's National Focal Point, Law 49 (I) / 2018 indicates the Director of the Department of Environment, Ministry of Agriculture, Rural Development and Environment as the competent body regarding the issues related to the Regulation (UE) 511/2014 e a Law 49 (I) / 2018. However, it was not possible to analyze the referred law, for it is available only in the local language.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / ( ) NO / (X) NOT AVAILABLE

As mentioned in the item 2.1, it was not possible to analyze the national law, for it is available only in the local language. However, other types of mandatory authorizations were appointed by the country's National Focal Point to the collection of plants species, which are available on the Cyprus Forest Law [L.25(I)/2012] and the Law for the Protection and Management of Nature and Wildlife [L.53(I)/2003].

EU regulations do not provide for procedures regarding access and benefit sharing, as those

are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in the item 2.1, it was not possible to analyze the national law, for it is available only in the local language.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / ( ) NO / (X) NOT AVAILABLE

As mentioned in the item 2.1, it was not possible to analyze the national law, for it is available only in the local language. Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / ( ) NO / (X) NOT AVAILABLE

As mentioned in the item 2.1, it was not possible to analyze the national law, for it is available only in the local language.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( ) NO / (X) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / () NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in the item 2.1, it was not possible to analyze the national law, for it is available only in the local language.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in the item 2.1, it was not possible to analyze the national law, for it is available only in local language.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

According to the country's National Focal Point, Law 49 (i)/2018 indicates the Director of the Department of Environment, Ministry of Agriculture, Rural Development and Environment as the responsible body for appointing the authorities for inspection, control and application of fines. However, the system of inspection and its competent authorities have not been implemented so far, so that no fines have been applied.

Also, article 9 of EU Regulation No. 511/2014 states that the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

According to the information provided by the National Focal Point, the Law 49 (I)/2018 provides sanctions applicable in those cases of irregular access, which are: fines up to 100.000 euros for transferring genetic resources and associated traditional knowledge without the IRCC or relevant documents or non-compliance of the obligations for whom has received research funding and the obligation of declaring finished product, and fines up to 50.000 euros in those cases of non-compliance of the obligation to inform and comply with procedural obligations related to access and benefit sharing.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Director of the Department of Environment, Ministry of Agriculture, Rural Development and Environment	This is the body responsible for matters related to the Regulation (EU) 511/2014 and Law 49 (I)/2018, as well as to appointing the authorities for inspection, control and application of fines.

6. Websites

ABSCH Cyprus Profile
https://absch.cbd.int/countries/CY

CBD Cyprus Profile
https://www.cbd.int/countries/?country=cy

Ministry of Agriculture, Natural Resources and Environment
http://www.moa.gov.cy/moa/agriculture.nsf/environment_en/environment_en

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Cyprus profile. Available in: *https://absch.cbd.int/countries/CY*> Accessed on 10/27/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Cyprus profile. Available in: h*ttps://www.cbd.int/countries/?country=cy*> Accessed on 10/27/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508*> Accessed on 10/27/2021

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-208044*> Accessed on 10/27/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808*> Accessed on 10/27/2021.

Czech Republic[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by approval, since March 3rd, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since August 4th, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The Ministry of Environment is the checkpoint indicated in the ABSCH website.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, Act No. 93/2018 Coll. on conditions of utilization of genetic resources under Nagoya Pro-

1. The information hereinafter has been updated until July 27th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

tocol addresses access and benefit sharing in the country.
As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
According to the website of the ABS Clearing House, the National Competent Authority is the Ministry of the Environment, which is responsible for all matters related to genetic resources in Czech Republic.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address authorizations in order to obtain genetic resources.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be composed by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Section 8 of the Act No. 93/2018 Coll. on conditions of utilization of genetic resources under Nagoya Protocol institutes the Czech Environmental Inspectorate as the institution responsible for ordering the noncompliant user to fulfill the obligations of the Act.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Section 9 of the Act No. 93/2018 Coll. on conditions of utilization of genetic resources under Nagoya Protocol establishes the applicable sanctions for offenses regarding Regulation (EU) No 511/2014.

According to Article 3 of Regulation 511/2014 of the European Union, "illegally acquired genetic resources" are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations ("user conformity" and "monitoring of user conformity", respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of the Environment	Responsible for all matters related to genetic resources

6. Websites

ABSCH Czech Republic Profile
https://absch.cbd.int/countries/CZ

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Czech Republic profile. Available in: https://absch.cbd.int/countries/CZ Accessed on 11/05/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Czech Republic profile. Available in: https://www.cbd.int/countries/?country=cz Accessed on 11/05/2021.

CZECH REPUBLIC. National Biodiversity Strategy of the Czech Republic 2016–2025. Ministry of the Environment. Prague, 2016. Available in: https://www.cbd.int/countries/?country=cz Accessed on 11/05/2021.

CZECH REPUBLIC. The Fifth National Report of the Czech Republic to the Convention on Biological Diversity. Ministry of the Environment. 2014. Available in: https://www.cbd.int/countries/?country=cz Accessed on 11/05/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: https://absch.cbd.int/database/record/ABSCHMSR-DE-204508 Accessed on 11/05/2021.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in https://absch.cbd.int/database/record/ABSCH-MSR-DE-208044 Accessed on 11/05/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: https://absch.cbd.int/database/ record/ABSCH-MSR-DE-201808 Accessed on 11/05/2021.

Denmark[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since March 21st, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by approval, since October 12th, 1994.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. According to the ABSCH website, the country has one checkpoint:

- The Danish Environmental Protection Agency

This Checkpoint is responsible for receiving due diligence declarations from users at the research funding stage and at the final development of the product.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoints communiqués:

- Research - Genetic resources: not needed
- Research - Genetic resources: PROTEIN2FOOD (635727) aims to develop innovative,

1. The information hereinafter has been updated until August 4th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

cost-effective and resource-efficient, locally produced, healthy plant protein food, with a positive impact on bioeconomy, environment, biodiversity, human health, food security and social innovation.

- Research - Genetic resources: BIG4 - Biosystematics, informatics and genomics of the big 4 insect groups: training tomorrow's researchers and entrepreneurs. EU Horizon 2020 MSCA Grant no 642241

- Research - Genetic resources: BIG4 - Biosystematics, informatics and genomics of the big 4 insect groups: training tomorrow's researchers and entrepreneurs. EU Horizon 2020 MSCA Grant no 642241

- Research - Genetic resources: BIG4 - Biosystematics, informatics and genomics of the big 4 insect groups: training tomorrow's researchers and entrepreneurs. EU Horizon 2020 MSCA Grant no 642241

- Research - Genetic resources: BIG4 - Biosystematics, informatics and genomics of the big 4 insect groups: training tomorrow's researchers and entrepreneurs. EU Horizon 2020 MSCA Grant no 642241

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Act 1375 of 2012 (Act on Sharing Benefits Arising from the Utilization of Genetic Resources), provides for the use of foreign genetic resources by domestic consumers.

- Executive Order (of October 6, 2014) on the Entry into Force of Act 1375 of 2012 (Act on Sharing Benefits Arising from the Utilization of Genetic Resources)

- Executive Order n. 867 of June 25th 2017 on the Entry into Force of the Act on Sharing Benefits Arising from the Utilization of Genetic Resources and Penalties for Violation of the Regulation (EU) 511/2014

As a regional organization, the European Union - of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good

practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The second article of the Executive Order n. 867 of June 25th 2017 on the Entry into Force of the Act on Sharing Benefits Arising from the Utilization of Genetic Resources and Penalties for Violation of the Regulation (EU) 511/2014, states that the Danish Environmental Protection Agency shall be the competent institution. Its responsibilities include the receipt of declarations of due diligence from users of the biodiversity in two stages: research and product development.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No. Act 1375 of 2012 (Act on Sharing Benefits Arising from the Utilization of Genetic Resources) does not address the need for prior authorization to obtain the genetic resources, establishing its article 6 that the Danish Ministry for the Environment may issue regulations requiring reports to be made on the collection of genetic resources of wild organisms in Denmark, including information on the intended use.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of

final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis. Article 4 of Act 1375 of 2012 (Act on Sharing Benefits Arising from the Utilization of Genetic Resources) provides only that access to the traditional knowledge associated with genetic resources of indigenous and local communities should be carried out in accordance to article 7 of the Nagoya Protocol, that is, it shall not violate the law of the country where the traditional knowledge has been accessed.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing. EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be composed by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

No. Article one of Act 1375, of 2012, (Act on Sharing Benefits Arising from the Utilization of Genetic Resources) states that the aim of this Act is to ensure the sharing of benefits arising from utilization of genetic resources. However, the norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to article 2 of the Executive Order of the Entry into force of the Act on Sharing Benefits Arising from the Utilization of Genetic Resources, the Danish Nature Agency, according, is the competent institution to inspect the access to genetic resources, monitoring and ensuring compliance with the European Parliament's rules and the dispositions of EU Regulation No. 511/2014.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Section 11 of Act 1375 of 2012 states that, unless a higher sanction is applicable under another law, a fine shall be imposed on any person who violates sections 3 and 4 (which address, respectively, the compliance with the provisions and obligations of the Nagoya Protocol on the use of genetic resources and the use of associated traditional knowledge). The statute of limitations for criminal liability is five years.

This article, in its subsections, further stipulates that the offender may be imprisoned for a period of time of no longer than two years, if the offense was committed intentionally or with gross negligence and, as a result of the offense, economic advantage has been obtained or was intended by the party concerned or third parties.
Act 1375 of 2012 does not indicate the values of the fines.

Also, according to the Executive Order of the Entry into force of the Act on Sharing Benefits Arising from the Utilization of Genetic Resources, fines shall be imposed on anyone who (1) does not inform subsequent users with the obligations of Article 4.2 of the EU Regulation; (2) does not keep information regarding access and benefit sharing for twenty years after the expiry of the utilization period; (3) does not submit a declaration of due diligence on the subject.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
The Agency for Water and Nature Management.	Its responsibilities include the receipt of declarations of due diligence from users of the biodiversity in two stages: research and product development. This checkpoint is also responsible for the ad hoc and scheduled monitoring of users of genetic resources and traditional knowledge associated with genetic resources.

6. Website

ABSCH Denmark Profile
https://absch.cbd.int/countries/DK

CBD Denmark Profile
https://www.cbd.int/countries/?country=dk

Ministry of Environment
http://www.mim.dk/eng/Topics

Ministry of Foreign Affairs: Development Policy Section
http://www.um.dk/en/menu/DevelopmentPolicy/DanishDevelopmentPolicy

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profile. Denmark profile. Available in: *https://absch.cbd.int/countries/DK* Accessed on 10/28/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Denmark profile. Available in: *https://www.cbd.int/countries/?country=dk* Accessed on 10/28/2021.

DANISH GOVERNMENT. 5th Danish Country Report To the Convention on Biological Diversity. Danish Ministry of the Environment. Nature Agency. 2014. Available in: *https://www.cbd.int/ countries/?country=dk* Access on 18/10/2016.

DANISH GOVERNMENT. 6th Danish Country Report To the Convention on Biological Diversity. Danish Ministry of the Environment. January 2019. Available in: *https://www.cbd.int/doc/nr/nr-06/dk-nr-06-p1-en.pdf* Accessed on 10/28/2021.

DANISH GOVERNMENT. Act on sharing information for the use of genetic resources (No. 1375 of 2012). Available in: *http://www.ecolex.org/details/legislation/act-on-sharing-information-forthe-use-of-genetic-resources-no--1375-of-2012-lex-faoc118607/* Access in 18/10/2016.

DANISH GOVERNMENT. Danish Nature Policy: Our Shared Nature. The Danish Government. 2014. Available in: *https://www.cbd.int/countries/?country=dk* Access in 18/10/2016.

DANISH GOVERNMENT. Order No. 1101 on entry into force of Act on sharing information for the use of genetic resources. Available in: *http://www.ecolex.org/details/legislation/order-no- 1101-on-entry-into-force-of-act-on--sharing-information-for-the-use-of-genetic-resources-lex-faoc137585/?* Access in 18/10/2016

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: *https://absch.cbd.int/database/record/ABSCHIMSR-DE-204508* Accessed on 10/28/2021.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-208044* Accessed on 10/28/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808* Accessed on 10/28/2021.

Dominica[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since July 5th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the Fifth National Biodiversity Report to the Conven-

1. The information hereinafter has been updated until November 11th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

tion on Biological Diversity (2014) the country has a draft law on the subject, but it could not be identified or analyzed by this study.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. The country's Fifth National Report to the CBD indicates the Ministry. of Legal Affairs, ECU, Forestry, Agriculture, Fisheries as the responsible agencies for implementing access and benefit sharing norms.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Dr. Reginald E. Thomas
Permanent Secretary (Ag)
Ministry of Agriculture , Food and Fisheries
Government Headquarters
Kennedy Avenue
Roseau
Dominica

ABS National Focal Point
+1 767 266 3282, +1 767 448 2401
+1 767 448 7999
psagriculture@dominica.gov.dm

6. Websites

ABSCH Dominica Profile
https://absch.cbd.int/countries/DM

CBD Dominica Profile
https://www.cbd.int/countries/?country=dm

Government of the Commonwealth of Dominica
http://www.dominica.gov.dm/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. DOMINICA. Available at: *https://absch.cbd.int/countries/DM*. Access on 05/05/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Dominica profile. Available at: *https://www.cbd.int/countries/?country=dm*. Access on 05/05/2020.

GOVERNMENT OF DOMINICA. **Dominica's 5th National Biodiversity Report on the Convention of Biological Diversity**. 2014. Available at: *https://www.cbd.int/countries/?country=dm* Access on 05/05/2020.

GOVERNMENT OF DOMINICA. **Dominica National Biodiversity Strategy and Action Plan 2014-2020**. Ministry of Environment, Natura Resources, Physical Planning and Fisherie. December 2013. Available at: *https://www.cbd.int/countries/?country=dm* Access on 05/05/2020.

Estonia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since October 25th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since March 19th, 2019.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoints:

- **Ministry of the Environment**

Responsible for receiving and validating due diligence declarations from users of wild genetic resources

- **Ministry of Rural Affairs**

Responsible for receiving and validating due diligence declarations from users of genetic resources in agriculture

- **Ministry of Education and Research**

Responsible for receiving and validating due diligence declarations from users of genetic resources at research funding stage

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

1. The information hereinafter has been updated until August 6th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
The Nagoya Protocol, as well as article 5° of Regulation 511/2014 of the European Union, have been implemented by paragraph 68 of the Nature Conservation Act.

As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Paragraph 68 of the Nature Conservation Act, establishes that the competent authorities relative to access to genetic heritage and associated traditional knowledge are:

- **Ministry of the Environment**

Responsible for receiving and validating due diligence declarations from users of wild genetic resources

- **Ministry of Rural Affairs**

Responsible for receiving and validating due diligence declarations from users of genetic re-

sources in agriculture

- **Ministry of Education and Research**

Responsible for receiving and validating due diligence declarations from users of genetic resources at research funding stage

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address authorizations in order to obtain genetic resources.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to the Patents Act (1994), "in the case of an invention containing genetic information, the exclusive right of the proprietor of the patent shall extend to all biological material in which the invention is incorporated and which performs its function according to the said genetic information".

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to

genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing. EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation

or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

In this regard, chapter 11 of the Nature Act establishes that the Environmental Inspectorate is responsible for taking administrative measures to ensure the compliance of this Act, including applying fines to those who disrespect this law.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No sanctions in case of irregular access were identified in the norms covered by this analysis. According to Article 3 of Regulation 511/2014 of the European Union, "illegally acquired ge-

netic resources" are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations ("user conformity" and "monitoring of user conformity", respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of the Environment	Responsible for receiving and validating due diligence declarations from users of wild genetic resources
Ministry of Rural Affairs	Responsible for receiving and validating due diligence declarations from users of genetic resources in agriculture
Ministry of Education and Research	Responsible for receiving and validating due diligence declarations from users of genetic resources at research funding stage

6. Websites

ABSCH Estonia Profile
https://absch.cbd.int/countries/EE

CDB Estonia Profile
https://www.cbd.int/countries/?country=ee

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Estonia profile. Available in: https://absch.cbd.int/countries/EE.Accessed on 10/28/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Estonia profile. Available in: *https://www.cbd.int/countries/default.shtml?country=ee*. Accessed on 10/28/2021.

EUROPEAN UNION. **Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user**. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-208044* Accessed on 10/28/2021.

EUROPEAN UNION. **Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union**. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-208044* Accessed on 10/28/2021.

EUROPEAN UNION. **EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union**. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808*> Accessed on 10/28/2021.

GOVERNMENT OF ESTONIA. **Nature Conservation Act**. April, 2004. Available in: *https://www.riigiteataja.ee/en/eli/ee/504092017004/consolide/current*. Accessed on 10/28/2021.

European Union[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the European Union has been a Party to the Convention, by approval, since March 21st, 1994.

A "Regional economic integration organization", such as the European Union, is defined by the Convention on Biological Diversity, under Article 2, as " an organization constituted by sovereign States of a given region, to which its Member-States have transferred competence in respect of matters governed by this Convention and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it".

According to articles 31, 33 and 34, any State or regional economic integration organization may become a party to the Convention. In the case of organizations, their right to vote will be proportional to the number of Member-States classified as Contracting Parties to the Convention or the pertaining protocol, as long as its Member-States do not make concomitant use of their right to vote. Moreover, Organizations that become a Contracting Party without any of its member states being Contracting Parties themselves, will be directly subjected to all the obligations of the Convention or the protocol.

On the other hand, if one or more of its Member-States are a Contracting Party, it shall be a responsibility of the Organization and its Member-States to decide on their respective responsibilities for meeting the obligations established in these instruments.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

The European Union approved the Nagoya Protocol on May 16, 2014 and became a Party on October 12th, 2014.

As explained in the previous item, the dispositions of the Convention on Biological Diversity allow the participation of regional economic integration organizations, including in the protocol adopted by the Conferences of the Parties to the Convention.

In relation to the representation of the Organization in relation to its Member-States, paragraph 3, article 33 of the Nagoya Protocol establishes that any ratification, acceptance or approval instrument deposited by an Organization will not be counted as additional to those deposited by their Member-States; therefore, each member of the European Union must ratify this Protocol individually.

1. The information hereinafter has been updated until November 18th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

The European Union does not have an officially recognized checkpoint in terms of Nagoya Protocol. However, according to the Interim Report of the European Union, each Member State has two checkpoints, pursuant to Article 7(1) of Regulation 511/2014, which are (i) the Competent Authority to receive due diligence declarations and; (ii) the Competent Authority to gather due diligence declarations at the final stage of product development.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in the European Union.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in the European Union.

2. Legal Information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the European Union already has the following regulations regarding access and benefit-sharing:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institution was identified in relation to access and benefit-sharing in the European Union. However, EU Regulation No. 511/2014 establishes in article 6 that member-states should designate one or more competent authorities responsible for the application of the aforementioned regulation.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to

genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills provide specific procedures for digital sequence information or synthetic biology? What is the specific terminology used in the domestic legislation?

( ) DSI / ( ) SYNTHETIC BIOLOGY / (X) NONE

None of those terms were identified in the norms covered by this analysis

2.9 Does the current legislation or any ongoing bills foresees species that have naturally developed their distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national

legislation.

3.2 What are the applicable procedures, rules and values?

( ) YES / ( ) NO / NOT AVAILABLE

The applicable procedures, rules and values are subject to each Member-State legislation.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Subject to Member-State regulations	Subject to Member-State regulations	Subject to Member-State regulations	Subject to Member-State regulations	Subject to Member-State regulations
Non Monetary	Subject to Member-State regulations	Subject to Member-State regulation	Subject to Member-State regulations	Subject to Member-State regulations	Subject to Member-State regulations

4. Sanctions

4.1 Is there an official inspection body? Are there any records of fines having been applied by such institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As an organization, the European Union does not have an official inspection body. However, each Member-State of the European Union is sovereign on their own biodiversity in relation to their inspection and conservation, and may have their own specific rules on procedures for applying sanctions against non-compliance with the rules adopted by the Organization.

According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

According to Article 3 of Regulation 511/2014 of the European Union, “illegally acquired genetic resources” are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall

establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations ("user conformity" and "monitoring of user conformity", respectively).

4.3 Is there any record of emblematic biopiracy cases or disputes related to access and benefit sharing in the country?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, European Union does not have an official competent authority, as EU Regulation 511/2014 establishes in article 6 that member-states should designate one or more competent authorities. However, the European Union has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH European Union Profile
https://absch.cbd.int/countries/EU

CBD European Union Profile
www.cbd.int/countries/?country=eu

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. European Union profile. Available in: *https://absch.cbd.int/countries/EU* Access on 03/11/2016.

COLCELLI, Valentina. Information of Access and Benefit Sharing Regarding the Utilization of Genetic Resources under the European Union Legal Regulation. June 2018.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. European Union profile. Available in: *https://www.cbd.int/countries/?country=eur* Access on 03/11/2016.

EUROPEAN COMMISSION. Communication From The Commission To The European Parliament, The Council, The Economic And Social Committee And The Committee Of The Regions - Our Life Insurance, Our Natural Capital: An EU Biodiversity Strategy To 2020. Brussels, 2011. Available in: *https://www.cbd.int/countries/?country=eu* Access on 03/11/2016.

EUROPEAN COMMISSION. Fifth Report Of The European Union To The Convention On Biological Diversity. 2014. Available in: *https://www.cbd.int/countries/?country=eu* Access on 03/11/2016.

EUROPEAN COMMISSION. Annex to the Report from the Commission to the European Parliament and the Council. Regulation EU/511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Brussels, 24.1.2019, COM 92019) 13 final. Available in: *https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1548339471740&uri=COM%3A2019%3A13%3AFIN* Access on 10/02/2020.

EUROPEAN COMMISSION. Report from the Commission to the European Parliament and the Council. Regulation EU/511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Brussels,24.1.2019, COM 92019) 13 final. Available in: *https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1548339471740&uri=COM%3A2019%3A13%3AFIN*Access on 10/02/2020.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: *https://absch.cbd.int/database/record/ABSCHMSR-DE-204508* Access on 04/11/2016.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR--DE-208044* Access on 04/11/2016.

EUROPEAN UNION. EU ABS Regulation - Regulation (Eu) No 511/2014 Of The European Parliament And Of The Council Of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefts Arising from their Utilization in the Union. Available in: https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808 Access on 04/11/2016.

EUROPEAN UNION. Directive 98/44/EC of the European Parliament and of the Council of 6 July on the legal protection of biotechnological inventions. Available in: *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31998L0044.* Accessed on 10/02/2020.

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Finland[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since October 25th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since September 1st, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, Finland has two checkpoints, the Natural Resources Institute Finland and the Finnish Environment Institute, which are federal institutions with similar responsibilities.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, Finland has the following legislation regarding access to genetic heritage and associated traditional knowledge, apart from the existing regulations within the European Union:

1 The information hereinafter has been updated until August 5th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Act on the Implementation of the Nagoya Protocol to the Convention on Biological Diversity - implements certain dispositions of the Nagoya Protocol on Access and Benefit Sharing, as well as the dispositions of EU Regulation No. 511/2014 of the European Parliament and the Council.

As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The country has the following competent institutions regarding access and benefit sharing:

- Natural Resources Institute Finland - responsible for all genetic resources originating from livestock, agriculture, forestry, game and fisheries, genetic resources from wild species used in food products, agriculture or reproduction, and the associated traditional knowledge of indigenous/local communities related to such resources

- Finnish Environment Institute - responsible for all other genetic resources (different from those covered by the Natural Resources Institute Finland) and the associated traditional knowledge of indigenous/local communities.

Section 12 of the Act on the Implementation of the Nagoya Protocol to the Convention on Biological Diversity same law defines that the aforementioned institutions are responsible for (1) enforcing the present law and the EU regulation on genetic resources, as well as the dispositions adopted under the scope of the present regulation. (2) performing the public authority

roles referred to in article 5 of the regulation, related to the registry of debt collection. (3) making available to the Center of Access Exchange and Exchange of Information the data referred to in item 2 of article 14 of the Nagoya Protocol, also taking responsibility for the monitoring and presentation of reports under the terms of article 29 of the protocol.

Users importing to Finland genetic resources or resources with associated traditional knowledge from local communities of a country committed to the dispositions of the Nagoya Protocol on access and benefit-sharing must notify the national competent authority one month prior to the importation. The National Competent Authority is also responsible for receiving the due diligence declarations of users in the financing stage of the research, as well as in the stage of final development of the product. Besides, they are also responsible for monitoring and inspecting domestic users of genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No, the legislation examined does not mention the requirement of prior authorization for obtaining genetic resources, unless they are related to traditional knowledge. Item 2.4 further describes the requirement of prior authorization for cases of access to Traditional Knowledge associated to genetic resources.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

According to section 6 of the Act on the Implementation of the Nagoya Protocol to the Convention on Biological Diversity, the Sami Parliament manages a database which registers the traditional knowledge of the Sami people associated to genetic resources aimed at research and development activities.

In addition to section 6, section 7 of the same Act establishes that the right to access the database referred to in section 6 should be requested by the competent authority. The request must

specify the relevant genetic resources, the purpose for the use of its associated knowledge, and detailed user information. The Sami Parliament will be notified by the competent authority. Apart from the aforementioned requirement, the user must also request the competent authority to approve the mutually agreed terms between the Sami Parliament and the user.

According to section 8 of the same Act, the use of the traditional knowledge included in the databank referred to in section 6 shall not cause prejudice, unless a negligible one, to the rights of the traditional people of preserving and developing their culture and dedicating themselves to their traditional livelihood.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

According to section 7 of the Act on the Implementation of the Nagoya Protocol to the Convention on Biological Diversity: (1) In order to gain access to the knowledge included in the databank, the user is required to submit a request to the competent authority submitting he mutually agreed terms between the Sami Parliament and the user for approval. The Parliament may request the fair and equitable sharing of the benefits resulting from the use of this knowledge, to be delivered to the Sami people as a means of promoting their language and culture, as well as their position as a local people. Despite this mention of the possibility of requesting benefit-sharing, there is no additional information in terms of its procedures, rules and values.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, according to sections 11 and 13 of the Act on the Implementation of the Nagoya Protocol to the Convention on Biological Diversity, Natural Resources Finland and the Finnish Environment Institute are responsible for inspections. There is no evidence of imposition of fines apart from the legal provisions establishing that they may be applied.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

According to section 17 of the Act on the Implementation of the Nagoya Protocol to the Convention on Biological Diversity, a person will be liable of committing a violation against the rules concerning genetic resources if (1) they fail to meet the obligations established for the user in relation to access and benefit-sharing or the regulatory requirements referred to in paragraph 1 of article 4 of the EU Regulation on Genetic Resources. (2) they fail to comply with the obligations established under paragraph 3 of article 4 of the EU Regulation on Genetic Resources requiring them to seek, maintain or transfer to any subsequent users the information specified in paragraph 3, subsections a and b. (3) they fail to comply with the obligations established under paragraph 6 of article 4 of the EU Regulation on Genetic Resources requiring them to store the information specified in paragraph 3, article 4, for at least 20 years after the end of the period of utilization. Or (4) they fail to meet the obligation of declaring and presenting the information specified under article 7, paragraph 2 of the EU Regulation on Genetic Resources or in the implementation measures adopted by paragraph 6, article 7 of the referred regulation.

The penalty imposed shall take the form of a fine for violations against the rules on genetic resources, unless they are considered a misdemeanor or if a more severe penalty is established by any other laws. There is no indication of value in relation to the fines.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Natural Resources Institute Finland	Rresponsible for all genetic resources originating from livestock, agriculture, forestry, game and fisheries, genetic resources from wild species used in food products, agriculture or reproduction, and the associated traditional knowledge of indigenous/local communities related to such resources

Finnish Environment Institute	responsible for all other genetic resources (different from those covered by the Natural Resources Institute Finland) and the associated traditional knowledge of indigenous/local communities.

6. Websites

ABSCH Finland Profile
https://absch.cbd.int/countries/FI

CBD Finland Profile
https://www.cbd.int/countries/?country=fi

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Finland profile. Available in: https://absch.cbd.int/countries/FI Accessed on 10/28/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Finland profile. Available in https://www.cbd.int/countries/?country=f Accessed on 10/28/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: https://absch.cbd.int/database/record/ABSCHMSR-DE-204508 Accessed on 10/28/2021.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in https://absch.cbd.int/database/record/ABSCH--MSR-DE-208044 Accessed on 10/28/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: https://absch.cbd.int/database/ record/ABSCH-MSR-DE-201808 Accessed on 10/28/2021.

FINLAND. Act on the Implementation of the Nagoya protocol to the Convention on Biological Diversity (Finnish). Available in: https://absch.cbd.int/database/record/ABSCH-MSR-FI-207673 Accessed on 10/28/2021.

FINLAND. Fifth National Report To The Convention On Biological Diversity Finland. Available in: https://www.cbd.int/countries/?country=f Access on 05/11/2016.

FINLAND. Sixth National Report To The Convention On Biological Diversity Finland. Available in: https://chm.cbd.int/database/record?documentID=243215. Accessed on 10/28/2021.

FINLAND. Government Resolution on the Strategy for the Conservation and Sustainable Use of Biodiversity in Finland for the years 2012–2020, 'Saving Nature for People'. Available in: https://www.cbd.int/countries/?country=f Access on 05/11/2016.

FINLAND. Implementation of the Convention on Biological Diversity's Programme of Work on Protected Areas. Available in: https://www.cbd.int/countries/?country=f Access on 05/11/2016.

FINLAND. Implementation of the Convention on Biological Diversity's Programme of Work on Protected Areas. Available in: https://www.cbd.int/countries/?country=f Access on 05/11/2016.

FINLAND. Saving Nature for People National action plan for the conservation and sustainable use of biodiversity in Finland 2013–2020. Available in: https://www.cbd.int/countries/?country=f Access on 05/11/2016.

France[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since September 29th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since November 29th, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoints:

- Ministère de L'Enseignement supérieur, de la Recherche et de l'Innovation (Ministry of Higher Education, Research and Innovation)

Responsible for receiving declarations of due diligence regarding projects of research and application at the European Union level.

- Ministère de la transition écologique (Ministry of Ecological Transition) - Direction générale de l'aménagement, du logement et de la nature (General Directorate of Planning, Housing and Nature), Direction de l'eau et de la biodiversité (Directorate of Waters and Biodiversity) and Bureau de l'encadrement des impacts sur la biodiversité (Management Office of Biodiversity Impacts)

Responsible for implementation of the legislation regarding access and benefit sharing in the country

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 587 IRCCs that are available on ABSCH website.

1. The information hereinafter has been updated until September 29th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

1. General information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- Law 2016-1807 on Biodiversity (Loi No. 2016-1087 of Aug 8, 2016, pour la reconquête de la biodiversité, de la nature et des paysages, Loi Biodiversité").
- Environmental Code (Code de L'Environnement);
- Decree n° 2017-848 of 9th of May 2017 (Décret d'application n° 2017-848 du 9 mai 2017);
- Ordinance of September 13th, 2017, which establishes the benefit sharing agreement model;
- Ordinance of November 8th, 2017, which establishes the forms of declaration and request of authorization of access to genetic resources and associated traditional knowledge;

It is important to highlight that the website "French Biodiversity Clearing House Mechanism"[5] maintained by the French Government encourages anyone who wishes to access their genetic heritage to contact the National Focal Point for matters related to ABS, since it is the institution responsible for clarifying which legislation is applicable for each case. The website presents as examples the norms on protected species and protected areas, norms about health, CITES, etc., which may be applicable according to each case. In addition, users wishing to contact the National Focal Point must fill out and submit an online form (called Formulaire de demande d'accès en France aux ressources génétiques et aux connaissances traditionnelles associées), and forward it to the National Focal Point.

As for the dependent territories, it should be noted that France has jurisdiction over all matters related to the environment, although, if necessary, the country may transfer some of its powers to local administrations in overseas regions and departments (Guadeloupe, French Guiana, Martinique, Mayotte, Réunion, Clipperton, St Martin, St Pierre and Miquelon, as well as the French areas of Antarctica). It is important to note, however, that the French Government has no jurisdiction over the territories of New Caledonia, St Barthélemy, French Polynesia and Wallis and Futuna. For the sake of information, these are the territories that currently have their own legislation on the matter:

- French Guiana: Article L. 331-15-6 of the Environmental Code (Law no. 2006-436), of

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.
5. http://biodiv.mnhn.fr/info/mise-en-oeuvre-du-protocole-sur-l-acces-et-le-partage-des-avantages

2006;

- New Caledonia: Organic Law no.99-209, of 1999;

- French Polynesia: Articles LP 100-1 of the Environmental Code of French Polynesia.

For all such cases, it is advisable to forward the aforementioned form directly to the competent authorities of each territory. Their contacts are included in the annex of this document.

In the quality of regional organization, the European Union - of which France is a member - has its own regulations on this subject applicable to all its Member-States, which are the following:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are very general and broad, being a responsibility of each member-country to create more specific and detailed norms according to their own interests and needs.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The ABSCH website identifies the Ministère de la Transition Écologique (Ministry of Ecological Transition), Direction générale de l'aménagement, du logement et de la nature (General Directorate of Planning, Housing and Nature), Direction de l'eau et de la biodiversité (Directorate of Waters and Biodiversity) and Bureau de l'encadrement des impacts sur la biodiversité (Management Office of Biodiversity Impacts) as the competent institutions, which are responsible for implementation of access and benefit sharing regarding the Law nº 2016-1087 of October 8th, 2016.

At the regional level, the ABSCH website identifies the Province Sud de Nouvelle-Calédonie as the competent authority for access and benefit sharing in this province.

Also, the "Agence française pour la biodiversité" (French Agency for Biodiversity) was created by article 21 of Law 2016-1807, which is responsible to counter biopiracy, while also having competence over a number of subjects related to biodiversity, in particular monitoring and offering support in any matters related to access to genetic resources and the fair and equitable sharing of the benefits arising from their use, as well as the application of compensatory measures for occasional damages to the biodiversity.

In addition, according to article 37, paragraph 8, subsection 3, other competent authorities may be created under the scope of EU Regulation No. 511/2014

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The rules for obtaining access to genetic resources and associated traditional knowledge are established in article 37 of the Biodiversity Law. Authorization requests for access activities must be directed to the competent administrative authority, and the public institution responsible for the national park must also be notified when access is carried out within their premises. The communities involved or impacted by the access must be involved in the authorization process, and the competent authority shall be responsible for monitoring the activities and communications promoted by the users with the relevant communities.

The authorization document shall specify the conditions for use of the genetic resources, as well as the benefit-sharing agreement, which must be signed between the user and the competent authority. The authorization may be denied when:

1. The Parties fail to sign a benefit-sharing agreement;

2. The benefit-sharing proposed by the user does not correspond to their technical and financial capabilities;

3. The activity or its application has a potential of negatively impacting biodiversity, restricting the sustainable use of a resource or exhausting the genetic resource.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The dispositions concerning traditional knowledge associated with genetic resources are listed under article 37 of the Biodiversity Law, as well as in the Environmental Code and in the Decree 2017-848. In this sense, apart from offering the definitions of “use of traditional knowledge associated to genetic resources” and “traditional knowledge associated to genetic resources”, the article also establishes specific procedures for obtaining access to that knowledge, which are different from those applicable to genetic resources.

First, it is necessary to obtain the prior informed consent from the communities involved. As for the benefit-sharing, there is a requirement that it must be applied to benefit the communities involved, and it should be established and implemented in consultation and with the participation of the members of these communities. The community will be supported by a public institution for carrying out the Environmental Cooperation under the terms of article L.14311 of the General Code for Local Authorities, the Advisory Council mentioned in article L. 711 211 of the same code or, in their absence, the State or one of the public institutions with competence over the environment. This institution of public law will also be responsible for negotiating and signing the access and benefit sharing agreement with the user.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 37, subsection 3 – which deals with the rules on the use of genetic resources and associated traditional knowledge – II, 2nd, which alters art. L. 412-18e ss. of the French Forest Code, establishes the involvement of the national intellectual property authority in the analysis of patents arising from access to genetic resources or associated traditional knowledge. The institution shall observe the national regulations and ensure compliance with the ABS norms established by the European Union.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis. However, article 37, paragraph 8, of the Biodiversity Law, establishes that the transfer of genetic resources or traditional knowledge to third parties by an authorized user must be requested via a transfer document, an authorization or the relevant declaration.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and it comprises the utilization of genetic resources and associated traditional knowledge. The responsibility to share the benefits lies on the user.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. The Biodiversity Law establishes in its article 37 that the benefit-sharing shall be addressed in a dedicated agreement, and can be carried out in the following modalities:

- In situ or ex situ conservation of biodiversity, including sustainable use practices;

- Conservation of traditional knowledge associated to genetic heritage and maintenance of sustainable practices;

- Local contribution to creating jobs for individuals involved in the sustainable use of genetic resources or traditional knowledge;

- Collaboration, cooperation and contribution to research, education, capacity-building and awareness-raising of the public and local professionals, including technology transfer initiatives;

- Maintenance, conservation, management, support or restoration of ecosystem services in a given area;

- Financial aid.

It is important to highlight that the legal instrument that details these practices establishes actions 1-5 as priority, and therefore it can be understood that there is a preference for non-monetary benefit-sharing.

According to item V of article L412-8 of Environmental Code, monetary benefit sharing shall be up to 5% of the annual net sales of the products or processes obtained from the genetic resources which are subject to authorization. The monetary benefits will be due if the annual net sales surpasses a thousand euros.

Finally, a benefit-sharing agreement template is available as an annex of the Decree 2017-848.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Allocation to French Agency to Biodiversity	up to 5% of the annual net sales of the products or processes obtained from the genetic resources, if they surpass EUR 1000	Not defined	Not defined

Non Monetary	Not defined	In situ or ex situ conservation of biodiversity; Conservation of traditional knowledge associated to genetic heritage and maintenance of sustainable practices; Local contribution to creating jobs for individuals involved in the sustainable use of genetic resources or traditional knowledge; Collaboration, cooperation and contribution to research, education, capacity-building and awareness-raising of the public and local professionals, including technology transfer initiatives; Maintenance, conservation, management, support or restoration of ecosystem services in a given area;	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 38 of the Biodiversity Law (Loi Biodiversité) amends article L. 4151 of the French Forest Code to include the competence of carrying out inspections related to ABS violations, as well as the obligations established in Article 4 of EU Regulation 511/2014. In this sense, this competence is a responsibility of: officials for competition and consumption according to Book V of the French Consumer Code; officials designated by the Ministry of Defense; officials designated by the Ministry of Inquiry; the officials referred to in items L. 142-1-1, L.L. 143-5-7 and 541-2-1 of the French Public Health Code; regional park officials; local authority officials and their respective divisions; officials designated by the Ministry of Agriculture.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 39 of the Biodiversity Law (Loi Biodiversité) included a new article in the Environmental Code, which addresses the applicable penalties in case of irregular access. In this sense, a penalty of imprisonment for no longer than one year and fine of 150,000 € will be applicable under the following circumstances:

1. Access or use of genetic resources or traditional knowledge in disagreement with the legal dispositions, including disagreement with articles 3 and 4 of EU Regulation No. 511/2014. In this case, the fine can be increased up to 1 million Euro in cases where commercial use is identified.

2. Failure to seek, maintain or provide the relevant information on access and benefit sharing related to genetic resources and associated traditional knowledge.

Finally, in certain cases, a supplementary penalty may also be applied to prohibit the request of new authorizations for access to genetic resources or traditional knowledge for up to 5 years.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministère de L'Enseignement supérieur, de la Recherche et de l'Innovation (Ministry of Higher Education, Research and Innovation)	Responsible for receiving declarations of due diligence regarding projects of research and application at the European Union level.
Ministère de la transition écologique (Ministry of Ecological Transition) - Direction générale de l'aménagement, du logement et de la nature (General Directorate of Planning, Housing and Nature), Direction de l'eau et de la biodiversité (Directorate of Waters and Biodiversity) and Bureau de l'encadrement des impacts sur la biodiversité (Management Office of Biodiversity Impacts)	National Competent Authority for implementation of the legislation regarding access and benefit sharing in the country.

6. Websites

National CHM
http://biodiv.mnhn.fr/

Ministry of Ecological Transition
https://www.ecologie.gouv.fr/

Foundation for Research on Biodiversity
http://www.fondationbiodiversite.fr/en/

Agence française pour la biodiversité
http://www.afbiodiversite.fr/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. **Country Profiles. France profile**. Available in: <https://absch.cbd.int/countries/FRFR> Accessed on 09/29/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. **Country Profiles. France profile**. Available in: <https://www.cbd.int/countries/?country=frfr> Accessed on 09/29/2021.

EUROPEAN UNION. **Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices**. Available in: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Accessed on 11/04/2016.

EUROPEAN UNION. **Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union**. Available in: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-208044> Accessed on 04/11/2016.

EUROPEAN UNION. EU ABS **Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union**. Available in: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Accessed on 11/04/2016.

FRANCE. **Décret nº 2017-848 du 9 mai 2017 relatif à l'accès aux ressources génétiques et aux connaissances traditionnelles associées et au partage des avantages découlant de leur utilisation**. Available in: <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000034630780/> Accessed on 10/09/2020.

FRANCE. **Loi nº 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages**. Available in:<https://www.ecolex.org/details/legislation/loi-n-2016-1087-du-8-aout-2016-pour-la-reconquete-de-la-biodiversite-de-la-nature-et-des-paysages-lex-faoc159133/?q=&type=legislation&xkeywords=biodiversity&xcountry=Wallis+and+Futuna+Islands+%28France%29&xdate_min=&xdate_max=> Accessed on 03/17/2017.

FRANCE. **Loi nº 2006-436 relative aux parcs nationaux, aux parcs naturels marins et aux parcs naturels régionaux**. Available in: <https://www.ecolex.org/details/legislation/loi-no-2006-436-relative-aux-parcs-nationaux-aux-parcs-naturels-marins-et-aux-parcs-naturels-regionaux-lex-faoc064441/?q=2006-436&type=legislation&xcountry=Wallis+and+Futuna+Islands+%28France%29&xdate_min=&xdate_max=>. Accessed on 03/17/2017.

FRANCE. **Ségolène Royal, Ministre de l'écologie presente le cinquième rapport national de la France à la Convention sur la Diversité Biologique**. 2014. Available in: https://www.cbd.int/countries/?country=fr Access in 17/03/2017.

FRANCE. Stratégie nationale pour la biodiversité 2011-2020. 2011. Available in: <https://www.cbd.int/countries/?country=fr> Accessed on 03/17/2017.

Georgia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since August 31st, 1994.

1.2 s the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No legislation on access to genetic heritage or associated traditional knowledge was found. However, according to Georgia's Sixth National Report to the Convention on Biological Diversity (2018), the country is elaborating a draft law on Biodiversity, which will comprise rules on access and benefit sharing. The Regulatory Impact Assessment (RIA) of the Draft Law of

1 The information hereinafter has been updated until July 29th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Georgia on Biodiversity (2018) informs that the draft law will provide for commercial and non commercial permits to be issued by the Ministry of Environment and Natural Resources. Also, according to the same document, there will be an electronic registry in order to monitor the use of genetic resources originating from Georgia or imported from other countries.

Also, Regulations concerning plant resources licenses (No. 64 of 1997) establishes some rules regarding extraction and studying of plants in Georgia.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. However, according to the Implementation of the Convention on Biological Diversity in Georgia (2016), the main national agency that is responsible for the environment and implementation of the CBD in the country is:

- **Ministry of Environment and Natural Resources Protection**

The Ministry of Environment and Natural Resources Protection is responsible for implementing environmental protection policies, public administration of the environment and use of natural resources, state control over the environment and use of natural resources, development of national policies, governance over protected areas, coordination and control of activities, monitoring of biological diversity, regulation on utilization of fauna and flora species for scientific means, and granting of environmental licenses and previous authorization.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

Ms. Nona Khelaia
Biodiversity Division
Biodiversity and Forest Department
Ministry of Environment and Agriculture
6 Gulua str.
0114 Tbilisi
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teonakarchava@yahoo.com
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6. Websites

ABSCH Georgia Profile

https://absch.cbd.int/countries/GE

CDB Georgia Profile

https://www.cbd.int/countries/?country=ge

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Georgia profile. Available in: <https://absch.cbd.int/countries/GE > Accessed on 11/12/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profile. Georgia profile. Available in: <https://www.cbd.int/countries/?country=ge> Accessed on 11/12/2021.

GEORGIA. The Law of Georgia on Environmental Permit, October 15 of 1996. Available at: <https://www.ecolex.org/details/legislation/law-on-environmental-permit-lex-faoc014559/?q=The+Law+of+Georgia+on+Environmental+Permit+georgia&type=legislation&xdate_min=&xdate_max=> Access in: 05/11/2018.

GEORGIA. The Forestry Code of Georgia, June 22 of 1999. Available at: <https://www.ecolex.org/details/legislation/forest-code-of-the-republic-of-georgia-lex-faoc020885/?q=The+Forestry+Code+of+Georgia> Access in: 05/11/2018.

GEORGIA; Ministry of Environment and National Resources Protection. 5th National Report to the Convention on Biological Diversity, 2015. Available at: <https://www.cbd.int/doc/world/ge/ge-nr-05-en.pdf> Access in: 05/11/2018.

GEORGIA; Ministry of Environment and National Resources Protection. 6th National Report to the Convention on Biological Diversity, 2018. Available at: <https://www.cbd.int/doc/world/ge/ge-nr-05-en.pdf> Access in: 18/08/2020.

GEORGIA, Ministry of Environment Protection and Agriculture; Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ). Regulatory Impact Assessment (RIA) of the Draft Law of Georgia on Biodiversity. Final Report. February, 2018.

MACHARASHVILI, Irakli. Implementation of the Convention on Biological Diversity in Georgia. Green Alternative, Tbilisi, 2016. Available at: <http://greenalt.org/wp-content/uploads/2016/05/CBD_ENG.pdf> Access in: 05/11/2018.

Germany[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since March 21st, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since April 21st, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. the Federal Agency for Nature Conservation is an officially recognized checkpoint, responsible for:

- Receiving due diligence declarations from users at two different points in time: at the research funding stage as well as at the stage of final development of a product;
- Ad-hoc and scheduled monitoring of users of genetic resources and of traditional knowledge associated with genetic resources.
- When necessary, imposing sanctions in the event of failure by users to comply with due diligence, declaration or cooperation obligations.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 26 Checkpoints communiqués that are available on ABSCH website.

1. The information hereinafter has been updated until October 26th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Although the Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No. 511/2014 does not establish any specific procedures or obligations on access and benefit sharing for biodiversity users, it formalizes the implementation of the European Union legislation described below, while also establishing some responsibilities for the National Competent Authority.

As a regional organization, the European Union – of which Germany is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The German country profile of ABSCH website identifies Federal Agency for Nature Conservation as the competent institution, which is responsible for receipt due diligence declarations from users at two different points in time: at the research funding stage as well as at the stage of final development of a product; Ad-hoc and scheduled monitoring of users of genetic resources and of traditional knowledge associated with genetic resources and intervention and where necessary imposition of sanctions in the event of failure by users to comply with due diligence, declaration or cooperation obligations among others responsibilities to cover all aspects of the genetic resources within EU Regulation No. 511/2014 and EU Execution Regu-

lation No 2015/1866.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Although Germany does not have any legislation regulating access. However, as informed by the National Focal Point, if an invention is based on or uses biological material of plant or animal origin, the patent application shall include information on the geographical origin of such material, if known, as per Section 34a of the German Patent Act (Section 34a of the German Patent Act). In the same sense, simultaneously with the Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No. 511/2014, the Patent Law was amended on July 1, 2016, inserting a new section 34a (2) which stipulates that the Patent Office shall notify the Federal Agency for Nature Conservation as the competent national authority of the information on

geographical origin.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the country's National Focal Point, access to genetic resources in the territory of the Federal Republic of Germany is free from the requirements of obtaining Prior Informed Consent and the conclusion of the Mutually Agreed Terms, but subject to the restrictions of public law (such as the nature conservation law and species) and, when applicable, private law. On the other hand, genetic resources obtained through a German collection (ex situ resources) may however be subject to the obligations of obtaining Prior Informed Consent and the conclusion of the Mutually Agreed Terms of the country where they were originally collected in situ.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the bene-

fits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the member-countries have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) institutes the Federal Agency for Nature Conservation as the official inspection body responsible for all matters related to access and benefit-sharing in the country.

According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country should promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In

the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: In article 4, the breaches described in items 1 and 2 may suffer penalty of an administrative fine of 50,000 EUR. Furthemore, according to National Focal Point, the German law provides that regulatory fines may exceed the financial benefit that an author obtained .

According to Article 3 of Regulation 511/2014 of the European Union, "illegally acquired genetic resources" are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations ("user conformity" and "monitoring of user conformity", respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Federal Agency for Nature Conservation	Ilts responsibilities cover all aspects of genetic resources, within EU Regulation No. 511/2014 and EU Execution Regulation No. 2015/1866.

6. Websites

ABSCH Germany Profile
https://absch.cbd.int/countries/DE

CBD Germany Profile
www.cbd.int/countries/?country=de

Federal Agency for Nature Conservation
https://www.bfn.de/?L=1

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Germany profile. Available in: < https://absch.cbd.int/countries/DE > Access on July 15, 2020.

BERTRAM, Verena. The implementation of the Nagoya Protocol in Germany. Taylor Wessing. Synapse, Law for Life Sciences. January, 2016. Available in: < https://united-kingdom.taylorwessing.com/synapse/ti-nagoya-germany.html > Access on July 21, 2020

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profles. Germany profle. Available in: < https://www.cbd.int/countries/?country=de > Access on July 15, 2020.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: https://absch.cbd.int/database/record/ABSCHMSR-DE-204508 Access on July 16, 2020.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefts Arising from their Utilisation in the Union. Available in: < https://absch.cbd.int/database/record/ABSCH--MSR-DE-208044> Access on July 17, 2020.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefts Arising from their Utilization in the Union. Available in: https://absch.cbd.int/database/ record/ABSCH-MSR-DE-201808 Access on July 20, 2020.

GOVERNMENT OF GERMANY. Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No. 511/2014. Available in: https://absch.cbd.int/database/ record/ABSCH-MSR-DE-207328 Access on July 20, 2020.

GOVERNMENT OF GERMANY. Fifth National Report Convention on Biological Diversity . Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB). Government of Germany. Rostock, March, 2015. Available in: < https://www.cbd.int/countries/?country=al > Access in July 21, 2020.

GOVERNMENT OF GERMANY. Nature Conservation Action Programme 2020. Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB). Government of Germany. Rostock, October, 2015. Available in: < https://www.cbd.int/countries/?country=al > Access on July 21, 2020.

HOLM-MÜLLER, Karin; RICHERZHAGEN, Carmen e; TÄUBER, Sabine. Users of Genetic Resources in Germany: Awareness, Participation and Positions regarding the Convention on Biological Diversity. Federal Agency for Nature Conservation, Government of Germany. Bonn, 2005. Available in: < https://www.bfn.de/fleadmin/MDB/documents/skript126.pdf> Access on July 17, 2020.

Greece[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 2nd, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since May 14th, 2020.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / ( ) NO / (X) NOT AVAILABLE

According to Maria and Limniou (2015), Law 3937/2011 addresses biodiversity and states that there shall be restrictions regarding ABS. However, only versions in local language were found which is why it could not be analysed by this research.

1 The information hereinafter has been updated until July 23rd, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Paragraph 68 of the Nature Conservation Act, establishes that the competent authorities relative to access to genetic heritage and associated traditional knowledge are:

- **Ministry of Environment, Energy and Climate Change (MoEECC)**

This is the Ministry of Environment, Energy and Climate Change, that has as its main functions, among others: simplify and codify environment laws, and reinforce the compliance mechanisms of these laws, protect biodiversity and, in accordance with Law 3937/2011, grant prior authorizations of access to genetic heritage.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / ( ) NO / (X) NOT AVAILABLE

It was not possible to access the law that has ABS dispositions, since it was only found in the local language. However, according to scientific articles -and official documents, Law 3937/2011 determines that research and studies with endemic species must have prior authorization granted by MoEECC in cooperation with MoRDF.

The above-mentioned law differentiates academic research by members of the scientific community, which follow the procedures of article 17(3)(4) for the grant of prior authorization, and must be made with a license granted by the State.

In addition, according to Maria e Limniou (2015), even though there is no legal determination

for a Mutually Agreed Term, recently the State has granted prior authorization with the condition that, if the research results are used for economic gain, a Mutually Agreed Term must be signed between the researcher and the State, represented by MoEECC.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / ( ) NO / (X) NOT AVAILABLE
It was not possible to access the law that has ABS dispositions, since it was only found in the local language.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / ( ) NO / (X) NOT AVAILABLE

It was not possible to access the law that has ABS dispositions, since it was only found in the local language.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection

and access of exotic species?
( ) YES / ( ) NO / (X) NOT AVAILABLE
It was not possible to access the law that has ABS dispositions, since it was only found in the local language.
The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / ( ) NO / (X) NOT AVAILABLE
It was not possible to access the law in force in the country to confirm this item, since it is only found in the local language. However, according to scientific articles and official documents, the Forestry Code, in its art. 8 determines that for cases of collection of protected and unprotected species for research purposes, an authorization should be required when the material collected is to be exported.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / ( ) NO / (X) NOT AVAILABLE
It was not possible to access the law that has ABS dispositions, since it was only found in the local language.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / ( ) NO / (X) NOT AVAILABLE
It was not possible to access the law that has ABS dispositions, since it was only found in the local language.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
It was not possible to access the law that has ABS dispositions, since it was only found in the local language.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

It was not possible to access the law in force in the country to confirm this item, since it is only found in the local language. However, according to Maria e Limniou (2015), even though there is no legal determination for a Mutually Agreed Term, recently the State has granted prior authorization with the condition that, if the research results are used for economic gain, a Mutually Agreed Term must be signed between the researcher and the State, represented by MoEECC.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / ( ) NO / (X) NOT AVAILABLE

It was not possible to access the law that has ABS dispositions, since it was only found in the local language.

According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

It was not possible to access the law that has ABS dispositions, since it was only found in the local language.

According to Article 3 of Regulation 511/2014 of the European Union, "illegally acquired genetic resources" are the genetic resources and associated traditional knowledge accessed in

disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations ("user conformity" and "monitoring of user conformity", respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Environment, Energy and Climate Change	It is the body responsible for legislating in the field of environment and biodiversity and, according to Law 3937/2011, the body responsible for controlling access to genetic heritage.

6. Websites

ABSCH Greece Profile
https://absch.cbd.int/countries/GR

CBD Greece Profile
https://www.cbd.int/countries/?country=gr

Ministry of Environment, Energy and Climate Change
http://www.minenv.gr

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Greece profile. Available in: *https://absch.cbd.int/countries/GR* Accessed on 10/29/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Greece profile. Available in: *https://www.cbd.int/countries/?country=gr* Accessed on 10/29/2020.

HELLENIC REPUBLIC. Fifth National Report of Greece. Available at: <*https://www.cbd.int/doc/world/gr/gr-nr--05-en.pdf*> Accessed on 10/29/2020.

MARIA, Efpraxia-Aithra; LIMNIOU, Georgia-Panagiota. Legal Framework in Greece regarding the ABS regime, implementation gaps and issues requiring national and international attention. In: Implementing the Nagoya Protocol: Comparing Access and Benefit-Sharing regimes in Europe. Leiden: Brill Nijhoff, 2015. Cap. 5, p. 137-161.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available at: <*https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508*> Accessed on 10/29/2020.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union. Disponível em: *https://absch.cbd.int/database/record/ABSCH--MSR-DE-208044*> Accessed on 10/29/2020.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available at: <*https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808*>Accessed on 10/29/2020.

Holy See[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

( ) YES / (X) NO

No, the country is not a Party to the Convention on Biological Diversity.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1 The information hereinafter has been updated until October 1st, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / ( ) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / ( ) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / ( ) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

H.E. Archbishop Hubertus Matheus Maria Van Megen
Apostolic Nuncio
Apostolicv Nunciature of the Holy See (Vatican City) in Nairobi, Kenya
Manyani Road West, Wayaki Way
P.O. Box 14326
Nairobi
Kenya

CBD Primary NFP
+254 20 214 8971, 258 9703
+254 20 263 1120
nunciokenya@nunciokenya.org
nunciokenya@gmail.com

6. Websites

ABSCH Holy See Profile
https://absch.cbd.int/countries/VA

CBD Holy See Profile
https://www.cbd.int/countries/?country=va

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Holy See profile. Available at: *https://absch.cbd.int/countries/VA*> Access in11/09/2020.

CONVENTION ON BIOLOGICAL DIVERSITY. **Holy See Profile.** Available at: <*https://www.cbd.int/countries/?-country=va*> Access in: 11/09/2020.

Hungary[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, Hungary has been a Party to the Convention on Biological Diversity, by ratification, since May 25th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, Hungary has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoints:

Pest County Government Office: Competent authority as established in Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

- National Food Chain Safety Authority: created by Government Decree No. 3/2016, competent in the area of licensing, distribution and control of products developed from the use of genetic resources or associated traditional knowledge.

- National Environmental and Nature Protection Inspectorate: competent national authority, according to EUROPEAN UNION requirement n° 511/2014, competent to verify compliance by the genetic resources users with their legal obligations, including obtaining prior consent and signing of mutual agreement among the parties.

- National Office of Research, Development and Innovation: designed by the Government Decree No. 3/2016, competent in the area of research that involves the use of genetic resources or associated traditional knowledge.

- Hungarian Academy of Sciences: designed by the Government Decree No. 3/2016, competent in the area of research that involves the use of genetic resources or associated tradi-

1 The information hereinafter has been updated until July 27th, 2021.

Z3. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

tional knowledge.

- National Institute of Pharmacy and Nutrition: created by the Government Decree No. 3/2016, competent in the area of licensing, distribution and control of products developed from the use of genetic resources or associated traditional knowledge.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the country already has the Regulation 3/2016 (I. 20.) of the Government on the rules of implementation of certain international and European community legislation in relation to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization. The Nagoya Protocol, approved by Act VIII of 2014 publishing the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.

As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

According to the ABSCH website, the responsible institution for all matters related to genetic resources in Hungary is the Pest Country Government Office.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The national legislation does not provide for prior authorizations but mentions in Article 3, Regulation 3/2016 (I.20) that for research on genetic resources it is necessary for the user to make a declaration that he has fulfilled the obligations of the Regulation of the European Union 2015/1866, to be presented the National Inspection of Environmental and Natural Protection.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8. Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE
The norms covered by this analysis do not address this information about benefit sharing.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be composed by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE
The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if

users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Article 5 of Government Decree no. 3/2016 establishes legal consequences regarding access to and use of genetic resources. The Pest County Government Office may impose a fine on violators of the provisions of Article 5 in the amount of Forints 100,000 (one hundred thousand) Forints ten million (10 million).

According to Article 3 of Regulation 511/2014 of the European Union, “illegally acquired genetic resources” are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”, respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found. Yes, according to {XX}, fines have already been applied in the country. [Also/Yes], one emblematic case related to [biopiracy/irregular access] was [XX], in which [...].

5. Summary - Competent authorities

Authority	Competence
Pest Country Government Office	all matters related to genetic resources

6. Websites

ABSCH Hungary Profile
https://absch.cbd.int/countries/HU

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Hungary profile. Available in: *https://absch.cbd.int/countries/HU* Accessed on 10/29/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Hungary profile. Available at: *https: ttps://www.cbd.int/countries/?country=hu* Accessed on 10/29/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: *https://absch.cbd.int/database/record/ABSCHMSR-DE-204508* Accessed on 10/29/2021.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH--MSR-DE-208044* Accessed on 10/29/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808* Accessed on 10/29/2021.

HUNGARY. Act VIII of 2014 on the publication of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. Available in: *https://absch.cbd.int/countries/HU* Accessed on 10/29/2021.

HUNGARY. Fifth National Report to the Convention on Biological Diversity - Hungary. Available in *https://www.cbd.int/countries/?country=hu* Accessed on 10/29/2021.

HUNGARY. National Strategy for the Conservation of Biodiversity in 2015-2020. Available in: *https://www.cbd.int/countries/?country=hu Accessed* on 10/29/2021.

HUNGARY. Regulation 3/2016 (I. 20.) of the Government on the rules of implementation of certain international and European community legislation in relation to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization. Available in: *https://absch.cbd.int/countries/HU* Accessed on 10/29/2021.

Iceland[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 11th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated tradi-

1. The information hereinafter has been updated until December 4th. 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

tional knowledge in the country. According to the Fourth National Report to the Convention on Biological Diversity (2010), the rules on access and benefit sharing in the country only apply for geothermal bacteria. Also, the document informs that Nature Conservation Act has been revised to amplify its scope of protection over the national biodiversity.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. However, the Nature Conservation Act indicated the Ministry of Culture and Education as responsible for matters related to nature conservation in the country.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed

distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or

public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

Mr. Sigurdur Armann Thrainsson
Head of Division
Department of Land and Natural Heritage
Ministry for the Environment and Natural Resources
Skuggasund 1
IS-101 Reykjavik
Iceland

Icelandic Museum of Natural History
P.O. Box 5320
IS-125 Reykjavik
Iceland

CBD Primary NFP
+354 545 8600
+354 562 4566
sigurdur.thrainsson@environment.is
sigurdur.thrainsson@uar.is
sigurdur.thrainsson@umh.stjr.is

CBD Secondary NFP
+354 562 98 22
+354 562 08 15

6. Websites

ABSCH Iceland Profile
https://absch.cbd.int/countries/IS

CDB Iceland Profile
https://www.cbd.int/countries/?country=is

National CH
https://eng.umhverfisraduneyti.is/

The Environment and Food Agency of Iceland
http://www.ust.is/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Iceland Profile. Available at: *https://absch.cbd.int/countries/IS*> Access on 12/04/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Iceland profile. Available at: *https://www.cbd.int/countries/?country=is*> Access on 12/04/2020.

GOVERNMENT OF ICELAND. **Fourth National Report to the Convention on Biological Diversity.** Available at: *https://www.cbd.int/doc/world/is/is-nr-04-en.pdf*> Access on 16/05/2018.

Ireland[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since June 20th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Protocol, but has been a signatory country since February 1st, 2012

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has one checkpoint:
National Parks and Wildlife Service (DCHG)

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following law regarding access and benefit-sharing:

1 The information hereinafter has been updated until August 5th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Statutory Instrument 253 of 2019, which provides for implementation of the Eu Regulation in the country.
As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. However, Statutory Instrument No. 253 of 2019 provides that there shall be a competent authority.

No official competent institution was identified in relation to access and benefit-sharing in the European Union. However, EU Regulation No. 511/2014 establishes in article 6 that member-states should designate one or more competent authorities responsible for the application of the aforementioned regulation.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address authorizations in order to obtain genetic resources.

Within the European Union, of which Ireland is a member, the requirement of prior authorization to access genetic resources and traditional knowledge has not been identified.

EU regulations do not provide for procedures regarding access and benefit sharing, as those

are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific

procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 5 of Statutory Instrument 253 of 2019 establishes that the competent authority may appoint authorised officers for ensuring compliance with those regulations and EU Regulations.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 8 of Statutory Instrument 253 of 2019 establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: summary conviction to a class A fine, or imprisonment for a term not exceeding 6 months, or both or; conviction on indictment, to a fine not exceeding EUR 100,000, or to imprisonment for a term not exceeding 2 years or both.

According to Article 3 of Regulation 511/2014 of the European Union, “illegally acquired genetic resources” are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”, respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Alan Moore
Assistant Principal Officer
Biodiversity Policy
Department of Culture, Heritage and the Gaeltatcht
7 Ely Place
Dublin
2 DO2 TW08
Ireland

ABS National Focal Point
+353 1 888 3206
alan.moore@chg.gov.ie
biodiversitypolicy@chg.gov.ie

6. Websites

ABSCH Ireland Profile
https://absch.cbd.int/countries/IE

CBD Ireland Profile
https://www.cbd.int/countries/?country=ie

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles: Ireland. Available at: *https://absch.cbd.int/countries/IE*> Accessed on: 10/29/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles: Ireland. Available at: <*https://www.cbd.int/countries/?country=ie*> Accessed on: 10/29/2021.

IRELAND. Fifth National Report to the Convention on Biological Diversity, 2014. Available at: <*https://www.cbd.int/doc/world/ie/ie-nr-05-en.pdf*> Accessed on: 10/29/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508* Accessed on: 10/29/2021.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH--MSR-DE-208044* Accessed on: 10/29/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808 Acesso em 11/11/2016* Accessed on: 10/29/2021.

Italy[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since July 14, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in Italy, but there are two laws that address the subject. The first one covers patents involving biological material of animal or plant origin, and the second one covers the protection of the genetic heritage of the region of Basilicata.

1 The information hereinafter has been updated until July 7th, 2021

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Code of Industrial Property - regulates intellectual property and patents in the country.

- Official Bulletin of the Basilicata Region No. 50 of Oct 16, 2008 - Protection of the genetic heritage of native plants and animals of agricultural relevance in the region of Basilicata.

It's important to note that Italy was notified by the Commission[5] of the EU that it would be referred to the EU Court of Justice (Coj) for infringement of EU legislation about Access and Benefit Sharing. According to the press release entitled by the EU Commission in February 2020, Italy was appointed to have an insufficient ABS system.

As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

No official competent institution was identified in relation to access and benefit-sharing in the European Union. However, EU Regulation No. 511/2014 establishes in article 6 that member-states should designate one or more competent authorities responsible for the application of the aforementioned regulation.

5. Infringement - Commission takes Italy to Court for its incomplete regime of access to genetic resources. Press Corner European Commission, 2020. Disponível em: <https://ec.europa.eu/commission/presscorner/detail/en/IP_20_215> Acesso em: 18/09/2020

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4. Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the Code of Industrial Property, 170-bis:

- For the purpose of evaluating the patentability of biotechnological inventions, the Italian Patent and Trademark Office, in order to ensure compliance with item b), paragraph 1 of Article 81-quinquies, may request an opinion from the National Committee for Biosafety and Biotechnologies.

- The provenance of biological material of animal or plant origin, which is the basis of the invention, is to be declared together with the application of the patent both with reference to the country of origin, in order to verify compliance with import and export legislation, and

in relation to the biological organism from which it was isolated.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Although there is no national law on ABS, the Official Bulletin of the Basilicata Region No. 50 deals with the subject for the region of Basilicata. Article 7 states that the wealth of genetic resources of plants or animals are deemed as collective rights. The benefits shall therefore be evenly distributed among the local

community which encompasses these resources, as the community is the main agent responsible for their conservation.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be composed by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where

the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

As explained under item 2.1, Italy does not have any legislation on access and benefit sharing. However, the Code of Industrial Property mentions under section 170-ter (sanctions) the applicable sanctions in the case of false statements concerning the origin of biological material from animals or plants, which shall be punishable with an administrative fine from 10,000 to 100,000 Euros.

According to Article 3 of Regulation 511/2014 of the European Union, "illegally acquired genetic resources" are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations ("user conformity" and "monitoring of user conformity", respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

ABS National Focal Point (NFP)

Ms. Silvia Jardina
Officer Directorate General for Natural Heriage Ministry for Ecological Transition via Cristoforo Colombo 44 00147 Rome
ABS National Focal Point
Italy

6. Websites

ABSCH Italy Profile
https://absch.cbd.int/countries/IT

CBD Italy Profile
https://www.cbd.int/countries/?country=it

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Italy profile. Available in: *https://absch.cbd.int/countries/IT* Accessed on 11/10/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Italy profile. Available in: *https://www.cbd.int/countries/?country=it* Accessed on 11/10/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: *https://absch.cbd.int/database/record/ABSCHMSR-DE-204508* Accessed on 11/10/2021.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH--MSR-DE-208044* Accessed on 11/10/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/ record/ABSCH-MSR-DE-201808* Accessed on 11/10/2021.

ITALY. Industrial Property Code (Legislative Decree No. 30 of February 10, 2005, as amended up to Decree-Law No. 1 of January 24, 2012, converted into law with changes by Law No. 27 of March 24, 2012). Available in: *http://www.wipo.int/wipolex/en/details.jsp?id=13123* Accessed on 11/10/2021.

ITALY. Italian National Biodiversity Strategy. Ministero dell'Ambiente e della Tutela del Territorio e del Mare – ATTM. Available in: *https://www.cbd.int/countries/?country=it* Accessed on 11/10/2021

ITALY. Italy's Fifth National Report To The Convention On Biological Diversity (2009-2013). Ministry for the Environment, Land and Sea. Available in: *https://www.cbd.int/countries/?country=it* Accessed on 11/10/2021.

ITALY. La Strategia Nazionale per la Biodiversità. Ministero dell'Ambiente e della Tutela del Territorio e del Mare – MATTM. Available in: *https://www.cbd.int/countries/?country=it* Accessed on 11/10/2021.

ITALY. Legge Regionale N. 26 Del 14-10-2008 Regione Basilicata. Available in: *https://www.regione.basilicata.*

it/giunta/files/docs/DOCUMENT_FILE_304418.pdf. Accessed on 11/10/2021.

ITALY. Mid-term review of the National Biodiversity Strategy to 2020. Available in: *https:// www.cbd.int/countries/?country=it* Accessed on 11/10/2021.

EU. The Infringement Commission takes Italy to Court for its incomplete regime of access to genetic resources. Press Corner European Commission, 2020. Disponível em: *https://ec.europa.eu/commission/presscorner/detail/en/IP_20_215*> Accessed on 11/10/2021.

Latvia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since March 13th, 2013.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has one checkpoint:

- **Nature Conservation Agency**

This institution is responsible for receiving due diligence declarations and submitting declarations as checkpoint communiquès on the ABSCH Mechanism.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following law regarding access and benefit-sharing:

1.The information hereinafter has been updated until October 29th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Law on Use of Genetic Resources (2019), which provides for compliance measures for users on EU Regulation No. 511/2014

As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 4 of the Law on Use of Genetic Resources (2019) establishes that the Competent Authority within the meaning of Regulation (EU) No 511/2014 shall be the Nature Conservation Authority.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address authorizations in order to obtain genetic resources. Within the European Union, of which Latvia is a member, the requirement of prior authorization to access genetic resources and traditional knowledge has not been identified.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will

generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9. Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE
The norms covered by this analysis do not address this information about benefit sharing.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE
The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Article 8 of Law on Use of Genetic Resources (2019) institutes the Nature Protection Board as the official inspection body responsible for all matters related to access and benefit-sharing in the country.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Law on Use of Genetic Resources (2019) establishes that there shall be fines from twenty to one hundred and forty fine units (natural person) or two thousand eight hundred fine units (legal person), when there is access or transfer of genetic resources without permits; failure to disclose documentation or information required or failure to submit a due diligence declaration.

According to Article 3 of Regulation 511/2014 of the European Union, "illegally acquired genetic resources" are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations ("user conformity" and "monitoring of user conformity", respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Nature Conservation Agency	Responsible for receiving due diligence declarations and submitting declarations as checkpoint communiquès on the ABSCH Mechanism.

6. Websites

ABSCH Latvia Profile
https://absch.cbd.int/countries/LV

CBD Latvia Profile
https://www.cbd.int/countries/?country=lv

Latvian Biodiversity Clearing-House Mechanism
http://biodiv.daba.gov.lv/

Ministry of Environment Protection and Regional Development
http://www.varam.gov.lv/eng/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Latvia profile. Available in: *https://absch.cbd.int/countries/LVCG* Accessed on 10/28/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Latvia profile. Available in: *https://www.cbd.int/countries/?country=lvcg* Accessed on 10/28/2021.

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EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH--MSR-DE-208044* Accessed on: 10/29/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808 Acesso em 11/11/2016* Accessed on: 10/29/2021.

LATVIA. **6th National Report to the Convention on Biological Diversity**, 2014. Available in: <*https://chm.cbd.int/database/record?documentID=248109*> Accessed on 10/28/2021.

LATVIA. Law on the Use of Genetic Resources (Ģenētisko resursu izmantošanas likums). 2019. Available in: <*https://absch.cbd.int/database/record/ABSCH-MSR-LV-249136*>. Accessed on 10/28/2021.

Liechtenstein[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 17th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1 The information hereinafter has been updated until October 27th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

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6. Websites

ABSCH Liechtenstein Profile
https://absch.cbd.int/countries/LI

CBD Liechtenstein Profile
https://www.cbd.int/countries/?country=li

National Website
https://www.liechtenstein.li/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Liechtenstein Profile. Available at: *https://absch.cbd.int/countries/LI*> Access on October 27th, 2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Liechtenstein profile. Available at: *https://www.cbd.int/countries/?country=li*> Access on October 27th, 2021.

GOVERNMENT OF LIECHTENSTEIN. **Fifth National Report to the Convention on Biological Diversity.** Available at: *https://www.cbd.int/doc/world/li/li-nr-05-en.pdf*> Access on October 27th, 2021.

Lithuania[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since May 1st, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Protocol, but has been a signatory country since December 29th, 2011.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Law on Environment Protection (1992) states that utilization of natural resources shall be adopted on the basis of its law.

1 The information hereinafter has been updated until August 5th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

No official competent institution was identified in relation to access and benefit-sharing in the European Union. However, EU Regulation No. 511/2014 establishes in article 6 that member-states should designate one or more competent authorities responsible for the application of the aforementioned regulation.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on

access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

However, the country has a Law on patents that in its article 2° establishes that new inventions, of all fields of technology, may be patented, if they are new, demonstrate to have an inventive degree, and has industrial utilization, and it excludes the possibility of patent of species of plants, animals or biological processes that are essential to their development.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

According to Article 3 of Regulation 511/2014 of the European Union, “illegally acquired genetic resources” are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”, respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Brenislevas Gelvonauskis
Director
Plant Gene Bank
Ministry of Environment
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LT-558242
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Lithuania

ABS National Focal Point
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6. Websites

Parliament of the Republic of Lithuania
http://www.lrs.lt/sip/portal.show?p_k=2

ABSCH Lithuania Profile
https://absch.cbd.int/countries/LT

CBD Lithuania Profile
https://www.cbd.int/countries/?country=lt

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Lithuania profile. Available in: https://absch.cbd.int/countries/LT> Accessed on 10/29/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Lithuania profile. Available in: https://www.cbd.int/countries/?country=lt> Accessed on 10/29/2021.

EUROPEAN UNION. **Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices.** Available in: https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508 Accessed on 10/29/2021.

EUROPEAN UNION. **Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union**. Available in: https://absch.cbd.int/database/record/ABSCH-MSR-DE-208044 Accessed on 10/29/2021.

EUROPEAN UNION. **EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union**. Available in: https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808 Acesso em 11/11/2016 Accessed on 10/29/2021.

Luxembourg

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since August 7th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since January 23rd, 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As a regional organization, the European Union – of which the country is a member - has its

1 The information hereinafter has been updated until October 25th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institution was identified in relation to access and benefit-sharing in the European Union. However, EU Regulation No. 511/2014 establishes in article 6 that member-states should designate one or more competent authorities responsible for the application of the aforementioned regulation.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

What about the regional legislation, there's not any reference to DSI, Synthetic biology or other terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

What about the regional legislation, there's no reference to species that have naturally developed their distinctive properties.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection body was identified in the country, and it neither has any legislation on access and benefit-sharing.

According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As explained in item 2.1, Luxembourg does not have any legislation on access and benefit sharing.

According to Article 3 of Regulation 511/2014 of the European Union, “illegally acquired genetic resources” are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”, respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the

country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Laurent Sohley
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6. Websites

ABSCH Luxembourg Profile
https://absch.cbd.int/countries/LU

CBD Luxembourg Profile
https://www.cbd.int/countries/?country=lu

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Luxembourg. Available in: <*https://absch.cbd.int/countries/LU*>. Accessed on 11/05/2021.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Luxembourg. Available in: < *www.cbd.int/countries/?country=lu*> Accessed on 11/05/2021.

EUROPEAN UNION. Commission notice -- Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union. Available in: <*https://absch.cbd.int/database/record/ABSCH-MSR--EU-201808*> Accessed on 11/05/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: <*https://absch.cbd.int/database/record/ABSCH-MSR-LU-204508*> Accessed on 11/05/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: <*https://absch.cbd.int/database/record/ABSCH-MSR-LU-201808*> Accessed on 11/05/2021.

Malta[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since March 29, 2001.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since March 1st. 2017.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The Plant Protection Directorate is a checkpoint indicated in the ABSCH website, responsible for managing access to genetic resources and MATs, PICs and IRCCs in the country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 11 IRCCs that are available on ABSCH website.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the Subsidiary Legislation 549.111 - Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization Regulations, 2016 - Legal Notice, 379 of 2016

1 The information hereinafter has been updated until July 30th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. TThe "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

addresses access and benefit sharing in the country. There are also user guides, pre-informed consent forms, among other documents and templates available online to assist users of the country's genetic heritage.

As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The ABS Law identifies the Director of Plant Protection Directorate as the competent institution, which is responsible for all genetic resources, including on helping to establish PIC and MAT for genetic resources pertinent to wildlife, birds and marine resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Rule 5 of the ABS Law, access to genetic resources requires the prior informed consent of the competent or the assisting authorities under rule 4, (3). As described in rule 7 of the same standard, for the request for prior consent and for confidential information, the applicant shall submit a written request to the competent authority or to the assisting competent authority at least six months before its use.

In addition, rule 5 (4) mentions that the competent authority shall issue a certificate of compliance as evidence that prior informed consent and mutually agreed terms have been defined.

It should be noted that the country provides online forms for requesting prior informed con-

sent, like the forms described below:

1. Application for R&D entities to obtain Prior Informed Consent (PIC) to access Genetic Resources for which Malta has sovereign rights:

2. Application for Academic Researchers to obtain Prior Informed Consent (PIC) to access Genetic Resources for which Malta has sovereign rights:

3. Genetic resources registration form.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Notwithstanding the procedures described in item 2.3, in cases where access to associated traditional knowledge is concerned, PIC is required. According to Rule 6 of the ABS Law, the use of traditional knowledge associated with genetic resources held by local communities will require prior informed consent or authority only after consultation with the relevant competent authority and the community or communities related to the case, where applicable.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This

resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. Rule 5 (3) of the ABS Law provides that access to genetic resources must ensure that the benefits arising from the use of genetic resources, as well as any subsequent application and marketing shall be distributed fairly and equitably. Similarly, rule 6(3) defines that mutually agreed terms will ensure that the benefits arising from the use of traditional knowledge are shared fairly and fairly with the community or communities involved.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits

resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be composed by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The ABS Law institutes the Director of the Plant Protection Directorate as the official inspection body responsible for all matters related to access and benefit-sharing in the country.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The ABS Law establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as:

- In the case of a first offense, a fine of not less than eight hundred euro (€800) is applicable. not exceeding four thousand and six hundred and fifty-eight euro and seventy-five cents (€4,658.75).

- In case of repeated offense, a fine of not less than € 6,000, but not exceeding €10,000, or imprisonment not exceeding two years, or cumulatively fine and imprisonment is applicable.

According to Article 3 of Regulation 511/2014 of the European Union, "illegally acquired genetic resources" are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations ("user conformity" and "monitoring of user conformity", respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Plant Protection Directorate	Responsible for all genetic resources, including on helping to establish PIC and MAT for genetic resources pertinent to wildlife, birds and marine resources.

6. Websites

ABSCH Malta Profile
https://absch.cbd.int/countries/MT

CBD Malta Profile
https://www.cbd.int/countries/?country=mt

Government of Malta. Plant Protection Directorate. Available in
https://agriculture.gov.mt/en/phd/Pages/dirOffice.aspx

7. References

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE, Absch. Country profile. Malta. Available in: <https://absch.cbd.int/countries/MT>. Accessed on 11/05/2021.

CONVENTION ON BIOLOGICAL DIVERSITY, Cbd. Country profile. Malta. Available in: < www.cbd.int/countries/?country=mt> Accessed on 11/05/2021.

EUROPEAN UNION. Commission notice -- Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: <https://absch.cbd.int/database/record/ABSCH-MSR--EU-201808> Accessed on 11/05/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: <https://absch.cbd.int/database/record/ABSCH-MSR-LU-204508> Accessed on 11/05/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: <https://absch.cbd.int/database/record/ABSCH-MSR-LU-201808> Accessed on 11/05/2021.

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REPUBLIC OF MALTA. Application for Academic Researchers to obtain Prior Informed Consent (PIC) to access Genetic Resources for which Malta has sovereign rights. Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization. 2015. Available in: <https://agriculture.gov.mt/en/phd/Documents/awp/applicationForAcademicResearchersToObtainPriorInformedConsentPIC.pdf> Accessed on 11/05/2021.

REPUBLIC OF MALTA. Genetic resources registration form. Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization. 2015. Available in: < https://agriculture.gov.mt/en/phd/Documents/awp/geneticResourcesRegistrationForm.pdf> Accessed on 11/05/2021.

REPUBLIC OF MALTA. Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization. 2015. Available in:< https://agriculture.gov.mt/en/phd/Pages/awp.aspx> Accessed on 11/05/2021.

Republic of Moldova[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since January 18th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since November 21st, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

According to the Interim National Report on the Implementation of Nagoya Protocol, although

1 The information hereinafter has been updated until October 7th, 2020.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

there is no specific ABS legislation or PIC and MAT requirements, other laws provide for matters related to agriculture plant varieties, intellectual property rights, seeds, and others. In this sense, the ABSCH website indicates the Law on seeds (Law n. 68 of 05.04.2013) and Law on Protection of Plant Varieties, which address procedures on these issues.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. The ABSCH website identifies the Ministry of Agriculture, Regional Development and Environment as the competent institution, which is responsible for all genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / ( ) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found..

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Agriculture, Regional Development and Environment	All genetic resources matters

6. Websites

ABSCH. Country Profiles
https://absch.cbd.int/countries/MD

CBD. Country Profiles
https://absch.cbd.int/countries/mdd

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Republic of Moldova profile. Available in: https://absch.cbd.int/countries/MD Access on 07/10/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Republic of Moldova profile. Available in: https://absch.cbd.int/countries/mdd Access on 07/10/2020.

REPUBLIC OF MOLDOVA. **Decision nº 274 of 18 May, 2015 On the approval of the Strategy on Biological Diversity of the Republic of Moldova for 2015-2020 and the Action Plan for enforcing it**. Ministry of Environment, Ministry of Finance and Ministry of agriculture and food industry. Chisinau, 2015. Available in: https://www.cbd.int/countries/?country=md Access on 06/10/2016.

REPUBLIC OF MOLDOVA. **Interim National Report on the Implementation of the Nagoya Protocol. 2017** Available in: https://absch.cbd.int/pdf/documents/absNationalReport/ABSCH-NR-MD-238665/1 Access on 07/10/2020.

REPUBLIC OF MOLDOVA. **Fifth National Report On Biological Diversity**. Project"National Biodiversity Planning to Support the Implementation of the CBD 2011-2020 Strategic Plan in the Republic of Moldova": United Nations Development Programme. Ministry of Environment; Natural Resourcesand Biodiversity Division;"Biodiversity" Office. Chisinau, 2013. Available in: https://www.cbd.int/countries/?country=md Access on 06/10/2016.

REPUBLIC OF MOLDOVA. **Sixth National Report On Biological Diversity.** The Clearing-House Mechanism of the Convention on Biological Diversity. Last updated January 2019. Available in: https://chm.cbd.int/database/record?documentID=241350 Access on 07/10/2020.

Monaco[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1 The information hereinafter has been updated until November 17th, 2020.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

Madame Céline van Klaveren-Impagliazzo
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M. Raphael Simonet
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6. Websites

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Monaco Profile. Available in
https://absch.cbd.int/countries/MC

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Monaco profile. Available in
https://www.cbd.int/countries/?country=mc

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Monaco Profile. Available in: https://absch.cbd.int/countries/MC> Access on 11/17/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Monaco profile. Available in: https://www.cbd.int/countries/?country=mc> Access on 11/17/2020.

GOVERNMENT OF MONACO. **Fifth National Report to the Convention on Biological Diversity**. Department of Environmental and Urban Plant Equipment. August, 2014. Available in: https://www.cbd.int/doc/world/mc/mc-nr-05-fr.pdf. Access on 18/05/2018.

Montenegro[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by succession, since June 3rd, 2006.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since November 12th, 2020.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the Law on Nature Protection (2016) regulates matters

1 The information hereinafter has been updated until December 17th, 2020

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

which may relate to ABS, such as collection of species, scientific research and institution of a Gene bank. According to the Fifth National Report, the referred law is under review to comply with the demands of the Convention on Biological Diversity.

Also, according to official documents, the country is preparing to make an entrance in the European Union by 2025 and, therefore, is making arrangements to adjust its national legal framework, including those related to biodiversity, with the rules of the European Union. According to the National Focal Point, the implementation of the Regulations of the European Union on Access and Benefit Sharing will occur by means of adoption of the Law on the Confirmation of the Nagoya Protocol, which will appoint the competent authorities on the matter.

According to the National Focal Point, at the same time of the elaboration of the Law on the Confirmation of the Nagoya Protocol, a national plan of implementation will be adopted to guarantee the full compliance of the obligations provided on the European Union Regulations, as for example: verification of compliance, due diligence declarations and criminal system.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to article 74 of Law on Nature Protection (2016), scientific and educational research in protected areas are subject to permission of the administrative body, as well as the use of biological material from gene banks, as per article 99 of the same legislation.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to article 98 of Nature Protection Law (2016), genetic material synthesized as of the genetic material of species of plants, animals and fungi are not subject to property rights.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Montenegro Profile

https://absch.cbd.int/countries/ME

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Montenegro Profile. Available in: https://absch.cbd.int/countries/ME> Access on 18/09/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Monaco profile. Available in: https://www.cbd.int/countries/?country=me> Access on 18/08/2020.

MONTENEGRO; MINISTRY OF SUSTAINABLE DEVELOPMENT AND TOURISM. The Fifth National Report to the **United Nations Convention on Biological Diversity**, 2014. Available at: < https://www.cbd.int/doc/world/me/me-nr-05-en.pdf> Access in: 05/22/2018.

MONTENEGRO; MINISTRY OF SUSTAINABLE DEVELOPMENT AND TOURISM. The Sixth National Report to the **United Nations Convention on Biological Diversity,** 2018. Available at: < https://www.cbd.int/doc/nr/nr-06/me-nr-06-en.pdfn.pdf> Access in: 19/08/2020.

MONTENEGRO; MINISTRY FOR SPATIAL PLANNING AND ENVIRONMENT. National Biodiversity Strategy with the **Action Plan for the period 2016-2020,** 2015. Available at: <https://www.cbd.int/doc/world/me/me-nbsap-v2-en.pdf> Access in: 05/22/2018.

Netherlands[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by acceptance, since October 10th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by acceptance, since November 17th, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The checkpoint indicated in the ABSCH website is the Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit, NVWA), responsible for receiving of due diligence declarations from users at the research funding stage as well as at the stage of final development of a product. The responsibilities of the NVWA also include monitoring and inspections of the domestic users of genetic resources.The NVWA may impose sanctions if users fail to comply with obligations.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has 5 checkpoints communiqués, which are available on the ABSCH website.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic

1 The information hereinafter has been updated until August 6th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

heritage and associated traditional knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
The Netherlands have the following legislation regarding access to genetic heritage and associated traditional knowledge:

- Nagoya Protocol Implementation Act - provides legal rules to implement the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of the benefits arising from their use in the Convention on Biological Diversity and relevant regulations of the European Union.

- Regulation in Implementation of the Nagoya Protocol Implementation Act (Regulation of the Minister for Agriculture of 31 March 2016, No. WJZ/15145152)

Also, Decision from the Minister of Economic Affairs, March 31, 2016 and Decree of the Minister for Agriculture of 31 March 2016, No. WJZ/15163191 appoints supervisors and focal points for the implementation of the Nagoya Protocol.

As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
The Nagoya Protocol Implementation Act, in article 4, establishes the Minister as the national competent authority on access and benefit-sharing under the terms of article 13, second paragraph, of the Nagoya Protocol. The Minister is also the competent authority responsible for the application of the EU regulations on genetic resources. Therefore, and according to the official

website of the CBD, the National Competent Authority is Ms. Kim van Seeters, from the Ministry of Economic Affairs.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

In contact with the Netherlands National Focal Point, it was informed that the legislation for the implementation of the Nagoya Protocol in the Netherlands does not regulate access to genetic resources, since the Dutch government considers that it is not necessary to exercise its sovereignty over access to resources genetic factors occurring in the Netherlands in their national legislation (Section 6.2.1 Of The Explanatory Memorandum Accompanying the Nagoya Protocol (Implementation) Act). This means that the user does not need PIC to access genetic resources in the Netherlands. However, access may be restricted, through legislation and regulatory requirements in the area of species protection, territorial protection, and animal and plant diseases. In such cases, permission to collect genetic resources must be obtained from the owner, whether private or public. Environmental impact rules may also apply. The genetic resources of farms or gardens are kept privately and therefore the transfer of these genetic resources in any form requires the consent of the owner. In this way, it is perceived that the Country uses a policy of free access, and the PIC is not necessary. However, other types of licenses may be required.

Also, The Rules for implementation of the Nagoya Protocol (Nagoya Protocol Implementation Act) Explanatory Memorandum provides a basis for the implementation of the Nagoya Protocol on access to genetic resources and fair and equitable sharing of benefits arising from their use, indicates the competent national authority and provides for sanctions and other measures.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / ( ) NO / NOT AVAILABLE
The norms covered by this analysis do not address this information about benefit sharing.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / ( ) NO / NOT AVAILABLE
The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / ( ) NO / ( ) NOT AVAILABLE
According to the Nagoya Protocol Implementation Act, article 4, paragraph 4, the inspection of the compliance with the obligations established in the referred law is a responsibility of: (a) the officials of the Netherlands Food Safety Authority (Nederlandse Voedsel- en Warenautoriteit) appointed by decision of the Minister for Economic Affairs from March 31, 2016; (b) the Minis-

ter of Security and Justice under the terms of article 17 of the Economic Offenses Act responsible for the identification of the offenses defined under the terms of this law.

In addition, Article 6.4.1 of the Nagoya Protocol Implementation Act (Explanatory Memorandum) refers to Article 4 (4) of the Rules for the Implementation of the Nagoya Protocol (Nagoya Protocol Implementation Act) Bill.
There is no evidence of imposition of fines apart from the legal provisions establishing that they may be applied.
According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / ( ) NO / ( ) NOT AVAILABLE
According to the Nagoya Protocol Implementation Act, its article 6 defines that the Minister for Economic Affairs, according to the applicable EU regulations on genetic resources, can take immediate temporary measures against users who act in violation of the provisions established under the terms of this law. These measures may involve the seizure of the genetic resources or resulting by-products or the decision on the imposition of:

a. A ban on the transportation, processing or marketing of genetic resources or its by-products;

b. A prohibition on the further use of genetic resources or its by-products;

c. The obligation to temporarily store the genetic resources or its by-products;

d. The obligation to immediately inform holders or alleged holders of genetic resources or its by-products that certain resources or products have not been acquired in agreement or under the terms of this law;

e. The obligation to send the genetic resources back to their country of origin;

f. The obligation to recall and withdraw from market products developed from the genetic resources or its by-products;

g. The requirement to identify and register the genetic resources.

There is no specification in terms of fines or their values.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / ( ) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Economic Affairs	Responsible for the application of the EU regulations on genetic resources

6. Websites

ABSCH Netherlands Profile
https://absch.cbd.int/countries/NL

CBD Netherlands Profile
https://www.cbd.int/countries/?country=nl

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Netherlands profile. Available in: https://absch.cbd.int/countries/NL Accessed on 10/20/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Netherlands profile. Available in: https://www.cbd.int/countries/?country=nl Accessed on 10/20/2021.

EUROPEAN UNION. **Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices**. Available in: https://absch.cbd.int/database/record/ABSCHMSR-DE-204508 Accessed on in 10/20/2021

EUROPEAN UNION. **Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union.** Available in: https://absch.cbd.int/database/record/ABSCH-MSR-DE-208044 Accessed on 10/20/2021

EUROPEAN UNION. **EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union**. Available in: https://absch.cbd.int/database/ record/ABSCH-MSR-DE-201808 Accessed on in 10/20/2021

NETHERLANDS. 26 407 Biodiversity (Natural Capital Agenda: conservation and sustainable use of biodiversity). Nr. 85 Letter From The State Secretary For Economic Affairs And The State Secretary For Infrastructure And The Environment. Hague, 2013. Available in: https://www.cbd.int/countries/?country=nl Access on 06/11/2016.

NETHERLANDS. **Convention on Biological Diversity Fifth National Report of the Kingdom of the Netherlands.** Ministry of Economic Affairs. Available in: https://www.cbd.int/countries/?country=nl Access on 06/11/2016.

NETHERLANDS. **Nagoya Protocol (Implementation) Act**. Available in: https://absch.cbd.int/ countries/NL Access on 06/11/2016.

NETHERLANDS. **Nature Policy Plan The Caribbean Netherlands 2013-2017.** Available in: https://www.cbd.int/countries/?country=nl Access on 06/11/2016.

NETHERLANDS. **The Natural Way Forward Government Vision 2014**. Ministry of Economic Affairs. Available in: https://www.cbd.int/countries/?country=nl Access on 06/11/2016.

North Macedonia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since March 2nd, 1998.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 44 of Law on Nature Protection states that the procedures for use of genetic and biological material shall be prescribed by the government of

1 The information hereinafter has been updated until July 31st, 2020.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

the Republic and the Minister in charge of nature protection. This legislation also provides for permits regarding scientific research.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.]

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Betim Lamallari
Advisor to the Minister
Cabinet of the Minister of Environment and Physical Planning
Ministry of Environment and Physical Planning (MOEPP)
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1000
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ABS National Focal Point
+389 2 3251 403
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b.lamallari@moepp.gov.mk
betim.lamallari@gmail.com

6. Websites

ABSCH North Macedonia Profile
https://absch.cbd.int/countries/MK

CBD North Macedonia Profile
https://www.cbd.int/countries/?country=mk

Ministry of Environment and Physical Planning
http://www.moepp.gov.mk/?lang=en

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. North Macedonia Profile. Available at: https://absch.cbd.int/countries/MK. Access on 31/07/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. North Macedonia profile. Available at: https://www.cbd.int/countries/?country=mk. Access on 31/07/2020.

REPUBLIC OF MACEDONIA. **Fifth National Report to the Convention on Biological Diversity,** 2014. Available at: <http://www.moepp.gov.mk/wp-content/uploads/2014/12/Fifth-National-report_EN1.pdf> Access on: 05/05/2018.

REPUBLIC OF MACEDONIA. **National Biodiversity Strategy and Action Plan**, 2003. Available at: < https://www.cbd.int/doc/world/mk/mk-nbsap-01-en.pdf> Access on: 05/25/2018.

Norway[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

1 The information hereinafter has been updated until December 24th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Yes, the country already has the following laws with provisions regarding access and benefit-sharing:

- The Nature Diversity Act (2009);
- Marine Resources Act (2009);
- Patents Act(1967)

Besides this law, the country has the following rules related to the theme:

- Amendment to the Nature Diversity Act, june 2013, called Traditional knowledge associated with genetic resources, adding section 61 "a" to the Nature Diversity Act;
- Regulations relating to the protection of traditional knowledge associated with genetic material, having entered into membership since January 1, 2017.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The ABSCH website identifies The Norwegian Environment Agency as the competent institution regarding access and benefit sharing.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address authorizations in order to obtain genetic resources. However, article 58 of the Nature Diversity Act states that the King may determine that a permit from the Ministry is required for the collection and use of the Norwegian genetic resources. The King shall establish any specific norms, including provisions on the use of the traditional knowledge of indigenous peoples and local communities, and on the benefit-sharing arising from the use of Norway's biodiversity.

In relation to the access to foreign genetic resources, article 60 establishes that in the case of utilization of genetic material from another country in Norway, for the purpose of research or commercial exploitation, the material shall be accompanied by information on the supplier country. If the supplier country's legislation requires specific authorizations for the collection of biological material, the material shall be accompanied by this information, including on the effect obtained by the authorization. Even if the supplier country is not the country of origin, it is still required that the biological material is accompanied by the information on its country of origin.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Nature Diversity Act was amended in June 2013 to include in this legal instrument some specific provisions related to associated traditional knowledge in order to allow the country to ratify the Nagoya Protocol. In this sense, article 60 (A) provides that the authorities must respect and protect the interests of indigenous peoples and local communities in the case of access and use of their traditional knowledge.

The amendment also states that the King may enact regulations on the access and use of associated traditional knowledge, on the requirement of prior informed consent from the indigenous or local communities, and on the applicable norms and sanctions against the unlawful misappropriation of traditional knowledge. This regulation may determine the application of the same conditions to the traditional knowledge of indigenous and local communities from other States, provided that the national legislation of the country providing such knowledge

requires prior informed consent to allow the access or use of traditional knowledge associated with genetic resources in their territory.

According to information obtained from the National Focal Point, a regulation was adopted by the Royal Decree of November 25, 2016 (Regulations relating to the protection of traditional knowledge associated with genetic material) pursuant to Section 61a of the Nature Diversity Act. This regulation establishes the requirement to obtain prior informed consent in access to traditional knowledge associated with genetic heritage, which entered into force on January 1, 2017.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Article 59 of the Nature Diversity Act establishes that the user of genetic material obtained from public collections shall refrain from claiming intellectual property rights, in Norway or abroad, in means that could limit the use of such material, such as use for food or agriculture, except in the case of genetic modification.

It should be noted that the country also has specific norms concerning patents. The Patents Act No. 09, of Dec 15, 1967 (updated with the latest amendment in 2013) in its Chapter 2 article 8 b establishes that the patent request related to inventions that concern or use biological material or traditional knowledge shall include information on the country of collection or receipt of such knowledge or material, as well as information on the procurement of prior informed consent when the legislation of the country of origin of the materials or knowledge requires.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, the legislation addresses this matter as the definition of genetic material comprises DSI, as provided in Section 3 of the Nature Diversity Act: “genes and other hereditary material in ant biological material that can be transferred to other organisms with or without the help of technology, except for human genetic material”.

2.9 Does the current legislation or any ongoing bills foresees species that have developed distinctive properties within the country’s territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country’s territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As exposed on item 2.1, the Nature Diversity Act leaves a great deal of its contents for future regulation. Article 57 of this act only stresses the importance of adopting appropriate measures for the sharing of benefits resulting from the use of genetic resources, and in such a way that protects the rights of indigenous and traditional populations.

Therefore, the law does not establish the procedures, norms and values for the benefit sharing.

BENEFIT SHARING

Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Nature Diversity Act institutes the Royal Norwegian Ministry of Climate and Environment as the official inspection body responsible for all matters related to access and benefit-sharing in the country.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Chapter IX of the Nature Diversity Act establishes the applicable sanctions for cases of non-compliance with the legal obligations set out in this Act. These include: coercive fine (art. 73, with no indication of value); environmental compensation (art. 74); penal measures (art. 75: imprisonment for a term no longer than one year or fine; or for gross contraventions, imprisonment for a term no longer than three years, or fine).

It should be noted that article 67 of the Nature Diversity Act states that the competent author-

ity may cancel or amend the conditions under which the permit was granted, or establish new conditions and, if necessary, revoke the permit, for any of the cases listed under subsections a) to h) of the referred article.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Royal Norwegian Ministry of Climate and Environment (The Norwegian Environment Agency)	National Competent Authority on ABS

6. Websites

Norwegian Environment Agency
https://www.environmentagency.no/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Norway profile. Available in: https://absch.cbd.int/countries/NO Access on 12/22/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Norway profile. Available in https://www.cbd.int/countries/?country=no Access on 12/22/2021.

NORWEGIAN GOVERNMENT. **Marine Resources Act**. Available in: https://absch.cbd.int/database/record/ABS-CH-MSR-NO-208517 Access on 12/22/2021.

NORWEGIAN GOVERNMENT. **Nature Diversity Act Chapter VII Access to genetic material**. Available in: https://absch.cbd.int/database/record/ABSCH-MSR-NO-203981 Access on 12/22/2021.

NORWEGIAN GOVERNMENT. **Norway´s Fifth National Report to the Convention on Biological Diversity**. Ministry of Climate and Environment. Available in: https://www.cbd.int/countries/?country=no Access on 12/22/2021.

NORWEGIAN GOVERNMENT. Norway's national biodiversity action plan. Ministry of Climate and Environment. Available in: https://www.cbd.int/countries/?country=no Access on 12/22/2021.

NORWEGIAN GOVERNMENT. **Norwegian Patents Act (Act no. 09 of 15 December 1967)**. Available in http://www.wipo.int/edocs/lexdocs/laws/en/no/no107en.pdf Access on 12/22/2021.

NORWEGIAN GOVERNMENT. **Regulation on traditional knowledge associated with genetic material.** Available in: https://absch.cbd.int/database/record/ABSCH-MSR-NO-208516 Access on 12/22/2021.

NORWEGIAN GOVERNMENT. **Traditional knowledge associated with genetic resources.** Available in https://absch.cbd.int/database/record/ABSCH-MSR-NO-203982 Access on 12/22/2021.

Poland[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since April 17th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the Minister of the Environment is the checkpoint indicated in the ABSCH website.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the Act of July 19th, 2016 on Access to Genetic Resources and Sharing Benefits Arising from their Utilisation addresses ABS in the country.

1 The information hereinafter has been updated until August 6th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to the ABSCH website, the Ministry of Environment is the competent authority for genetic resources in the country.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address authorizations in order to obtain genetic resources.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a

web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be composed by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 s there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

According to article 3 of the ABS Law, the national inspection authority is the Inspectorate for Environmental Protection. Also, according to the Act of Jul 19, 2016, Art. 5, in the case of article 9 paragraph 6, Regulation nº511/2014, the provincial inspector shall advise the user to take the corrective measures referred to in this instrument, and establish a deadline for its execution.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The ABS law indicates the sanctions for irregular access of genetic heritage according to the following articles:

- Art 11 Transfer of genetic resources or associated traditional knowledge without mutually agreed terms. Subject to a fine to the amount of 5,000 zl to 50,000 zl.

- Art 12 Maintenance of genetic resources of associated traditional knowledge without a certificate of conformity or relevant documents for twenty years after the end of the utilization period is subject to a fine to the amount of 1,000 zl to 50,000 zl.

- Article 13 Any one who uses genetic resources, despite failure to obtain the access authorization or its equivalent, and does not establish mutually agreed conditions, is subject to a fine to the amount of 10,000 zl to 100,000 zl.

- Article 14 Any person who did not submit a due diligence declaration, will be fined to the amount of 1,000 zl to 10,000 zl.

- Article 15 Any person who did not submit a due diligence declaration or did not submit the information referred to in this provision, will be subject to a fine to the amount of 5,000 zl to 50,000 zl.

Still, according to the Act of Jul 19, 2016, article 19 states that the pecuniary sanctions must be paid within 14 days of the date on which the decision imposing the sanction becomes final, in the bank account indicated in that decision. According to article 21, pecuniary sanctions shall not be imposed after 5 years from the date on which the offense was identified.

According to Article 3 of Regulation 511/2014 of the European Union, “illegally acquired genetic resources” are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”,

respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Environment	All genetic resources in the country.

6. Websites

ABSCH Poland Profile
https://absch.cbd.int/countries/PL

CBD Poland Profile
https://www.cbd.int/countries/?country=pl

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Poland profile. Available in: https://absch.cbd.int/countries/PL Accessed on 11/10/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Poland profile. Available in: https://www.cbd.int/countries/?country=pl Accessed on 11/10/2021.

EUROPEAN PARLIAMENT. European Parliament Resolution of January 15, 2013 regarding aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). Available in: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=//EP//TEXT+TA+P7TA20130007+0+DOC+XML+V0//EN. Accessed on 11/10/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: https://absch.cbd.int/database/record/ABSCHMSR-DE-204508 Accessed on 11/10/2021.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in https://absch.cbd.int/database/record/ABSCH--MSR-DE-208044 Accessed on 11/10/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: https://absch.cbd.int/database/ record/ABSCH-MSR-DE-201808 Accessed on 11/10/2021.

POLAND. Fifth National Report On The Implementation Of The Convention On Biological Diversity. Warsaw, 2014. Available in: https://www.cbd.int/countries/?country=pl Accessed on 11/10/2021.

POLAND. Resolution No. 213 Of The Council Of Ministers of 6 November 2015 on the approval of "The programme of conservation and sustainable use of biodiversity along with Action Plan for the period 2015-2020". Available in: https://www.cbd.int/countries/?country=pl Accessed on 11/10/2021.

POLAND. The law of July 19, 2016 on access to genetic resources and the distribution of benefits from their use. Available in: http://dziennikustaw.gov.pl/du/2016/1340 Accessed on 11/10/2021.

Romania[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since November 15th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since August 20th, 2019.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

As a regional organization, the European Union – of which the country is a member - has its own

1 The information hereinafter has been updated until July 26th, 2021

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

No official competent institution was identified in relation to access and benefit-sharing in the European Union. However, EU Regulation No. 511/2014 establishes in article 6 that member-states should designate one or more competent authorities responsible for the application of the aforementioned regulation.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According

to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information,

synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

According to Article 3 of Regulation 511/2014 of the European Union, “illegally acquired genetic resources” are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”, respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Nicolae Manta
Senior Adviser

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6. Wesites

ABSCH Romania Profile
https://absch.cbd.int/countries/RO

CBD Romania Profile
https://www.cbd.int/countries/?country=ro

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Romania profile. Available at: https://absch.cbd.int/countries/RO> Accessed on 11/05/2021.
CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Romania profile. Available at: https://www.cbd.int/countries/?country=ro> Accessed on 11/05/2021.

ROMANIA. CBD Fifth National Report - Romania (English version), 2014. Disponível em: <https://www.cbd.int/doc/world/ro/ro-nr-05-en.pdf> Accessed on 11/05/2021.

ROMANIA. National Strategy and Action Plan for Biodiversity Conservation: 2014 – 2020. Disponível em: <https://www.cbd.int/doc/world/ro/ro-nbsap-v3-en.pdf> Accessed on 11/05/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Disponível em: https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Accessed on 11/05/2021.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR--DE-208044> Accessed on 11/05/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-20180> Accessed on 11/05/2021.

Russia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since July 4th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the 5th National Report on the Convention of Biological Diversity, the country is in the process of adopting a legal system to regulate

1 The information hereinafter has been updated until October 28th, 2020.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

access and benefit sharing within its territory.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

Department of International Cooperation
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Russian Academy of Sciences
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6. Websites

ABSCH Russian Federation Profile
https://absch.cbd.int/countries/RU

CBD Russian Federation Profile
https://www.cbd.int/countries/?country=ru

BioDat
http://biodat.ru/

REC_Biodiversity
http://education.rec.org/ru/en/biodiversity/in_russia/index.shtml

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Russian Federation profile. Available in: https://absch.cbd.int/countries/RU Access on 10/29/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Russian Federation profile. Available in: https://www.cbd.int/countries/?country=ru Access on 10/29/2020.

RUSSIAN FEDERATION. **Fifth National Report "Biodiversity Conservation In Russian Federation".** Ministry of Natural Resources and Ecology Russian Federation. Moscow, 2014. Available in: https://www.cbd.int/countries/?-country=ru Access in 15/10/2016.

RUSSIAN FEDERATION. **Strategy and Executive Plan for the Conservation of Biodiversity within the Russian Federation**. Ministry of Natural Resources and Ecology Russian Federation. Moscow, 2014. Available in: https://www.cbd.int/countries/?country=ru Access on 15/10/2016.

San Marino[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since January 26th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1 The information hereinafter has been updated until December 17th, 2020.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

Mr. Tonino Ceccoli
Head
Ecologic Supervision and Environment Protection Service
Environmental and Agricutural Resources Management Office
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6. Websites

ABSCH San Marino Profile
https://absch.cbd.int/countries/SM

CBD San Marino Profile
https://www.cbd.int/countries/?country=sm

República de San Marino – Consiglio Grande e Generale
https://www.consigliograndeegenerale.sm/on-line/home.html

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. San Marino profile. Available at: https://absch.cbd.int/countries/SM. Access on 12/17/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. San Marino profile. Available at: https://www.cbd.int/countries/?country=sm> Access on 12/07/2020.

GOVERNMENT OF SAN MARINO. **Fifth National Report on the Convention of Biological Diversity.** Ministry of Territory and Environment. Available at: https://chm.cbd.int/database/record?documentID=207502 Access on 08/19/2018.

Serbia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since May 30th, 2002.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since January 28th, 2019.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / ( ) NO / (X) NOT AVAILABLE

No specific legislation was found on access to genetic heritage and associated traditional knowledge in the country, as it was not possible to access any law as they are only available in Serbian.

1 The information hereinafter has been updated until November 23rd, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Serbia's Profile on the ABSCH website identifies the Ministry of Environmental Protection as the competent institution, which is responsible for all genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / ( ) NO / (X) NOT AVAILABLE
The norms covered by this analysis do not address authorizations in order to obtain genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / ( ) NO / (X) NOT AVAILABLE
No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / ( ) NO / (X) NOT AVAILABLE
No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / ( ) NO / (X) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / ( ) NO / (X) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / ( ) NO / (X) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / ( ) NO / (X) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / ( ) NO / (X) NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing.

3.2 Are there any specific procedures, rules and values?

( ) YES / ( ) NO / (X) NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / ( ) NO / (X) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / ( ) NO / (X) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of Environmental Protection	According to Serbia's profile on the ABSCH website, this institution has legislative, administrative and policy measure competence and has the responsibility to all Serbian genetic resources.

6. Websites

ABSCH Serbia's Profile
https://absch.cbd.int/en/countries/RS

CBD Serbia's Profile
https://www.cbd.int/countries/?country=rs

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Serbia profile. Available at: https://absch.cbd.int/countries/RS> Access on November 23rd, 2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Serbia profile. Available at: https://www.cbd.int/countries/?country=rs. Access on November 23rd, 2021.

GOVERNMENT OF SERBIA.ST. **Biodiversity Strategy of the Replubic of Servia for the period 2011-2018.** Ministry of Environment and Spatial Planning. Belgrade, 2011. Available at: https://www.informea.org/en/countries/RS/action-plans> Access on November 23rd, 2021.

GOVERNMENT OF SERBIA. **The Fifth National Report to the United Nations on the Convention of Biological Diversity**. Ministry of agriculture and Environmental Protection. Available at: https://chm.cbd.int/database/record?documentID=201935> Access on November 23rd, 2021.

Slovakia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by approval, since November 23rd, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since March 28th, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoints:

- The Central Controlling and Testing Institute in Agriculture: responsible for receiving information related to the prior informed consent, the origin of the genetic resources, the procurement of mutually agreed terms, the use of genetic resources in agriculture;

- Institute for State Control of Veterinary Biologicals and Medicaments: responsible for receiving information related to the prior informed consent, the origin of the genetic resources, the procurement of mutually agreed terms, the use of genetic resources in veterinary medicine;

- Ministry of Economy of the Slovak Republic: responsible for receiving information related to the prior informed consent, the origin of the genetic resources, the procurement of mutually agreed terms, the use of genetic resources in biocidal products;

- Public Health Authority of the Slovak Republic: responsible for receiving information related to the prior informed consent, the origin of the genetic resources, the procurement of mutually agreed terms, the use of genetic resources in new foods and dietary supplements;

- The State Institute for Drug Control: responsible for receiving information related to the prior informed consent, the origin of the genetic resources, the procurement of mutually agreed terms, the use of genetic resources in human medicine or medical devices;

- Ministry of Environment of the Slovak Republic: receives information relevant to the terms

1 The information hereinafter has been updated until August 8th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

of article 17, paragraph 1 (a) (i) of the Nagoya Protocol, if other designated bodies or entities are not competent to receive them under Law No. 263 / 2015 Col. This covers special cases where further research and development on genetic resources will arise in the future or the activities are simply not covered by other competent authorities.

In addition, the National Focal Point points to the fact that there is also another checkpoint with special status, not provided on the ABSCH website, called "Other authorities in the area of genetic resource use"). It is not a single institution but a group of institutions. This group includes research funding agencies that receive declarations under Article 7 (1) of the EU Regulation.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO
No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO
No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE
Slovakia does not have any legislation regulating access to the genetic heritage and associated traditional knowledge. However, Act No. 263/2015, which establishes competences in the area of access to genetic resources and the sharing of benefits arising from their utilization, designated some national entities to deal with the matter within their scope of activities and subject areas.

As a regional organization, the European Union – of which Slovakia is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the official competent institution responsible for the area of genetic resources in Slovakia is the Ministry of the Environment.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be composed by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The competent authority for genetic resources in Slovakia is the Ministry of the Environment. However, there is no information as to whether it is the institution responsible for inspecting access to genetic resources. Through information obtained from the National Focal Point, it is known that the governmental environmental inspection body called the Slovak Environmental Inspectorate prepares its work plan in December of each year, and is subsequently approved by the Ministry of the Environment of the Slovak Republic Environment of the Slovak Republic). Based on this plan, the province also prepares a quarterly verification plan. In 2016, 16 legal entities were verified - 12 from the public sector and 4 from the private sector. No violation of national legislation or of the EU ABS Regulation has been recorded.

In this way, the Slovak Environmental Inspectorate is the authority responsible for conducting verifications, as the supervisory body of the Ministry of the Environment.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

As explained under item 2.1, Slovakia does not have any legislation on access and benefit sharing. However, Law No. 263/2015, on competencies in the area of access to genetic resources and benefit-sharing derived from their use (Act No. 263-2015 Coll. On Competencies In Area Of The Access To Genetic Resources), provides in its articles 10 and 11 the infractions against genetic resources and associated traditional knowledge. Infringement of the above provisions:

- Legal entity or entrepreneur: the Competent Authority must impose a penalty ranging from EUR 500 to EUR 100000 according to the offense.

- Natural person: The Competent Authority must impose penalties that can vary from 100 to 2500 EUR, depending on the infraction.

- Legal or physical person: where the competent authority repeatedly violates the above provisions, it shall impose a penalty of up to twice the maximum limit of fines established by law. In other words, it means that fines may be as high as EUR 200000 (legal entity) or EUR 5000 (natural person).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Ministry of the Environment	Responsible for all genetic resources

6. Websites

ABSCH Slovakia Profile
https://absch.cbd.int/countries/SK

CBD Slovakia Profile
https://www.cbd.int/countries/?country=sk

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Slovakia profile. Available in: https://absch.cbd.int/countries/SK Accessed on 10/28/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Slovakia profile. Available in: https://www.cbd.int/countries/?country=sk Accessed on 10/28/2021.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: https://absch.cbd.int/database/record/ABSCHMSR-DE-204508 Accessed on 10/28/2021.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union. Available in: https://absch.cbd.int/database/record/ABSCH--MSR-DE-208044 Accessed on 10/28/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808 Accessed on 10/28/2021.

SLOVAK REPUBLIC. Act. No. 263/2015 Col. on competences in area of the access to genetic resources and sharing of benefts araising from its utilization. Available in: https://absch.cbd. int/database/record/ABSCH-MSR--SK-207103 Accessed on 10/28/2021.

SLOVAK REPUBLIC. Fifth National Report On The Implementation Of The Convention On Biological Diversity In The Slovak Republic. Available in: https://www.cbd.int/countries/?country=sk Accessed on 10/28/2021.

SLOVAK REPUBLIC. Sixfth National Report On The Implementation Of The Convention On Biological Diversity In The Slovak Republic. Available in: https://chm.cbd.int/database/record?documentID=246532. Accessed on 10/28/2021.

Slovenia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since October 7th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

As a regional organization, the European Union – of which the country is a member - has its

1 The information hereinafter has been updated until August 6th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encour-

aged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be comprised by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each member-country shall promote efficient and proportional control mechanisms to verify if users are adhering to the practices established in their agreements. These controls include the examination of the measures adopted by the users for meeting their obligations in relation to Regulation 511/2014, followed by a review of the documentation and the registries that prove the due diligence obligation, and, if necessary, the promotion of inspections on the site where the research is being developed.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

According to Article 3 of Regulation 511/2014 of the European Union, “illegally acquired genetic resources” are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”, respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Robert Bolješić
Secretary
Sector for Nature Conservation

Ministry of the Environment and Spatial Planning
Dunajska 48
Si - 1000
Ljubljana
Slovenia

ABS National Focal Point
+386 1 478 7471
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6. Websites

CBD Slovenia Profile
https://www.cbd.int/countries/?country=si

ABSCH Slovenia Profile
https://absch.cbd.int/countries/SI

The treasures of Slovenian Nature (Natura 2000)
http://www.natura2000.si/en/

7. References

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EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: https://absch.cbd.int/database/record/ABSCH-MSR-SI-204508 Access on 09/05/2018.

Spain[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since March 21st, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. According to the ABSCH website, Ministério para la Transición Ecológica (MITECO) - Ministry for the Ecological Transition is the checkpoint for matters related to Nagoya Protocol.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has issued and registered 150 IRCCs that are available on ABSCH website, most of them for non

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

1 The information hereinafter has been updated until October 8th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Yes, the country already has the following laws regarding access and benefit-sharing:

- Law 42/2007 of the Natural Heritage and Biodiversity, of December 13, 2007 (modified by law No. 33/2015) - This law establishes the baseline framework for conservation, sustainable use, improvement and restoration of natural heritage and biodiversity, as part of the duty for conservation and the right to enjoy a healthy environment for an individual's development, created under article 45,2 of the National Constitution.

- Instrument of Ratification of the Nagoya Protocol concerning access to genetic resources and fair and equitable benefit sharing resulting from their utilization to the Biological Diversity Convention. Of August 9,2012.

- Royal Decree 124/2017 Relating to Access to Genetic Resources from Wild Taxon and Control of Utilization - regulates articles 71, 72, 74, 80 and 81 of Law 42/2007, dated December 13, 2007, on Natural Resources and Biodiversity Heritage, as well as ensuring the correct use of genetic resources in accordance with Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on measures to comply with users of the Protocol of Nagoya in the Union and with Commission Implementing Regulation (EU) No 2015/1866 of 13 October 2015, laying down detailed rules for the implementation of Regulation (EU) No. 511/2014

- Real Decreto 429/2020, de 3 de marzo (Royal Decree 429/2020, of March 3rd) This decree approves the Regulation on Accesso to Plant Genetic Resources for Food and Agriculture, which include provisions that establish that some dispositions on scope of Nagoya Protocol shall also apply for plant genetic (phytogenetic) resources. - In the quality of regional organization, the European Union - of which Spain is a member - has its own regulations on this subject applicable to all its Member-States, which are the following:

  ◊ EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

  ◊ EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices. - Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are very general and broad, being a responsibility of each member-country to create more specific and detailed norms according to their own interests and needs.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The ABSCH website indicates the following competent authority in the national level:

Dirección General de Biodiversidad, Bosques y Desertificación del Ministerio para la Transición Ecológica y el Reto Demográfico

In contact with the National Focal Point, it was informed that the competent authorities described in articles 5 and 13 of Royal Decree 124/2017.

Article 5 indicating to the competent authorities access to Spanish genetic resources coming from wild taxa. In turn, Article 13 provides for the designation of the competent Spanish authorities for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014.

According to article 8 of Royal Decree 429/2020, in the case of access to plant genetic resources (phytogenetic), the competent authorities to provide prior informed consent and establish mutually agreed terms shall be indicated by the autonomous community in the corresponding territory when it regards an in situ species, and by the manager of the collection, when it regards an ex situ species. The Nagoya Protocol checkpoint shall be informed on access on these matters.

- Also, the ABSCH indicates the following competent authorities in the regional level:
- Dirección General de Medio Natural y Planificación Rural del Principado de Asturias
- Dirección General de Medio Natural y Gestión Forestal del Gobierno de Aragón
- Dirección General de Evaluación Ambiental y de Medio Natural de la Comunidad Valenciana
- Dirección General de Medio Natural y Biodiversidade de Castilla-La Mancha
- Dirección General de Patrimonio Natural y Política Forestal de la Junta de Castilla y León
- Dirección General de Biodiversidad y Recursos Naturales de la Comunidad de Madrid
- Dirección General de Medio Natural de la Región de Murcia
- Dirección General de Lucha contra el Cambio Climático y Medio Ambiente del Gobierno de Canarias
- Consejería de Medio Ambiente y Territorio de las Islas Baleares

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 71, item 2, of Law 42/2007, provides that an access authorization will be issued as proof of obtaining prior informed consent and if mutually agreed conditions have been established. Also, article 7 of Royal Decree 429/2020 establishes that access to plant genetic resources (phytogenetic), whether in situ or ex situ, shall be subject to authorization of access, which requires prior informed consent and mutually agreed terms. This shall apply for when there is utilization of plant genetic resources, according to its definition on Convention of Biological Diversity, as per Article 2.3.b of Royal Decree 429/2020.

The Royal Decree Bill, in article 4, items 1 to 3, also provides the need for authorization. Noticing that the article 8 of the referred decree provides for the possibility of an exceptional authorization for cases of access in emergency situations.

Within the European Union, of which Germany is a member, the requirement of prior authorization to access genetic resources and traditional knowledge could not be identified in the form that some countries require previous licenses/authorizations in order to carry out access activities.

On the other hand, other mandatory types of authorization were identified. According to item 1.7 of this form, "illegally acquired genetic resources" are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent. In this sense, the prior informed consent is a right of the supplier regulated by the CBD and the Nagoya Protocol, and which was reinforced by the legislation of the European Union.

Through articles 4 and 7 of Regulation 511/2014, the European Union imposes obligations to the users of genetic resources and associated traditional knowledge. According to article 4 of this documents, users are obliged to exercise due diligence in order to ensure that the genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation and, in this case, also with the legislation of the organization dealing with benefit-sharing as to ensure a fair and equitable sharing of benefits as established in the Mutually-Agreed Terms.

Moreover, users are required to maintain the relevant information on access and benefit-sharing for a time interval of twenty years after the period of utilization. According to article 7, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis. In relation to the European Union, it does not foresee specific procedures for accessing associated traditional knowledge; however, all right-holders of traditional knowledge associated to genetic resources protected by the Convention on Biological Diversity and the Nagoya Protocol are equally reinforced by the legislation of this Regional Organization.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Royal Decree 124/2017, in its article 14.3, provides for this purpose. The exercise of due diligence by users of genetic resources and traditional knowledge associated with applying for a patent shall be subject to the following conditions:

a. Users of genetic resources and traditional knowledge associated with these resources shall

make a declaration of due diligence through the electronic headquarters of the Ministry of Agriculture and Fisheries, Food and Environment or in any of the forms provided for in article 16.4 of Law 39 / 2015, of October 1, so that it is incorporated into the state information system before filing the patent application. The form of this due diligence statement shall conform to the requirements set forth in the Commission Implementing Regulation (EU) 2015/1866, dated October 13, 2015, for the due diligence statements set forth in 14.1 and 14.2

b. The Spanish Patent and Trademark Office (Oficina Española de Patentes y Marcas) must verify compliance by the user with the presentation of the due diligence declaration by requesting in its procedures and forms the information that justifies the accomplishment of the declaration in accordance with paragraph "a". Failure by the user to comply with the obligation to submit a due diligence declaration shall not prejudge the validity of the patent in advance or will paralyze the processing of the request, as provided in article 23.2 of Law 24/2015 of July 24, on Patents, (Ley 24/2015, de 24 de julio, de Patentes) without prejudice to the cooperation obligation established in the following section.

Furthermore, according to article 23.2 of Law 24/2015 of 24 of July, when an invention refers to biological material of plant or animal origin, the application for patent must disclose its geographic origin.

Also, article 23 of Royal Decree 429/2020 establishes that there shall not be intellectual property rights on traditional knowledge associated with plant genetic resources (phytogenetic) which may restrict the utilization by the autonomous communities which have been using and protecting them.

In relation to the European Union, although the theme is not covered by the legislation mentioned in item 2.1., within intellectual property law, there is the European Parliament Resolution of January 15, 2013 regarding aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biol-

ogy or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and it incides over utilization of genetic resources. The responsibility to share the benefits lies on the applicant.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

Yes. Law 42/2007 provides that the use of genetic resources and traditional knowledge associated with genetic resources must comply with the provisions of the CBD, the Nagoya Protocol and Regulation (EU) No 511/2014. Section 7 of article 71 of the law states that: "The benefits derived from the use of genetic resources will be primarily for the conservation of biodiversity and the sustainable use of its components. In the case of genetic resources which access has been granted by the State General Administration, the benefits derived from their use will be channeled through the Fund for Natural Heritage and Biodiversity". The aforementioned Spanish law, in article 74, "b", provides that the benefits arising from the use of traditional knowledge must be equitable shared.

Article 6 of Royal Decree states that, for non-commercial activities, the request for access must be accompanied by mutually agreed terms on the distribution of benefits, containing at least the requirements set out in Annex III of the Decree. Article 7 deals with access for commercial purposes and establishes that the access requirement must be accompanied by mutually agreed terms of benefit sharing, containing at least the requirements set forth in Annex III of said Decree. No more specific provisions on rules and values were found.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the member-countries have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge. In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Deposit into Fund for Natural Heritage and Biodiversity	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Government
Non Monetary	Not defined	Not defined	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Government

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the Royal Decree 124/2017 designates competent authorities to sanction and control the activities of users of genetic resources. In its article 13, item 1, "f", it is established that the Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente, which is now currently named Dirección General de Biodiversidad, Bosques y Desertificación del Ministerio para la Transición Ecológica y el Reto Demográfico, as the focal point of the Nagoya Protocol, which will be the competent authority responsible for sanctioning users who are public institutions of character or state ownership when it finds that non-compliance with Regulation (EU) No. 511/2014. In the same article, item 2, b, provides that the competent bodies designated to the autonomous communities, within their powers, have the responsibility to sanction users who are not public institutions of character or state ownership.

Lastly, Article 15 states that it is the responsibility of the regional body to carry out conduct checks on users domiciled in the territory of the respective autonomous community in order to prove that they are complying with all the obligations relating to Articles 4 and 7 of Regulation (EU) No 511/2014. Exceptionally, in the case of users who are public institutions of character or state ownership, this competence will be of the Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente., currently named Dirección General de Biodiversidad, Bosques y Desertificación del Ministerio para la Transición Ecológica y el Reto Demográfico.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Article 19 of Royal Decree 124/2017 provides for the system of sanctions. Failure to comply with the provisions of the Royal Decree shall constitute an infraction and shall be punished as provided in articles 80; particularly in sections 1.u and 1.v; and Law 42/2007 defines in article 81 the offenses and their classifications; under item u) and v) are described as irregular access and use of genetic heritage and traditional knowledge with breach to the obligations

established by the law. For such cases violations may be considered as serious infringements or serious offenses. Fine for such serious offenses will vary from 3,001 to 200,000 Euros, for serious infringements from 200,001 to 2,000,000 Euros, and may be increased if there is prejudice to autonomous communities.

It is important to highlight that, according to article 3 of Regulation 511/2014 of the European Union, "genetic resources illegally acquired" are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and that requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries should establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations ("user conformity" and "monitoring of user conformity", respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Dirección General de Biodiversidad, Bosques y Desertificación del Ministerio para la Transición Ecológica y el Reto Demográfico	All matters related to genetic resources
Dirección General de Medio Natural y Planificación Rural del Principado de Asturias	Regional competent Authority
Dirección General de Medio Natural y Gestión Forestal del Gobierno de Aragón	Regional competent Authority
Dirección General de Evaluación Ambiental y de Medio Natural de la Comunidad Valenciana	Regional competent Authority
Dirección General de Medio Natural y Biodiversidad de Castilla-La Mancha	Regional competent Authority
Dirección General de Patrimonio Natural y Política Forestal de la Junta de Castilla y León	Regional competent Authority
Dirección General de Biodiversidad y Recursos Naturales de la Comunidad de Madrid	Regional competent Authority

Dirección General de Medio Natural de la Región de Murcia	Regional competent Authority
Dirección General de Lucha contra el Cambio Climático y Medio Ambiente del Gobierno de Canarias	Regional competent Authority
Consejería de Medio Ambiente y Territorio de las Islas Baleares	Regional competent Authority

6. Websites

Ministry of Agriculture, Food and Environment
http://www.mma.es

World Tourism Organization
http://www.world-tourism.org

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Spain profile. Available in: https://absch.cbd.int/countries/ES Access in 08/10/2020.

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CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Spain profile. Available in: https://www.cbd.int/countries/?country=es Access on 18/10/2020.

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EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: https://absch.cbd.int/database/ record/ABSCH-MSR-DE-201808 Access on 04/11/2016.

GOBIERNO DE ESPAÑA. Instrumento de Ratificación del Protocolo de Nagoya sobre acceso a los recursos genéticos y participación justa y equitativa en los beneficios que se deriven de su utilización al Convenio sobre la Diversidad Biológica, hecho en Nagoya el 29 de octubre de 2010. Available on: https://www.boe.es/diario_boe/txt.php?id=BOE-A-2014-8817 Access in 18/10/2016.

GOBIERNO DE ESPAÑA. Ley 42/2007, de 13 de diciembre, del Patrimonio Natural y de la Biodiversidad modificada mediante la Ley 33/2015, de 21 de septiembre. Available on: https:// absch.cbd.int/database/record/ABSCH-MSR-ES-204413 Access on 18/10/2016.

GOBIERNO DE ESPAÑA. Quinto Informe Nacional Sobre La Diversidad Biológica. 2014. Available in: https://www.cbd.int/countries/?country=sk Access in 18/10/2016.

GOBIERNO DE ESPAÑA. Real Decreto 124/2017, de 24 de febrero, relativo al acceso a los recursos genéticos procedentes de taxones silvestres y al control de la utilización. Available on: https://www.boe.es/boe/dias/2017/03/14/pdfs/BOE-A-2017-2743.pdf Access in 18/10/2016.

Sweden[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since March 16th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since December 7th, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The Swedish Environmental Protection Agency is the checkpoint indicated on the ABSCH website, responsible for:

- Receiving declarations of due diligence from users undertaking research and development activities in Sweden with focus on two specific aspects: research financing and product commercialization;
- Submitting the declarations of due diligence as checkpoint communiqués to the ABS Clearing House;
- If necessary, applying sanctions against Swedish users who fail to comply with the due diligence requirements and their obligations in terms of the declaration and cooperation activities.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

1 The information hereinafter has been updated until July 29th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has legislations which address access and benefit-sharing:

Ordinance on Use of Genetic Resources and Traditional Knowledge (2016:858)

- The Swedish Environmental Code
- Ordinance on Environmental Sanction Charges (2012:259)
- Act (2004:159) Amending the Patents Act (1967:837)
- Regulation (2004:162) Amending the Patents Decree

As a regional organization, the European Union – of which the country is a member - has its own regulations on this subject applicable to all its Member-States:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - related to measures concerning user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.
- EU Execution Regulation 2015/1866, of October 13, 2015 - establishes the norms of the execution of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.
- Guide on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and the Council in relation to measures dealing with user compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

It is important to highlight that these regulations were outlined with the objective of assisting European Union countries in the creation of their own national rules; therefore, its regulations are general and broad. It is the responsibility of each member-country to create more specific and detailed norms according to their own interests and needs. EU regulations address compliance issues regarding access and benefit sharing, while access norms remain under State Parties' responsibilities. The EU provides guidelines and best practices documents in order to orient ABS legislation in the State Parties, but it does not establish procedures or sanctions to implement them.

2.2. Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, according to the ABS Clearing House, the Swedish Environmental Protection Agency is the only competent authority in the country, responsible for matters related to genetic resources.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address authorizations in order to obtain genetic resources.

EU regulations do not provide for procedures regarding access and benefit sharing, as those are subject to each Member State legislation. The regulations establish that users shall exercise due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation, also that prior informed consent and Mutually Agreed Terms are respected.

According to the EU regulations, users are required to maintain the relevant information on access and benefit-sharing for a period of twenty years after the period of utilization. According to article 7 of Regulation EU 511/2014, all beneficiaries using genetic resources and associated traditional knowledge will be required by the Member-States of the European Union to declare that all the required diligences have been carried out.

To comply with the due diligence obligations instituted by EU regulations, users are encouraged to submit declarations required by Article 7 of Regulation EU 511/2014 into DECLARE, a web-based system which will generally be linked with Member States' national systems. Due diligence declarations shall be submitted at the stage of research funding and at the stage of final development of a product, when those situations involve the utilization of genetic resources or traditional knowledge associated with genetic resources.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

The European legislation does not foresee specific procedures for accessing associated traditional knowledge, as the Member States have competence and responsibility over this subject.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures requesting patents arising from research or technological developments involving the access were identified in the norms covered by this analysis. However, Regulation (2004:162) Amending the Patents Decree states that inventions which concern biological materials shall include information on the geographical origin of such material.

Within intellectual property law, the European Parliament Resolution of January 15, 2013 addresses aspects of the development of intellectual property rights in matters related to genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish any procedures or obligations, but it acknowledges the CBD, the Nagoya Protocol, the rights of holders of traditional knowledge, the issue of biopiracy and other related subjects. Also, according to the Directive 98/44 of 1998 on the legal protection of biotechnological inventions, biotechnological inventions shall be subject to the national patent law.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing. EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be composed by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

As mentioned in item 1.3, the Swedish Environmental Protection Agency is the institution responsible for applying sanctions against Swedish users who fail to comply with the due diligence requirements and their obligations in terms of the declaration and cooperation activities.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No sanctions in case of irregular access were identified in the norms covered by this analysis.

According to Article 3 of Regulation 511/2014 of the European Union, “illegally acquired genetic resources” are the genetic resources and associated traditional knowledge accessed in disagreement with the national legislation or the regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

Under these terms, article 11 of the same regulation establishes that member-countries shall establish the applicable rules and sanctions for breaches against the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”, respectively).

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Swedish Environmental Protection Agency	Receiving declarations of due diligence from users undertaking research and development activities in Sweden with focus on two specific aspects: research financing and product commercialization; Submitting the declarations of due diligence as checkpoint communiqués to the ABS Clearing House; If necessary, applying sanctions against Swedish users who fail to comply with the due diligence requirements and their obligations in terms of the declaration and cooperation activities.

6. Websites

ABSCH Sweden Profile
https://absch.cbd.int/countries/SE

CDB Sweden Profile
https://absch.cbd.int/countries/SE

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Sweden profile. Available in: *https://absch.cbd.int/countries/SE Accessed on 11/05/2021.*

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Sweden profile. Available in: *https://www.cbd.int/countries/?country=se Accessed on 11/05/2021*.

EUROPEAN UNION. Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. Available in: *https://absch.cbd.int/database/record/ABSCHMSR-DE-204508* Accessed on 11/05/2021.

EUROPEAN UNION. Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/record/ABSCH--MSR-DE-208044* Accessed on 11/05/2021.

EUROPEAN UNION. EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on compliance measures for users from the Nagoya Protocol

on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Available in: *https://absch.cbd.int/database/ record/ABSCH-MSR-DE-201808* Accessed on 11/05/2021.

SWEDEN. A Swedish strategy for biodiversity and ecosystem services. Swedish Environmental Protection Agency 2013. Available in: *https://www.cbd.int/countries/?country=se* Accessed on 11/05/2021.

SWEDEN. Fifth National Report to the Convention on Biological Diversity. Swedish Environmental Protection Agency. Available in: *https://www.cbd.int/countries/?country=se* Accessed on 11/05/2021.

SWEDEN. Ordinance on Environmental Sanction Charges (2012:259). Available in: *https:// absch.cbd.int/countries/SE* Accessed on 11/05/2021.

SWEDEN. Ordinance on Use of Genetic Resources and Traditional Knowledge (2016:858). Available in: *https:// absch.cbd.int/countries/SE* Accessed on 11/05/2021.

SWEDEN. The Swedish Environmental Code. Available in: *https://absch.cbd.int/countries/SE*. Accessed on 17/10/2016.

Switzerland[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 19th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has the following checkpoints:

- **Swiss Federal Institute of Intellectual Property**

This is a Federal agency for matters that concern intellectual property in Switzerland. About Genetic resources and Traditional knowledge, this agency is responsible for the implementation of the disclosure of source requirements for genetic resources and traditional knowledge in patent applications.

- **Federal Office for the Environment**

This is a Federal Office for the Environment (FOEN), a centralized checkpoint actor that receives information from the users of genetic resources and/or traditional knowledge. Beyond that, this institution has to be notified by the users about the use of genetic resources and traditional knowledge before the market authorization has been obtained or, if such authorization isn't required, before the commercialization of products developed on the basis of utilized genetic resources.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1 The information hereinafter has been updated until July 29th, 2021.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4.The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- [Federal Act on the Protection of Nature and Cultural Heritage of Jul 1st, 1966]: Under the scope of the Nagoya Protocol, this act provides for the protection of the indigenous flora and fauna, their biological diversity and natural habitats, and the promotion of biological diversity conservation and the sustainable use of its components through the fair and equitable sharing of the benefits arising from the use of genetic resources.

- [Federal Act on Patents for Inventions of Jun 25, 1954] Provides regulations on patents applications and establishes norms and requirements.

- [Decree on the Nagoya Protocol on access to genetic resources and the fair and equitable benefit-sharing deriving from their use] regulates access to and utilization of genetic resources and associated traditional knowledge, as well as benefit-sharing.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Decree on the Nagoya Protocol, in article 10 and the official website of the CBD identifies the Federal Office for the Environment as the competent institution, which is responsible for all genetic resources and:

- To make available all information relating to compliance with the due diligence requirement;

- To operate an electronic database that contains information regarding due diligence and reporting obligations, additional information, official forms, and frequently asked questions.

- To verify compliance if tangible signs of their violation exist or when carrying out spot checks (it may also involve the cantons).

- To operate a public register of best practices, recognising collections and other procedures.

These responsibilities are one of the obligations prescribed for FOEN among other responsibilities.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to the Federal Act on the Protection of Nature and Cultural Heritage in its article 19, the collection of wild plants and capture of animals living in the wild for commercial purposes are subject to approval by the Regional Competent Authority (Competent Cantonal Authority). Such approval may be restricted to particular species, areas, seasons and quantities or numbers, or in other ways, and organized collection or capture activities and the promotion thereof may be prohibited. The foregoing does not apply to normal agricultural and forestry exploitation, or to the collection of conventional amounts of fungi, berries, and herbs used in teas and for medicinal purposes, unless the species in question are protected. In addition to the above, article 23q defines that the Federal Council may make access to genetic resources in Switzerland subject to notification or authorization and to an agreement that regulates the utilization of genetic resources and the sharing of benefits arising from their utilization.

For access to genetic resources in Switzerland, the user must record and retain the following information and pass it on to subsequent users: 1.The name and address of the user; 2. Description of the genetic resource or subject matter and its utilization; 3. Date on which and location where the genetic resource was accessed; 4. In case of direct acquisition of the genetic resource from a third party: the name and address of this person and the date of acquisition; 5. In case of the transfer of genetic resources: the name and address of the subsequent user and the date of the transfer.

After informing the responsible authorities, the information specified above must be retained and be made available on request to the implementing authorities for 10 years after the end of utilization or directly benefiting therefrom; and for as long as the genetic resource or the product developed on the basis of the utilized genetic resources are retained. The user receives a register number as evidence of the notification, and upon request, an attestation to the effect that the Swiss provisions on access and sharing of benefits have been complied with. Genetic resources which have already been recorded and made available to the FOEN in global form in connection with a different procedure are exempted from the notification requirement.

There is no legal benefit sharing obligation for users utilizing genetic resources of Switzerland. However, the FOEN encourages users to voluntarily share the benefits arising from the utilization of genetic resources or associated traditional knowledge in a fair and equitable way even when there is no legal obligation to do so. It aims to ensure that the benefits are used to conserve biological diversity and the sustainable use of their components.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to the Federal Act on the Protection of Nature and Cultural Heritage, article 23p, any person who, according to the Nagoya Protocol, utilizes genetic resources or benefits arising directly from their use (users) must apply due diligence appropriate to the circumstances to ensure that (1) the resources have been legally accessed; and (2) Mutually agreed terms have been established for the fair and equitable benefit-sharing.
In addition to the due diligence, the user must send to FOEN a notification of compliance with the due diligence requirement before market authorization has been obtained or, if such authorization is not required, before the commercialization of products developed on the basis of utilized genetic resources.

The access to Associated Traditional Knowledges does not require the above procedures if such traditional knowledge is already freely available to the public.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to the Federal Act on Patents for Inventions of Jun 25, 1954:

- Article 8a27: 2. If the products directly obtained by the process concern biological material, the effects of the patent also extend to products obtained by propagating the biological material and which demonstrate the same characteristics.

- Article 49a112: The patent application must contain information on the source:

  – Of the genetic resource to which the inventor or the patent applicant had access, provided the invention is directly based on this resource.

  – Of traditional knowledge of indigenous or local communities of genetic resources to which the inventor or the patent applicant had access, provided the invention is directly based on this knowledge.

According to the Federal Act on Patents for Inventions of Jun 25, 1954, Article 2, paragraph 2, are also excluded from patentability: B. Plant varieties and animal varieties or essentially biological processes for the production of plants or animals; however, subject to the reservation of paragraph 1, microbiological or other technical processes and the products obtained thereby as well as inventions that concern plants or animals are patentable, provided that their application is not technically confined to a single plant or animal variety.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

According to the Federal Act on the Protection of Nature and Cultural Heritage, Art. 23¹: for foreign animal or plant species: mandatory approval.

The establishment of non-native animal and plant species, subspecies and breeds which are alien to the country or area shall be subject to approval by the Federal Council. The foregoing does not apply to enclosures, gardens and parks, or to agricultural and forestry enterprises.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis. The Federal Act on the Protection of Nature and Cultural Heritage only mentions, in Art. 20, concerning the protection of rare animals and plants, that, for the purposes of species protection, the Federal Council may also impose conditions on, restrict or prohibit the production, placing on the market, import, export and transit of plants or plant products.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and

procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
According to the Federal Act on the Protection of Nature and Cultural Heritage, Art. 23n[1]: any person who in accordance with the Nagoya Protocol utilizes genetic resources or benefits arising directly from their utilization (users) must apply due diligence appropriate to the circumstances to ensure that: (a) the resources have been legally accessed; and (b) mutually agreed terms for the fair and equitable sharing of the benefits have been established.

Despite the existence of the obligation of Benefit Sharing, the Act does not define any specific procedures, norms or values.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. In the Decree on the Nagoya Protocol, article 11, the competent authorities verified if the products placed on the market are in conformity with the regulations indicated in the decree, for both products developed from genetic resources and associated traditional knowledge. Each authority is responsible for one type of product according to the following list.

- (1) Therapeutic products (therapeutic products for human and animal use) - Swiss Agency for Therapeutic Products (Swissmedic)
- (1) Immunologic therapeutic products for veterinary use and (2) Food products, additives, processing agents - Federal Food Safety and Veterinary Office (FSVO)
- (1) Plant production, (2) plant propagating material for all other uses, (3) fertilizers, (4) food products - Federal Office for Agriculture (FOAG)
- (1) Biocides and Chemical Products - Federal Office of Public Health (FOPH)
- (1) Plant propagation material exclusive for forestry use and (2) other products - FOEN

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to the Federal Act on the Protection of Nature and Cultural Heritage, it establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as:

- Art. 24a: 2. Any person who willfully fails to provide information or provides false information under Article 23o shall be liable to a fine not exceeding 100,000 Swiss francs. In cases of negligence, the penalty shall be a fine not exceeding 40,000 Swiss francs.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Federal office for the environment	This is a Federal Office for the Environment (FOEN), a centralized checkpoint actor that receives information from the users of genetic resources and/or traditional knowledge. Beyond that, this institution has to be notified by the users about the use of genetic resources and traditional knowledge before the market authorization has been obtained or, if such authorization isn't required, before the commercialization of products developed on the basis of utilized genetic resources.

6. Websites

ABSCH Switzerland Profile
https://absch.cbd.int/countries/CH

CBD Switzerland Profile
www.cbd.int/countries/?country=ch

Federal Office for the Environment - Biotechnology section - Nagoya Protocol. Available in
https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/info-specialists/nagoya-protocol.html

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Switzerland profile. Available in: https://absch.cbd.int/countries/CH Access on 12/17/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Switzerland profile. Available in: https://www.cbd.int/countries/?country=ch Access on 12/17/2021.

KRAUS, Daniel; RÜSSLI, Markus. **Study on Access and Beneft Sharing User Measures in the Swiss Legal Order**. Federal Offce for the Environment (FOEN). 48 p. Berne: Swiss InformationSystem Biodiversity (SIB), 2009. Availablen:http://www.sib.admin.ch/en/documentation/publications-addressing-biodiversity/2009/abs-user-measures-in-the-swiss-legal-order/ Access in 12/17/2021.

SWITZERLAND. **Federal Act on Patents for Inventions (Patents Act, PatA) of 25 June 1954**. Available in: https://absch.cbd.int/countries/CH Access on 12/17/2021.

SWITZERLAND. **Federal Act on the Protection of Nature and Cultural Heritage (NCHA)**. Available in: https://absch.cbd.int/countries/CH Access on 12/17/2021.

SWITZERLAND. **Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Ordinance, NagO).** Available in: https://absch. cbd.int/countries/CH Access on 12/17/2021.

SWITZERLAND. **Swiss Biodiversity Strategy.** Federal Office for the Environment (FOEN). 2012. Available in: https://www.cbd.int/countries/?country=ch Access on 12/17/2021.

SWITZERLAND. **Switzerland's Fifth National Report under the Convention on Biological Diversity.** Federal Offce for the Environment (FOEN). Bern, 2014. Available in: https://www.cbd.int/countries/?country=ch Access on 12/17/2021.

THE INTERNATIONAL FRAGRANCE ASSOCIATION; INTERNATIONAL ORGANIZATION OF THE FLAVOR INDUSTRY. **IFRA-IOFI Guidance document for the Flavor and Fragrance Industry for dealing with the Nagoya Protocol and Access and Benefit Sharing (ABS) Regulations**. Brussels, 2020. Available at https://ifeat.org/wp-content/uploads/2020/04/IL1090-09-04-2020-IFRA-IOFI-Guidance-Document-on-Nagoya--Protocol-and-ABS-Regulations-Att.-01-Guidance-Document-April-9-2020.pdf.

Ukraine[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since May 8th, 1995.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1 The information hereinafter has been updated until November 22nd, 2020.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefi sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Sergiy Gubar
Depuy Director - Head of Division
Division of Econet Development and Biosafety, Directorate of Natural Resources Protection
Ministry of Ecology and Natural Resources of Ukraine
Mytropolyta Vasylia Lypkivs´kogo str., 35
03035
Kyiv
Ukraine

ABS National Focal Point
+ 380 44 206 31 66
+ 380 44 206 31 33

6. Websites

ABSCH Ukraine Profile
https://absch.cbd.int/countries/UA

CBD Ukraine Profile
https://www.cbd.int/countries/nfp/?country=ua

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Ukraine profile. Available in: https://absch.cbd.int/countries/UA Access on 11/22/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Ukraine profile. Available in https://www.cbd.int/countries/?country=ua Access on 11/22/2020.

UKRAINE. **Fifth National Report Of Ukraine To The Convention On Biological Diversity**. Available in: https://www.cbd.int/countries/?country=ua Access on 11/22/2020.

UKRAINE. **The Main Principles (Strategy) Of The National Environmental Policy Of Ukraine Until 2020 - (Law of Ukraine "On the Main Principles (Strategy) of the National Environmental Policy of Ukraine until 2020" (adoption - December 21, 2010, No. 2818; entry into force - January 14, 2011)).** Available in: https://www.cbd.int/countries/?country=ua Access on 11/22/2020.

United Kigndom[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since September 1st, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since May 22nd, 2016.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has one checkpoint indicated on the ABSCH website:

- The Office for Product Safety and Standards (OPSS)

This institution is responsible for requesting due diligence declarations from users on receipt of research funding; receiving due diligence declarations from users conducting research and development in the United Kingdom at two checkpoints (receipt of research funding and placing a product on the market); submitting due diligence declarations as checkpoint communiques on the ABS Clearing House; monitoring user compliance in the UK; and where necessary enforcing compliance obligations of UK users of genetic resources and genetic resources associated with traditional knowledge.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

(X) YES / ( ) NO

Yes. The country has 5 checkpoints communiqués which are available on the ABSCH website.

1 The information hereinafter has been updated until January 10th, 2022.

2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.

3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.

4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Even though the United Kingdom left the European Union in 2020, the country decided to convert the two European regulations into a UK-specific regime, to ensure that the regulations are still operable outside the EU legal framework.[5]

So, the United Kingdom has the Regulation No. 821 of 2015 (The Nagoya Protocol (Compliance) Regulations 2015 No. 821), responsible for implementing the monitoring and compliance requirements under the regulations below. These regulations were adapted to make them operable in the country after they left the European Union:

- EU Regulation No, 511/2014 of the European Parliament and the Council, of April 16, 2014 - compliance measures for users from the Nagoya Protocol on Access to genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union;

- Commission Implementing Regulation (EU) 2015/1866, of October 13, 2015 - lays down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European PArliament and of the Council as regards the register of collections, monitoring user compliance and best practices.

- The Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 - responsible to change Regulation No. 821 of 2015 to make it operable in the country after their withdraw from European Union;

- The Environment and Wildlife (Legislative Functions) (EU Exit) Regulations 2019.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The ABSCH website identifies the Office for Product Safety and Standards, Department for Business, Energy & Industrial Strategy as the competent institution, which is responsible for all matters related to genetic resources.

In addition, the Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018 altered the Regulation No. 821 of 2015 (The Nagoya Protocol (Compliance) Regulations 2015 No. 821) and established several obligations to the Secretary of State, as the responsibility to designate the competent authorities to be responsible for the application of the Regulation 821/2015.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

5. Explanatory memorandum to The Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018.

No. The country's legislation does not provide for prior authorization, it only strengthens and establishes procedures for compliance with the European Union legislation on access and benefit-sharing.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for access to Associated Traditional Knowledge were identified in the norms covered by this analysis.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7. Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address this information about benefit sharing.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the Member-States have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

According to the Annex to the Report from the Commission to the European Parliament and the Council, benefit sharing shall be composed by contracts (Mutually Agreed Terms) and subject to contract legislation, as well as compliant to benefit sharing Member States' national legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

No. As already mentioned, the legislation of the United Kingdom establishes requirements and procedures to enforce that users of genetic resources and traditional knowledge comply with the European Union legislation and the Nagoya Protocol. In this sense, it does not establish any benefit-sharing obligations.

EU Regulation No. 511/2014 acknowledges all the obligations established by the Convention on Biological Diversity and the Nagoya Protocol. In this sense, article 2 establishes that its dispositions are applicable to the genetic resources and associated traditional knowledge over which the member-countries have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and their associated traditional knowledge.

In this context, the obligations of users of genetic resources and traditional knowledge include the exercise of due diligence in order to guarantee compliance with the applicable legislation or regulations concerning matters of access and benefit-sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Genetic Resources/ATK	Not defined
Non Monetary	Not defined	Not defined	Not defined	Genetic Resources/ATK	Not defined

4. Sanctions

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Regulation No. 821 of 2015 (The Nagoya Protocol (Compliance) Regulations 2015 No.

821) stipulates in its article 7 that the Secretary of State may impose civil sanctions against the users of genetic resources and associated traditional knowledge in the case of non-compliance with the Nagoya Protocol and the European Union regulations.

To ensure compliance with these norms, the Secretary of State may also authorize a person, designated as the "inspector", to conduct inspections according to article 9 of the same national compliance regulations.
In addition, according to item 1.3, the checkpoint of the United Kingdom shall also have competence to take the necessary measures to ensure that the users of genetic resources and traditional knowledge within the United Kingdom comply with the applicable legal obligations.

In contact with the National Focal Point, it was informed that, to date, no fines have been imposed in relation to ABS.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Articles 7 and 8 and the Annex of Regulation No. 821 of 2015 (The Nagoya Protocol (Compliance) Regulations 2015 No. 821) establish the civil sanctions that may be applied by the Secretary of State. Articles 13 to 16 provide for the possible offenses and penalties. Some offenses have the maximum value of the fine stipulated in the law, while others lack information on the minimum and maximum values. There is also the penalty of imprisonment, depending on the offense.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary - Competent authorities

Authority	Competence
Office for Product Safety and Standards, Department for Business, Energy & Industrial Strategy	Responsible for all matters related to genetic resources in the country.

6. Websites

Department for Environment, Food and Rural Affairs (Defra)
https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. United Kingdom of Great Britain and Northern Ireland profile. Available in: https://absch.cbd.int/countries/GB Access on 01/10/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. United Kingdom of Great Britain and Northern Ireland profile. Available in: https://www.cbd.int/countries/?country=gb Access in 01/10/2021.

ENGLAND. Biodiversity 2020: A strategy for England's wildlife and ecosystem services. Department for Environment, Food and Rural Affairs. Available in: https://www.cbd.int/countries/?country=gb Access on 13/11/2016.

NORTHERN IRELAND. A Biodiversity Strategy for Northern Ireland to 2020. Department of the Environment, 2015. Available in: https://www.cbd.int/countries/?country=gb Access on 01/10/2021.

SCOTTISH GOVERNMENT. 2020 Challenge for Scotland's Biodiversity - A Strategy for the conservation and enhancement of biodiversity in Scotland. Edinburgh, 2013. Available in: https:// www.cbd.int/countries/?country=gb Access on 01/10/2021.

UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND. Consultation on implementing the Nagoya Protocol in the UK A summary of responses and the government reply. Department for Environment Food And Rural Affairs, Department of the Environment, and The Scottish Government. 2015. Available in: https:// www.gov.uk/government/uploads/system/uploads/attachment_data/fle/415474/nagoya-consult-sum-resp.pdf Access on 01/10/2021.

UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND. Fifth National Report to the United Nations Convention on Biological Diversity: United Kingdom. Peterborough: JNCC, 2014. Available in: https://www.cbd.int/countries/?country=gb Access on 01/10/2021.

UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND. The Nagoya Protocol (Compliance) Regulations 2015 No. 821. Available in: https://absch.cbd.int/countries/GB Access on 01/10/2021.

UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND. The Nagoya Protocol (Compliance) (Amendment) (EU Exit) 2018. Available in: https://assets.publishing.service.gov.uk/media/5bed96bf40f0b667a-46ce0ea/NP-01_Nagoya_exit_SI_with_draft_watermark_for_sift_2018_11_14.pdf Access in 01/10/2021.

UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND. EXPLANATORY MEMORANDUM TO THE NAGOYA PROTOCOL (COMPLIANCE) (AMENDMENT) (EU EXIT) REGULATIONS 2018. Available in: https://assets.publishing.service.gov.uk/media/5bed9748e5274a085c6a3f7a/Nagoya_Explanatory_Memorandum_-_SRO_CLEARED.pdf. Access on 01/10/2021.

WALES. The Nature Recovery Plan for Wales Setting the course for 2020 and beyond. 2015. Available in: https://www.cbd.int/countries/?country=gb Access on 01/10/2021.



Oceania

Austalia[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Protocol, but has been a signatory country since January 20th, 2012.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. At federal level (Commonwealth areas), the country has the following laws regarding access and benefit sharing:

1. The information hereinafter has been updated until November 11, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

- Environment Protection and Biodiversity Conservation Act (1999).

- Environmental Protection and Biodiversity Conservation Regulations 2000.

Currently, the Environment Protection and Biodiversity Conservation Act is under its second independent review, commenced on 29 October 2019.

Furthermore, each subnational jurisdiction (states and territories) has its own legislation on the matter. The website of the Australian Department of the Environment and Energy lists a number of laws related to these topics; however, not all of them deal specifically with access and benefit-sharing, and the federal laws are the most relevant regulations.

In that sense, at regional/territorial level, the following norms are the most relevant ones:

- **Queensland:**
  Biodiscovery Act 2004
  Nature Conservation (Protected Areas Management) Regulation 2017

- **Northern Territory:**
  Biological Resources Act 2014

- **Capital Territory:**
  Nature Conservation Act 2014 (2020

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Department of Agriculture, Water and the Environment identifies in its website the following competent institutions regarding access and benefit sharing:

Western Australia: Life Sciences Team - Science, Innovation and Business Division, Department of Commerce. Also, in order to obtain authorization to access genetic resources at the Great Barrier Reef, the competent institution is the Great Barrier Reef Marine Park Authority, and to carry out research in the Australian Antarctic Territory, the portion of that territory claimed by Australia, the relevant institution is the Australian Government Antarctic Division.

Australian Capital Territory:
Natural Environment and Resource Management - Environment and Sustainable Development Directorate.

Queensland:
Office of Biotechnology and Therapeutic Medicines and Devices - Department of Employment, Economic Development and Innovation.

South Australia:
Science Resource Centre, Client Services - Department of Environment and Natural Resources

Tasmania:
Department of Primary Industries, Parks, Water and Environment

Victoria:
Biodiversity Policy and Programs - Department of Sustainability and Environment

New South Wales:
Strategic Policy and Communications Group - NSW Department of Premier and Cabinet.

Federal Level (Australian Government):
Protected Area Policy and Biodiscovery Section - Department of Sustainability, Environment, Water, Population and Communities.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. Within federal areas, according to the Environmental Protection and Biodiversity Conservation Regulations (2000) described in Part 8A, Division 8A.1, Section 8A.06 and 8A.11, the access to biological resources requires prior authorization, which must be requested according to Part 17 of these regulations, or otherwise a fine of 50 penalty units shall be applicable, as mentioned in item 4.2 of this document. The application form is provided by the Department of Agriculture, Water and the Environment website.

In addition, also according to Section 8A.06, the authorization shall only be issued if a copy of the Benefit-Sharing Agreement is sent to the Minister, as these agreements must be signed by each provider of the accessed resources, according to Division 8A.2, Section 8A.07.

It is important to highlight that this norm establishes different procedures for commercial and non-commercial access, the former being regulated by Division 8A.2 and the latter by Division 8A.3. The main difference between them is that benefit-sharing is only required for commercial uses, whereas for scientific purposes there is a requirement to obtain authorization from the access provider.

Part 17 of the aforementioned law covers all the authorizations addressed in the Environmental Protection and Biodiversity Conservation Regulations (2000). The content of these authorizations is under Section 17.02. Sections 17.03A and 17.03B, and deal specifically with permits for access to biological resources. On its turn, Part 18 addresses authorization fees.

According to Australia's Sixth National Report to the Convention on Biological Diversity 206 permits of access in Commonwealth areas have been issued between January 2014 and December 2018.

The applicable legislation in Queensland being the Biodiversity Act 2004, it also requires prior authorization for access to biological resources, according to Part 3 of that Act.

As for the Northern Territory, the Biological Resource Act 2014 establishes this obligation in Part 3, Division 1.
Regarding the Capital Territory, Part. 8.5 "Access to biological resources in reserves", item 201 of the Nature Conservation Act 2014 (2020), sets that the user must obtain a license and enter into a benefit-sharing agreement in order to access biological resources in reserves.

In relation to other regions or Territories, although not all of them have a specific legislation on ABS, it is important to remember that each Territory has its own competent authority on ABS, therefore, users should seek more information on territorial and regional procedures.

servation Act 2014 (2020), sets that the user must obtain a license and enter into a benefit-sharing agreement in order to access biological resources in reserves.

In relation to other regions or Territories, although not all of them have a specific legislation on ABS, it is important to remember that each Territory has its own competent authority on ABS, therefore, users should seek more information on territorial and regional procedures.

- **Northern Territory:**
  Biological Resources Act 2014

- **Capital Territory:**
  Nature Conservation Act 2014 (2020)

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. There are special procedures in place regarding indigenous lands, but not to traditional knowledge per se. According to the Environmental Protection and Biodiversity Conservation Regulations (2000), Division 8A.2, Section 8A.07, when the access occurs in lands or waters located within indigenous territory, besides the Benefit-Sharing Agreement, a contract on the use of the indigenous land must also be signed, according to the Native Title Act 1993. Besides, Section 8A.10 of the same norm establishes that in such cases it is necessary to obtain the informed consent from the indigenous populations. The basic requirements are established in the same section.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
It was not possible to identify in the legislation and the other documents analyzed any specific procedures for that. However, this should not be understood as an absence of rules for the importation and exportation of specimens for scientific purposes, as addressed in Part 9.A of the Environmental Protection and Biodiversity Conservation Regulations (2000).

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes, according to CBD 2020 study on DSI, Queensland legislation addresses this matter on its Biodiscovery Act 2004, which defined “biodiscovery research” as the “analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material”. In this sense, “genetic information” is understood as linked to DSI.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country’s territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address species that have developed distinctive properties within the country’s territory.

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

Yes, benefit sharing is mandatory and it incides over access to biological resources for commercial purposes, according to Part 8A, Division 8A.2, Section 8A.07 of Environmental Protection and Biodiversity Conservation Regulations (2000). The responsibility to share the benefits lies on the applicant, according to the same article.

3.2 Are there any specific procedures, rules and values?

(X) YES / ( ) NO / NOT AVAILABLE

According to the Environmental Protection and Biodiversity Conservation Regulations (2000), Part 8A, Division 8A.2, Section 8A.07, for genetic resources utilized for commercial or potentially commercial purposes, the access permit shall only be granted after the requesting party signs a benefit-sharing agreement with the provider of the relevant resources. The requirements for the benefit-sharing agreement are listed under Section 8A.08.

The benefit-sharing requirement in Queensland is addressed in Part 3, Division 2, Section 17 of the Biodiversity Act 2004. The Parties to the Agreement are the user and the State Government according to Part 5 Division 1, Section 33, and its content and clauses must comply with sections 24 and 25, respectively.

As for the Northern Territory, the benefit-sharing is covered by Sections 27 to 32 of Part 4 of the Biological Re sources Act 2014.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Genetic Heritage and Associated Traditional Knowledge	Government
Non Monetary	Not defined	Not defined	Not defined	Genetic Heritage and Associated Traditional Knowledge	Government

4.1 Is there an official inspection body?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The legislation found at federal level does not specify any inspection bodies. In the Queensland territory, the Biodiversity Act 2004, Part 8 Division 1, does not designate a specific institution but it provides that it should be established by the executive head of the relevant department, according to the Gene Technology Act 2001 or the Nature Conservation Act 1992.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Under the Environmental Protection and Biodiversity Conservation Regulations (2000), Part 8A, Division 8A.1, Section 8A.06, in case of access to biological resources without a prior request for authorization, a fine of 50 penalty units shall be applicable[5]. In the same regulations, Sections 17.01 and 17.08 establish the offences and violations against these legal dispositions, establishing a fine of 50 penalty units for the holder of an access authorization that commits any illegal acts.

As for Queensland, the Biodiversity Act 2004, Part 7, Division 1, Section 50, states that the unauthorized collection of species shall be liable to the payment of a fine of 3000 penalty units or imprisonment of 2 years. Division 2, Section 54 states that the use of biological material without a benefit-sharing agreement shall be liable to the payment of a fine of 5000 penalty units or the payment of the full commercial value of the commercialization of the product.

In the Northern Territory, the Biological Resources Act 2014, Part 6, Section 38 to 41 establishes the conducts considered to be legal offences: unauthorized bioprospection, providing false information, violation of the conditions of the authorization, and violation of the conditions of the benefit-sharing agreement. The maximum penalty for such cases shall have the cost of 500 penalty units.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. One emblematic case regarding traditional knowledge relates to the Smokebush plant, traditionally used by the Nyoongah people because of its healing properties. A licence to collect and research was given to the US National Cancer Institute in the 1990s, and no acknowledgement of Nyoongah people was made.

5. Summary – Competent authorities

Authority	Competence
Great Barrier Reef Marine Park Authority	Responsible for the access to genetic resources in the Great Barrier Reef.

5. "Penalty units" is the unit adopted to measure the value of the fines established by the country's federal norms. Currently, one penalty unit corresponds to 180 Australian dollars.
Fonte: http://www.austrac.gov.au/enforcement-action/penalty-units

Australian Government Antarctic Division	Responsible for the access to Australia's genetic resource in the area claimed by Australia in Antarctica.
Protected Area Policy and Biodiscovery Section	Competence within "Commonwealth áreas". Key contact: Ben Phillips, Director Protected Area Policy and Biodiscovery Section - Department of Sustainability, Environment, Water, Population and Communities Email: grm@environment.gov.au
Natural Environment and Resource Management	Competence over Australian Capital Territory Key contact: Ian Baird, Principal Policy Officer Natural Environment and Resource Management - Environment and Sustainable Development Directorate Email: Ian.Baird@act.gov.au
Strategic Policy and Communications Group	Competence over New South Wales Key contact: Ian Hunter, Executive Director Strategic Policy and Communications Group - NSW Department of Premier and Cabinet Email: Ian.Hunter@dpc.nsw.gov.au
Office of Biotechnology and Therapeutic Medicines and Devices	Competence over Queensland Key contact: Sue Coke, Principal Policy Officer Office of Biotechnology and Therapeutic Medicines and Devices - Department of Employment, Economic Development and Innovation Email: sue.coke@deedi.qld.gov.au
Science Resource Centre	Competence over South Australia Key contact: Research Permits Officer Science Resource Centre, Client Services - Department of Environment and Natural Resources Email: DENRresearchpermits@sa.gov.au
Department of Primary Industries, Parks, Water and Environment	Competence over Tasmania Key contact: Brooke Craven, Manager, Policy Branch, Policy and Projects Group Department of Primary Industries, Parks, Water and Environment Email: brooke.craven@dpipwe.tas.gov.au
Biodiversity Policy and Programs	Competence over Victoria Key contact: Director Biodiversity Policy and Programs - Department of Sustainability and Environment Email: customer.service@dse.vic.gov.au
Science, Innovation and Business Division	Competence over Western Australia Key contact: Howard Shawcross, Project Officer, Life Sciences Team Science, Innovation and Business Division - Department of Commerce, Government of Western Australia Email: howard.shawcross@commerce.wa.gov.au

6. Websites

The following websites were indicated by the Department of Agriculture, Water and Environment as relevant to the Australian ABS framework:

Australia's biological resources
https://www.environment.gov.au/topics/science-and-research/australias-biological-resources

Australia's Biotechnology Organisation (AusBiotech)
http://www.ausbiotech.org/

Australian Antarctic Division
http://www.antarctica.gov.au/

Australian Institute of Marine Sciences
http://www.aims.gov.au/

Australian Microbial Resources Information Network
http://amrin.ala.org.au/

Australian National Botanic Gardens
http://www.anbg.gov.au/

Commonwealth Scientific and Industrial Research Organization
http://www.csiro.au/

Great Barrier Reef Marine Park Authority
http://www.gbrmpa.gov.au/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. **Country Profiles. Australia profile.** Available in: *https://absch.cbd.int/countries/AU* Accessed on 03/05/2020.

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. **Country Profiles. Australia profile.** Available in: *https://absch.cbd.int/countries/AU* Accessed on 03/05/2020.
CONVENTION OF BIOLOGICAL DIVERSITY - CBD. **Country Profiles. Australia profile**. Available in: *https://www.cbd.int/countries/?country=au* Accessed on 03/05/2020.

DAWKINS, Verity. **Combating biopiracy in Australia: Will a disclosure requirement in the Patents Act 1990 be more effective than the current regulations?**. J World Intellect Prop. 2018; 21:15–31. Available in: *https://doi.org/10.1111/jwip.12086.* Accessed on 05/13/2020.

GOVERNMENT OF AUSTRALIA. **Australia's fifth National Report to the Convention on Biological Diversity. Department of Environment.** Australian Government. Canberra, 2014. Available in: *https://www.cbd.int/countries/?country=au.* Accessed on 10/18/2016.

GOVERNMENT OF AUSTRALIA. **Australia's Sixth National Report to the Convention on Biological Diversity 2014–2018**. Commonwealth of Australia. Canberra, 2020. Available in: *http://www.environment.gov.au/biodiversity/international/un-convention-biological-diversity.* Accessed 11/12/2020.

GOVERNMENT OF AUSTRALIA. **Biodiscovery Act 2004**. State of Queensland. Available in: *https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/B/BiodiscovA04.pdf* Accessed on 10/18/2016.

GOVERNMENT OF AUSTRALIA. **Biological Resources Act 2014. Northern Territory**. Available in: *https://legislation.nt.gov.au/Pages/~/link.aspx?_id=7C3FA89E-D742451592672A1DDBC5A87F&_z=z* Accessed on 10/18/2016.

GOVERNMENT OF AUSTRALIA. **Department of the Environment**. Available in: *http://www.environment.gov.au/* Accessed on 10/18/2016.

GOVERNMENT OF AUSTRALIA. **Environment Protection and Biodiversity Conservation Act (1999)**. Available in: *http://www.environment.gov.au/epbc Acesso em 18/10/2016* Accessed on 10/18/2016.

GOVERNMENT OF AUSTRALIA. **Environmental Protection and Biodiversity Conservation Regulations (2000)**. Available in: *https://www.legislation.gov.au/Series/F2000B00190* Accessed on 10/18/2016.

GOVERNMENT OF AUSTRALIA. **Native Title Act 1993**. Available in: *https://www.legislation.gov.au/Details/C2016C00748* Accessed on 10/18/2016.

GOVERNMENT OF AUSTRALIA. **National Objectives and Targets for Biodiversity Conservation 2001–2005. Department of the Environment and Heritage, Australian Government. Canberra, 2001**. Available in: *https://www.cbd.int/countries/?country=au* Accessed on 10/18/2016.

JANKE, Terri. **'From smokebush to spinifex: Towards recognition of Indigenous knowledge in the commercialization of plants' (2018) 1 International Journal of Rural Law and Policy**. Article ID 5713. Available in: *http://dx.doi.org/10.5130/ijrlp.i1.2018.5713*. Accessed on 05/13/2020.

CONVENTION ON BIOLOGICAL DIVERSITY. **Fact-finding Study on How Domestic Measures Address Benefit-Sharing Arising From Commercial and Non-Commercial Use of Digital Sequence Information on Genetic Resources for Research and Development**. Canada, 2020. Available in: *https://www.cbd.int/doc/c/428d/017b/1b0c60b47af50c81a1a34d52/dsi-ahteg-2020-01-05-en.pdf* Accessed 11/12/2020.

Cook Islands[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

According to the Fifth National Report (2017), the country does not have legislation on access to genetic heritage, but is currently working in cooperation with the Global Environment Fund and the United Nations Development Program, to elaborate a regulation on the matter. Also, an Access and Benefit Sharing Policy was published in 2018, establishing guidelines and pro-

1. The information hereinafter has been updated until December 17th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

cedures on the subject, although it is not clear whether its provisions are mandatory or subject to future legislation.

Besides that, Cook Island has the Traditional Knowledge Act (2013), on the protection of traditional knowledge. In its article 4, the law provides a list of practices considered as Traditional Knowledge for means of this law, which includes any traditional process or beverage recipes, food or medicines, or any other substance to be applied in the body.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

As for the Associated Traditional Knowledge, the Traditional Knowledge Act (2013) identifies the Are Korero as the agency authorized by the traditional chiefs to represent their interests. Also, item "B" of the ABS Policy Annex states that a Competent National Authority shall be established in accordance with legislative, administrative or policy measures.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, according to the website The ABS Capacity Development Initiative, researches with genetic resources in the Cook Island need the Government's previous authorization. In an article, the New Zealand University explains that the application form for previous authorization of researches is available by the Cook Islands National Research Committee. The requirement must be made through a payment fee of NZD$80,00 and the form must be sent to the Foundation of National Research, agency attached to the Prime Minister's Office.

Although there is not a legislation regarding ABS in the country, the ABS Policy establishes the procedure for access genetic resources and/or traditional knowledge, as it follows:

1. Application: the applicant shall submit the application to the Are Korero of the corresponding instalant, in order to obtain Prior Informed Consent from the providers of genetic heritage and/or traditional knowledge;

2. Approval: Cook Islands Competent National Authority shall approve the applications;

3. Approval from the Research Secretariat: After, the application will be forwarded to the Cook Islands Research Secretariat for approval.

It is not clear whether these procedures are mandatory or are subject to future legislation.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

According to the Traditional Knowledge Act (2013), article 8, every access to a registered traditional knowledge needs to be made with a previous authorization, granted by the people to whom that traditional knowledge belongs. However, there is no description of procedures for the requirement of access to traditional knowledge. Also, article 8.4 of the ABS Policy states that Are Korero on each island provides effective participation of local communities in PIC and MAT regarding traditional knowledge associated with genetic resources.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 8.5 of the ABS Policy states that in the case of application of intellectual property rights, the provider of genetic resources shall have joint ownership of those rights, unless waived by the provider.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 8.3.3 of the ABS Policy establishes that benefit sharing shall be agreed between the user and provider and those will vary depending on the case. According to the same Policy, the responsibility to share benefits lies on the provider. It is not clear of whether the dispositions of this Policy are mandatory or subject to future legislation.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The ABS Policy states on its Annex

that benefit sharing shall be covered on MAT, will depend on the circumstances and monetary and non monetary benefits shall include but not be limited to those referred on the Nagoya Protocol Annex. Also, article 8.5.7 of the same Policy institutes that a portion of benefit sharing shall be directed towards the conservation and sustainable use of biological diversity in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

The Traditional Knowledge Act (2013) establishes, in its articles 35 and 45, the sanctions applicable to access to traditional knowledge in nonconformity with the rules and procedures, as follows: be held responsible criminal or civil actions, repair damages, retraction or payment of a penalty of $500.000,00.

Also, the ABS Policy Annex on its item “e” establishes that sanctions shall be considered upon contractual agreements.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority regarding ABS, but only for traditional knowledge. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mr. Nga Puna
Director
National Environment Service
P.O. Box 371
Rarotonga
Cook Islands

ABS National Focal Point
+682 21 256
nga.puna@cokislands.gov.ck

6. Websites

ABSCH Cook Island Profile
https://absch.cbd.int/countries/CK

CBD Cook Island Profile
https://www.cbd.int/countries/default.shtml?country=ck

National Environment Service
http://environment.gov.ck/

Biodiversity Website
http://www.biodiversity.gov.ck/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Cook Islands profile. Available in: < *https://absch.cbd.int/countries/CK* > Access in 12/17/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Cook Islands profile. Available in: <*https://www.cbd.int/countries/?country=ck* > Access in 12/17/2021.

COOK ISLANDS. **5th National Report to the Convention on Biological Diversity**, 2017. Available at: <*https://www.cbd.int/doc/world/ck/ck-nr-05-en.pdf*> Access in: 12/17/2021.

COOK ISLANDS. **Traditional Knowledge Act**, December 6 of 2018. Available at: <*https://www.pacificclimatechange.net/sites/default/files/documents/Traditional%20Knowledge%20Act%202013.pdf*> Access in: 12/17/2021.

COOK ISLANDS NATIONAL ENVIRONMENT SERVICE. Cook Islands Access and Benefit Sharing Policy. The Nagoya Protocol, 2018. Available at: *https://www.google.com/search?q=COOK+ISLANDS+NATIONAL+ENVIRONMENT+SERVICE.+Cook+Islands+Access+and+Benefit+Sharing+Policy.+The+Nagoya+Protocol%2C+2018.&oq=COOK+ISLANDS+NATIONAL+ENVIRONMENT+SERVICE.+Cook+Islands+Access+and+Benefit+Sharing+Policy.+The+Nagoya+Protocol%2C+2018.&aqs=chrome..69i57.519j0j7&sourceid=chrome&ie=UTF-8*. Access in 12/17/2021.

THE ABS CAPACITY DEVELOPMENT INITIATIVE. **Country Visit**: In-Country Consultation Cook Islands. Available at: <*http://www.abs-initiative.info/countries-and-regions/pacific/cook-islands/cook-islands-country-visit/*> Access in: 12/17/2021.

MASSEY UNIVERSITY. **Pacific Research Guidelines and Protocols.** Available at: <*https://www.massey.ac.nz/massey/fms/Colleges/College%20of%20Humanities%20and%20Social%20Sciences/pacific-research-and-policy-centre/192190%20PRPC%20Guidelines%202017%20v5.pdf?4D6D782E508E2E-272815C5E3E1941390*> Access in: 12/17/2021.

Fiji[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until October 27th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Ms. Sandeep Singh
Director
Department of Environment

Ministry of Waterways and Environment
Levels 1 & 2, Bali Tower, 318 Toorak Road
P.O. Box 2109, Government Buildings
Suva
Fiji

ABS National Focal Point
+679 3311699
singhsk@govnet.gov.fj

6. Websites

ABSCH Fiji Profile
https://absch.cbd.int/countries/FJ

CDB Fiji Profile
https://www.cbd.int/countries/?country=fj

Biodiversity Clearing House Mechanism Fiji
https://chmfiji.wordpress.com/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Fiji profile. Available in: *https://absch.cbd.int/countries/FJ* Access in 10/27/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Fiji profile. Available in: *https://www.cbd.int/countries/?country=fj* Access in 10/27/2020.

FIJI. **Fiji Biodiversity Strategy And Action Plan**. Ministry of Labour, Industrial Relations, Tourism and Environment. Available in: *https://www.cbd.int/countries/?country=fj* Access in 10/27/2020.

FIJI. **Fiji's Fifth National Report to the United Nations Convention on Biological Diversity**. Department of Environment. Available in: *https://www.cbd.int/countries/?country=fj* Access in 10/27/2020.

FIJI. **Implementation Framework 2010 – 2014 For The National Biodiversity Strategy And Action Plan 2007 Fiji Islands**. Department of Environment. Available in: *https://www.cbd.int/countries/?country=fj* Access in 10/27/2020.

Kiribati[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since November 14th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The country does not have a specific law that regulates access to genetic heritage and associated traditional knowledge. There is only a mention of associated traditional knowledge in the Environment Act of 1999, sub-section 4B, item (c) that determines that any decision made under the scope of this Act must take in account the respect for the traditional knowledge of the country.

1. The information hereinafter has been updated until November 19th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

Also, according to the Fifth National Report on the Convention of Biological Diversity (2014), the country has not yet established actions to implement the Nagoya Protocol.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Mrs. Taare Aukitine
Secretary
Ministry of Environment, Lands and Agricultural Development (MELAD)
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Tarawa
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+686 28334
secretary@melad.gov.ki
ds@melad.gov.ki

ABS National Focal Point
+686 28211
+686 28334
secretary@melad.gov.ki
ds@melad.gov.ki

6. Websites

Pacific Islands Legal Information Institute
http://www.paclii.org/

ABSCH Kiribati Profile
https://absch.cbd.int/countries/KI

CBD Kiribati Profile
https://www.cbd.int/countries/?country=ki

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Kiribati Profile. Available at: *https://absch.cbd.int/countries/KI*> Access on 11/19/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Kiribati profile. Available at: *https://www.cbd.int/countries/?country=ki*> Access on 11/19/2020.

GOVERNMENT OF KIRIBATI. **Fifth National Report to the Convention on Biological Diversity.** Available at: *https://www.cbd.int/doc/world/ki/ki-nr-05-en.pdf*> Access on 17/05/2018.

GOVERNMENT OF KIRIBATI. **Environment Act of 1999**. Available at: *https://www.informea.org/sites/default/files/legislation/kir35369.pdf.* Accessed on 17/05/2018.

Marshall Islands[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since January 8th, 2015.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

1. The information hereinafter has been updated until October 28th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Ms. Clarence Samuel
Director (CDB Operational Focal Point)
Office of Environmental Planning and Policy Coordination (OEPPC)
Office of the President
P.O. Box 975
Majuro
96960
Marshall Islands

ABS National Focal Point
+692 625 7944, 7945
+ 692 625 7918

6. Websites

ABSCH Marshall Islands Profile
https://absch.cbd.int/countries/MH

CDB Marshall Islands Profile
https://www.cbd.int/countries/?country=mh

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Marshall Islands profile. Available in: *https://absch.cbd.int/countries/FJ* Access in 10/28/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Marshall Islands profile. Available in: *https://www.cbd.int/countries/?country=fj* Access in 10/28/2020.

MARSHALL ISLANDS. Republic of the Marshall Islands' Fifth National Report to the United Nations Convention on Biological Diversity. Office of Environmental Planning Policy Coordination. February 2017. Available in: *https://rmi-data.sprep.org/system/files/RMI%205NR_CBD_Final_2017*.pdf Access in 10/28/2020.

Micronesia (Federated States of)[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since September 18th, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12th, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated tradition-

1. The information hereinafter has been updated until October 29th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

al knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Ms. Vanessa Fread
ABS NFP, ABS Clearing House Publishing Authority, Protected Areas NFP
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Micronesia (Federated States of)
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+691 320 5854

6. Websites

ABSCH Micronesia Profile
https://absch.cbd.int/countries/FM

CBD Micronesia Profile
www.cbd.int/countries/?country=fm

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Micronesia (Federated States of) profile. Available in: *https://absch.cbd.int/countries/MF* Access in 10/29/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Micronesia (Federated States of) profile. Available in: *https://www.cbd.int/countries/?country=mf* Access in 10/29/2020.

THE FEDERATED STATES OF MICRONESIA. **National Biodiversity Strategy and Action Plan**. National Environmental Management and Sustainable Development Council. 2002. Available in: *https://www.cbd.int/countries/?country=mf* Access in 10/29/2020.

THE FEDERATED STATES OF MICRONESIA. **Fifth National Report to the Convention on Biological Diversity**. Micronesia Conservation Trust; the Federated States of Micronesia Resources and Development Department; and Global Environment Facility. 2014. Available in: *https://www.cbd.int/countries/?country=mf* Access in 10/29/2020.

Nauru[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since February 08, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

1. The information hereinafter has been updated until October 29th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However,

it has a National Focal Point recognized by the Convention on Biological Diversity:

Convetion on Biological Diversity

Mrs. Berilyn Jeremiah
Secretary of Commerce, Industry and Environment
Department of Commerce, Industry and Environment
Government Building
Yaren District
Nauru

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secretaryciennauru@gmail.com

6. Websites

Pacific Island Legal Information Institute
http://www.paclii.org/

ABSCH Nauru Profile
https://absch.cbd.int/countries/NR

CBD Nauru Profile
https://www.cbd.int/countries/?country=nr

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Nauru Profile. Available at: < *https://absch.cbd.int/countries/NR*> Access on 10/29/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Nauru profile. Available at: *https://www.cbd.int/countries/?country=nr*> Access on 10/29/2020.
.
GOVERNMENT OF NAURU. **Fifth National Report to the Convention on Biological Diversity**. Available at: *https://www.cbd.int/doc/world/nr/nr-nr-05-en.pdf*> Access on 10/29/2020.

New Zealand[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country and according to its Fifth National Report (2014), New Zealand does not have specific legislation on access to genetic heritage and associated traditional knowledge. The National Focal point has appointed the Wildlife Act and Reserves Act as laws

1. The information hereinafter has been updated until October 11th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

related to the theme of access and benefit sharing, and recommended that those who intend to make access in the country must consult previously with the local governments and representatives of the Maori people about possible procedures and obligations. Also, the National Focal Point has appointed the Department of Conservation's website, *<https://www.doc.govt.nz/get-involved/apply-for-permits/apply-for-a-permit/>*, in which it is possible to require the collection of samples from Crown's land. However, analyzing the appointed legal instruments, it was not possible to identify determinations related to access to genetic heritage and associated traditional knowledge.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 226 of the Patents Act 2013 determines that the Maori Advisory Committee must advise the Commissioner of Patents, when requested, on a patent application that uses Maori's traditional knowledge or indigenous plants and animals, and if their commercial use is contrary to Maori's values. The Commissioner must consider the Maori advice in the decision making process for the grant of patent, but is not bound by it.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, article 226 of the Patents Act 2013 determines that the Maori Advisory Committee must advise the Commissioner of Patents, when requested, on a patent application that uses Maori's traditional knowledge or indigenous plants and animals, and if their commercial use is contrary to Maori's values. The Commissioner must consider the Maori advice in the decision making process for the grant of patent, but is not bound by it.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heri-

tage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

National Focal Point

Ms. Liese Galvin
CBD Primary NFP, SBSTTA NFP, ABS NFP, Cartagena Protocol Primary NFP
Ministry of Foreign Affairs and Trade
195 Lambton Quay Private Bag 18 901
Wellington
5045
New Zealand
liese.galvin@mfat.govt.nz
+62 21 418 589

6. Websites

ABSCH New Zealand Profile
https://absch.cbd.int/countries/NZ

CBD New Zealand Profile
https://www.cbd.int/countries/?country=nz

National CHM
http://www.biodiversity.govt.nz

Department of Conservation
http://www.doc.govt.nz

Environmental Protection Authority
http://www.epa.govt.nz

Ministry for Primary Industries
http://www.mpi.govt.nz

Ministry of Foreign Affairs and Trade
http://www.mfat.govt.nz

Te Puni Kokiri
http://www.tpk.govt.nz

7. References

CARRIZOSA, Santiago, et al. Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity. **IUCN Environmental Policy and Law Paper**, Gland and Cambridge, n. 54, 2004. Available at: *https://www.cbd.int/financial/bensharing/g-abs-iucn.pdf*. Access in: October 11th, 2021.

MEDAGLIA, Jorge Cabrera; PERRON-WELCH, Frederic; PHILLIPS, Freedom-Kai. **Overview of national and regional measures on access and benefit sharing: Challenges and opportunities in implementing the Nagoya Protocol**. CISDL Biodiversity & Biosafety Law Research Programme, 3 ed., 2014. Available at: *https://www.absfocalpoint.nl/upload_mm/5/f/4/008c9cc8-19f3-4926-b380-5f13fd1eb705_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf*. Access in: October 11th, 2021.

NEW ZEALAND. **New Zealand's Fifth National Report to the United Nations Convention on Biological Diversity**, 2014. Available at: *https://www.cbd.int/doc/world/nz/nz-nr-05-en.pdf.* Access in: October 11th, 2021.

NEW ZEALAND. **Patents Act 2013**, September 13th, 2013. Available at: *http://www.wipo.int/wipolex/en/text.jsp?file_id=327197*. Access in: October 11th, 2021.

Niue[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since May 28th, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The country does not have a specific law that regulates access to genetic heritage and associated traditional knowledge as established by the Convention on Biological Diversity and the Nagoya Protocol. On the other hand, the country has the Taoga Niue Act (2012), which protects traditional knowledge and cultural expressions in the

1. The information hereinafter has been updated until November 3rd, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House

country, but does not associate it directly to biodiversity or genetic heritage.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Potocol on Acess and Benefit-sharing

Mr. Sauni Tongatule
Director
Department of Environment
Ministry of Natural Resources
P.O. Box 80
Alofi
Niue

ABS National Focal Point
+683 4021
+683 4010
sauni.tongatule@gmail.gov.nu

6. Websites

ABSCH Niue Profile
https://absch.cbd.int/countries/NU

CBD Niue Profile
https://www.cbd.int/countries/?country=ni

UNDP Cook Islands, Niue, Samoa and Tokelau
http://www.ws.undp.org/content/samoa/en/home.html

Internet Niue
http://internetniue.nu/

Pacific Island Legal Information Institute
http://www.paclii.org/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Niue profile. Available at: https://absch.cbd.int/countries/NU. Access on 11/03/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Niue profile. Available at: https://www.cbd.int/countries/?country=ni> Access on 11/03/2020.

GOVERNMENT OF NIUE. Fifth National Report Of Niue: Convention on Biological Diversity. Available at: https://www.cbd.int/countries/?country=nu> Access on 21/05/2018.
GOVERNMENT OF NIUE. Environment Act 2003 N° 264. Available at: http://prdrse4all.spc.int/node/4/content/niue-environment-act-2003. Access on 21/05/2018.

GOVERNMENT OF NIUE. TAOGA NIUE ACT N° 320. Available at: https://www.ecolex.org/details/legislation/taoga-niue-act-2012-no-320-lex-faoc136950/. Access on 21/05/2018.

Palau[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since April 8th, 1999.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since September 11th, 2018

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- RPPL Nº10-28, Creating a National Framework for access and fair and equitable sharing of benefits of genetic resources and traditional knowledge associated with genetic resources within the Republic, and for related

1. The information hereinafter has been updated until July 30th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4.The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

purposes (2018)

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found. However the RPPL N°10-28 provides that the Ministry of Natural Resources, Environment and Tourism shall be the institution responsible for regulations regarding ABS in the country.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. According to the RPPL N°10-28 all access activities in the country must comply with the procedures described below:

1. Application: the applicant shall apply to the ABS Committee, presenting details about the access to be performed.

2. ABS Agreement: the Committee shall verify compliance, establish Mutually Agreed Terms and form an ABS Agreement.

3. Negotiation with Resource Owner:the Committee shall meet with the resource owner and present the terms of the ABS Agreement. The Committee shall facilitate the negotiations between the resource owner and the applicant.

4. Approval of Resource Owner: the resource owner shall approve or reject the ABS Agreement.

2.4. Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
(X) YES / ( ) NO / ( ) NOT AVAILABLE
Yes. Notwithstanding the procedures described in item 2.3, in cases where access to associated traditional knowledge is concerned, article 5006 (7) establishes that if an ABS agreement involves the use of traditional knowledge, the ABS Committee shall ensure that the holder of traditional knowledge receives adequate benefits as a result of the access and use of the associated genetic resources.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for requesting patents were identified in the norms covered by this analysis.

2.6. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domes-

tic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9. Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
(X) YES / ( ) NO / NOT AVAILABLE
Yes, benefit sharing is mandatory and it incides over utilization of genetic resources. The responsibility to share the benefits lies on the user.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
The norms covered by this analysis do not address procedures, rules and values about benefit sharing. However, article 5014 establishes that an ABS Fund shall be established.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Deposit into a Fund	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Not defined
Non Monetary	Not defined	Not defined	Not defined	Genetic Heritage/ Associated Traditional Knowledge	Not defined

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. House Bill 10-66-5S, HD1, SDI establishes the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: fines between two hundred and fifty thousand dollars and one million dollars per violation and returning of genetic resources.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

National Focal Point

Mr. King Sam
Special Assistant to Minister/Programme Manager
Protected Areas Network
Ministry of Natural Resources, Environment and Tourism
P.O. Box 6051
Koror
96940
Palau

ABS National Focal Point
+680 767 5435, 3125
+680 767 3380
esuroi1@gmail.com

6. Websites

ABSCH Palau Profile
https://absch.cbd.int/countries/PW

CBD Palau Profile
https://www.cbd.int/countries/?country=pw

National Clearing House Mechanism
http://palau.chm-cbd.net/

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles: Palau. Available at: *https://absch.cbd.int/countries/PW* Access on: 13/10/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles: Palau. Available at: *https://www.cbd.int/countries/?country=pw* Access on: 13/10/2021.

REPUBLIC OF PALAU. **Republic of Palau Fifth National Report to the Convention on Biological Diversity**, 2014. Available at: < *https://www.cbd.int/doc/world/pw/pw-nr-05-en.pdf*> Access in: 05/25/2018.

REPUBLIC OF PALAU. **National Biodiversity and Action Plan**, 2014. Available at: < *https://www.cbd.int/doc/world/pw/pw-nbsap-01-en.pdf*> Access on: 05/25/2018.

Papua New Guinea[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29th, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

( ) YES / (X) NO

No, the country is not a Party to the Nagoya Protocol.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, Michelle F. Rourke in her article "Access and benefit-sharing in practice: non-commercial research scientists face legal obstacles to accessing genetic resources" affirms that according to Eric Kwa, there are rules and procedures regarding ABS in Papua New Guinea. Similarly, according to the 6th National Report on the Convention of Biological Diversity (2019), some aspects related to ABS are comprised in the Papua New Guinea

1. The information hereinafter has been updated until November 12th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

legal system, but no specific legislation was indicated.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, Michelle F. Rourke states in her aforementioned article that an application for access shall be filed before the Secretariat of the Papua New Guinea Institute of Biodiversity (PNBlio) at least six months prior to the beginning of the research activities, according to Eric Kwa.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / ( ) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol.

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

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CBD Papua New Guinea Profile
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Pacific Islands Legal Information Institute
http://www.paclii.org/

7. References

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CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Papua New Guinea profile. Available at: *https://www.cbd.int/countries/?country=pg*> Accessed on 11/12/2021.

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GOVERNMENT OF PAPUA NEW GUINEA. **Environment Act 2000, nº64 of 2000**. Available at: *https://www.informea.org/en/www.paclii.org%3B%20mra.gov.pg* Access on 22/05/2018.

ROURKE, Michelle F. Access and benefit-sharing in practice: non-commercial research scientists face legal obstacles to accessing genetic resources. Journal of Science Policy & Governance. Policy Analysis: ABS in Practice. JSPG, Vol, 13, Issue 1, October 2018.

Samoa[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since May 10, 1994.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since October 12, 2014.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, Forestry Management Act 2011 in art. 30, item 3, sub-item f, and in art. 58, item 2, sub-item d, establish that the government shall protect and

1. The information hereinafter has been updated until January 21th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

regulate the access to genetic resources and ensure that Samoa receives an equitable share of the benefits from such resources.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

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6. Websites

ABSCH Samoa Profile
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CBD Samoa Profile
www.cbd.int/countries/?country=ws

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Samoa profile. Available in: *https://absch.cbd.int/countries/WS* Access in 09/04/2020.

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SAMOA. **Samoa's National Biodiversity Strategy and Action Plan (NBSAP) 2015 – 2020**. Ministry of Natural ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Samoa profile. Available in: *https://absch.cbd.int/countries/WS* Access in 09/04/2020.

Solomon Islands[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since January 1st, 1996.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since January 22nd, 2020.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The country does not have any specific legislation for access to genetic heritage and associated traditional knowledge. On the other hand, the Protected Areas Act (2010) defines standards for obtaining authorization to conduct biodiversity research or bioprospecting and establishes that the Advisory Committee shall not approve any application for a permit involving customary land or customary fishing areas unless the Committee is satisfied that an agreement is entered into with the owners relating to right of access, acquisition of biological resource, technology transfer, monetary benefit or compensation on the biological prospecting, acquisition of biological resources

1. The information hereinafter has been updated until December 21st, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4.The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

or for any commercial benefit that may be obtained as a result of the permit.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation on access to genetic heritage and associated traditional knowledge has been found, thus no competent authorities on the matter were identified. However, according to the Protected Areas Act of 2010, and the Environmental Act of 1998, the following bodies are responsible for matters related to biodiversity in the country:

- **Environment and Conservation Division**
  This is the Environment and Conservation Division, founded by the Environmental Act, published on October 20th, 1998. Its main mission is the protection of the Environment and to develop public policies that aim at the promotion of sustainability in the country. Besides that, the Division may receive, through its Director, requests of authorization for researches using natural resources in the country.

- **Protected Areas Advisory Committee**
  This is the Committee on Protected Areas, established by the Environmental Act, published on October 20, 1998. Its main mission under the aforementioned law is to advise the Division of Environment and Conservation and the Ministry of the Environment. In addition, the Protected Areas Act (2010) delegates to the agency the inspection of protected areas, conduct inquiry, negotiate and administer applications for authorization for protected areas, including the agreement between the owner of the biological resources and the applicant.

Both bodies are linked to the Ministry of the Environment, Climate Change, Natural Disasters and Meteorology.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As provided for in Chapter 5 of the Protected Areas Act (2010), every research on biodiversity or with bioprospecting purposes carried out in protected areas, must have a prior authorization issued by the Protected Areas Advisory Committee, which has the power to grant, refuse, suspend and cancel a request. The cancellation or refusal of a request has to be justified.

The legislation provides that the application form should contain information on those responsible for the research, nature, type and method of research, among other relevant information. The Advisory Committee may also ask for more information if it comes to the conclusion that it does not have enough.

The applicant may also choose to send the request to the Director of the Environment and Conservation Division, who will send the form to the Advisory Committee for evaluation.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5. Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the Protected Areas Act (2010), in its article 18, provides that authorizations for access on public land or public fishing areas shall only be granted by the Advisory Committee if the request for access includes a benefit sharing agreement with the holders of the genetic resource, monetary or non-monetary modality.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found. Nevertheless, the Protected Areas Act (2010) determines that the Ministry of Environment, Climate Change, Natural Disasters and Meteorology is the responsible authority for indicating the inspection bodies for the means of the Protected Areas Act (2010).

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, the Protected Areas Act (2010), in its chapter 5, establishes the following sanctions applicable to irregular access to genetic resources originated from protected areas: prison sentence for a maximum of 5 years and / or payment of a fine in the maximum amount of 500 thousand SBD, the equivalent of approximately $ 62,150.00 dollars.

In this sense, the Research Act (1982) states that researches carried out inside the country that don't comply with the procedural rules, are considered illegal and subject to the payment of a fine in the amount of 1 thousand SBD, equivalent to approximately $ 125.00 dollars.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority . However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

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6. Websites

Ministry of the Environment
http://www.mecdm.gov.sb/index.php

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Solomon

Islands profile. Available in: < *https://absch.cbd.int/countries/SB* > Access on 22/12/2021.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Solomon Islands profile. Available in: <*https://www.cbd.int/countries/?country=sb* > Access on 22/12/2021.

CARRIZOSA, Santiago, et al. Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity. IUCN Environmental Policy and Law Paper, Gland and Cambridge, n. 54, 2004. Available at: <*https://www.cbd.int/financial/bensharing/g-abs-iucn.pdf*> Access on: 22/12/2021.

MEDAGLIA, Jorge Cabrera; PERRON-WELCH, Frederic; PHILLIPS, Freedom-Kai. Overview of national and regional measures on access and benefit sharing: Challenges and opportunities in implementing the Nagoya Protocol. CISDL Biodiversity & Biosafety Law Research Programme, 3 ed., 2014. Available at: <*https://www.absfocalpoint.nl/upload_mm/5/f/4/008c9c-c8-19f3-4926-b380-5f13fd1eb705_Overview%20of%20national%20and%20regional%20measures%20on%20access%20and%20benefit%20sharing.pdf*> Access on: 22/12/2021.

SOLOMON ISLANDS; Ministry of Education and Human Resources Development. Procedures for applying for a Research Permit. Available at: *http://www.mehrd.gov.sb/101-uncategorised/202-procedures-for-applying-for-a-research-permit&gt.* Access on: 22/12/2021.

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SOLOMON ISLANDS. Protected Areas Act, March 29 of 2010. Available at: <*http://extwprlegs1.fao.org/docs/pdf/sol94186.pdf*> Access on: 22/12/2021.

SOLOMON ISLANDS. Environmental Act, 20 de outubro de 1998. Disponível em: <*https://www.ecolex.org/details/legislation/environment=-act1998--no8--of1998--lex-fao065422c/?q-environment+act+1998*> Access on: 22/12/2021.

SOLOMON ISLANDS. The Research Act, July 28 of 1982. Available at: <*http://www.parliament.gov.sb/files/legislation/Acts/1982/THE%20RESEARCH%20ACT%201982.pdf*>. Access on: 22/12/2021.

SOLOMON ISLANDS. Wildlife Protection and Management Act 1998, November 3 of 1998. Available at: <*http://www.parliament.gov.sb/files/legislation/Acts/1998/The%20Wildlife%20Protection%20and%20Management%20Act%201998.pdf*> Access on: 22/12/2021.

Tonga[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by accession, since August 17th, 1998.

1.2 Is the country a Party to the Nagoya Protocol?

(X YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by accession, since January 1st, 2020.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.2 Does the current legislation or any ongoing bills identify the competent institution?

( ) YES / (X) NO / ( ) NOT AVAILABLE

1. The information hereinafter has been updated until September 25th, 2020.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4.The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity:

Convention on Biological Diversity

Hon. Mr. Poasi Mataeli Tei
Minister (Political CBD Focal Point)
Ministry of Meteorology, Energy, Information, Disaster Management, Environment, Climate Change and Communications (MEIDECC)

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6. Websites

ABSCH Tonga Profile
https://absch.cbd.int/countries/TO

CBD Tonga Profile
https://www.cbd.int/countries/?country=to

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Tongs Profile.
Available in: < *https://absch.cbd.int/countries/LK*> Access on 12/24/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Tonga Profile. Available in: < *https://www.cbd.int/countries/?country=lk*> Access on 12/24/2020.

THE KINGDOM OF TONGA. **Kingdom of Tonga's Fifth National Report to the Convention on Biological Diversity**, 2014. Available at: < *https://www.cbd.int/doc/world/to/to-nr-05-en.pdf*> Access on: 06/07/2018.

Tuvalu[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since March 20th, 2003.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, Tuvalu has been a Party to the Nagoya Protocol, by accession, since November 26th, 2018.

1.3 Does the country have any officially recognized "checkpoints"[2] under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. Nonetheless, article 30 of the Environmental Protection Act (2008) establishes that the Department of Environment shall be responsible for developing, applying and enforcing policies regarding the protection of biodiversity, which shall include re-

1. The information hereinafter has been updated until November 9th, 2020.
2.Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

gulating access to genetic resources and equitable sharing of benefits arising from their exploitation, as well as acting for recognition and protection of traditional knowledge related to the utilization of biological diversity.

2.2 Does the current legislation or any ongoing bills identify the competent institution?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official competent institutions concerned with access and benefit-sharing under the terms of the Nagoya Protocol were found.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to access genetic resources?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.7 Does the current legislation establish procedures for the shipment of samples?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies ? If so, what is the specific terminology used and procedures established in the domestic legislation?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

3.2 Are there any specific procedures, rules and values?
( ) YES / (X) NO / NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	No legislation	No legislation	No legislation	No legislation	No legislation
Non Monetary	No legislation	No legislation	No legislation	No legislation	No legislation

4. Sanctions

4.1 Is there an official inspection body?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?
( ) YES / (X) NO / ( ) NOT AVAILABLE
As mentioned in item 2.1, no specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?
( ) YES / (X) NO / ( ) NOT AVAILABLE
No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However,

it has a National Focal Point recognized by the Nagoya Protocol:
Nagoya Protocol on Access and Benefit-sharing

Ms. Tilia Tima
Biodiversity Officer
Ministry of Foreign Affairs, Trade, Tourism, Environment and Labour
Private Mail Bag
Funafuti
Tuvalu

ABS National Focal Point
tilia.tima@gmail.com

6. Websites

ABSCH Tuvalu Profile
https://absch.cbd.int/countries/TV

Biodiversity Tuvalu
https://new-tv.chm-cbd.net/

CBD Tuvalu Profile
https://www.cbd.int/countries/?country=tv

7. References

ACCESS AND BENEFIT-SHARING CLEARING HOUSE - ABSCH. Country Profiles. Tuvalu. Available in: *https://absch.cbd.int/countries/TV.* Access on: 11/09/2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Tuvalu. Available in: *https://www.cbd.int/countries/?country=tv*. Access on: 11/09/2020.

TUVALU. **Tuvalu National Biodiversity Strategy and Action Plan: Fifth National Report to the Convention on Biological Diversity**, 2016. Available at: *<https://www.cbd.int/doc/world/tv/tv-nr-05-en.pdf>* Access on: 08/25/2020.

TUVALU. Environmental Protection Act (2008). Available at: *http://extwprlegs1.fao.org/docs/pdf/tuv99601.pdf*. Access on 11/09/2020.

Vanuatu[1]

1. General information

1.1 Is the country a signatory to the Convention on Biological Diversity?

(X) YES / ( ) NO

Yes, the country has been a Party to the Convention, by ratification, since December 29, 1993.

1.2 Is the country a Party to the Nagoya Protocol?

(X) YES / ( ) NO

Yes, the country has been a Party to the Nagoya Protocol, by ratification, since October 12, 2014.

1.3 Does the country have any officially recognized "checkpoints" [2]under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoints were found in this country.

1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC[3] under the terms of Article 17 of the Nagoya Protocol?

( ) YES / (X) NO

No IRCCs were found in this country.

1.5 Does the country have any officially recognized "checkpoint communiqués"[4] under the terms of Article 17, 1(a) of the Nagoya Protocol?

( ) YES / (X) NO

No checkpoint communiqués were found in this country.

2. Legal information

2.1 Does the country already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes, the country already has the following laws regarding access and benefit-sharing:

- The Environmental Management and Conservation Act, No. 12 of 2002: This legislation

1. The information hereinafter has been updated until May 20th, 2021.
2. Checkpoint is the entity designated by the parties to effectively collect or receive the relevant information on the prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms and/or the utilization of the genetic resources, while also being responsible for maintaining a registry in the ABS Clearing House. Available at: https://absch.cbd.int/about.
3. Certificate constituted from the information on the permit or equivalent document registered in the ABS Clearing-House serving as evidence that the genetic resource which it addresses has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow the monitoring of the utilization of the genetic resources by all users throughout the value chain. Available at: https://absch.cbd.int/about.
4. The "checkpoint communiqué" is a summary of the information collected or received by the "checkpoint" with regard to the prior informed consent, the genetic resource provider, the establishment of mutually agreed terms and/or the use of the genetic resources. The "checkpoint communiqué" is registered in the ABS Clearing- House.

is devoted on conservation, sustainable development and environmental management in Vanuatu. Part 4 “Biodiversity and Protected Areas” of this standard regulates activities understood as “bioprospecting”.

- Patents Act n. 2 of 2003: The part number 12 (Article 47) of Patent Act provides for the registration of a patent involving indigenous knowledge.
- Protection of Traditional Knowledge and Expressions of Culture Act (Act No. 21 of 2019)
- Design Act no. 3 of 2003.
- Draft Oceans Policy
- Draft National Scientific Research Council Bill
- Intellectual property
- Draft Traditional Knowledge Bill
- Draft MSG Treaty on the Protection of TK

2.2 Does the current legislation or any ongoing bills identify the competent institution?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Biodiversity Advisory Council was created through Article 29 of the Environmental Management and Conservation Act, No. 12 of 2002. The Director of the Environment Department will be the President of the Council, who will be responsible for advising the Minister on issues related to implementation of the Convention on Biological Diversity, especially with regard to commercial bioprospecting. According to articles 33 and 34 of the same law, requests for authorization should be directed to the aforementioned Director who will analyze and submit such request to the approval of the Biodiversity Advisory Council.

2.3 Does the current legislation or any ongoing bills foresee the need for prior authorization in order to obtain genetic resources?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. According to Environmental Management and Conservation Act, No. 12 of 2002 all access activities in the country must comply with the procedures described below:

1. Authorization for bioprospecting: The authorization for bioprospecting is necessary, the following acts being punishable if carried out without it:

- Initiate or conduct biodiversity prospecting without proper bioprospecting authorization;
- export or attempt to export any specimens obtained in the prospecting of biodiversity without proper bioprospecting authorization;
- Importing or attempting to import any foreign organism that may cause significant adverse impacts to the native flora and fauna of the country, without proper authorization;

The request and the deliberation on bioprospecting authorization are described respectively in Articles 33 and 34 of the Environmental Management and Conservation Act, No. 12 of 2002. The request should be made directly to the Director of the Biodiversity Advisory Council and,

if he understands that all the requirements of item 2, article 33 of the Law, will redirect to the Council that it should decide to accept, request complementation or deny the request for authorization.

2.4 Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Yes. The Patents Act No. 2 of 2003, entitled “Part 12 Indigenous Knowledge”, regulates the registration of patents originating or containing elements of “Indigenous Knowledge”. Within indigenous knowledge include:

- Those created, acquired or inspired by economic, spiritual, ritual, narrative, decorative or recreational tradition;
- Those knowledge in which nature or use has been transmitted from generation to generation; and
- The knowledge belonging to a certain indigenous person or people in Vanuatu.

The legal provisions inserted in this chapter ensure the establishment of prior informed consent and benefit sharing.

The Environmental Management and Conservation Act, No. 12 of 2002 mentions that the word “bioprospecting” means, among other things, the knowledge, innovation or habitual practice of local communities associated with genetic resources and their derivatives. Therefore, the same bioprospecting procedures described in Part 4 - Biodiversity And Protected Areas of the Environmental Management and Conservation Act, No. 12 of 2002, apply to traditional knowledge.

2.5 Does the current legislation or any ongoing bills provide specific procedures for requesting patents (right to intellectual property) arising from research or technological developments involving the access?

(X) YES / ( ) NO / ( ) NOT AVAILABLE

Pursuant to item 2.4., Patents Act No. 2 of 2003, title “Part 12 Indigenous Knowledge”, regulates the registration of patents originating or containing elements of “Indigenous Knowledge”

2.6 Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for collection and access of exotic species were identified in the norms covered by this analysis.

2.7 Does the current legislation establish procedures for the shipment of samples?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No specific procedures for shipment of samples were identified in the norms covered by this analysis.

2.8 Does the current legislation or any ongoing bills address digital sequence information, synthetic biology or similar terminologies? If so, what is the specific terminology used and procedures established in the domestic legislation?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address digital sequence information, synthetic biology or similar terminologies.

2.9 Does the current legislation or any ongoing bills foresee species that have developed distinctive properties within the country's territory?

( ) YES / (X) NO / ( ) NOT AVAILABLE

The norms covered by this analysis do not address species that have developed distinctive properties within the country's territory.

3. Benefit sharing

3.1 Is Benefit-Sharing mandatory? With whom lies the responsibility to share the benefits?

(X) YES / ( ) NO / NOT AVAILABLE

The main rule regulating access to genetic resources in the country, which is the Environmental Management and Conservation Act, No. 12 of 2002, is unclear about the need to share the benefits of exploiting the genetic resources or traditional knowledge. According to article 33, item 2 "a", in the request for bioprospecting authorization, the applicant must discriminate its name and data, including associates, affiliates and parties that may benefit or distribute the research or obtain any benefit from the research. It does not mention whether this party would benefit from the provision of genetic resources or traditional knowledge.

In Article 34, item 6, "a", "iii", the Biodiversity Advisory Council that examines the application for bioprospecting authorization must certify that the applicant has entered into a contract with the owners of the collection sites or holders of traditional knowledge which establishes the rights of access and acquisition of the biological resource or traditional knowledge, as well as fees, royalties or concessions that will be owed due to the research or acquisition of any biological resource or traditional knowledge, or due to the existence of commercial benefits obtained by the applicant.

On the other hand, according to the Patent Act nº 2 of 2003, article 47, item 3, b, e 4 "c", mention benefit sharing, not specifying procedures, rules or values. A patent of invention that incorporates elements of indigenous knowledge cannot be registered if the applicant hasn't celebrated an agreement with the holder of this knowledgement, that predicts the payment by the applicant to the holder of the equitative portion of perceived benefits with the exploration of the patent.

3.2 Are there any specific procedures, rules and values?

( ) YES / (X) NO / NOT AVAILABLE

The norms covered by this analysis do not address procedures, rules and values about benefit sharing.

BENEFIT SHARING					
Category	Link in the production chain	Mode	Value	Genetic Heritage / Associated Traditional Knowledge	MTA / Beneficiary
Monetary	Not defined	Not defined	Not defined	Not defined	Not defined
Non Monetary	Not defined	Not defined	Not defined	Not defined	Not defined

4. Sanctions

4.1 Is there an official inspection body?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No official inspection bodies concerned with access and benefit-sharing were found.

4.2 Does the legislation establish sanctions in case of irregular access? What are they? In the case of fines, is there an indication of value?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No sanctions in case of irregular access were identified in the norms covered by this analysis.

4.3 Is there any records of fines that have been applied, emblematic biopiracy cases or public disputes related to access and benefit sharing in the country, including irregular access to traditional knowledge?

( ) YES / (X) NO / ( ) NOT AVAILABLE

No record of fines, biopiracy cases or disputes related to access and benefit sharing in the country were found.

5. Summary – Competent authorities

As mentioned in item 2.2, the country does not have an official competent authority. However, it has a National Focal Point recognized by the Nagoya Protocol:

Nagoya Protocol on Access and Benefit-sharing

Ms. Donna Kalfatak Moli
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6. Websites

ABSCH Vanuatu Profile

https://absch.cbd.int/countries/VU

CBD Vanuatu Profile

www.cbd.int/countries/?country=by

7. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Vanuatu profile. Available in: *https://absch.cbd.int/countries/VU* Access in April 28, 2020.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Vanuatu profile. Available in: *https://www.cbd.int/countries/?country=vu* Access in April 28,2020.

SUMMARY Report of Nagoya Protocol Workshop. Port Vila, Vanuatu Cultural Centre: [s.n.], 2015. Report compiled by the organizing committee. Vanuatu, 2015. Available in: *http://www.abs-initiative.info/fileadmin//media/Events/2014/16-17_September_2014__Porta_Vila__Vanuatu/Summary_of_Nagoya_Protocol_Workshop_Sept_2015__final_19_10_15.pdf* Access in April 28,2020.

VANUATU. **Environmental Management and Conservation Act 2002 (Cap. 283)**. Available in: *https://www.ecolex.org/details/legislation/environmental-management-and-conservation-act-2002-cap-283-lex-faoc053103/?q=&type=legislation&xkeywords=biodiversity&xcountry=Vanuatu&xdate_min=&xdate_max=* Access in April 28,2020.

VANUATU. **Fifth National Report – Country Report to the Conference of the Parties on the Convention on Biological Diversity**. Department of Environmental Protection and Conservation. Available in: *https://www.cbd.int/countries/?country=vu* Access in April 28, 2020.

VANUATU. **Patents Act No. 2 of 2003**. Available in: *http://www.wipo.int/wipolex/en/details.jsp?id=10727* Access in April 28,2020.

VANUATU. **Vanuatu National Biodiversity Strategy And Action Plan Project**. Cultural Centre; Forestry Department; Fisheries Department; Vanuatu Quarantine & Inspection Services; Rural Water Supply Section; Department of Economic and Strategic Development. Available in: *https://www.cbd.int/countries/?country=vu* Access in April 28,2020.

About Gss Carbon and Bioinnovation

GSS Carbon and Bioinnovation is a Brazilian company based in Curitiba (PR), São Paulo (SP) and Brasília (DF) formed by professionals with experience in national and international projects involving biodiversity, climate change and corporate sustainability.
The GSS team brings together the knowledge acquired in working with several companies in the public and private sectors, providing its clients with strategic thinking and competitive capacity aligned with current challenges and opportunities.

The notion of corporate success has changed. It is not enough to achieve expressive numbers and results. Responsible companies need to be aware of the impacts generated throughout the production chain, from the extraction of raw material to the moment the product is discarded. This demand comes from civil society, the government and major actors in the international community who constantly meet to discuss good practices and agreements concerning the environment. At GSS, we closely monitor all these movements to act quickly and efficiently, helping companies to achieve results in the best possible way: respecting our planet, mitigating their GHG emissions and valuing Brazilian biodiversity. Thus, we walk hand in hand with our customers and partners who are concerned with growing more sustainably.
We believe in our role, which is why coherence between speech and action is the fundamental premise of GSS.

The activities of GSS are broad and include:

Management Strategies for Sustainable Use of Biodiversity.

- Guidance on best practices in Benefit Sharing and Community Relations.
- Strategic monitoring with CGEN and competitive intelligence services.
- Monitoring national and international meetings, including the Conference of the Parties (COP).
- Support for designing a Benefit Sharing Policy.
- Participatory diagnosis of local communities.
- Field activities for managing the use of Biodiversity.
- Monitoring of projects and follow-up of indicators.
- Prospecting for supplies, raw materials and potential communities that provide genetic resources.
- Participatory construction of community protocols.
- Community development, strengthening of local associations and cooperatives.

- Risk assessment of activities involving the use of ingredients by the company in its products. Passive and preventive.

- Assessment of biodiversity supplies to identify the center of origin and any applicable national or international legislation.

- Evaluation of supplies, ingredients, raw materials and bibliographic references in order to identify access to associated traditional knowledge.

- Analysis of international legislation on access and benefit sharing and framework of activities under the Nagoya Protocol.

- Process of registration, notification, adequacy and regularization of access with SisGen.

Development of activities and strategies related to the use of biodiversity, access to genetic heritage, associated traditional knowledge and benefit sharing.

- Adequacy and regularization of activities carried out in disagreement with MP 2.186/01 under the terms of the new Biodiversity Law.

- Registration and Notification of research and products developed after the new Biodiversity Law came into force.

About Croda

Croda, a focused Life Sciences and Consumer Care company, creates, makes and sells specialty ingredients used by industries and consumers around the world. Through its Commitment to science-based targets and the United Nations Sustainable Development Goals (SDGs), Croda's ambition is to become the most sustainable supplier of innovative ingredients, developing solutions to tackle some of the biggest challenges the world is facing. By 2030 it will be Climate, Land and People Positive.

Croda's Purpose, Smart science to improve lives™, is made possible due to its distinctive values-led culture, which brings together in-house knowledge, passion, and entrepreneurial spirit. This governs how the company interacts with customers, how employees work together, and guides its relationships with partners.

In 2022 Croda announced, as part of its Land Positive commitment, the ambition to become Net Nature Positive by 2030. This aspiration recognises the importance the company places on understanding impacts and dependencies on nature and the role the company has in driving positive change across its supply chains, and the contribution this makes to achieving a nature positive future, one in which natural capital is protected and restored, is essential for the health, wellbeing and prosperity of us all.

Built on a foundation of turning renewable raw materials into innovative ingredients, the company harnesses innovation to create market-leading products, whilst ensuring sustainability is at the heart of the business. The company's smart science is found in products that touch our lives every day, from sustainable processes and innovative ingredients helping to protect skin, reduce carbon emissions and grow more food, to improving wellbeing and the efficacy of life-saving drugs.

About Natura

One of the leading businesses in the area of cosmetics, perfumes and personal hygiene in Brazil, Natura is dedicated, since its foundation in 1969, to add value to all it's network of relations.

Natura's relationship with biodiversity dates back a long time, as it was a world pioneer in incorporating the theme of sustainable development and the use of Brazilian biodiversity as an instrument of innovation in cosmetics. And in the year 2000, signed a commitment to the Amazon - while launching products based on Brazilian biodiversity assets, it started to operate a new sustainable business model that includes partnerships to carry out actions with social and environmental impact in the region.

This journey led to the formation of the Natura &Co Group, with four iconic beauty brands – Natura, Avon, The Body Shop and Aesop – whose aspiration is to continuously innovate and to promote a positive impact and become the best beauty company in the world. Today, one of the global leaders in direct-to-consumer sales, with almost 8 million consultants and representatives, and present in over 100 countries, with revenues of more than R$40 billion worldwide and R$10 billion in Brazil, promoting the wealth of Brazilian biodiversity and social plurality.

Natura's history is a concrete example of the potential that Brazil has to become a world leader in forestry bioeconomy and the great opportunity that lies ahead for many countries in South America.

Continuing the company's history with environmental causes, in 2020, Natura &Co launched

a public commitment with sustainability goals for 2030, called 'Commitment to Life':

• Net zero emissions of greenhouse gases - GHG (delivering the targets for a reduction of 1.5°C twenty years before the UN commitment);

• Adopt the Science-Based Goals (SBTi) initiative for all group companies;

• Expand the influence on Amazon conservation from the current 2 million to 3 million hectares of forest;

• Share R$60 million (or more) in value with traditional communities that are part of sociobiodiversity chains (starting at R$33 million);

• Encourage collective efforts towards zero deforestation by 2025.

Information on the public commitment "Commitment to Life" available in the Annual Report on the website: https://www.natura.com.br/relatorio-anual

Coordination:

gss
CARBONO E
BIOINOVAÇÃO

Institutional Support:

natura

CRODA



Edition:

2020 UN BIODIVERSITY CONFERENCE
COP 15 - CP/MOP10-NP/MOP4
Ecological Civilization-Building a Shared Future for All Life on Earth
KUNMING – MONTREAL