



*Access and  
Benefit-Sharing  
Around the World:*

The Brazilian law  
contrasted with  
international  
regulations



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This is a previous edition of the Brogota Project. The final version will be released in Egypt in the occasion of COP14.

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regulations

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(CONFEDERAÇÃO NACIONAL DA INDÚSTRIA) – CNI**

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# Summary

	Africa	America
09	Preface	201 Antigua and Barbuda
10	Introduction	205 Argentina
13	Conference of the Parties, its Protocols and the Nagoya Protocol	211 Bolivia
20	International rules	220 Brazil
658	About Natura	234 Canada
659	About GSS Sustainability	240 Chile
	23 South Africa	244 Colombia
	27 Angola	255 Costa Rica
	31 Botswana	265 Ecuador
	36 Burkina Faso	272 United States
	42 Burundi	276 Guatemala
	47 Cameroon	282 Honduras
	52 Côte d'Ivoire	286 Mexico
	56 Djibuti	292 Panama
	60 Egypt	299 Paraguay
	64 Ethiopia	303 Peru
	69 Gabon	313 Dominican Republic
	73 Gambia (the)	319 Uruguay
	77 Guinea-Bissau	
	81 Mauritius Islands	
	84 Lesotho	
	91 Liberia	
	96 Madagascar	
	100 Malawi	
	105 Mali	
	109 Morocco	
	113 Mauritania	
	117 Mozambique	
	121 Namibia	
	125 Niger	
	131 Kenya	
	136 Benin	
	140 Congo	
	144 Rwanda	
	150 Sao Tome and Principe	
	154 Seychelles	
	158 Senegal	
	162 Sierra Leone	
	166 Swaziland	
	176 Sudan	
	180 United Republic of Tanzania	
	184 Togo	
	190 Uganda	

## Asia

324 Butan  
329 Cambodia  
333 Qatar  
337 Kazakhstan  
341 China  
347 Republic of Korea  
351 United Arab Emirates  
355 India  
380 Indonesia  
384 Israel  
388 Japan  
393 Jordan  
397 Kuwait  
401 Lao  
405 Malaysia  
409 Mongolia  
413 Myanmar  
417 Pakistan  
421 Kirgyzstan  
426 Syrian Arab Republic  
430 Thailand  
435 Tajikistan  
439 Turkey  
444 Viet Nam

## Europe

451 Albania  
455 Germany  
462 Austria  
468 Belgium  
474 Belarus  
480 Bulgaria  
486 Croatia  
494 Denmark  
502 Slovakia  
509 Spain  
518 Finland  
525 France  
532 Netherlands  
539 Hungary  
545 Italy  
552 Luxembourg  
558 Malta  
565 Republic of Moldova  
569 Norway  
575 Poland  
581 Portugal  
588 United Kingdom  
594 Czech Republic  
600 Russian Federation  
604 Sweden  
610 Switzzerland  
616 Ukrain  
620 European Union

## Oceania

627 Australia  
636 Fiji  
640 Marshall Islands  
644 Micronesia  
648 Samoa  
652 Vanuatu



# Preface

The economic globalization established the interdependence of the countries in commercial, scientific, technological, environmental and social relations. Such globalization highlighted problems that strike all countries and that require international cooperation to search for consensual solutions.

The system of Access and Benefit-Sharing, addressed by the Nagoya Protocol, aims to achieve economic, social and environmental benefits that lead to the conservation and sustainable use of biodiversity in megadiverse countries, such as Brazil, based on the recognition of rights over natural resources and associated knowledge. The Protocol, as well as the Convention on Biological Diversity - CBD, recognizes the sovereignty of the countries concerning the right of usage of their genetic resources and creates mechanisms for the access to genetic resources and the sharing of benefits arising from its use.

By ratifying the Protocol, the Parties must comply with its content. However, how each Party will proceed may vary, considering their political decisions and the participation of the society in the process of decision-making. Therefore, the critical uncertainties in the implementation of the Protocol are related to the rules that each signatory country establishes in their national legislation in regard to the conditions of access, benefit sharing, understanding of who is the provider, as well as to the alignment with other international treaties. Thus, the entry into force of the Nagoya Protocol will make significant changes in the course of national legislations and in the relations between users and providers of national and foreign genetic resources.

The obligations established by the Nagoya Protocol imply diverse impacts for the users of biodiversity. Such impacts can represent new opportunities to the user, such as access to and transfer of technologies, qualification of human resources, voluntary adoption of codes of conduct, guides and better practices, strategic and operational reformulation of the industrial sectors that use genetic resources in their process and products. Consequently, they can increase the sustainable use of biodiversity.

Good quality information is the basis to a successful decision making. Therefore, the characterization of the international scenario, monitoring of progress, trend analysis, and the analysis of possible impacts are crucial steps towards the production of quality information that subsidize objective and pragmatic decisions and investments.

Understanding the progress of the negotiations over ABS in the context of the Nagoya Protocol, as well as having access to qualified information, will help users of biodiversity from all over the world in assessing the impacts of the implementation of the Nagoya Protocol and of ABS national rules.

In honor to **Bia Bulhões**.

**Elisa Romano Dezolt**

# *Introduction*



The Brazilian National Confederation of Industry (Confederação Nacional da Indústria – CNI) recognizes the indispensable role of businesses to the economic growth allied with environmental sustainability. Actions in favor of biodiversity are crucial to the successful pursuit of the 2030 Agenda for Sustainable Development and to reach the Sustainable Development Goals.

Aware of this responsibility, since 2012, CNI took on the Secretariat of the Brazilian Business and Biodiversity Initiative (IBNB). The Initiative was released during Rio+20 aiming to act as a direct channel between the Brazilian business sector and the UN Convention on Biological Diversity (CBD), bringing Brazilian companies closer to the international biodiversity agenda.

In 2015, noted for its leadership and representativeness of the business sector, CNI was elected chair of CBD Global Partnership for Business and Biodiversity. The main purpose of the Partnership is to enhance the engagement of the private sector in regard to the goals of the Convention: conservation and sustainable use of biodiversity and the sharing of benefits that arise from its use.

Thus, CNI assumed an important attribution in disseminating information and facilitating the dialogue with the business sector all over the world. This led to the recognition of Brazil as a global reference of business engagement in actions related to biodiversity conservation and its sustainable use

Since Brazil is the most biological diverse country in the world, the implementation of CBD goals is essential for the scientific, technological, economic and social development of the country. Many subjects discussed in the scope of CBD are reflected in national public policies and can affect business operations, including access to genetic resources and benefit sharing, which are the basis of the Nagoya Protocol.

Due to its implications in other topics – such as national sovereignty, international politics, economic development, local and indigenous communities, scientific research, biotechnology, intellectual property rights, industries that depend of genetic resources, and conservation and sustainable use of the biodiversity – ABS is one of the most controversial themes of the Convention, and one of its greatest challenges.

With the purpose of offering sound information to companies that use genetic resources in Brazil and in the other Parties to CBD, CNI presents the compilation of rules and guidelines to the use of genetic resources and benefit sharing. We hope that this document may guide the decision-making of businesses in the investment of the new economy that arise with the development of products based in biodiversity.

*Robson Braga de Andrade*  
**President of the Brazilian National Confederation of Industry (CNI)**





# *Conference of the Parties, its Protocols and the Nagoya Protocol*

Ana Paula Rodrigues Viana

## *Conference of the Parties*

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

And in November 2018, COP 14 will take place in Sharm El-Sheikh, Egypt, which might be the next major event to define even more relevant issues related to the Nagoya Protocol, possibly with Brazil's participation in the negotiations if the country completes the ratification of the protocol.

## *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

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).

In this sense, 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.

### *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 norms, 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 biochemistry 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-

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 activities, 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.



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 according 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 information 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, sub-items 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, according 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.

### *Sources:*

BELLORD, K & MOREIRA, L. (2012). O Protocolo de Nagoya e a Legislação Brasileira sobre Acesso e Distribuição de Benefícios Advindos de Recursos Genéticos e Conhecimentos Tradicionais. São Paulo, São Paulo. Editora: Revista Dos Tribunais. Volume 916.

BRASIL. Decreto Legislativo no. 02, de 5 de junho de 1992. A Convenção sobre a Diversidade Biológica. Brasília, Distrito Federal. Acesso em: 06 de novembro de 2016, em [http://www.mma.gov.br/estruturas/sbf\\_dpg/\\_arquivos/cdbport.pdf](http://www.mma.gov.br/estruturas/sbf_dpg/_arquivos/cdbport.pdf).

Estudo sobre os Impactos da Adoção e Implementação do Protocolo de Nagoya para a Indústria Brasileira. (2014). Brasília, Distrito Federal. Confederação Nacional da Indústria. Acesso em: 06 de novembro de 2016, em [http://www.fieam.org.br/site/fieam/files/2014/05/Protocolo\\_de\\_Nagoia\\_para\\_a\\_Ind%C3%BAstria\\_Brasileira\\_v3.pdf](http://www.fieam.org.br/site/fieam/files/2014/05/Protocolo_de_Nagoia_para_a_Ind%C3%BAstria_Brasileira_v3.pdf).

FIORILLO, C & e DIAFÉRIA, A. (2012). Biodiversidade, patrimônio genético e biotecnologia no Direito Ambiental (2ª. edição). São Paulo, São Paulo: Editora Saraiva.

GROSS, A. (2013). Diálogo sobre o Protocolo de Nagoia entre Brasil e União Europeia. Brasília, Distrito Federal: Editora do Ministério do Meio Ambiente

Perguntas frequentes sobre o Protocolo de Nagoya em Relação a ABS. Union for Ethical Biotrader. (2014). São Paulo, São Paulo. Acesso em: 06 de novembro, em [http://ethicalbiotrader.org/dl/benefit-sharing/UEBT\\_ABS\\_FAQ\\_POR\\_2014.pdf](http://ethicalbiotrader.org/dl/benefit-sharing/UEBT_ABS_FAQ_POR_2014.pdf).

Protocolo de Nagóia sobre Acesso a Recursos Genéticos e Repartição Justa e Equitativa dos Benefícios Derivados de sua Utilização, mensagem no. 245. Brasília, Distrito Federal. Acesso em: 06 de novembro de 2016, em [http://www.camara.gov.br/proposicoesWeb/prop\\_mostrarintegra;jsessionid=EE6545445BB1B20B7A95B5B851034603.proposicoesWeb1?codteor=1000094&filename=MSC+245/2012](http://www.camara.gov.br/proposicoesWeb/prop_mostrarintegra;jsessionid=EE6545445BB1B20B7A95B5B851034603.proposicoesWeb1?codteor=1000094&filename=MSC+245/2012).

VIANA, A (2015). Convenção sobre a Diversidade Biológica, Protocolo de Nagoia e a Legislação Brasileira de Acesso ao Patrimônio Genético e ao Conhecimento Tradicional Associado. Dissertação Mestrado em Gestão e Auditoria Ambiental. Fundação Ibero Americana.







Africa



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

YES /  NO

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

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since May 7, 2017.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO



As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

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## 4. Websites

### *Ministério do Ambiente*

<http://www.minamb.gov.ao/>

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Austria profile. Disponível em: <https://absch.cbd.int/countries/AT>> Acesso em 04/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Austria profile. Disponível em: <https://www.cbd.int/countries/?country=at> Acesso em 04/11/2016.

GOVERNMENT OF AUSTRIA. **Fifth National Report Of Austria: Convention on Biological Diversity**. Umweltbundesamt (Environmental Protection Agency). Vienna, 2014. Disponível em: <https://www.cbd.int/countries/?country=at> Acesso em 04/11/2016.

GOVERNMENT OF AUSTRIA. **Biodiversity Strategy Austria 2020+**. Federal Ministry of Agriculture, Forestry, Environment and Water Management. Vienna, December, 2014 Disponível em: < <https://www.cbd.int/countries/?country=at>> Acesso em 04/11/2016.

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**. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Acesso em 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 Utilisation in the Union**. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-208044> Acesso em 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**. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Acesso em 11/11/2016 Acesso em 04/11/2016.

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Set 28, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge. However, the country indicates in its official profile on The ABSCH - The Access and Benefit-Sharing Clearing House as the only Competent National Authority in the field of genetic resources, Sehounkpindo Gaston Akouehou, General Director of the Center d'Etude de Recherche Et de Formation Forestiere Ministère de Cadre de Vie et du Développement Durable Cotonou “.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**3. Summary – Competent Authorities**

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

Authority	Competence
Sehounkpindo Gaston Akouehou, Diretor Geral do “Centre d'Etude de Recherche et de Formation Forestiere Ministère de Cadre de Vie et du Développement Durable Cotonou”.	Responsible for all issues related to genetic resources.

**Nagoya Protocol on Access and Benefit-sharing**

**M. Hugues Akpona**

Direction Générale des Forêts et des Ressources Naturelles  
Ministère de l'Environnement, de l'Habitat et de l'Urbanisme  
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Cotonou  
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**ABS National Focal Point**

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**Sehounkpindo Gaston Akouehou**

Directeur General du Centre d'Etude de Recherche et de Formation Forestiere Ministère de Cadre de Vie et du Développement Durable  
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**ABS Competent National Authorities**

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## 4. Websites

### *National CHM*

<http://bj.chm-cbd.net>

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Benin profile. Available in: <https://absch.cbd.int/countries/BJ> Access in 16/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Benin profile. Available in: <https://www.cbd.int/countries/?country=bj> Access in 16/11/2016.

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 in 16/11/2016.

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 in 16/11/2016.

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Jan 10, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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.

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

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.

Section 2, Part I of the Standard 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 Section 5, Part I of the Intellectual 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 distribution Geographical area.

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?**

YES /  NO

Yes, according to item 2.4, Section 5, Part I of the Intellectual Property Act, states that Trademark, Patents and Drawings may be registered by Trademark Attorney, the procedures and details of this registration are delimited by “Part XII - Traditional Knowledge and Crafts “.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Yes, the benefit sharing obligation is contained in Section 124 and 125, Part XII of the Industrial Property Act, 2010, however there are no procedures, rules and values. Only the right to receive this apportionment is covered by the law, with the knowledge holder and the third party trading the securities.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### Nagoya Protocol on Access and Benefit-Sharing

#### Mr. Charles K. Mojalemotho

ABS National Focal Point

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kebkeoagile@gov.bw

Director

Department of Environmental Affairs

Ministry of Environment, Natural Resources Conservation and Tourism

Private Bag 0068

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## 4. Websites

### *Department of environmental affairs*

*<http://www.mewt.gov.bw/DEA/>*

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Botswana profile. Disponível em: <https://absch.cbd.int/countries/BW>> Acesso em 02/10/2016.

BENNETT, Bem; CHILUME, Yvonne. **Making the most of natural advantages: intellectual property and natural products in Botswana.** Botswana Council of Non-governmental Organisations; and Botswana Trade and Poverty Programme. 2007. Disponível em: <https://www.africaportal.org/>

*dspace/articles/making-most-natural-advantages-intellectual-property-and-natural-products-botswana* > Acesso em 06/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Botswana profile. Disponível em: <https://www.cbd.int/countries/?country=bw> Acesso em 02/10/2016.

REPUBLIC OF BOTSWANA. **Fifth National Report to the Convention on Biological Diversity. Department of Environmental Affairs** – DEA. 2015. Disponível em: <https://www.cbd.int/countries/?country=bw> Acesso em 02/10/2016.

REPUBLIC OF BOTSWANA. **Industrial Property Act**, 2010 (Act No. 8 of 2010). Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=9602> Acesso em 06/11/2016.

REPUBLIC OF BOTSWANA. **National Biodiversity Strategy and Action Plan**. Department of Environmental Affairs – DEA. 2016. Disponível em: <https://www.cbd.int/countries/?country=bw> Acesso em 02/10/2016.

# Burkina Faso

## 1. General Information

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

YES /  NO

Yes, Burkina Faso has been a party to the Convention on Biological Diversity, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Burkina Faso has been a party to the Protocol since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

No official inspection body was mentioned, and there is no evidence of imposition of fines.

1 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>.

2 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>.

3 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.

### 1.7 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

No sanctions or fines for irregular access have been identified.

## 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

The country does not have specific legislation on access to genetic heritage and associated traditional knowledge. Nevertheless, as clarified by the National Focal Point of the country, the following legislations have devices related to the theme:

- **LOI No. 006-2013/NA Portant Code De L'environnement Au Burkina Faso** - Law that establishes the basic rules for the environment in Burkina Faso. It applies to the environment understood as all elements of biological, economic, physical, chemical, social, political and cultural nature, whether natural or artificial, that affect the process of maintenance of life, and transformation and development of the environment, the natural or non-natural resources and human activities. This law seeks to protect living beings against damage, harm and risks that hamper or threaten their existence due to environmental degradation while promoting the improvement of their living conditions.

- **LOI No. 010-2006/NA Portant Reglementation Des Semences Vegetales Au Burkina Faso** - This law regulates all sowing-related activities in Burkina Faso. The objective is to create favorable conditions for the promotion of quality production, commercialization and utilization of seeds, as a means to contribute to the achievement of the national target of intensification and modernization of agriculture, and of increasing increase agricultural and forestry production and food security.

- **DECRET N°2009-403/PRES/PM/MESSRS/MECV/MAHRH/MRA/MEF of June 10, 2009** - establishes the responsibilities, means of organization and means of operation of the National Management Commission of Plant Genetic Resources (Commission Nationale de Gestion des Ressources Phytogénétiques - CONAGREP).

For information, it should be highlighted that the National Biodiversity Strategy of Burkina Faso seeks to establish a national framework for access to genetic resources and the benefit-sharing deriving from their use. This national framework has the following responsibilities:

- To create an institutional framework on ABS;
- To make human and financial resources available;
- To develop and implement a law on ABS;
- To establish an ABS focal point, including a national correspondent for the Cross-Governmental Committee;

According to the National Focal Point, LOI N ° 070-2015 / CNT Portant Loi D'orientation Agro-Sylvo-Pastorale, Halieutique Et Faunique Au Burkina Faso is of great importance to the theme. Section 5 of this Act addresses the issue of genetic resources. Article 100 of this Law 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. The State is also responsible for overseeing: (1) the conservation, assessment and sustainable use of genetic resources and associated traditional knowledge to preserve and enhance their diversity in order to ensure the perpetuity of living systems; (2) the development of plant genetic resources for food and agriculture in particular because of their importance to food and nutrition security and ensuring the preservation of traditional local varieties. Article 101, however, 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. However, the conditions of access to national genetic resources, as well as the modalities of benefit sharing, will be laid down in a decree of the Council of Ministers. Article 102 indicates that the State recognizes, protects and guarantees the inalienable rights of local communities in relation to access to traditional knowledge associated with genetic resources, as well as the fair and equitable sharing of benefits resulting from use with such communities. The State shall ensure that Prior Informed Consent of local communities is obtained for access to the traditional knowledge associated with genetic resources and for the fair and equitable sharing of benefits arising from the use of this traditional knowledge.

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

YES /  NO

According to item 2.1., LOI N ° 070-2015 / CNT Portant Loi D'orientation Agro-Sylvo-Pastorale, Halieutique et Faunique Au Burkina Faso attributes to the State several responsibilities, however, a body with specific competence for ABS under 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 /  NO

Although there is no specific legislation on access to genetic heritage and associated traditional knowledge, LOI No. 010-2006/NA regulates the use of seeds in the country and establishes norms on the use of native seeds. Article 14 of the said law establishes that no traditional seed variety may leave the national territory, for the purpose of conducting research, without a prior authorization from the ministers responsible for research and forests or research and agriculture.

In addition, as explained by the National Focal Point to Loi N ° 070-2015 / CNT Portant loi d'orientation agro-sylvo-pastorale, halieutique et faunique au Burkina Faso deals with the subject in articles 103 and 104.

The other laws mentioned in item 2.1 do not mention the need for prior authorization.

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

YES /  NO

None of the laws presented under item 2.1 mentions specific procedures for requesting patents. However, Loi N ° 070-2015 / CNT Portant loi d'orientation agro-sylvo-pastorale, halieutique et faunique au Burkina Faso establishes the need for 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 /  NO

None of the laws presented under item 2.1 mentions specific procedures for requesting patents.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for obtaining access to genetic heritage when performing activities on behalf the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

There are no specific norms for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Although there is no specific legislation on access to genetic heritage and associated traditional knowledge and benefit-sharing, LOI No. 006-2013/NA, which establishes the basic rules enforced in terms of the environment, determines in its article 8 that the local population has a right of use of natural resources. These usage rights grant them, most notably, access to the genetic resources and the sharing of the benefits arising from their exploration. However, the referred law does not provide any specific provisions on how benefit-sharing shall occur.

LOI No. 010-2006/NA, which regulates the use of seeds in the country, establishes in article 15 that the benefits from the use of native plant genetic resources shall benefit the local populations and the traditional users that work to protect these resources. However, the referred law does not provide any specific provisions on how benefit-sharing shall occur.

As a matter of fact, it should be highlighted that the National Biodiversity Strategy of Burkina Faso has established, in its action No. 5, a benefit-sharing 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:

- To create an institutional framework on ABS;
- To make human and financial resources available;
- To develop and implement a law on ABS;
- To establish an ABS focal point, including a national correspondent for the Cross-Governmental Committee;

Also, in contact with the National Focal Point, it was informed that Loi N ° 070-2015 / CNT Portant loi d'orientation agro-sylvo-pastorale, halieutique et faunique au Burkina Faso establishes only the basic procedures. In the future, a regulatory decree will be instituted to specify the issues of benefit-sharing.

### 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

No established procedures for the shipment of samples were identified in the relevant legislation.

## 3. Websites of Interest

*Information Exchange Centre on Biological Diversity of Burkina Faso CHM*

*<http://bf.chm-cbd.net/>*

## 4. Summary – Competent Authorities

### Nagoya Protocol on Access and Benefit-Sharing

**M. Daogo Léon Ouoba**

ABS National Focal Point

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pour le Développement Durable

Ministère de l'environnement de l'économie  
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Burkina Faso



ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Burkina Faso profile. Disponível em: <https://absch.cbd.int/countries/BF>> Acesso em 30/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Burkina Faso profile. Disponível em: <https://www.cbd.int/countries/?country=bf>> Acesso em 30/10/2016.

GOUVERNEMENT DU BURKINA FASO. **Cinquieme Rapport National Du Burkina Faso A La Conference Des Parties A La Convention Sur La Diversite Biologique.** Disponível em: <https://www.cbd.int/countries/?country=bf>> Acesso em 30/10/2016.

GOUVERNEMENT DU BURKINA FASO. **Decret N°2009-403/PRES/PM/MESSRS/MECV/MAHRH/MRA/MEF du 10 juin 2009 portant création, attributions, organisation et fonctionnement d'une commission nationale de gestion des ressources phytogénétiques (CONAGREP).** Disponível em: < [http://www.legiburkina.bf/m/Sommaires\\_JO/D%C3%A9cret\\_2009\\_00403.htm](http://www.legiburkina.bf/m/Sommaires_JO/D%C3%A9cret_2009_00403.htm)> Acesso em 30/10/2016.

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. Disponível em: <http://slideplayer.fr/slide/9360368/>> Acesso em 30/10/2016.

GOUVERNEMENT DU BURKINA FASO. **Loi N° 010-2006/NA Portant Reglementation Des Semences Vegetales Au Burkina Faso.** Disponível em: <http://www.ecolex.org/fr/details/legislation/loi-n-010-2006-portant-reglementation-des-semences-vegetales-au-burkina-faso-lex-faoc065928/> Acesso em 30/10/2016.

GOUVERNEMENT DU BURKINA FASO. **Loi N°006-2013/NA Portant Code De L'environnement Au Burkina Faso.** Disponível em: <http://www.legiburkina.bf/Documents/CODE%20DE%20L'ENVIRONNEMENT.pdf>> Acesso em 30/10/2016.

GOUVERNEMENT DU BURKINA FASO. **Plan D'action National 2011-2015 Du Burkina Faso Pour La Mise En Œuvre De La Convention Sur La Diversite Biologique.** Ministere De L'environnement Et Du Developpement Durable - Secretariat Permanent Du Conseil National Pour L'environnement Et Le Developpement Durable. Ouagadougou, 2011. Disponível em: <https://www.cbd.int/countries/?country=bf>> Acesso em 30/10/2016.

## 1. General Information

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

YES /  NO

Yes, Burundi has been a Party to the CBD, by ratification, since Jul 14, 1997.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by acceptance, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

No inspection body is indicated in the laws presented under item 2.1., and there is no evidence of application of fines either.

1 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>.

2 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>.

3 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.

**1.7 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

The legislation presented under item 2.1 does not specify the cases of irregular access, and there is no indication of values either.

## 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

- **Burundi Law on Industrial Property of Jul 28, 2009** - has the purpose of organizing and protecting industrial property. It regulates in particular the rights relating to patents, utility model certificates, industrial designs, layout designs for integrated circuits, traditional knowledge, crafts objects and distinctive signs.

- **Burundi Law of Accession to the Nagoya Protocol of Jun 06, 2014** - Burundi does not have any specific legislation concerning the Nagoya Protocol. However, Burundi does have a national strategy on access and benefit sharing adopted on Aug 1st, 2016, with no legal effect, but which has sufficient relevance and appears indicated on the ABSCH website. In addition to the two laws presented above, a bill of 2013 was also identified; but it has not been adopted yet, according to information from the Focal Point, which states that all current legislation is displayed on the ABSCH website.

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

YES /  NO

The legislation presented under item 2.1 above does not indicate any competent institution.

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

YES /  NO

The legislation presented under item 2.1 does not mention the need for prior authorization to obtain the genetic resource.

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

YES /  NO

There are no specific procedures for accessing associated traditional knowledge; however, according to item 2.5 of this form, communities holding associated traditional knowledge have specific procedures to protect their rights over the 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 /  NO

According to item 2.1, Burundi does not have any specific legislation concerning the Nagoya Protocol. 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

None of the laws presented under item 2.1 mention any specific procedures concerning the matter.

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

YES /  NO

None of the laws presented under item 2.1 mention any specific procedures concerning the matter.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

None of the laws presented under item 2.1 mention the requirement of benefit-sharing.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

None of the laws presented under item 2.1 mention any procedures for the shipment of samples.

### 3. Websites Of Interest

***Clearing House Mechanism of Information Burundi:***

*<http://bi.chm-cbd.net/>*

### 4. Summary – Competent Authorities

As mentioned in item 2.3., Burundi does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

## Nagoya Protocol on Access and Benefit-Sharing

### M. Benoît Nzigidahera

ABS National Focal Point  
+257 75 81 72 49  
+257 22 40 30 32  
nzigidaherabenoit@yahoo.fr

Chef, Service de la Recherche en Biodiversité  
Gestionnaire, Site Web National en matière de Biodiversité  
Office Burundais pour la Protection de l'Environnement (OBPE)  
B.P. 2757  
Bujumbura, Avenue de l'Imprimerie Jabe, no 12  
Bujumbura  
Burundi

### Ministère de l'Eau de l'Environnement de l'Aménagement du Territoire et de l'Urbanisme (ME-EATU)

ABS Competent National Authorities  
(+257) 22 22 49 79, (+257) 22 22 67 18  
info@meeatu.go.bi  
BURUNDI  
BUJUMBURA  
B.P.631  
Burundi

## 5. Referências Bibliográficas

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Burundi profile. Disponível em: <https://absch.cbd.int/countries/BI> Acesso em 30/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Burundi profile. Disponível em: <https://www.cbd.int/countries/?country=bi> Acesso em 30/10/2016.

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. Disponível em: <http://bi.chm-cbd.net/implementation/questions-transsectorielles/acces-aux-ressources-genetiques-et-partage-des-avantages/etude-sur-le-niveau-de-comprehension-des-groupes-cibles-sur-les-enjeux-du> Acesso em 30/10/2016.

REPUBLIQUE DU BURUNDI. **Loi n° 1/13 du 28 juillet 2009 relative à la propriété industrielle au Burundi.** Disponible em: <http://www.wipo.int/wipolex/en/details.jsp?id=8324> Acesso em 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.** Disponible em: <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> Acesso em 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'aménagement Du Territoire Et De L'urbanisme. Bujumbura, 2012. Disponible em: <https://www.cbd.int/countries/?country=bi> Acesso em 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'aménagement Du Territoire Et De L'urbanisme. Bujumbura, 2013. Disponible em: <https://www.cbd.int/countries/?country=bi> Acesso em 30/10/2016.

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Jan 17, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Feb 28, 2017.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

On the other hand, in order to establish a standard in accordance with the objectives of the Nagoya Protocol, the country established in 2012 a National Strategy on Access to Genetic Resources and the fair and equitable sharing of benefits arising from its use (“Stratégie Nationale sur l’Accès aux Ressources Génétiques et le Partage juste et équitable des Avantages découlant de leur utilisation”) which will underpin future legislation. In 2014 the country created a draft Decree to regulate access and benefit sharing in the country<sup>4</sup>, formulated based on the experience accumulated in some cases of access and benefit sharing developed in Cameroon during this absence of regulatory norms on the subject.

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

YES /  NO

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 /  NO

The draft decree regulator created in 2014 provides in article 5 that access to genetic resources and associated traditional knowledge of the country for the purpose of research, technological development, commercialization or patent application, are conditioned to (a) obtain authorization Will be examined in a dossier by the Ministry of the Environment, (b) obtaining prior informed consent (PIC) from the Minister of the Environment, (c) as well as Mutually Agreed Terms (MAT).

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

YES /  NO

.....  
<sup>4</sup> The Draft Decree accessed corresponds to the version dated 05/23/2014, available in [http://www.abs-initiative.info/fileadmin/media/Events/2015/The\\_Echinops\\_ABS\\_Case/Arr\\_t\\_R\\_APA\\_valid\\_R\\_propre.pdf](http://www.abs-initiative.info/fileadmin/media/Events/2015/The_Echinops_ABS_Case/Arr_t_R_APA_valid_R_propre.pdf). Acesso em 02/05/2017.



As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

According to item 2.3, the draft decree regulator created in 2014 states in its article 5 that the application for patents arising from access to genetic heritage or associated traditional knowledge are conditioned to (a) obtain authorization that will be analyzed in a lawsuit by the Ministry of Environment, (b) obtaining Prior Informed Consent (PIC) from the Minister for the Environment, (c) as well as Mutually Agreed Terms (MAT).

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Yes, benefit sharing is mandatory and its requirements are described in Chapter IV of the draft Decree. The benefits obtained from research, development or commercial exploitation will be freely negotiated between the Parties of Mutually Agreed Terms (MAT), which may be divided into monetary or non-monetary modalities.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

According to Article 6 of the draft Decree regulating ABS issues, the collection and export of biological resources for research, technological development or commercial exploitation are subject to the prior authorization of the current legislation on flora and fauna of the country.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### Nagoya Protocol on Access and Benefit-sharing

##### **Mr. Albn William Lemnyuy Banye**

ABS National Focal Point

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Sub Director of Waste, Toxic and Hazardous Chemicals Management  
Department of Standards and Control  
Ministry of Environment, Protection of Nature and Sustainable Development  
P.O. Box 320  
Yaoundé  
Cameroon

### 4. Websites

#### **Clearing House Mechanism Cameroon**

*<http://cm.chm-cbd.net>*

#### **Ministère de l'Environnement, de la Protection de la Nature et du Développement Durable**

*<http://www.minep.gov.cm/>*

#### **Ministère des Forêts et de la Faune**

*<http://www.minfof.cm/>*

### 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Cameroon profile. Disponível em: *<https://absch.cbd.int/countries/CM>* Acesso em 02/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Cameroon profile. Disponível em: *<https://www.cbd.int/countries/?country=cm>* Acesso em 02/10/2016.

NCHOUTPOUEN, Chouaibou. **Etude De L'état De Lieux De La Prise En Compte De L'accès Aux Ressources Genétiques Et Le Partage Juste Et Equitable Des Avantages Decoulant De Leur Utilisation Dans Les Lois Et Textes Reglementaires Au Cameroun.** Ministere De L'environnement Et

De La Protection De La Nature. Republique Du Cameroun. Disponível em: [http://www.abs-initiative.info/fileadmin//media/Events/2015/The\\_Echinops\\_ABS\\_Case/Rapport\\_Final\\_Etude\\_APA\\_du\\_Cameroun.pdf](http://www.abs-initiative.info/fileadmin//media/Events/2015/The_Echinops_ABS_Case/Rapport_Final_Etude_APA_du_Cameroun.pdf) Acesso em 02/10/2016.

REPUBLIC OF CAMEROON. **Arrete N° XX Minepeded Du XX Fixant les conditions et les modalités d'accès aux ressources génétiques, aux connaissances traditionnelles associées et de partage juste et équitable des avantages découlant de leur utilisation.** Disponível em: [http://www.abs-initiative.info/fileadmin/media/Events/2015/The\\_Echinops\\_ABS\\_Case/Arr\\_\\_t\\_R\\_APA\\_valid\\_\\_R\\_\\_propre.pdf](http://www.abs-initiative.info/fileadmin/media/Events/2015/The_Echinops_ABS_Case/Arr__t_R_APA_valid__R__propre.pdf) Acesso em 02/10/2016.

REPUBLIC OF CAMEROON. **National Biodiversity Strategy And Action Plan Version II.** Ministry of Environment, Protection of Nature and Sustainable Development – MINEPDED. 2012. Disponível em: <https://www.cbd.int/countries/?country=cm> Acesso em 02/10/2016.

REPUBLIQUE DU CAMEROUN. **Cinquieme 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. 2014. Disponível em: <https://www.cbd.int/countries/?country=cm> Acesso em 02/10/2016.

## 1. General Information

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

YES / (  ) NO

Yes, the country has been a Party to the Protocol, by ratification, since Feb 27, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES / (  ) NO

Yes, the country has been a party to the Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC2 under the terms of Article 17 of the Nagoya Protocol?

(  ) YES / (  ) NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoint communiqués were found in this country.

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

(  ) YES / (  ) NO

In Côte d'Ivoire, the environmental inspection body is the Ministère de l'Environnement, the Santé Publique et du Développement Durable. However, there is no indication that this is the competent body for access and benefit sharing.

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 from the exploitation of genetic resources, which requires the State to develop appropriate regulations on access and sharing of genetic resources and knowledge and technologies of local communities. Article 24, however, 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.

Therefore, there is no specific legislation to regulate access to the genetic heritage and associated traditional knowledge of the country, although the current legislation determines 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 /  NO

The Ministry of Environment and Sustainable Development (Ministère de l’Environnement et du Développement Durable) 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

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

## 4. Websites

### *National CHM - Côte d'Ivoire*

<http://ci.chm-cbd.net>

### *Ministère de l'Environnement, de la Salubrité Urbaine et du Développement Durable*

<http://www.environnement.gouv.ci/>

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Côte d'Ivoire profile. Disponível em: <https://absch.cbd.int/countries/CI> Acesso em 03/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Cambodia profile. Disponível em: <https://www.cbd.int/countries/?country=ci> Acesso em 03/10/2016.

KINGDOM OF CAMBODIA. **National Biodiversity Strategy And Action Plan**. National Council for Sustainable Development. 2016. Disponível em: <https://www.cbd.int/countries/?country=kh> Acesso em 03/10/2016.

KINGDOM OF CAMBODIA. **The Fifth National Report To The Convention On Biological Diversity**. National Biodiversity Steering Committee. 2014. Disponível em: <https://www.cbd.int/countries/?country=kh> Acesso em 03/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Nov 30, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Dez 30, 2015.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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.

1 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>.

2 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>.

3 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.



**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 / 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 should be addressed in specific regulations.

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

YES /  NO

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 obtain genetic resources?**

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge. However, the above-mentioned law, in its art. 69, provides that licenses granted to an exporting country relating to pharmaceutical products must pay a certain fee set forth in art. 31 of the TRIPS Agreement.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

Authority	Competence
Ministère de l'Habitat, de l'Urbanisme, de l'Environnement et de l'Aménagement du Territoire	Competent national body on environmental issues.

## Nagoya Protocol on Access and Benefit-sharing

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Direction de l'Environnement  
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## 4. Websites

### *Djibouti Biodiversity*

*<http://djiboutinature.org/>*

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Djibouti profile. Available in: <https://absch.cbd.int/countries/DJ> Access in 04/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Djibouti profile. Available in: <https://www.cbd.int/countries/?country=dj> Access in 04/10/2016.

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> Access in 04/10/2016.

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-l-environnement-lex-faoc092357/> Access in 04/10/2016.

RÉPUBLIQUE DE DJIBOUTI. **Stratégie Et Programme D'action National De 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. 2006. Available in: <https://www.cbd.int/countries/?country=dj> Access in 04/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Aug 31, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 1. Legal Information

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

YES /  NO

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the 5th National Report for the CBD, there is already a bill to regulate this matter, however, the text of this project is not easily accessible.

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

Law No. 82 of 2002 on the protection of intellectual property in Egypt mentions in article 200 that for patents for new plant varieties, it will be necessary to prove that the plant was legally acquired, including the traditional knowledge rights of Populations or local communities. Provision should also be made for obtaining authorization from the competent bodies, if Egyptian law requires this procedure. Lastly, Article 200 still establishes the obligation to distribute the benefits obtained if the regulation provides for this obligation.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

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***Egyptian Clearing-house Mechanism:***

<http://www.egyptchm.info/>

***Egypt Plant Genetic Resources Knowledge Network:***

<http://egypt.plantgenetic.com/>

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Egypt profile. Available in: <https://absch.cbd.int/countries/EG> Access in 04/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Egypt profile. Available in: <https://www.cbd.int/countries/?country=eg> Access in 04/10/2016.

EGYPT. **Egypt's Fifth National Report To The Convention On Biological Diversity**. Ministry of Environment. UNDP, GEF, PIMS no. 4864. 2016. Available in: <https://www.cbd.int/countries/?country=eg> Access in 04/10/2016.

EGYPT. **Egyptian Biodiversity Strategy And Action Plan (2015 – 2030)**. Ministry of Environment. UNDP, GEF, PIMS no. 4864. 2016. Available in: <https://www.cbd.int/countries/?country=eg> Access in 04/10/2016.

EGYPT. **Law No 4 of 1994 - The Environment Law**. Available in: <http://extwprlegs1.fao.org/docs/pdf/egy4984E.pdf> Access in 04/10/2016.

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 in 04/10/2016.

# Ethiopia

## 1. General Information

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

YES /  NO

Yes, Ethiopia has been a Party to the CBD, by ratification, since Jul 4, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Ethiopia has been a Party to the Protocol since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

Law 482/2006, in article No. 20(1), determines that the Institute of Biodiversity Conservation shall follow-up the execution of access agreements, including through inspections. In addition to that, the Ethiopian Environmental Protection Authority (EPA) has the role of protecting and monitoring

1 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>.

2 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>.

3 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 issues in general. No concrete cases were found during the survey in relation to the application of fines.

**1.7 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

Yes, breaches and penalties are defined in article 35 of Law 482/2006. The applicable sanctions are the following:

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 offence 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 offences 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 offence, simple imprisonment for no less than 3 months.

## 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

Ethiopia has the following laws on access to genetic heritage and associated traditional knowledge:

- 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;
- 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;

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

YES /  NO

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, Law 482/2006, in article No. 27, 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.

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

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 such access requests should 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

Law 482/2006, concerning the access to genetic resources and community knowledge, provides in its article 12 (1) that access to traditional knowledge is subject to prior informed consent granted by the local community.

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

Article 17(12) of law 482/2006 includes among the obligations of the access permit holder: when seeking to acquire intellectual property rights over the genetic resources accessed, or parts thereof, to negotiate a new agreement with the Institute of Biodiversity Conservation.

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for gaining access to genetic heritage in activities performed on behalf of the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

There are no specific norms for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

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.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

For the genetic resources found in in situ or ex situ conditions in Ethiopia, an export authorization shall be requested 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, unless it is not possible.

## 4. Websites of Interest

***CBD Clearing House Mechanism of Ethiopia***

*<http://et.chm-cbd.net>*

## 4. Summary – Competent Authorities

Authority	Competence
Ethiopian Biodiversity Institute (Institute of Biodiversity Conservation)	All matters related to the access to genetic resources and community knowledge

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Ethiopia profile. Disponível em: <https://absch.cbd.int/countries/ET> Acesso em 31/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Ethiopia profile. Disponível em: <https://www.cbd.int/countries/?country=et> Acesso em 31/10/2016.

REPUBLIC OF ETHIOPIA. **Access to Genetic Resources and Community Knowledge and Community Rights Proclamation (Proclamation No. 482/2006)**. Disponível em: <https://absch.cbd.int/countries/ET> Acesso em 31/10/2016.

REPUBLIC OF ETHIOPIA. **Access to Genetic Resources and Community Knowledge, and Community Rights Council of Ministers Regulation No. 169/2009**. Disponível em: <http://goalgoole.com/regulation-no-1692009-access-to-genetic-resources-and-community-knowledge-and-community-rights-council-of-ministers-regulation/> Acesso em 31/10/2016.

REPUBLIC OF ETHIOPIA. **Ethiopia's Fifth National Report to the Convention on Biological Diversity**. Ethiopian Biodiversity Institute. 2014. Disponível em: <https://www.cbd.int/countries/?country=et> Acesso em 31/10/2016.

REPUBLIC OF ETHIOPIA. **Ethiopia's National Biodiversity Strategy and Action Plan 2015-2020**. Ethiopian Biodiversity Institute. 2015. Disponível em: <https://www.cbd.int/countries/?country=et> Acesso em 31/10/2016.

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since June 12, 1997.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by acceptance, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 obtain genetic resources?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**M. Emmanuel Bayani Ngoyi**

ABS National Focal Point

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Chargé d'études du Directeur Général de l'Environnement et de la Protection de la Nature

Ministère de la Forêt, de la Mer et de l'Environnement

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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Gabon profile. Disponível em: <https://absch.cbd.int/countries/GA> Acesso em 05/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Gabon profile. Disponível em: <https://www.cbd.int/countries/?country=ga> Acesso em 05/10/2016.

REPUBLIQUE GABONAISE. **Second Rapport National sur la Diversité Biologique**. Ministère De L' Economie Forestiere, Des Eaux, De La Peche, Charge De L' Environnement Et De La Protection De La Nature. Secretariat General. Direction Generale De L' Environnement. Observatoire National De La Biodiversite. 2004. Disponível em: <https://www.cbd.int/countries/?country=ga> Acesso em 05/10/2016.

REPUBLIQUE GABONAISE. **Stratégie Nationale et Plan D'action sur la Diversité Biologique du Gabon**. Ministère des Eaux et Forêts, de la Peche, du Reboisement Charge de L'environnement et de la Protection de la Nature. Direction Generale de L'environnement. 1999. Disponível em: <https://www.cbd.int/countries/?country=ga> Acesso em 05/10/2016.

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

YES /  NO

Yes, the country has been a Party to the CBD, by ratification, since Sep 8, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

No official institution responsible for inspections on access and benefit-sharing was identified in this country. However, it should be noted that articles 41 and 42 of the National Environment Act

1 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>.

2 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>.

3 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.

(1994) provide that inspectors appointed by the National Environment Agency will have responsibility for carrying out inspections on environmental issues in general. No concrete cases were found in relation to the application of fines.

### **1.7 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

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

However, it should be noted that the National Environment Act (1994), in its article 51 (concerning general offences), provides that any natural or legal person who commits an offence 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.

## **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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the 5th National Report presented to the Convention on Biological Diversity, dated 2014, Gambia recognizes the need to develop a national regime on access and benefit-sharing, and since 2013 a wildlife conservation bill which establishes some procedures and norms on access and benefit-sharing has been under analysis.

The National Environment Act (1994) reinforces in its article 35 the possibility that the matter may be regulated in the future through a specific legal instrument.

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

YES /  NO

Gambia has only one competent institution identified through the Access and Benefit-Sharing Clearing-House, the Department of Parks & Wildlife Management, responsible for all issues involving the country's biodiversity 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

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated 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

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**3. Summary – Competent Authorities**

Authority	Competence
Department of Parks & Wildlife management	Responsible for all genetic resources.

## 4. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Gambia profile. Disponível em: <https://absch.cbd.int/countries/GM> Acesso em 31/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Gambia profile. Disponível em: <https://www.cbd.int/countries/?country=gm> Acesso em 31/10/2016.

REPUBLIC OF THE GAMBIA. **National Environment Act (1994)**. Disponível em: <http://www.ecolex.org/details/legislation/national-environment-management-act-1994-act-no-13-of-1994-lex-faoc006275/?xcountry=Gambia&type=legislation&page=2> Acesso em 18/10/2016.

REPUBLIC OF THE GAMBIA. **The Fifth (5th ) National Report To The Convention Of Biological Diversity**. Department of Parks & Wildlife Management. Abuko, 2014. Disponível em: <https://www.cbd.int/countries/?country=gm> Acesso em 31/10/2016.

REPUBLIC OF THE GAMBIA. **The National Biodiversity Strategy And Action Plan (2015 – 2020)**. 2015. Disponível em: <https://www.cbd.int/countries/?country=gm> Acesso em 31/10/2016.

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Dez 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Jan 05, 2015.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 obtain genetic resources?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### Nagoya Protocol on Access and Benefit-sharing

**M. Daouda Kante**

Directeur Général Adjoint  
Centre d'Observation, de Surveillance et d'Information Environnementale  
(COSIE)  
Ministère de l'Environnement, des Eaux et Forêts (MEEF)  
Lansébounyi - Coléah Commune de Matam  
BP 761  
Conakry  
Guinea

**ABS National Focal Point**

+224 622 90 83 39  
kante54@yahoo.fr



## 4. Websites

### *National CHM*

<http://www.biodiversite-guinee.org>

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Guinea profile. Available in: <https://absch.cbd.int/countries/GN> Access in 05/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Guinea profile. Available in: <https://www.cbd.int/countries/?country=gn> Access in 05/10/2016.

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 in 05/10/2016.

RÉPUBLIQUE DE GUINÉE. Cinquieme Rapport National Sur La Mise En Œuvre De La Convention Sur La Diversite Biologique. Ministère De L'environnement, Des Eaux Et Forêts. 2016. Available in: <https://www.cbd.int/countries/?country=gn> Access in 05/10/2016.

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

YES /  NO

Yes, the country has been a Party to the CBD, by ratification, since Jan 25, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by acceptance, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints” under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

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

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués” under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

The country has the following institutions responsible for environmental inspection and control:

Institute for Biodiversity and Protected Areas (IBAP);

Unit for Environmental Impact Assessment (CAIA);

State Secretariat for Environment and Sustainable Development.

It is important to note that there is no particular institution regulating access specifically, but relating to the environment as a whole.

No concrete cases were found during the survey in relation to the application of fines.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in Guinea-Bissau.

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

YES /  NO

The National Competent Authority of Guinea-Bissau, according to The Access and Benefit-Sharing Clearing-House, 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 obtain genetic resources?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**3. Summary – Competent Authorities**

Authority	Competence
Mr. Guilherme da Costa.	There is no indication of position or competences, the website only informs that he is the only competent authority in the country, responsible for all matters related to genetic resources.

**5. References**

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Guinea-Bissau profile. Disponível em: <https://absch.cbd.int/countries/GW>\_ Acesso em 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Guinea-Bissau profile. Disponível em: <https://www.cbd.int/countries/?country=gw> Acesso em 18/10/2016.

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.

## 1. General Information

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

YES /  NO

Yes, Kenya has been a Party to the Convention, by ratification, since Oct 24, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Kenya has been a Party to the Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

According to the Access and Benefit-Sharing Clearing House at CBD, the country has 6 checkpoints, as follows:

- Kenya Revenue Authority (KRA), Customs Services Department
- Kenya Industrial Property Institute (KIPI)
- Kenya Plant Health Inspectorate Service (KEPHIS)
- Kenya Forest Service (KFS)
- National Museums of Kenya (NMK)
- Kenya Wildlife Service (KWS)

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

1 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>.

2 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>.

3 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.

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

( X ) YES / ( ) NO

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.

**1.7 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

A legal instrument called 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, or both.

## 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

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

- Environmental Management And Co-Ordination 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

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

**2.3. Does the current legislation or any ongoing bills identify the competent institution?**

( X ) YES / ( ) NO

The National Competent Authority established by Kenya is the National Environment Management

Authority - NEMA, created by the Environmental Management and Co-ordination Act N°. 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.

Besides, 6 checkpoints have been established, according to item 1.3 of this form. Finally, The Seeds And Plant Varieties (Amendment) Act, 2012 adds to The Seeds And Plant Varieties Act a new role 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 traditional knowledge and their use by the communities of Kenya.

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

( X ) YES / ( ) NO

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.

#### **2.5. Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?**

( ) YES / ( X ) NO

The current legislation does not establish any specific procedures for access to Associated Traditional Knowledge in the country. In this sense, according to article 15 of Legal Notice No. 160, the procedure is similar to the authorization request for accessing genetic resources, with the applicant being required to inform the associated traditional knowledge.

It is important to highlight that the country has its own policies, tools and protocols in place for other issues related to associated traditional knowledge, as informed in item 2.1.

#### **2.6. 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

No information was found specifically related to intellectual property arising from research and technological developments involving the access.

**2.7. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

No information was found specifically related to procedures for accessing Kenya's genetic resources on behalf of the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

The legislation presented in item 2.1 does not establish any specific procedures for collection and access of exotic species.

**2.12. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Article 20 of Legal Notice No. 160 regulates the means through which benefit-sharing will take place. Therefore, the authorization holder must include in the sharing agreement both monetary and non-monetary benefits.

The monetary benefits can be:

- (a) Access fees/fess 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 where 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.

### 2. 13. Does the current legislation establish procedures for the shipment of samples?

( X ) YES / ( ) NO

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.

### 3. Websites Of Interest

*UN Convention on Biological Diversity\_ Biodiversity in Kenya:*

<http://meas.nema.go.ke/cbdchm/>

### 4. 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.

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Kenya profile. Disponível em: <https://absch.cbd.int/countries/KE> Acesso em 13/11/2016.

AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION (ARIPO). **Swakopmund Protocol On The Protection Of Traditional Knowledge And Expressions Of Folklore**. Harare, 2010. Disponível em: [http://www.wipo.int/edocs/trtdocs/en/ap010/trt\\_ap010.pdf](http://www.wipo.int/edocs/trtdocs/en/ap010/trt_ap010.pdf) Acesso em 13/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Kenya profile. Disponível em: <https://www.cbd.int/countries/?country=ke> Acesso em 13/11/2016.

NATIONAL ENVIRONMENT MANAGEMENT AUTHORITY – NEMA. **Access and Benefit Sharing From Utilization of Biological Resources & Associated Traditional Knowledge in Kenya**. 2014. Disponível em: <http://meas.nema.go.ke/abs/download/Access%20and%20Benefit%20Sharing%20brochure%20final.pdf> Acesso em 13/11/2016.

REPUBLIC OF KENYA. **Environmental Management and Co-ordination Act, 1999 (Cap. 387)**. Disponível em: [https://www.ecolex.org/details/legislation/environmental-management-and-co-ordination-act-1999-cap-387-lex-faoc041653/?q=environmental+management&type=legislation&xcountry=Kenya&xdate\\_min=&xdate\\_max=](https://www.ecolex.org/details/legislation/environmental-management-and-co-ordination-act-1999-cap-387-lex-faoc041653/?q=environmental+management&type=legislation&xcountry=Kenya&xdate_min=&xdate_max=) Acesso em 13/11/2016.

REPUBLIC OF KENYA. **Fifth National Report To The Conference Of Parties To The Convention On Biological Diversity**. 2015. Disponível em: <https://www.cbd.int/countries/?country=ke> Acesso em 13/11/2016.

REPUBLIC OF KENYA. **Seeds and Plant Varieties (Amendment) Act, 2012 (No. 53 of 2012)**. Disponível em: [https://www.ecolex.org/details/legislation/seeds-and-plant-varieties-amendment-act-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=](https://www.ecolex.org/details/legislation/seeds-and-plant-varieties-amendment-act-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=) Acesso em 13/11/2016.

REPUBLIC OF KENYA. **The Environmental Management And Co-Ordination (Conservation Of Biological Diversity And Resources, Access To Genetic Resources And Benefit Sharing) Regulations, 2006**. Disponível em: [https://www.ecolex.org/details/legislation/environmental-management-and-co-ordination-conservation-of-biological-diversity-and-resources-access-to-genetic-resources-and-benefit-sharing-regulations-2006-ln-no-160-of-2006-lex-faoc071757/?q=The+Environmental+Management+And+Co-Ordination+%28Conservation+Of+Biological++Diversity+And+Resources%2C+Access+To+Genetic+Resources+And+Benefit+Sharing%29+Regulations%2C+2006&type=legislation&xcountry=Kenya&xdate\\_min=&xdate\\_max=](https://www.ecolex.org/details/legislation/environmental-management-and-co-ordination-conservation-of-biological-diversity-and-resources-access-to-genetic-resources-and-benefit-sharing-regulations-2006-ln-no-160-of-2006-lex-faoc071757/?q=The+Environmental+Management+And+Co-Ordination+%28Conservation+Of+Biological++Diversity+And+Resources%2C+Access+To+Genetic+Resources+And+Benefit+Sharing%29+Regulations%2C+2006&type=legislation&xcountry=Kenya&xdate_min=&xdate_max=) Acesso em 13/11/2016.

REPUBLIC OF KENYA. **The Kenya National Biodiversity Strategy And Action Plan.** Ministry of Environment & Natural Resources. 2000. Disponível em: <https://www.cbd.int/countries/?country=ke> Acesso em 13/11/2016.

REPUBLIC OF KENYA. **The National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009.** Disponível em: [http://www.wipo.int/wipolex/en/results.jsp?countries=KE&cat\\_id=18](http://www.wipo.int/wipolex/en/results.jsp?countries=KE&cat_id=18)> Acesso em 13/11/2016.

REPUBLIC OF KENYA. The National Policy on Traditional Knowledge, Genetic Resources and Traditional Cultural Expressions, 2009. Disponível em: [http://www.wipo.int/wipolex/en/results.jsp?countries=KE&cat\\_id=18](http://www.wipo.int/wipolex/en/results.jsp?countries=KE&cat_id=18) Acesso em 13/11/2016.

REPUBLIC OF KENYA. **Wildlife Conservation and Management Act, 2013 (No. 47 of 2013).** Disponível em: [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=](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=) Acesso em 13/11/2016.

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

YES /  NO

Yes, the country has been a Party to the CBD, by ratification, since Apr 10, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by adhesion, since Feb 10, 2015.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

No official inspection body was identified to carry out inspections on the access. No concrete cases were found during the survey in relation to the application of fines.

1 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>.

2 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>.

3 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.

### **1.7 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

Despite not having a specific law on access to genetic heritage and associated traditional knowledge, article 68 of the Lesotho Environment Act (2008) establishes under item 3 the applicable sanctions against violations to the dispositions of the article, according to the following terms: any person who contravenes the provisions of this article or this section commits an offence and is liable on conviction to a fine of up to M5,000 or to imprisonment for a term not less than 2 years, or both.

In relation to the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, it disposes in article 23.1 that: 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.

## **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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in Lesotho. Although it is not a law on access to genetic heritage and associated traditional knowledge, the Lesotho Environment Act 2008 establishes, in its Article 68, general provisions on the access to the country's genetic resources and on the possibility of a more detailed regulation on the subject in the future.

The country is also a party to the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore, which disposes on access to traditional knowledge.

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

YES /  NO

No competent institutions were identified in relation to access and benefit-sharing in this country.

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

YES /  NO

As explained under item 2.1, the country does not have any 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 /  NO

As explained under item 2.1, the country does not have any legislation on access and benefit sharing.

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, which also establish 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 /  NO

As explained under item 2.1, the country does not have any legislation on access and benefit sharing.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As explained under item 2.1, the country does not have any legislation on access and benefit sharing.

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

YES /  NO

As explained under item 2.1, the country does not have any legislation on access and benefit sharing.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As explained under item 2.1, the country does not have any legislation on access and benefit sharing; however, the country is a party to the Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore. This protocol disposes on the sharing of benefits arising from the utilization of traditional knowledge according to the following terms:

**Item 9.1** The protection to be extended to traditional knowledge holders shall include the fair and equitable sharing of benefits arising from the commercial or industrial use of their knowledge, to be determined by mutual agreement between the parties.

**Item 9.2** the national competent authority shall, in the absence of such mutual agreement, mediate between the concerned parties with a view to arriving at an agreement on the fair and equitable sharing of benefits.

**Item 9.3** the right to equitable remuneration might extend to non-monetary benefits, such as contributions to community development, depending on the material needs and cultural preferences expressed by the traditional or local communities themselves.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

No specific procedures for the shipment of samples were identified.

## 3. Summary – Competent Authorities

As mentioned under item 2.3., Lesotho does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### Nagoya Protocol on Access and Benefit-sharing

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Ministry of Tourism, Environment and Culture

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Maseru

Lesotho

## 4. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Lesotho profile. Disponível em: <https://absch.cbd.int/countries/LS> Acesso em 22/10/2016.

AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION – ARIPO. **Swakopmund Protocol on the Protection of Traditional Knowledge and Expressions of Folklore**. Disponível em: [http://www.wipo.int/wipolex/en/other\\_treaties/text.jsp?file\\_id=201022](http://www.wipo.int/wipolex/en/other_treaties/text.jsp?file_id=201022) Acesso em 22/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Lesotho profile. Disponível em: <https://www.cbd.int/countries/?country=ls> Acesso em 22/10/2016.

LESOTHO. **Environment Act 2008 (No. 10 of 2008)**. Disponível em: [https://www.ecolex.org/details/legislation/environment-act-2008-no-10-of-2008-lex-faoc128916/?q=&type=legislation&xsubjects=Environment+gen.&xcountry=Lesotho&xdate\\_min=&xdate\\_max=](https://www.ecolex.org/details/legislation/environment-act-2008-no-10-of-2008-lex-faoc128916/?q=&type=legislation&xsubjects=Environment+gen.&xcountry=Lesotho&xdate_min=&xdate_max=) Acesso em 22/10/2016.

LESOTHO. **Lesotho Fourth National Report On Implementation of Convention on Biological Diversity**. Department of Environment. 2009. Disponível em: <https://www.cbd.int/countries/?country=ls> Acesso em 22/10/2016.

LESOTHO. **Lesotho's Biological Diversity: Conservation and Sustainable Use**. National Environment Secretariat. Ministry of Environment, Gender and Youth Affairs. Maseru, 2000. Disponível em: <https://www.cbd.int/countries/?country=ls> Acesso em 22/10/2016.



# Liberia

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since Feb 06, 2001.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Nagoya Protocol, by accession, since Nov 15, 2015 .

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 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 /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites

No relevant websites have been identified regarding ABS.

### 4. Summary – Competent Authorities

As mentioned in item 2.2., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

**Mrs. Frances B. Seydou**

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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Republic of Liberia profile. Disponível em: <https://absch.cbd.int/countries/LR> Acesso em 07/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Republic of Liberia profile. Disponível em: <https://www.cbd.int/countries/?country=lr> Acesso em 07/10/2016.

# Madagascar

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since June 02, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Nagoya Protocol, by ratification, since Oct 12, 2014 .

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. However, 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) provides in two articles on the need to obtain an authorization for research and the conclusion 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?**

YES /  NO

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 /  NO

As mentioned in item 2.1, the Decree on the application of the Code of Protected Areas (Décret n° 2005-13 organization of the application no. 2001-005 portant Code de gestion des aires protégées) provides in 2 articles on the need to obtain an authorization for research and the conclusion of an agreement to define the distribution of the scientific study, as well as the sharing of commercial benefits arising from the use of the genetic resources accessed in the protected area.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, and on the basis of articles 58 and 59 of the Decree on the application of the Code of Protected Areas (Décret n° 2005-13 organization of the application of la loi n° 2001-005 portant Code de gestion des aires protégées) a in the case of research in areas it is necessary to conclude an agreement to define the distribution of the scientific study, as well as the sharing of the commercial benefits arising from the use of the genetic resources accessed in the protected area.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites

***National Clearing-house Mechanism***

*<http://mg.chm-cbd.net/>*

## 4. Summary – Competent Authorities

As mentioned in item 2.2., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### Nagoya Protocol on Access and Benefit-sharing

#### **Mrs. Naritiana Rakotoniaina Ranaivoson**

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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Madagascar profile. Available in: <https://absch.cbd.int/countries/MG> Access in 20/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Madagascar profile. Available in: <https://www.cbd.int/countries/?country=mg> Access in 20/11/2016.

REPOBLIKAN'I MADAGASIKARA. **5ème Rapport National de la Convention sur la Diversité Biologique de Madagascar**. Ministère de l'Environnement et des Forêts et Office National pour l'Environnement. 2014. Available in: <https://www.cbd.int/countries/?country=mg> Access in 20/11/2016.

REPOBLIKAN'I MADAGASIKARA. **Décret n° 2005-13 organisant l'application de la loi n° 2001-005 portant Code de gestion des aires protégées**. 2005. Available in: <https://www.ecolex.org/fr/details/legislation/decret-n-2005-13-organisant-l-application-de-la-loi-no-2001-005-portant-code-de-gestion-des-aires-protégees-lex-faoc092363/> Access in 20/11/2016.

REPOBLIKAN'I MADAGASIKARA. **Stratégie et Plan d'action National du Centre d'Echange d'Information de la Convention sur la Diversité Biologique**. Ministère de l'Environnement et des



Forêts et Office National pour l'Environnement. 2011. Available in: <https://www.cbd.int/countries/?country=mg> Access in 20/11/2016.

REPOBLIKAN'I MADAGASIKARA. **Strategie Et Plans D'actions Nationaux Pour La Biodiversite.** Ministère de l'Environnement et des Forêts et Office National pour l'Environnement. 2016. Available in: <https://www.cbd.int/countries/?country=mg> Access in 20/11/2016.

SANBAR, Sarah. **Environmental Law in Madagascar: Te Nagoya Protocol on Genetic Resource Use, Access and Benefit Sharing.** Independent Study Project (ISP) Collection. Paper 2176. 2015. Available in: [http://www.digitalcollections.sit.edu/isp\\_collection/2176](http://www.digitalcollections.sit.edu/isp_collection/2176) Access in 20/11/2016.

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

YES /  NO

Yes, the country has been a Party to the CBD, by ratification, since May 3, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Nov 24, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

No official inspection bodies were found to inspect access.

1 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>.

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 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.

### **1.7 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

Item G, 2, states that any person who violates Malawi's regulations on genetic resources shall be liable on conviction to a fine or imprisonment, or both, and be criminally prosecuted, under the Environmental Management Act.

## **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

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) is indicated by the country on the ABSCH website as the competent legislation on the subject. In this sense, articles 4 and 36 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.

In addition, the country has two non-binding guides on the subject: Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002) and 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?**

YES / (  ) NO

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?**

(  ) YES / (  ) NO

The legislation does not indicate the need for prior authorization; however, the Guide "Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi" (non-binding docu-

ment) affirms, in its section D, that any research activities will require the approval of the National Research Council of Malawi (NRCM).

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

YES /  NO

The Environmental Management Act (1996) does not provide any specific procedures for access to the Associated 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 /  NO

The Environmental Management Act (1996) does not present any specific procedures for patents requests.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for obtaining access to genetic heritage in activities performed on behalf the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

There are no specific norms for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Although the importance of benefit-sharing is acknowledged, none of the legal instruments analyzed establish a benefit-sharing requirement.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

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.

### 3. 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.

### 4. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Malawi profile. Disponível em: <https://absch.cbd.int/countries/MW> Acesso em 21/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Malawi profile. Disponível em: <https://www.cbd.int/countries/?country=mw> Acesso em 21/11/2016.

GOVERNMENT OF MALAWI. **Environment Management Act (No. 23 of 1996)**. Disponível em: <https://absch.cbd.int/countries/MW> Acesso em 21/11/2016.

GOVERNMENT OF MALAWI. **Fifth National Report to the Convention on Biological Diversity**. 2014. Disponível em: <https://www.cbd.int/countries/?country=mw> Acesso em 21/11/2016.

GOVERNMENT OF MALAWI. **National Biodiversity Strategy and Action Plan II**. Ministry of Natural Resources, Energy and Mining. Disponível em: <https://www.cbd.int/countries/?country=mw> Acesso em 21/11/2016.

GOVERNMENT OF MALAWI. **Procedures and Guidelines for the Conduct of Research in Malawi**. 2002. Disponível em: <https://www.cbd.int/financial/bensharing/Malawi-sharing.doc> Acesso em 21/11/2016.

GOVERNMENT OF MALAWI. Procedures And Guideline For The Conduct Of Research In Malawi. Sustainable Development Network Programme – SDNP. Disponível em: <http://www.sdn.org.mw/nrcm/programmes/programmes.htm> Acesso em 21/11/2016.

## 1. General Information

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

YES /  NO

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

### Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Nov 29, 2016.

### Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge, as well as there are no specific rules regarding the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

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Ingénieur

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## 4. Websites

### *National CHM*

<http://ml.chm-cbd.net>

## 4. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Mali profile. Available in: <https://absch.cbd.int/countries/ML> Access in 05/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Mali profile. Available in: <https://www.cbd.int/countries/?country=ml> Access in 05/10/2016.

REPUBLIQUE DU MALI. **Strategie Nationale Et Plan D'actions Pour La Diversite Biologique, Mali.** Ministere 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 in 05/10/2016.

REPUBLIQUE DU MALI. **Cinquieme Rapport National Sur La Mise En Œuvre De La Conventionsur La Diversite Biologique.** Ministere 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 in 05/10/2016.

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Nov 14, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Nov 16, 2015.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

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## **Cheikh Ould Sidi Mohamed**

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## **4. Websites**

### ***National CHM***

*<http://mr.chm-cbd.net>*

## **5. References**

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Mauritius profile. Available in: <https://absch.cbd.int/countries/MU> Access in 06/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Mauritius profile. Available in: <https://www.cbd.int/countries/?country=mu> Access in 06/10/2016.

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 in 05/10/2016.

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 in 03/06/2017.

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., Mauritius does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

**Mr. Vishnou Gondeea**

ABS National Focal Point

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Permanent Secretary  
Ministry of Agro Industry and Food Security  
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Port-Louis  
Mauritius



## 4. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Mauritius profile. Disponível em: <https://absch.cbd.int/countries/MU> Acesso em 08/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Mauritius profile. Disponível em: <https://www.cbd.int/countries/?country=mu> Acesso em 08/11/2016.

REPUBLIC OF MAURITIUS. **National Biodiversity Strategy and Action Plan for the Republic of Mauritius**. Ministry of Agro-Industry and Fisheries. Disponível em: <https://www.cbd.int/countries/?country=mu> Acesso em 08/11/2016.

REPUBLIC OF MAURITIUS. **Fifth National Report on the Convention on Biological Diversity**. Ministry of Agro-Industry and Food Security. 2015. Disponível em: <https://www.cbd.int/countries/?country=mu> Acesso em 08/11/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the CBD, by ratification, since Nov 19, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, Morocco is not a Party but it is a signatory to the Nagoya Protocol since Dec 9, 2011.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## **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

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

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

YES /  NO

No official competent institutions were found concerning access and benefit-sharing under the terms 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 /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

No. There is law No. 34-05 of 2006, which supplements law No. 2.00 of 2000, which deals with intellectual property rights; but it does not cover patents arising from research or technological developments arising from access activities.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites of Interest

**National CHM**

<http://ma.chm-cbd.net/>

**Ministry Delegate to the Minister of Energy, Mines, Water and Environment Morocco**

<http://www.environnement.gov.ma/fr/>

### 4. Summary – Competent Authorities

**Nagoya Protocol on Access and Benefit-sharing**

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No 9 Avenue El Araar  
Secteur 16, Hay Riad  
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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Morocco profile. Disponível em: <https://absch.cbd.int/countries/MA> Acesso em 03/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Morocco profile. Disponível em: <https://www.cbd.int/countries/?country=ma> Acesso em 03/10/2016.

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. Disponível em: <https://www.cbd.int/countries/?country=ma> Acesso em 03/10/2016.

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))**. Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=2985> Acesso em 03/10/2016.

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)**. Disponível em: [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=136955](http://www.wipo.int/wipolex/en/text.jsp?file_id=136955) Acesso em 03/10/2016.

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. Disponível em: <https://www.cbd.int/countries/?country=ma> Acesso em 03/10/2016.

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

YES /  NO

Yes, the country has been a Party to the CBD, by ratification, since Nov 23, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

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.

### **1.7 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

The sanctions are provided for in articles 22 and 25 of Decree No. 19/2007. In this sense, the economic exploration 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 offences:

- 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.

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

YES /  NO

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?

YES /  NO

Article 4, item 1, of Decree No. 19, of Aug 9, 2007, establishes that the Minister for the Coordination of Environment Action is the National Authority on matters of access and benefit sharing. According to article 5 of the referred Decree, the National Authority 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;
- 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, 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;
- 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?

YES /  NO

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.

It must be pointed out that, according to Article 12 of the same instrument, before the issuing of the prior authorization, prior consent must be obtained:

- From the local community involved, with the participation of the legal authority;
- From the competent institution, when the process occurs in a protected area;
- From the holder of the rights to land use and improvement, when access occurs in an area where such rights are applicable;



- From 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 /  NO

Articles 14 and 15, of Decree No. 19/2007, deal specifically with Associated Traditional Knowledge. In this sense, article 15, item 2 establishes the following rights:

- To present indication of the place of origin of the access to traditional knowledge in all publications, uses, activities and announcements;
- To prevent unauthorized third parties from using, conducting tests, research or exploration activities related to the associated traditional knowledge or from publishing, transmitting or re-transmitting data or information that integrate or constitute an associated traditional knowledge;
- To 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?**

YES /  NO

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 for 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific procedures for the collection and/or access for research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries.

#### **2.7. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?**

YES /  NO

There are no specific norms for the collection and access of exotic species.

#### **2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

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.

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.

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.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( X ) YES / ( ) NO

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.

## 3. Summary – Competent Authorities

Authority	Competences
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.

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Mozambique profile. Disponível em: <https://absch.cbd.int/countries/MZ> Acesso em 18/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Mozambique profile. Disponível em: <https://www.cbd.int/countries/?country=mz> Acesso em 18/11/2016.

REPÚBLICA DE MOÇAMBIQUE. **Decreto nº 19/2007**. Disponível em: <http://www.at.gov.mz/por/content/download/1411/10747/file/Decreto%20n.%C2%BA%209-2008%20de%2016%20de%20Abril.pdf> Acesso em 18/11/2016.

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. Disponível em: <https://www.cbd.int/countries/?country=mz> Acesso em 18/11/2016.

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. Disponível em: <https://www.cbd.int/countries/?country=mz> Acesso em 18/11/2016.

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Aug 14, 1997.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since ratification Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

### 1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

The country does not have a specific law to regulate access to the genetic heritage and associated traditional knowledge of the country, however, this does not mean that there are no specific rules and procedures for ABS in the country. The country worked on the development of a bill to regulate the subject (The Namibian Access to Genetic Resources and Associated Traditional Knowledge Bill - ABS Bill) from 1998 to 2007, when it paralyzed the work with a view to await the development of the Nagoya Protocol. According to the Fifth National Report to the Convention on Biological Diversity 2010-2014, the bill was again discussed in 2011.

While the legislation is not approved, the “Interim Bio-prospecting Committee”, established in 2007, has the function of controlling and promoting bioprospection and bio-trade activities in Namibia, defining criteria, Mutually Agreed Terms (MAT - Mutually Agreed Terms), among other issues necessary due to the absence of a legal framework.

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

YES /  NO

According to item 2.1., The country does not have specific law on access and benefit sharing under the Nagoya Protocol. While a bill is being studied by the Government of Namibia, the entity responsible for regulating and controlling access and benefit sharing, as well as the signing of the Mutually Agreed Terms (MAT), is the Interim Bio-prospecting Committee (IBPC). Established in 2007. Its functions include: requesting bioprospecting, facilitating and guaranteeing prior informed consent, issuing authorizations, monitoring compliance with contracts and authorization conditions, and receiving reports. The IBPC has a Secretariat, which can be contacted, as follows:

*Ministry of Environment and Tourism  
Directorate of Scientific Services (DSS),  
Wildlife Trade, Research and Permit Control  
Private Bag 13306, Windhoek - Namibia  
City Centre, Channel Life Building - M1 Floor  
Secretary: Toivo Uahengo, Kauna Schröder  
Telephone: +264 (61) 284-2506  
Fax: +264 (61) 258861  
E-Mail: tuahengo@met.na, Kauna@met.na*

On the other hand, it should be noted that the official Competent National Authority will only be established through the bill under discussion, and the function of the EORTC may be re-adjusted.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge. On the other hand, the document “Sharing the Benefits of Nature: Legitimate access to Namibia’s biological and genetic resources for scientific and commercial purposes”<sup>4</sup> encourages those who wish to conduct research or bioprospecting in contacting the “Interim Bio-prospecting Committee” , Since this body may provide more information on the necessity or not of authorizations for each case.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge. The Industrial Property Act, 2012 - Act No. 1 of 2012, in its article 24, item (2), contains provisions on patent applications derived from biological resources or associated with indigenous or Traditional.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

.....  
4 Ministry of Environment and Tourism (MET), Directorate of Environment, Interim Bio-prospecting Committee (IBPC). Sharing the Benefits of Nature: Legitimate access to Namibia’s biological and genetic resources for scientific and commercial purposes. 2nd Edition, published in November 2010, pg. 15.

## 2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?

( X ) YES / ( ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge. The Factsheet<sup>5</sup> published on the website of the Ministry of Environment and Tourism of Namibia, states that there are several agreements related to ABS involving “Commiphora resin”, “Maruline”, “Hoodia”, among other species and substances. In this sense, it is recommended to contact the “Interim Bio-prospecting Committee - IBPC”.

## 2.9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### Nagoya Protocol on Access and Benefit-sharing

#### Ms. Betty Kauna Schroder

ABS National Focal Point

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*kauna@met.na*

Directorate of Environmental Affairs  
Ministry of Environment and Tourism  
Private Bag 13306  
Windhoek  
Namibia

## 4. Websites

### Ministry of Environment and Tourism

*<http://www.met.gov.na>*

5 .....  
Access and Benefit-Sharing in Namibia: A Factsheet. Available in: <http://www.met.gov.na/files/files/Access%20and%20Benefit%20-%20Sharing%20in%20Namibia;%20A%20Factsheet.pdf> . Access in 16/05/2017.

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Myanmar profile. Available in: <https://absch.cbd.int/countries/MM> Access in 08/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Republic of Myanmar profile. Available in: <https://www.cbd.int/countries/?country=mm> Access in 08/10/2016.

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=mm> Access in 08/10/2016.

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=mm> Access in 08/10/2016.

REPUBLIC OF NAMIBIA. **Sharing the Benefits of Nature: Legitimate 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 in 08/10/2016.

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 in 08/10/2016.



## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since Oct 23, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Nagoya Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

1 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>.

2 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>.

3 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 inspection bodies have been identified in the scope of access and benefit-sharing covered by the Nagoya Protocol.

**1.7 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

As mentioned in item 2.1, the country does not have a specific law on access to genetic resources and associated traditional knowledge.

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

YES /  NO

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 Decem- ber 1998 concerning the Management of Environnement, which, in article 6, states that the genetic resources to which Niger exercises sovereignty can only be access by prior consent, and it is incumbent upon the State to take the necessary legislative and administrative measures to ensure the fair and equitable sharing of benefits.

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

YES /  NO

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 obtain genetic resources?**

YES /  NO

The country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

The country does not have any legislation on access to genetic resources and associated 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 /  NO

The country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

The country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

The country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have a specific law on access to genetic resources and associated traditional knowledge. Under the Loi Act No 98- 56 of 29 December 1998, it is for the State to take the necessary legislative and administrative measures to ensure fair and equitable benefit-sharing.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

The country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 2. Websites

***National CHM***

*<http://ne.chm-cbd.net>*

## 4. Summary – Competent Authorities

According to item 2.2., The country does not have an established competent authority. However, it has a recognized National Focal Point for the Nagoya Protocol:

## Nagoya Protocol on Access and Benefit-sharing

**Mr. Boukar Attari**

ABS National Focal Point

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Conseiller

Conseil National de l'Environnement pour un Développement Durable (CNEDD)

B.P. 10 193

Niamey

Niger

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Niger profile. Disponible em: <https://absch.cbd.int/countries/NE> Acesso em 07/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Niger profile. Disponible em: <https://www.cbd.int/countries/?country=ne> Acesso em 07/11/2016.

REPUBLIQUE DU NIGER. **Cinquieme Rapport National Sur La Diversite Biologique**. Conseil National de l'Environnement pour un Développement Durable (Secretariat Executif); Fonds pour l'Environnement Mondial (FEM); Programme des Nations Unies pour l'Environnement (UNEP). 2014. Disponible em: <https://www.cbd.int/countries/?country=ne> Acesso em 07/11/2016.

REPUBLIQUE DU NIGER. **Loi-cadre du 29 décembre 1998 relative à la gestion de l'environnement**. Disponible em: <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> Acesso em 07/11/2016.

REPUBLIQUE DU NIGER. **Strategie Nationale Et Plan D'actions Sur La Diversite Biologique, 2ème édition**. Conseil National de l'Environnement pour un Développement Durable (Secretariat Executif); Fonds pour l'Environnement Mondial (FEM); Programme des Nations Unies pour l'Environnement (UNEP). 2014. Disponible em: <https://www.cbd.int/countries/?country=ne> Acesso em 07/11/2016.

# Republic of the Congo

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since March 03, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Nagoya Protocol, by ratification, since May 05, 2015.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

1 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>.

2 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>.

3 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 inspection bodies have been identified in the scope of access and benefit-sharing covered by the Nagoya Protocol.

**1.7 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

Articles 81 and 82 of the Nature Conservation Act of January 2014 (Loi Relative de la Conservation de la Nature, 2014) indicate the imprisonment from six months to one year and a fine of one million to five million francs Congolese 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 or one of these penalties. The court may also order the withdrawal of the access authorization.

## 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

Although it is not a specific law, the articles of Title III, Chapters I to IV of the Nature Conservation Act of January 2014 (Loi Relative to Conservation of Nature, 2014), provide for access to genetic heritage and associated traditional knowledge.

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

YES /  NO

The Nature Conservation Act of January 2014 does not establish a competent body 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?**

YES /  NO

The Nature Conservation Act of January 2014 provides in its article 57 that the competent national authority must grant access and a certificate of prior informed consent. Procedures for obtaining prior consent should be covered by specific Decree. Finally, Article 58 states that authorization for access will be issued upon completion of mutually agreed terms.

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

YES /  NO

The Nature Conservation Act of January 2014 does not present a specific procedure for access to associated traditional knowledge, although its Article 56 only mentions the need to obtain 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?**

YES /  NO

No specific rules were found for this purpose.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

No specific rules were found for this purpose.

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

YES /  NO

No specific rules were found for this purpose.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Yes, there is an obligation to distribute benefits, 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 or rule 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.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

There is no specific procedure for shipping samples. However, 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 (already transcribed in item 1.7) is doubled.

#### **National CHM**

<http://cd.chm-cbd.net>

According to item 2.2., The country does not have an established competent authority. However, it has a recognized National Focal Point for the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

##### **M. Madzou Moukili**

ABS National Focal Point

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Secrétaire des affaires étrangères

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Ministère du Développement Durable, de l'Économie Forestière et de l'Environnement

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Congo

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Democratic Republic of the Congo profile. Available in: <https://absch.cbd.int/countries/CD> Access in 03/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Democratic Republic of the Congo profile. Available in: <https://www.cbd.int/countries/?country=cd> Access in 03/11/2016.

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 Développement Durable. 2014. Available in: <https://www.cbd.int/countries/?country=cd> Access in 03/11/2016.



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=](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 03/11/2016.

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 in 03/11/2016.

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

YES /  NO

Yes, the country has been a Party to the CBD, by ratification, since Aug 27, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Rwanda has been a party to the Protocol since Oct 12, 2014, having ratified it on Mar 20, 2012.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>2</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>3</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués” under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

There is no indication of any specific inspection bodies to inspect access.

1 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>.

2 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>.

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>.

No concrete cases were found during the survey in relation to the application of fines.

### **1.7 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

Yes. Article 37 of Law No. 70-2013, of Sep 2, 2013, which regulates Biodiversity in Rwanda, establishes some administrative sanctions. They 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).

## **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

- 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

No. Law No. 70-2013, of Sep 2, 2013, which regulates Biodiversity in Rwanda, 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

Yes. Article 27 of law No. 70-2013, of Sep 2, 2013, which regulates Biodiversity in Rwanda, states that the bioprospection and export of indigenous biological resources shall require a specific permit.

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

( X ) YES / ( ) NO

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 /  NO

Law N°. 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for gaining access to genetic heritage in activities performed on behalf the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

There are no specific norms for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

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.

Article 29: Rights to genetic resources and benefit sharing. If a stakeholder is interested in the provisions of article 28 of this law, the authority shall give permission in accordance with the provisions of the Minister's order.

**2. 9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

Article 27 of Law No. 70-2013 requires prior authorization for the export of indigenous biological resources.

### 3. Websites Of Interest

#### *National CHM*

<http://www.biodiv.be>

### 4. Summary – Competent Authorities

According to item 2.3., Rwanda does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

##### **Ms. Béatrice Cyiza**

ABS National Focal Point

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Environmental Audit and Monitoring Officer  
Rwanda Environment Management Authority  
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Kacyiru  
Kigali  
Rwanda

### 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Rwanda profile. Disponível em: <https://absch.cbd.int/countries/RW> Acesso em 04/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Rwanda profile. Disponível em: <https://www.cbd.int/countries/?country=rw> Acesso em 04/10/2016.

REPUBLIC OF RWANDA. *Fifth National Report To The Convention On Biological Diversity*. Global Environment Facility, 2014. Disponível em: <https://www.cbd.int/countries/?country=rw> Acesso em 04/10/2016.

REPUBLIC OF RWANDA. **Law No. 31/2009 of 26/10/2009 on the Protection of Intellectual Property**. Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=5249> Acesso em 04/10/2016.

REPUBLIC OF RWANDA. **Loi N°70/2013 du 02/09/2013 régissant la biodiversité au Rwanda.** Disponível em: [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](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) = Acesso em 04/10/2016.

REPUBLIC OF RWANDA. **National Biodiversity Strategy And Action Plan.** Global Environment Facility, 2016. Disponível em: <https://www.cbd.int/countries/?country=rw>  
Acesso em 04/10/2016.

# Sao Tome and Principe

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Dez 28, 1999.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Apr 10, 2017.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO



As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**Ms. Aline Capela Fernandes de Castro**

ABS National Focal Point

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Head of Department of Collection and Processing of Environmental Data

General Directorate of Environment

Ministère des Travaux Publiques et Ressources Naturelles

Sao Tomé

Sao Tome and Principe

### 4. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Sao Tome and Principe profile. Available in: <https://absch.cbd.int/countries/ST> Access in 06/10/2016.\

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Sao Tome and Principe profile. Available in: <https://www.cbd.int/countries/?country=st> Access in 06/10/2016.

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=st> Access in 06/10/2016.

REPÚBLICA DEMOCRÁTICA DE S.TOMÉ E PRÍNCIPE. **V Rapport National Sur la Diversité Biologique de São Tomé et Príncipe**. Ministério das Obras Públicas, Infraestruturas, Recursos Naturais e Meio Ambiente Direcção Geral do Ambiente. 2014. Available in: <https://www.cbd.int/countries/?country=st> Access in 06/10/2016.

## 1. General Information

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

YES / (  ) NO

Yes, the country has been a Party to the Protocol, by ratification, since Dez 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES / (  ) NO

Yes, the country has been a party to the Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

(  ) YES / (  ) NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoint communiqués were found in this country.

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

(  ) YES / (  ) NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

As stated in the National Strategy and Plan of Action 2015-2020, Seychelles has drafted a Bill for Access and Benefit Sharing (ABS) in 2005 (Seychelles Access to Genetic Resources and Benefit Sharing Bill, 2005<sup>4</sup>), however, the development of this legislation not advanced.

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

.....  
4 No version of this project was found for analysis, based on the search method for secondary sources.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

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ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Seychelles profile. Available on: <https://absch.cbd.int/countries/SC> Access on 07/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Seychelles profile. Available on: <https://www.cbd.int/countries/?country=sc> Access on 07/10/2016.

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.bioversityinternational.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.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Jan 15, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since June 01, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO



As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### Nagoya Protocol on Access and Benefit-sharing

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Ingénieur des Eaux et Forêts

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ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Seychelles profile. Available on: <https://absch.cbd.int/countries/SC> Access on 07/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Seychelles profile. Available on: <https://www.cbd.int/countries/?country=sc> Accesso em 07/10/2016.

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.biodiversityinternational.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. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by accession, since Mar 12, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Jan 30, 2017.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### Nagoya Protocol on Access and Benefit-sharing

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ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Sierra Leone profile. Available on: <https://absch.cbd.int/countries/SL> Access on 08/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Sierra Leone profile. Available on: <https://www.cbd.int/countries/?country=sl> Access on 07/10/2016.

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.

# South Africa

## 1. General Information

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

YES / (  ) NO

Yes, South Africa has been a Party to the CBD, by ratification, since Jan 31, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES / (  ) NO

Yes, South Africa has been a Party to the Nagoya Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES / (  ) NO

Yes, South Africa has one checkpoint, the National Department of Environmental Affairs. 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. An additional competence of this entity is to instruct users of the South African biodiversity or associated traditional knowledge on the applicable procedures and requirements for obtaining prior informed consent, as well as on the signature of mutually agreed terms.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES / (  ) NO

Yes, South Africa has an IRCC, issued by the National Competent Authority (National Department of Environmental Affairs) on February 23, 2015, and valid until February 22, 2020. The certificate was issued in favor of HG&H Pharmaceuticals (Pty) with the purpose of conducting bioprospection activities involving indigenous biological resources, genetic resources and associated traditional knowledge, in particular for conducting national and international research on the *Sceletium tortuosum* specimen for the purpose of commercialization of the end product, all in compliance with a

1 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>.

2 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>.

South African legislation called National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) and the Bioprospecting, Access and Benefit Sharing Regulations<sup>3</sup>.

The requirement of prior informed consent was respected, as well as the mutually agreed term signed between this user, the South African San Council and the Nama Community. The benefit-sharing was agreed in the form of payment to the Bioprospecting Trust Fund.

**1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?**

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

No official inspection body was mentioned, and there is no evidence on the imposition of fines apart from the legal provisions establishing that they may be applied.

**1.7 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

According to article 98, item 2 of the Biodiversity Act No. 10 of 2004 National Environmental Management, the regulations issued by the Minister may provide that any person who contravenes or fails to comply with this law is guilty of an offence and liable on conviction to (a) imprisonment for a period not exceeding five years; (b) an appropriate fine of up to five million rand and, in case of recidivism or subsequent conviction, up to 10 million rand or imprisonment for a period not exceeding 10 years or, in both cases, a combination of a fine and such imprisonment; (c) in both cases, both a fine and such imprisonment.

Furthermore, article 110 of the same 2004 Act establishes that a person is guilty of an offence if that person contravenes or fails to comply with a provision of articles 57(1) and (2), 65(1), 67(2), 69(1) and (2), 71(1), 73(1) or 81(1); or if they perform the activity in disagreement with the provisions of this law or the authorization; or fraudulently alter, fabricate or forge any authorizations or permits; or use, pass or have in their possession any altered or false document; or knowingly make any false statements or reports.

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 offence 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.

.....  
3 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.



Finally, Notice 447 of 2015: Amendments to the regulations on bio-prospecting, access and benefit-sharing establishes some penalties in its article 42:

- (I) Any person who commits an offence under article 40 (which deals with the Bioprospecting Trust Fund) is liable on conviction to the following penalties:
  - a) Imprisonment for a period not exceeding (10) ten years;
  - b) Fine of up to 10 million rand; or
  - c) Both a fine and such imprisonment.
- (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.

## 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

South Africa has the following laws on access to genetic heritage and associated traditional knowledge:

- **Biodiversity Act n°10 of 2004 National Environmental Management** – establishes the management and conservation of biodiversity and its components, the sustainable use of indigenous biological resources, the fair and equitable sharing of benefits arising from the bioprospecting involving such resources, and the protection of species and ecosystems.
- **Patents Amendment Act 2005** - Amendment that rules on patent requests for products involving indigenous biological resources, genetic resources, traditional knowledge or traditional usage.
- **Regulations on Bioprospecting, Access and Benefit Sharing (No. R 138 of 1008)** - Regulates the system of authorizations for research, prospecting and exportation activities in South Africa involving indigenous biological resources, and establishes the criteria and requirements for benefit sharing and material transfer agreement.
- **National Environmental Laws Amendment Act, 2009 No. 14 of 2009** - makes amendments to the aforementioned norm “National Environmental Management: Biodiversity Act, 2004”.
- **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.
- **Notice 447 of 2015: Amendments to the regulations on bio-prospecting, access and benefit-sharing** – makes amendments to the Biodiversity Act n°10 of 2004 National Environmental Management, under the terms of article 97, items 1, e, f, g and h of the same act.

- **Notice 73 of 2014: Draft Amendment regulations on bio-prospecting, access and benefit-sharing** – although only a minute, this draft was published in South Africa’s official gazette, and deals with the project presented by the Minister of Water and Environmental Affairs to amend/change the country’s regulation on bioprospecting, access and benefit-sharing.

In order to avoid misunderstandings on the scope of the legislation presented, it is important to highlight some definitions contained in the Biodiversity Act No. 10 of 2004 National Environmental Management:

- Indigenous biological resources, under the terms of Chapter 1, are:
  - (I) Those defined in article 80, item 2, for the matters defined therein; or
  - (II) When used for any other issues, it will mean any resources contained in (a) any living or dead animal, plant or indigenous organism; (b) anything deriving from that animal, plant or other indigenous organism; and (c) any genetic material of such animal, plant or other organism.
- Indigenous biological resource, under the terms of article 80, item 2:
  - (a) Includes:
    - (i) the same dispositions as above, even if collected from its natural environment or accessed by any other means, including animals, plants or other organisms of indigenous species that are cultivated, bred or maintained in captivity or cultivated or changed by any biotechnological means;
    - (ii) any cultivar, variety, strain, derivative, hybrid or fertile version produced from any indigenous species or any animals, plants or other organisms, according to item (a) above;
    - (iii) any exotic animals, plants or other organisms, whether gathered from the wild or accessed from any other source, which, through the use of biotechnology, have been altered with any genetic material or chemical compound found in any indigenous species or any animals, plants or other organisms, according to items (a) and (b) above.
  - (b) Are excluded from this concept:
    - (i) genetic material of human origin;
    - (ii) any exotic animals, plants or other organisms, other than those described in item (a) (iii); and
    - (iii) indigenous biological resources listed under the terms of the TIRFAA - International Treaty on Plant Genetic Resources for Food and Agriculture.
- Indigenous species, under the terms of Chapter 1: Any species that naturally occur, or have historically occurred, in free form in nature within the South African borders, but excludes species that have been introduced in the country as a result of human activity.

In this sense, when the legislation presented employs the term indigenous, it must be understood as a native species of the country.

Finally, it underlines that in order to educationally instruct users, providers and other entities on

access and benefit-sharing, the South African Government has created a guidebook called “South Africa’s Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators”.

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

YES / (  ) NO

According to article 6 of the Bioprospecting, Access and Benefit-Sharing Regulations, No. R. 138 of 2008, the Minister of Environmental Affairs has the authority to issue bioprospecting permits and integrated permits of export and bioprospecting. As for export permits, these must be issued by a member of the Executive Council of the province responsible for the conservation of that area.

According to the mechanism “The Access and Benefit-Sharing Clearing-House”, the National Competent Authority of South Africa is the National Department of Environmental Affairs.

However, Government Notice No. 596 of July 7, 2010, issued by the Department of Environmental Affairs, seconds the authority to issue bioprospecting permits and integrated permits of export and bioprospecting, as mentioned in article 6, item 1, of norm “Bioprospecting, Access and Benefit-Sharing Regulations, No. R. 138 of 2008”, to the Director-General of the Department of Environmental Affairs, which may also be subrogated.

On February 27, 2012, through Government Notice No. 147, the Director-General of the Department of Environmental Affairs subrogated their powers to allow the Director of Resource Utilization or the acting official in that position to act in partnership with the Director-General of the Department of Environmental Affairs. This notice also states that the holders of the highest positions in their respective departments (Chief Director of Biodiversity Management or Deputy Director-General of Biodiversity and Conservation) may also act on or execute such powers and functions.

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

YES / (  ) NO

According to article 81 of Biodiversity Act No. 10 of 2004 National Environmental Management, no bioprospecting or exportation activity may be carried out without a proper permit. 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.

Finally, the Bioprospecting, Access and Benefit-Sharing Regulations, No. R. 138 of 2008 establishes the required content and format of the authorization in its annexes.

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

YES /  NO

No special procedures were found in relation to access to associated 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 /  NO

In relation to intellectual property rights, there is no express provision in the country's norms regulating access and benefit-sharing, but the patent legislation briefly touches on the subject, as described below:

- **Patents Act 57 of 1978** - The objective of this Act is to define the registry and procurement of patents for inventions and matters related to it. It rules on the procurement of patents on microorganisms and microbiological processes, but prohibits the patenting of plants and animals.
- **Patents Amendment Act 2005** - All applicants applying for patents registration must inform if the relevant product is originated or derived from indigenous biological resources, genetic resources or traditional knowledge. If affirmative, applicants are required to provide proof of the authorization to utilize the relevant biological resources, traditional use or traditional knowledge.

**2.7. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

The law only waives from the authorization requirement the following activities: possessing, cultivating, removing, exchanging or utilizing biological resources that are not aimed at the development and production of products such as drugs, food flavorings, perfumes, cosmetics, emulsifiers, among others, according to item 2.4.1. of Notice of Exemption In Terms of Section 86 (No. R 149 of 2008).

Additionally, for the purposes of Biodiversity Act No. 10 of 2004 - National Environmental Management, commercialization must be understood as the "multiplication of indigenous biological resources through the cultivation, propagation, cloning or other available means to develop and produce products such as drugs, industrial enzymes, food flavorings, perfumes, cosmetics, emulsifiers, lycopene, colors and extracts."

In this sense, if the production of the aforementioned products utilizes indigenous biological resources, genetic resources, traditional knowledge, or traditional use, a proper permit is required, but there are no specific procedures for the cosmetic, personal hygiene and perfume industries.

According to a booklet issued and published by UEBT - Union Ethical BioTrade, up to 2014, 30 authorizations have been issued for the pharmaceuticals industry and 12 for the cosmetics industry.

## **2.8. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?**

YES /  NO

As already mentioned under item 2.1, the definition of Indigenous biological resource, under the terms of article 80, item 2, excludes any animals, plants or exotic organisms. The only exotic species covered by the legislation on access and benefit-sharing are those “in which the use of biotechnology has changed any genetic material or chemical compound in indigenous species or animals, plants or other organisms”.

## **2.9. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Yes, article 82 of Biodiversity Act No. 10 of 2004 National Environmental Management, establishes that, prior to issuing bioprospecting or export permits, the benefit-sharing regime must be established with the stakeholders. Article 83 of Biodiversity Act No. 10 of 2004 National Environmental Management is responsible for establishing the requirements of the benefit-sharing agreement, but it does not make any restrictions on the form or values applicable for the regime. However, the Bioprospecting, Access and Benefit-Sharing Regulations, No. R. 138 of 2008 establishes the content and format of the benefit-sharing agreement in its annexes. The law does not make any reference to values.

The Benefit-sharing agreements shall: specify the information on the relevant indigenous biological resource (type, area or origin, amount, any traditional or current potential uses), define who the parties of the agreement are, establish how and to which extent the relevant resource will be used, inform how stakeholders will promote benefit-sharing, and provide a regular review of the agreement as bioprospecting progresses. This agreement must be sent to the responsible Minister for approval, and will only be valid after their approval.

The Bioprospecting Trust Fund had been established to receive all funds allocated from benefit-sharing agreements, and all payments to stakeholders or payments for their benefit must be deposited in this trust fund. The transfer of funds shall be carried out annually, unless stated otherwise.

## **2. 10. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

The Biodiversity Act n°10 of 2004 National Environmental Management establishes in its article 81 that no one is authorized to export indigenous biological resources without prior authorization. This obligation is reinforced in article 5 of the Bioprospecting, Access and Benefit-Sharing Regulations, No. R 138 of 2008).

According to article 84 of the Biodiversity Act n°10 of 2004 National Environmental Management, the agreement for the shipping of samples shall specify: particularities of the provider and the exporter, type of resource provided, place from which the resource shall be collected/obtained, purpose of exportation, current potential use of the resource and specification of the situations in which the beneficiary may supply it or its by-products to third parties.

The Bioprospecting, Access and Benefit-Sharing Regulations, No. R. 138 of 2008 establishes the required content and format of the shipping authorization and the material transfer agreement in its annexes.

### 3. Websites Of Interest

**Department of Environmental Affairs:**

<https://www.environment.gov.za/content/home>

**SANBI (South African National Biodiversity Institute) \_ Biodiversity for Life:**

<http://www.sanbi.org/>

### 4. Summary – Competent Authorities

Authority	Competence
National Department of Environmental Affairs	It is the National Competent Authority of South Africa, according to the requirement established by the Convention on Biological Diversity. This authority has competence to issue bioprospecting permits and integrated permits of export and bioprospecting.
Director-General of the Department of Environmental Affairs	It was seconded to receive the same powers as the National Department of Environmental Affairs
Director of Resource Usage or official Chief Director of Biodiversity Management of Deputy Director-General of Biodiversity and Conservation	They received, according to the same act, the subrogated powers of the Director-General of the Department of Environmental Affairs

### 5. References

ACCESS AND BENEFIT SHARING - ABS: Understanding international and national laws. Disponível em: <[http://ethicalbiotrader.org/dl/benefit-sharing/ABS\\_Rules\\_2014\(2\).pdf](http://ethicalbiotrader.org/dl/benefit-sharing/ABS_Rules_2014(2).pdf)> Acesso em 31/10/2016.

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. South Africa profile. Disponível em: <<https://absch.cbd.int/countries/ZA>> Acesso em 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.  
Disponível em: < <https://www.cbd.int/financial/bensharing/southafrica-study.pdf>>. Acesso em 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. Disponível em: <<https://www.cbd.int/countries/?country=za>> Acesso em 18/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Biodiversity Act nº10 of 2004 National Environmental Management**. Disponível em <[https://www.environment.gov.za/sites/default/files/legislations/nema\\_amendment\\_act10.pdf](https://www.environment.gov.za/sites/default/files/legislations/nema_amendment_act10.pdf)> Acesso em 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **National Environmental Laws Amendment Act, 2009 No. 14 of 2009**. Disponível em < [https://www.environment.gov.za/sites/default/files/legislations/nema\\_amendment\\_act14.pdf](https://www.environment.gov.za/sites/default/files/legislations/nema_amendment_act14.pdf)> Acesso em 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Notice 447 of 2015: Amendments to the regulations on bio-prospecting, access and benefit-sharing**. Disponível em < [https://www.environment.gov.za/sites/default/files/legislations/nemba10of2004\\_babsregulations\\_amendments.pdf](https://www.environment.gov.za/sites/default/files/legislations/nemba10of2004_babsregulations_amendments.pdf)> Acesso em 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Notice 73 of 2014: Draft Amendment regulations on bio-prospecting, access and benefit-sharing**. Disponível em < <http://cer.org.za/wp-content/uploads/2014/02/20140217-National-Gazette-No-37331-of-17-February-2014-Volume-584.pdf>> Acesso em 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Notice of Exemption In Terms of Section 86 (No. R 149 of 2008)**. Disponível em < <http://extwprlegs1.fao.org/docs/pdf/saf85908.pdf> > Acesso em 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Patents Act 57 of 1978**. Disponível em < <http://www.gov.za/documents/patents-act-9-apr-2015-0827>> Acesso em 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Patents Amendment Act 2005**. Disponível em < [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=179614](http://www.wipo.int/wipolex/en/text.jsp?file_id=179614) > Acesso em 31/10/2016.

GOVERNMENT OF SOUTH AFRICA. **Regulations on Bioprospecting, Access and Benefit Sharing (No. R 138 of 2008)**. Disponível em < <http://www.ecolex.org/details/legislation/bioprospecting-access-and-benefit-sharing-regulations-2008-no-r-138-of-2008-lex-faoc085909/> > Acesso em 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. Disponível em: < <https://www.cbd.int/countries/?country=za> > Acesso em 18/10/2016.

TSHITWAMULOMONI, Lactitia, et. al. **South Africa's Legislative Framework On Bioprospecting, Access And Benefit Sharing**. Department of Environmental Affairs. 7th Pan-African ABS Workshop,

2013. Disponível em < [http://www.abs-initiative.info/uploads/media/Lactitia\\_Tshitwamulomoni\\_-\\_DEA\\_-\\_South\\_Africa\\_s\\_legislative\\_framework.pdf](http://www.abs-initiative.info/uploads/media/Lactitia_Tshitwamulomoni_-_DEA_-_South_Africa_s_legislative_framework.pdf) >. Acesso em 18/10/2016.

UEBT - Union for Ethical BioTrade. **Access and benefit sharing - ABS: Understanding international and national laws.** Union for Ethical BioTrade, 2014. Disponível em <[http://ethicalbiotrade.org/dl/benefit-sharing/ABS\\_Rules\\_2014\(2\).pdf](http://ethicalbiotrade.org/dl/benefit-sharing/ABS_Rules_2014(2).pdf)>. Acesso em 18/10/2016.



## 1. General information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Feb 07, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Dez 20, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### Nagoya Protocol on Access and Benefit-sharing

**Mr. Emmanuel Dlamini**

ABS National Focal Point

+268 2 404 6162

*fasidlamini@gmail.com*

*hlobskhos@yahoo.com*

*ceezet9@gmail.com*

Principal Secretary (Political Focal Point)

Ministry of Tourism and Environmental Affairs

P.O. Box 2652

Mbabane

Swaziland

### *Swaziland Environment Authority*

<http://www.sea.org.sz/>

### *Ministry of Tourism & Environmental Affairs*

[http://www.gov.sz/index.php?option=com\\_content&view=article&id=257&Itemid=207](http://www.gov.sz/index.php?option=com_content&view=article&id=257&Itemid=207)

### *Swaziland CHM Home*

<http://www.sea.org.sz/biodiversity/>

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Swaziland profile. Available on: <https://absch.cbd.int/countries/SL> Access on 08/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Swaziland profile. Available on: <https://www.cbd.int/countries/?country=sl> Access on 08/10/2016.

SWAZILAND. **Swaziland's Fifth National Report to the Convention of Biological Diversity**. Swaziland Environment Authority - SEA. 2014. Available on: <https://www.cbd.int/countries/?country=sl> Access on 08/10/2016.

SWAZILAND. **Swaziland's Second National Biodiversity Strategy and Action Plan**. Swaziland Environment Authority - SEA. 2014. Available on: <https://www.cbd.int/countries/?country=sl> Access on 08/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Jan 28, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since ratification Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**Dr. Nouredin Ahmed Abdalla**

ABS National Focal Point

+249 183 784279

*hcenr2005@yahoo.com*

Secretary General

Higher Council for Environment and Natural Resources (HCENR)

P.O. Box 10488

Khartoum

Sudan

### 4. Websites

**National CHM**

*<http://sd.chm-cbd.net>*

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Sudan profile. Disponível em: <https://absch.cbd.int/countries/SD> Acesso em: 04/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Sudan profile. Disponível em: <https://www.cbd.int/countries/?country=sd> Acesso em: 04/10/2016.

REPUBLIC OF SUDAN. **Sudan's Fifth National Report to the Convention on Biological Diversity.** Ministry of the Environment, Forestry and Physical Development. Higher Council for Environmental and Natural Resources (HCENR). Khartoum, 2014. Disponível em: <https://www.cbd.int/countries/?country=eg> Acesso em 04/10/2016.

REPUBLIC OF SUDAN. **National Biodiversity Strategy and Action Plan 2015 -2020.** Ministry of the Environment, Forestry and Physical Development. Higher Council for Environmental and Natural Resources (HCENR). Disponível em: <https://www.cbd.int/countries/?country=eg> Acesso em 04/10/2016.



## 1. General Information

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

YES /  NO

Yes, Togo has been a Party to the Convention, by acceptance, since Jan 2, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Togo has been a Party to the Protocol, by ratification, since May 5, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

According to article 136 of LOI N°. 2008-005 (Portant Loi-Cadre Sur L’environnement), detailed in sequence, the Ministry of Environment will create the Environmental Police (Police de l’envi-

1 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>.

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 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.

ronnement) with the mission of investigating violations against the dispositions of the current law and its regulations. There is no evidence of imposition of fines although there are legal provisions establishing that they may be applied.

### 1.7 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

According to the dispositions of LOI N°. 2008-005 article 154 the penalty of imprisonment from six (6) months to two (2) years and a fine from 50,000 to 5 million CFA francs, or any of the two penalties, will be imposed to anyone who carry out activities that may affect the fauna and flora in violation of articles 61 and 62 of the referred law. In this case, the referred articles deal with the rational use of biodiversity and the controlled access to endangered species.

In addition, LOI N°. 2008-09 (Portant Code Forestier) establishes sanctions against the use of wood and non-wood forest resources in the following articles: Article 110 establishes that any unauthorized exploration of forest resources from the State or independent federal agencies will be punished with a penalty of imprisonment from five (5) months to two (2) years and a fine from 500,000 to 1 million CFA francs, or any of the two penalties. Article 117 establishes that the unauthorized importation, exportation and re-exportation of wood and non-wood forest products will be punished with a penalty of imprisonment from three months to one year and a fine from 10,000 to 1 million CFA francs, or any of the two penalties. And Article 118 establishes that the unauthorized extraction or removal of rocks, sand, turf, earth, grass, gravel, leaves, roots, lianas, flowers or any other products from protected areas will be punished with a fine from 5,000 to 500,000 CFA francs. In case of recidivism, a complementary penalty of 15 days to one month of imprisonment will be imposed.

## 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

Togo has laws regulating the access to genetic heritage and associated traditional knowledge. They are:

- **LOI N°. 2008-005 Portant Loi-Cadre Sur L'environnement** - This law establishes the general legal framework for environmental management in Togo. Its objectives are: - to manage and preserve the sustainability of the environment; - to guarantee to all citizens an ecologically-balanced and healthy environment; - to create conditions for a rational and sustainable management of natural resources for present and future generations; - to establish the basic principles of management and protection of the environment against all forms of degradation; - to sustainably improve the life conditions of the population in relation to environmental balance.

- **LOI N°. 2008-09 Portant Code Forestier** - This Code has the objective of defining and harmonizing the rules for the management of forest resources seeking the balance of ecosystems and the sustainable use of forest resources.

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

YES /  NO

According to Article 10 of LOI N°. 2008-005 (Portant Loi-Cadre Sur L'environnement), the implementation of the national environmental policy is secured by the Ministry of the Environment. In the same way, the Ministry of the Environment is responsible for securing the environmental international commitments to which Togo has subscribed.

Besides, article 12 of the same law defines that the National Commission on Sustainable Development (Commission Nationale du Développement Durable), the advisory body linked to the Ministry of the Environment, is responsible for monitoring the integration of the environmental perspective with development strategies and policies. It also aims to guarantee the implementation and enforcement of international conventions on the environment ratified by Togo.

According to article 54 of LOI N°. 2008-09 (Portant Code Forestier) the Council of Ministers (Conseil des Ministres) is the body responsible for regulating the importation, exportation and re-exportation of wood and non-wood forest products. Also in relation to this law, article 59 establishes that the Administration of Forest Resources is responsible for the management of protected forest areas, soils and other relevant sites outside forest areas.

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

YES /  NO

According to article 62 of Law 2008-005 any native, rare or endangered plant and animal species, as well as their natural habitats, are subject to reinforced protection, with their exploration, commercialization and exportation subjected to regulation. The use of these protected species for scientific research is subject to previous authorization from the Ministry of the Environment. Because of that, the law establishes that the Ministry of the Environment, in collaboration with the stakeholders, will present a list of protected plants and animals and the terms for the protection and preservation of their habitats.

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

YES /  NO

None of the laws presented under item 2.1 mentions specific procedures for accessing Associated 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 /  NO

None of the laws presented under item 2.1 mentions specific procedures for requesting patents.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

None of the laws presented under item 2.1 mentions specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries

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

YES /  NO

None of the laws presented under item 2.1 mentions specific procedures for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

According to LOI N°. 2008-005 (Portant Loi-Cadre Sur L'environnement), article 34, 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. This law does not define, however any specific procedures, rules or values.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

Article 62 of LOI N°. 2008-005 only mentions that any native, rare or endangered species have their exploration, commercialization and exportation subjected to regulation, but it does not indicate the procedures to be followed.

Article 54 of LOI N°. 2008-09 only mentions that the importation, exportation and re-exportation of wood and non-wood forest products are regulated by the Order of the Council of Ministers without, however, describing the specific procedures to be followed.

### 3. Websites Of Interest

*Exchange of central Togo - Convention on Biological Diversity:*

<http://tg.chm-cbd.net/>

### 4. Summary – Competent Authorities

Authority	Competence
Ministry of the Environment	Responsible for the implementation of national environmental policies and also for ensuring that the international commitments ratified by Togo are integrated in the national laws and regulations. Besides, it is responsible for providing prior authorization on the use of protected species.
National Commission on Sustainable Development	Institution linked to the Ministry of the Environment which monitors the integration of environmental concerns to development strategies and policies. It also guarantees the implementation and enforcement of international conventions on the environment ratified by Togo.
Order of the Council of Ministers	Institution responsible for regulating the importation, exportation and re-exportation of wood and non-wood forest products.
Administration of Forest Resources	Institution responsible for the management of protected forest areas, soils and other relevant sites outside forest areas.

### 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Togo profile. Disponível em: <https://absch.cbd.int/countries/TG> Acesso em 20/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Togo profile. Disponível em: <https://www.cbd.int/countries/?country=tg> Acesso em 20/10/2016.

REPUBLIQUE TOGOLAISE. **Cinquieme Rapport National Sur La Diversite Biologique Du Togo 2009-2014**. Ministere De L'environnement Et Des Ressources Forestieres. 2014. Disponível em: <https://www.cbd.int/countries/?country=tg> Acesso em 20/10/2016.

REPUBLIQUE TOGOLAISE. **Stratégie et Plan d'Action National pour la Biodiversité du Togo SPANB 2011-2020**. Ministère De L'environnement Et Des Ressources Forestières. 2014. Disponível em: <https://www.cbd.int/countries/?country=tg> Acesso em 20/10/2016.

TOGO. **Loi n° 2008-09 portant Code forestier**. Disponível em: [https://www.ecolex.org/details/legislation/loi-n-2008-09-portant-code-forestier-lex-faoc085011/?q=2008-09&type=legislation&x-country=Togo&xdate\\_min=&xdate\\_max=](https://www.ecolex.org/details/legislation/loi-n-2008-09-portant-code-forestier-lex-faoc085011/?q=2008-09&type=legislation&x-country=Togo&xdate_min=&xdate_max=) Acesso em 20/10/2016.

TOGO. **Loi n° 2008-005 portant loi-cadre sur l'environnement**. Disponível em: <https://www.ecolex.org/details/legislation/loi-no-2008-005-portant-loi-cadre-sur-lenvironnement-lex-faoc085010/>> Acesso em 20/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the CBD, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Uganda has been a party to the Protocol since Oct 12, 2014, having acceded to it on Jun 25, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

The National Environment Act (1995), in its article 4, institutes the National Environmental Autho-

1 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>.

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 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.

ity, and in its article 5, states that this authority shall have the role of monitoring and supervising activities carried out in the environmental area. However, there is no information as to whether it is the institution responsible for inspecting access to genetic resources.

No concrete cases were found during the survey in relation to the application of fines.

### **1.7 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

The National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005, on articles 25 to 27, state:

Article 25. 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 offence 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 offence 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 offence 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 cancelled;
- Order the return of the genetic resources; and
- Make an order for the division of benefits occurring or likely to occur from access to genetic resources.

## **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

Uganda has the following laws on access to genetic heritage and associated traditional knowledge:



- 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 - the 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

Yes. Article 5 of the National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005 states that the National Council for Science and Technology, established by the Uganda National Council for Science and Technology Act, is the competent authority for the purposes of that Act.

## **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

Yes. 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.

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

The Guidelines for Access to Genetic Resources and Benefit Sharing in Uganda (2007) in its article 3.5 provide information on access to the traditional knowledge, the procedure is the same as to access the 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 /  NO

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

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for gaining access to genetic heritage in activities performed on behalf of the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

There are no specific norms for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

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; and
- Joint ownership of patents and other relevant forms of intellectual property rights.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( X ) YES / ( ) NO

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 offence.

## 3. Websites Of Interest

### *National CHM:*

<http://www.biodiv.be>

### *National Environmental Management Authority (NEMA):*

<http://www.biosafety.be/bch/bch.html>

### *Uganda National Council for Science and Technology:*

<http://www.uncst.go.ug>

## 4. 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.

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Uganda profile. Disponível em: <https://absch.cbd.int/countries/UG> Acesso em 21/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Uganda profile. Disponível em: <https://www.cbd.int/countries/?country=ug> Acesso em 21/10/2016.

REPUBLIC OF UGANDA. **Guidelines for Access to Genetic Resources and Benefit Sharing in Uganda (2007)**. Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=11628> Acesso em 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. Disponível em: <https://www.cbd.int/countries/?country=ug> Acesso em 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. Disponível em: <https://www.cbd.int/countries/?country=ug> Acesso em 21/10/2016.

REPUBLIC OF UGANDA. **The National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005**. Disponível em: <https://absch.cbd.int/countries/UG> Acesso em 21/10/2016.

REPUBLIC OF UGANDA. **The National Environmental Act (1995)**. Disponível em: <http://www.ulii.org/ug/legislation/consolidated-act/153> Acesso em 21/10/2016.

# United Republic of Tanzania

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since June 6, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, the country is not a party to the Nagoya Protocol and neither is signatory.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

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. According to item 2.1, Article 66 of this law imputes to the Minister designated to ensure the conservation and sustainable use of national genetic resources, as well as the fair and equitable sharing of benefits.

## 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

There is no specific legislation regarding access to genetic heritage and associated traditional knowledge in the country. Although, the Environmental Management Act No. 20 of 2004 states briefly in section 66, section 1 that it will be up to the Minister responsible for ensuring the conservation and sustainable use of national genetic resources, as well as the fair and equitable sharing of benefits.

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 develop-**

**ments involving the access?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites

***Tanzania Biodiversity Information Facility (TanBIF)***

*www.tanbif.org*

***Ministry of Natural Resources and Tourism***

*www.mnrt.go.tz*

***National Environment Management Council (NEMC)***

*www.nemc.org.tz*

***Ministry of Agriculture and Natural Resources – Zanzibar***

*www.kilimoznz.or.tz*

## 4. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### Nagoya Protocol on Access and Benefit-sharing

#### Mr. Faraja Ngeregeza

ABS National Focal Point

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Principal Environment Officer

Vice President's Office

P. O. Box 5380

Dar es Salaam

United Republic of Tanzania

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. United Republic of Tanzania profile. Disponível em: <https://absch.cbd.int/countries/TZ> Acesso em 17/06/2016.

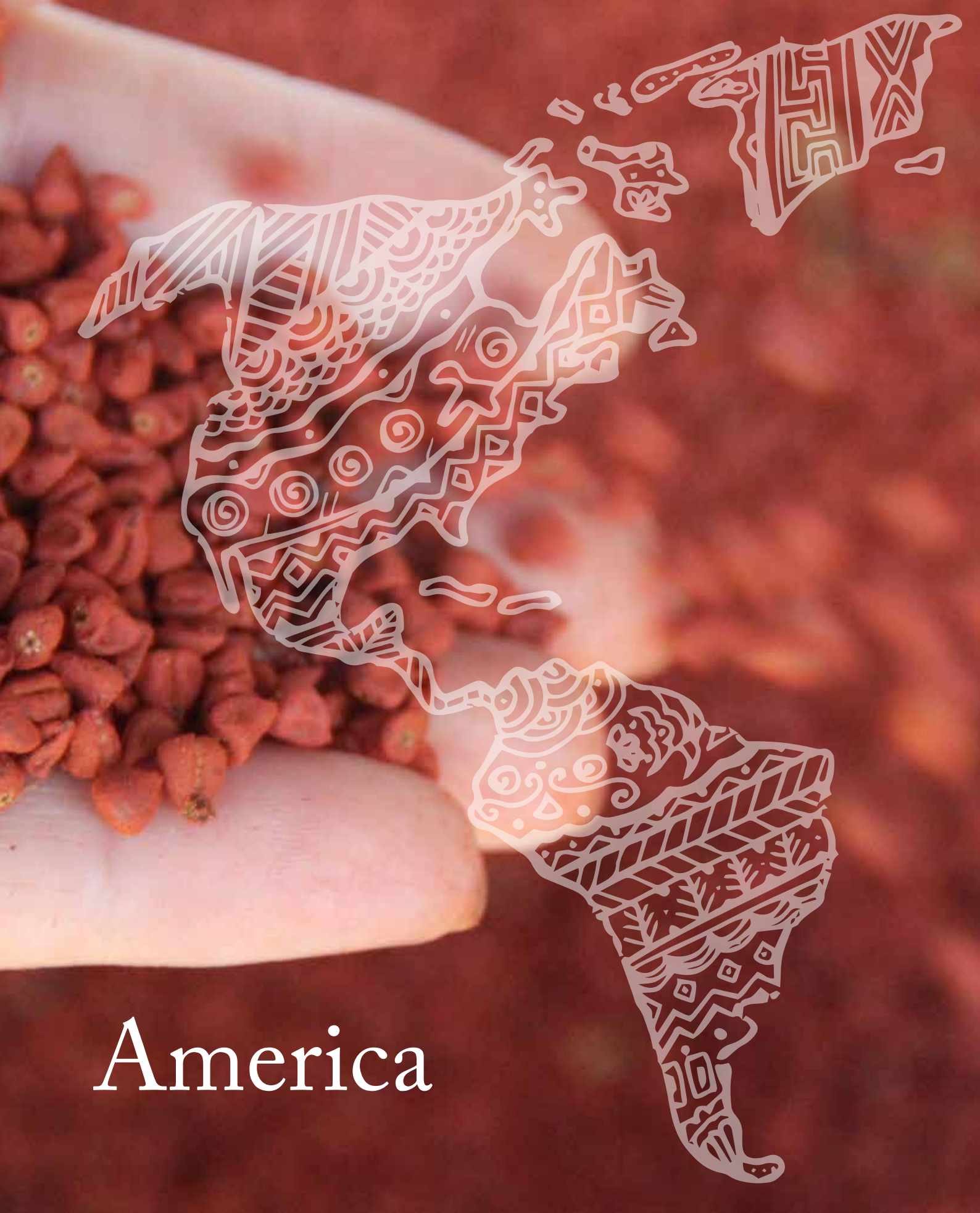
CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. United Republic of Tanzania profile. Disponível em: <https://www.cbd.int/countries/?country=tz> Acesso em 17/06/2016.

UNITED REPUBLIC OF TANZANIA. **Environmental Management Act, 2004 (No. 20 of 2004)**. Disponível em: [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=&xdate\\_max=](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=&xdate_max=) Acesso em 17/06/2016.

UNITED REPUBLIC OF TANZANIA. **Fifth National Report on the Implementation of the Convention on Biological Diversity**. Vice President's Office, Division of Environment. 2014. Disponível em: <https://www.cbd.int/countries/?country=tz> Acesso em 17/06/2016.

UNITED REPUBLIC OF TANZANIA. **National Biodiversity Strategy and Action Plan (NBSAP) 2015-2020**. Vice President's Office, Division of Environment. 2015. Disponível em: <https://www.cbd.int/countries/?country=tz> Acesso em 17/06/2016.





America

# Antigua and Barbuda

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Dez 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Mar 12, 2017.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC2 under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**Ms. Diann Black-Layne**

ABS National Focal Point

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*dcblack11@gmail.com*

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*antiguaenvironmentdivision@gmail.com*

Chief Environment Officer

Environment Division

Ministry of Health and the Environment

#1 Victoria Park Botanical Gardens

Factory Road

St. John's

Antigua and Barbuda

## 4. Websites

### *The Environmental Awareness Group of Antigua & Barbuda*

<http://www.eagantigua.org/index.html>

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Antigua and Barbuda profile. Disponível em: <https://absch.cbd.int/countries/AG> Acesso em 29/09/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Antigua and Barbuda profile. Disponível em: <https://www.cbd.int/countries/?country=ag> Acesso em 29/09/2016.

GOVERNMENT OF ANTIGUA AND BARBUDA. **Antigua & Barbuda National Strategic Biodiversity Action Plan (2014-2025)**. Ministry of Health and the Environment. Disponível em: <https://www.cbd.int/countries/?country=ag> Acesso em 29/09/2016.

GOVERNMENT OF ANTIGUA AND BARBUDA. **Fifth National Report to the Convention on Biodiversity**. Environment Division. Disponível em: <https://www.cbd.int/countries/?country=ag> Acesso em 29/09/2016.

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

YES /  NO

Yes, Argentina has been a Party to the CDB, by ratification, since Feb 20, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, Argentina is a signatory to the Protocol since Nov 15, 2011, but it is not yet a Party to the Nagoya Protocol.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

1 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>.

2 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>.

3 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 laws that regulate access to genetic heritage and associated traditional knowledge do not establish an inspection body. There is no evidence of application of fines.

### 1.7 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

There is no indication of sanctions or fines in the relevant legislation.

## 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

- Law 24,375 of 1994 - Approves the Convention on Biological Diversity, introduces general and conceptual dispositions, including some comprehensive dispositions on access to genetic resources under article 15 (items 1 to 7) and on the management of biotechnology and benefit-sharing sharing under article 19 (items 1 to 4)

- 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.

- **Resolution 693 of 2004** - Creates the National Advisory Commission on Genetic Resources for Food and Agriculture (CONARGEN)
- **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.
- **Resolution 226 of 2010** - Regime of access to genetic resources, which also institutes a registry of access to genetic resources.

Besides these Resolutions and Laws, Argentina also has provincial laws which deal specifically with access to genetic heritage and the associated traditional knowledge. They are:

- **Law 2,600 of the Rio Negro Province** on Biodiversity, Conservation and Access;
- **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;
- **Provincial Law 3,337 of October 3, 1996**, of the Misiones Province on biodiversity.

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

YES /  NO

Article 1 of Decree 1,347 of 1997 establishes that the Secretariat of Natural Resources and Sustainable Development at the Presidency is the entity responsible for the application of Law 24,375 of 1994.



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

YES /  NO

Yes. Article 1st of Resolution 226 of 2010 establishes that the natural or legal persons, of public or private character, of Argentinean or foreign nationality, who access the genetic material defined under article 2 of the Convention on Biological Diversity, originated from the biodiversity, collected from the wild or acquired by any other means, for scientific or research purposes applied to the industry or commerce, seeking their importation or exportation, must submit a request for authorization to access the said material to the Secretariat of the Environment and Sustainable Development within the Cabinet of the Ministers' Office.

According to article 2, the permit must be issued by the National Directory of Environmental Planning and Biodiversity Conservation. In order to receive the authorization, the user must fill out the form presented in the annex of the resolution and enter into an agreement between the parties signed by both the user and the competent authority according to the jurisdiction.

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

YES /  NO

No, Resolution 226 of 2010 does not deal with ATK.

Notwithstanding, it is worth mentioning that item c) of Annex I establishes that the Agreement between Parties signed between the applicant and the competent authority from the place of origin of the genetic material shall contain, at least, a clause establishing "elements that guarantee the respect, preservation and maintenance of knowledge, innovations and practices of local and indigenous communities", under the terms of item VI.

**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

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for obtaining access to genetic heritage when performing activities on behalf the perfume, personal hygiene and cosmetic industries.

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

YES /  NO



There are no specific norms of access to genetic heritage related to procedures of collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( X ) YES / ( ) NO

Resolution 1,659 of 2007, which provides guidance on access to genetic resources and benefit-sharing, orients that Benefit-sharing should give priority to the public interest when the resource used is under public domain or private ownership of the Provincial or National State.

Appendix I of the referred Resolution indicates the possible monetary and non-monetary means in which benefit-sharing can occur.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

No procedures for the shipment of samples were identified.

**3. Websites Of Interest**

***Biodiversity Foundation - Argentina***

<http://biodiv.org.ar/>

***Foundation for the Conservation of Species and the Environment - FUCEMA***

<http://www.fucema.org.ar/>

***Darwinion Botanical Institute***

<http://www.darwin.edu.ar/>

***Ministry of Environment and Sustainable Development***

<http://www.ambiente.gov.ar/>

***National Biodiversity Observatory***

<http://obio.ambiente.gob.ar/>

***Genomic Data National System - Republic of Argentina***

<http://www.datosgenomicos.mincyt.gob.ar/>

***National System of Biological Data in Argentina***

<http://datos.sndb.mincyt.gob.ar/>

**4. Summary – Competent Authorities**

Authority	Competence
Secretariat of Natural Resources and Sustainable Development at the Presidency	Entity responsible for the application of Law 24,375 of 1994, which ratifies the Convention on Biological Diversity.

<p>Secretariat of the Environment and Sustainable Development at the Cabinet of the Ministers' Office</p>	<p>Article 1st of Resolution 226 of 2010 establishes that the natural or legal persons, of public or private character, of Argentinean or foreign nationality, who access the genetic material defined under article 2 of the Convention on Biological Diversity, originated from the biodiversity, collected from the wild or acquired by any other means, for scientific or research purposes applied to the industry or commerce, seeking their importation or exportation, must submit a request for authorization to access the said material to this Secretariat.</p>
<p>National Directory of Environmental Planning and Biodiversity Conservation of the Under Secretariat for Planning and Environmental Policy.</p>	<p>As established under Article 2 of Resolution 226 of 2010, this authority shall enforce the requirements established under article 1 of the resolution and shall issue the permits for access activities, and exportation or importation of genetic material originating from the biological diversity.</p>

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Argentina profile. Disponible em: < <https://absch.cbd.int/countries/AR>> Acceso em 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Argentina profile. Disponible em: < <https://www.cbd.int/countries/?country=ar>> Acceso em 18/10/2016.

GOBIERNO DE ARGENTINA. Decreto Nacional 1.347/97. Autoridad de aplicación de la Ley sobre Diversidad Biológica (Creación de la CONADIBIO). Disponible em: < <http://www2.medioambiente.gov.ar/mlegal/tratados/dec1347.htm>> Acceso em 18/10/2016.

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. Disponible em: < [http://www2.medioambiente.gov.ar/mlegal/biodiversidad/res91\\_03.htm](http://www2.medioambiente.gov.ar/mlegal/biodiversidad/res91_03.htm)> Acceso em 18/10/2016.

GOBIERNO DE ARGENTINA. Ley N° 2.600 Biodiversidad: Conservación y Acceso. Provincia de Río Negro. Disponible em: < <http://www2.medioambiente.gov.ar/sian/rnegro/normat/leyn2600.htm>> Acceso em 18/11/2016.

GOBIERNO DE ARGENTINA. Ley n° 24.375 que Aprueba el Convenio sobre la Diversidad Biológica. Disponible em: < <http://desarrollosustentable.tierradelfuego.gov.ar/wp-content/uploads/2017/02/LEY-24375-Aprobacion-del-Convenio-sobre-Diversidad-Biologica.pdf>> Acceso em 18/10/2016.

GOBIERNO DE ARGENTINA. Ley N° IX-0851-2013 Acceso Y Registro De Los Recursos Genéticos Y Bioquímicos De La Diversidad Biológica Provincial. Provincia de San Luis. Disponible em: <

<http://www.diputadosanluis.gov.ar/diputadosasp/paginas/verNorma.asp?NormalD=931>  
> Acceso em 18/11/2016.

GOBIERNO DE ARGENTINA. Ley Provincial 3337 Ley de la Biodiversidad. Posadas, 3 de octubre de 1996. Provincia de Misiones. Disponible em: < <http://www.ecolex.org/es/details/legislation/ley-no-3337-ley-provincial-de-la-biodiversidad-lex-faoc135088/>> Acceso em 18/11/2016.

GOBIERNO DE ARGENTINA. Quinto Informe Nacional para la Conferencia de las Partes del Convenio Sobre la Diversidad Biológica (CDB). Secretaria de Ambiente y Desarrollo Sustentable, Republica Argentina. Julio, 2015. Disponible em: < <https://www.cbd.int/countries/?country=ar>> Acceso em 18/10/2016.

GOBIERNO DE ARGENTINA. Resolución N° 1.659/2007 - Aprueba los “Lineamientos o directrices sobre acceso a los recursos genéticos y participación justa y equitativa en los beneficios derivados de su utilización”. Disponible em: < <http://www.ecolex.org/details/legislation/resolucion-no-16592007-aprueba-los-lineamientos-o-directrices-sobre-acceso-a-los-recursos-geneticos-y-participacion-justa-y-equitativa-en-los-beneficios-derivados-de-su-utilizacion-lex-faoc075320/>> Acceso em 18/11/2016.

GOBIERNO DE ARGENTINA. Resolución N° 226/2010 - Régimen de acceso a los recursos genéticos. Créase un Registro de Acceso a los Recursos Genéticos. Disponible em: < <http://www.ecolex.org/details/legislation/resolucion-no-2262010-regimen-de-acceso-a-los-recursos-geneticos-crease-un-registro-de-acceso-a-los-recursos-geneticos-lex-faoc095044/>> Acceso em 18/11/2016.

GOBIERNO DE ARGENTINA. Resolución N° 693/2004 - Créase la Comisión Nacional Asesora en Recursos Genéticos para la Alimentación y la Agricultura (CONARGEN). Disponible em: < <http://www.ecolex.org/details/legislation/resolucion-no-6932004-crease-la-comision-nacional-asesora-en-recursos-geneticos-para-la-alimentacion-y-la-agricultura-conargen-lex-faoc121919/>> Acceso em 18/10/2016.

## 1. General Information

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

YES /  NO

Yes, Bolivia has been a Party to the CBD, by ratification, since Jan 1st, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Bolivia is scheduled to become a party to the Protocol, by acceptance, from Jan 4, 2017. Bolivian law No. 811, of June 16, 2016, regulates the effective ratification of the Nagoya Protocol.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

1 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>.

2 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>.

3 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. Regulations on Decision 391, in its article 60, establishes the National Secretariat of Natural Resources and the Environment as the institution responsible for imposing sanctions against violations to the aforementioned decree that regulates access in Bolivia.

As for records of application of fines, no concrete cases were found during the survey.

### **1.7 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

According to Regulations on Decision 391, article 60, the sanctions may include:

(1) 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;

(2) progressive fines in case of infraction, applied to a value equivalent to 60 days of fines. In case of persisting infractions or if new infractions are committed, the National Secretariat of Natural Resources and the Environment will successively increase the fine by one hundred percent over the base of the previous fine, up to the limit of three cumulative fines.

(3) Suspension of access activities and preventive or definitive seizure, in case of flagrant contraventions that imply alterations to the ecosystems and/or the biological diversity, the National Secretariat of Natural Resources and the Environment shall determine the immediate suspension of the access activities and the preventive or definitive seizure of the goods and/or instruments of the perpetrator.

4) Revocatory of authorization and incapacitation to request new accesses, in cases of recidivism or resistance to fulfil the imposed sanctions, the National Secretariat of Natural Resources and the Environment may also decide for the revocatory of the access authorization and the incapacitation to request new accesses.

(5) Resolution of the access contract. Without prejudice to the aforementioned sanctions, the National Competent Authority may annul the access contract for the following reasons: 1. Breach of the obligations established in the access contract and its annexes. 2. Transference of the acceded genetic resource to third parties without the authorization of the National Competent Authority. 3. Impossibility to reach a satisfactory agreement between the parties of the contract in relation to the benefits required by the preceding condition.

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 incapacitation of perpetrators in requesting new accesses, for cases of:

- Breach against the dispositions of this Decision;
- Transactions involving products derived or synthesized 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 include any indication of value for the fines.

## 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

Domestically, the following legislation is applicable in Bolivia regarding access to genetic resources and related affairs:

- **Law 811 of 2016** - ratifies the Nagoya Protocol.
- **Law Nº. 530 of May 23, 2014** - This law has the objective of defining policies that require the classification, registration, restitution, repatriation, protection, conservation, restoration, transmission, defense, ownership, custody, management, procedural declaration and safeguard of cultural heritage.
- **Supreme Decree No. 28,594 of January 14, 2006** - establishes mechanisms of the commercialization of vicuña wool (vicuña being a wildlife species and natural heritage of Bolivian origin, whose conservation is of great cultural, social, economic and ecological value);
- **Regulation on Decision 391 Common Regime on Access to Genetic Resources** - This Supreme Decree has the objective of regulating Decision 391 from the Commission of the Cartagena Agreement of July 22, 1996, which regulates the Common Regime on Access to Genetic Resources, establishing the jurisdiction for subscribing access contracts between users and the Bolivian Government. The referred contract establishes the rights and obligations of the parties in the use of genetic resources that have Bolivia as its country of origin.

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

Yes. The Regulation on Decision 391, in its article 4, establishes as the competent authority for the regime of access to genetic resources the Ministry of Sustainable Development and the Environment through the Secretariat of the Department of Natural Resources and the Environment.

In relation to cultural heritage, it must be highlighted that its management is decentralized, as article 3 of the Law on the Bolivian Cultural Heritage (Law 530 of 2014) establishes: “The management of the Bolivian Cultural Heritage shall be a joint action coordinated between the different autonomous territorial units, central State-level institutions and organized societies. The Ministry of Culture and Tourism is the institution responsible for promoting this coordination”.

Furthermore, Article 1 of Decision 391 of the Andean Pact defines as National Competent Authority:

State entity or public institution appointed by each Member Country, 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 this common regime and to ensure their performance.

In this sense, Article 50 establishes that the Member Countries of the Andean Community should establish a National Competent Authority according to the capacities and attributions listed in items ‘a’ to ‘p’ of this article. Furthermore, the set of directors from these National Competent Authorities (group formed of directors from each member country) 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

Yes. Article 16 of Resolution 391 of the Andean Pact establishes that:

All access procedures shall require the presentation, admittance, publication and approval of an application, the signing of a contract, the issuing and publication of the corresponding Resolution and the declarative registration of the acts connected with that access.

Articles 26 and 30 of the aforementioned decision establish the procedures for requesting access authorizations. According to article 46, anyone who performs access activities without the respective authorization shall be liable for sanctions.

In this sense, article 17 of the Regulation on Decision 391 establishes that the access to genetic resources shall require prior access request submitted to the National Competent Authority. Annex I of the referred Decree presents a standard model on access to genetic resources, to be followed by applicants.

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

YES /  NO

It was not possible to identify any specific procedures for access to associated traditional knowledge, although there are mentions to ownership and protection of traditional knowledge.

Law No. 530, in article 12, Recognizes the collective and community ownership of cosmovisions, music, sacred sites, rituals, myths, tales, legends, ancient knowledge, culinary, traditional technologies, agriculture, farming, medicine, botany and genetics. It is a responsibility of the Plurinational State of Bolivia to register the ownership of the intangible and ethnographic, collective and community cultural heritage in name of the origin community or communities, or nations or indigenous peoples, or intercultural or afro-Bolivian communities.

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. (Biber-Klemm Et Al, 2014, p. 11)

#### **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

Domestically, article 36 of Supreme Decree No. 24,676 of June 21, 1997, establishes that:

Article 36. The National Competent Authority, through the Under secretariat of Natural Resources, will negotiate with the applicant the terms of the access contract regarding the benefits deriving from the access, the means and timing of their distribution, the conditions for determining the ownership of the intellectual property rights and the conditions for the commercialization of the results.

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 synthesized 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for gaining access to genetic heritage in activities performed on behalf the perfume, personal hygiene and cosmetic industries.

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

YES /  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 in 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.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Domestically, the Regulation on Decision 391 establishes, 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. These benefits shall be distributed to promote the

conservation, sustainable use and development of genetic resources in the national territory. The benefit-sharing deriving from the access to genetic resources 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”.

The only article of Andean Decision 1,391 that deals with the benefit-sharing requirement is article 35, which establishes as follows:

**Art. 35** – When access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of the contract, an annex stipulating the fair and equitable distribution of the profits from the use of that component.

The annex shall be signed by the supplier of the intangible component and the applicant for the access. It may also be signed by the National Competent Authority, in accordance with the provisions of the national law of the Member Country. If that annex is not signed by the National Competent Authority, it shall be subject to the suspensive condition referred to in Article 42 of this Decision. Failure to comply with the stipulations of the annex shall constitute grounds for the rescission and nullification of the access contract.

## **2. 9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

Decision 391 of the Andean Community does not mention the shipment of genetic resources, but there is one occasion, in the fourth complimentary disposition, in which it establishes that the health certificates supporting the exportation of genetic resources shall include, according to Decision 328 of the Commission, the following phrase: “Use as genetic resource NOT authorized”.

### 3. Websites Of Interest

**Ministry of Environment and Water:**

<http://www.mmaya.gob.bo/>

### 4. Summary – Competent Authorities

Authority	Competence
Ministry of Culture and Tourism	To coordinate the decentralized management of the Bolivian Cultural Heritage
National Secretariat of Natural Resources and the Environment	Competent Authority for the regime of access to genetic resources

### 4. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Bolivia profile. Disponível em: <https://absch.cbd.int/countries> Acesso em 04/11/2016.

COMUNIDAD ANDINA. **Decision 448 - Modificación de la Octava Disposición Transitoria de la Decisión 391: Régimen Común sobre Acceso a los Recursos Genéticos.** Disponível em: < <http://www.wipo.int/edocs/lexdocs/laws/es/can/can015es.pdf>> Acesso em 04/11/2016.

COMUNIDAD ANDINA. **Decision 486 - Régimen Común sobre Propiedad Industrial.** Disponível em: < <http://www.wipo.int/edocs/lexdocs/laws/es/can/can012es.pdf>> Acesso em 04/11/2016.

COMUNIDAD ANDINA. **Decisión N° 391 que establece el Régimen Común sobre Acceso a los Recursos Genéticos.** Disponível em: < <http://www.wipo.int/wipolex/es/details.jsp?id=9446>> Acesso em 04/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Bolivia profile. Disponível em: [https://www.cbd.int/countries/?country=bo\\_](https://www.cbd.int/countries/?country=bo_) Acesso em 04/11/2016.

GOBIERNO DE BOLIVIA. **Decreto Supremo N° 28.593 - Mecanismos para la comercialización de la fibra de vicuña.** Disponível em: < [http://www.ecolex.org/details/legislation/decreto-supremo-no-28593-mecanismos-para-la-comercializacion-de-la-fibra-de-vicuna-lex-faoc070640?q=&type=legislation&xkeywords=access+and+benefit+sharing&xcountry=Bolivia+%28Plurinational+State+of%29&xdate\\_min=&xdate\\_max=>](http://www.ecolex.org/details/legislation/decreto-supremo-no-28593-mecanismos-para-la-comercializacion-de-la-fibra-de-vicuna-lex-faoc070640?q=&type=legislation&xkeywords=access+and+benefit+sharing&xcountry=Bolivia+%28Plurinational+State+of%29&xdate_min=&xdate_max=>) Acesso em 04/11/2016.

GOBIERNO DE BOLIVIA. **Estrategia Nacional de Biodiversidad.** Ministerio de Desarrollo Sostenible y Planificación. La Paz, 2001. Disponível em: <https://www.cbd.int/countries/?country=bo> Acesso em 04/11/2016.

GOBIERNO DE BOLIVIA. **Ley N° 530 de 23 de mayo de 2014 del patrimonio cultural boliviano.** Disponible em: < [http://www.wipo.int/wipolex/es/text.jsp?file\\_id=337062](http://www.wipo.int/wipolex/es/text.jsp?file_id=337062)> Acceso em 04/11/2016.

GOBIERNO DE BOLIVIA. **Ley núm. 811, de 16 de junio de 2016, que ratifica el Protocolo de Nagoya.** Disponible em: < [https://www.ilo.org/dyn/natlex/natlex4.detail?p\\_lang=es&p\\_isn=102549](https://www.ilo.org/dyn/natlex/natlex4.detail?p_lang=es&p_isn=102549)> Acceso em 04/11/2016.

GOBIERNO DE BOLIVIA. **Reglamento de la Decisión 391 Régimen Común de Acceso d los Recursos Genéticos.** Disponible em: < <http://www.wipo.int/edocs/lexdocs/laws/es/can/can011es.pdf>> Acceso em 04/11/2016.

GOBIERNO DE BOLIVIA. **V Informe Nacional CDB. Ministerio De Relaciones Exteriores y Ministerio de Medio Ambiente y Agua.** 2015. Disponible em: <https://www.cbd.int/countries/?country=bo> Acceso em 04/11/2016.

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.** Gobierno de Bolivia. Viceministerio de Recursos Naturales y Medio Ambiente. Dirección General de Biodiversidad. La Paz, 2004. Disponible em: < [http://www.bivica.org/upload/ag\\_recursos-geneticos.pdf](http://www.bivica.org/upload/ag_recursos-geneticos.pdf)> Acceso em 04/11/2016.

## General Information

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

YES /  NO

Yes, Brazil has been a Party to the CBD, by ratification, since May 29, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, Brazil is not a Party to the Protocol, but has been a signatory country since Feb 2, 2011.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

Yes. Art 28 of Law 13,123/2015 establishes that the competent federal institutions shall be responsible for the inspection, interception and seizure of samples containing accessed genetic heritage, byproducts or reproductive material obtained from access to genetic resources or associated

1 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>.

2 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>.

3 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, in cases where the access or economic exploitation has been carried out in disagreement with the dispositions of the Law and its regulations. This way, according to article 93 of Decree 8,772/2016, the competent authorities for inspecting and investigating administrative breaches are the Brazilian Institute of the Environment and Renewable Natural Resources - IBAMA and the Navy Command.

Therefore, it is the responsibility of IBAMA to verify compliance with the rules established by these regulations in relation to access to the Brazilian genetic heritage and associated knowledge, benefit-sharing, remittance and international shipping of biological material containing samples of genetic heritage, as well as on the economic exploitation of byproducts and end products developed from components of the Brazilian biodiversity. And MAPA, in relation to access to genetic heritage for agricultural activities, under the terms established by article 3 of Law 10,883/2004.

IBAMA has already issued several notices of infraction related to irregular access to genetic resources and associated traditional knowledge, including the so-called New Paths Operation I and II (in two stages), between August 2010 and April 2011, aimed at encouraging regularization and preventing irregular activities related to access to genetic heritage and associated traditional knowledge, which notified more than 470 users who were in disagreement with the law, including companies, universities and biotechnology centers.

### **1.7 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

Chapter IV of Decree 8,772/2016 presents a list of infractions and administrative sanctions. The administrative sanctions, without prejudice to other applicable criminal and civil responsibilities, are punishable with the following sanctions, either cumulatively or not:

- Written notice.
- Fine, which can vary from R\$1,000.00 to R\$100,000.00 when an infraction is perpetrated by a natural person; or from R\$10,000.00 to R\$10,000,000.00 when the infraction is committed by a company or in association with a company. The act of a new infraction by the same agent, within a period of five years counted from the final decision of the administrative order that confirmed the previous infraction, shall triple the value of the imposed fine in cases where the same infraction has been committed; or doubled it, if dealing with a different infraction.
- Seizure of the samples containing accessed genetic heritage; of the tools used in the collection or processing of the accessed genetic heritage or associated traditional knowledge; or of any products obtained from information on associated traditional knowledge;
- Temporary suspension of the manufacturing or commercialization of the end product or reproductive material derived from the access to genetic heritage or associated traditional knowledge until its due regularization;
- Embargo of specific activities related to the infraction;
- Partial or total interdiction of the establishment, activity or enterprise;
- Suspension of certificate or authorization;
- Cancellation of certificate or authorization.

The sanctions shall be applied according to the gravity of the fact, the history of the offender in relation to compliance with the legislation on genetic heritage and associated traditional knowledge; recidivism; and the financial status of the offender in case of the imposition of a fine. The competent entity or institution may also establish, through technical norm, additional criteria for increasing or decreasing the applicable administrative sanctions.

As for the infractions committed in relation genetic heritage and associated traditional knowledge, for the economic exploitation of end product or reproductive material derived from access to genetic heritage or associated traditional knowledge without prior notification, regardless of the number of accessed species for the development of the end product or reproductive material:

- Minimum fine of R\$3,000.00 and maximum of R\$30,000.00, when related to a natural person.
- Minimum fine of R\$10,000.00 and maximum of R\$200,000.00 when related to a company considered to be a micro-business or small business or cooperatives of traditional farmers with an annual gross income equal or smaller than the maximum limit established under item II of art. 3 of Complementary Law No. 123 of December 14, 2006.
- Minimum fine of R\$30,000.00 and maximum of R\$10,000,000.00 for any other institutions.

The value of the fine shall be doubled if the end product or reproductive material developed from the access is commercialized abroad. The same sanctions are applicable to anyone who presents a benefit-sharing agreement in disagreement with the legal dispositions.

The law also includes the value of the fines and other specific dispositions for anyone who:

- Makes an international remittance, either directly or through an intermediary, of samples of genetic heritage without prior registration or in disagreement with it.
- Request intellectual property rights resulting from access to genetic heritage or associated traditional knowledge, in Brazil or abroad, without prior accreditation;
- Publish final or partial results, in scientific media or means of communication, without prior accreditation.
- Fail to register the access before the commercialization of any byproducts.
- Access associated traditional knowledge of identifiable origin without obtaining prior informed consent or in disagreement with it.
- Fail to indicate the origin of the associated traditional knowledge of identifiable origin in the publication, utilization, exploitation and promotion of the results obtained from the access.
- Fail to pay the annual instalment due to the National Fund of Benefit-Sharing (FNRB) in relation to the economic exploitation of end product or reproductive material developed from the access to genetic heritage or associated traditional knowledge. The same sanctions are applicable to anyone who discontinues or only partially fulfil the agreed benefit-sharing obligations, whether monetary or non-monetary.
- Produce or present any information, document, study, analysis or report with false or misleading data, whether in the official systems or in any other administrative procedure related to the genetic resource or associated traditional knowledge.



- Fail to comply with orders for the suspension, embargo or interdiction arising from administrative infractions related to genetic heritage or associated traditional knowledge.
- Create difficulties or barriers to the inspection of the obligations established by Law no. 13,123 of 2015
- Fail to fully comply with the terms of this Law after a period of 1 year from the date of the publication of the CGen registry for users who, from June 30, 2000, accessed genetic heritage or associated traditional knowledge and economically exploited end product or reproductive material arising from access to genetic heritage or associated traditional knowledge.
- Fail to fully comply with the terms of this Law after a period of 1 year from the date of the publication of the CGen registry for users who, between June 30, 2000, and November 17, 2015, have accessed genetic heritage or associated traditional knowledge in disagreement with the valid legislation at the time; economically exploited product or process arising from the access; remitted; or published, transmitted or retransmitted data or information that integrate or constitute associated traditional knowledge.
- Fail to comply with the legal dispositions or regulations when notified by the competent authority in the timeframe established

## 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

Yes, Brazil has the following current norms related to this topic:

- **Law No. 13,123, of May 20, 2015:** details the assets, rights and obligations related to:
  - Access to the country's genetic heritage, asset of common use found in in situ conditions, including domesticated species and spontaneous populations, or kept in ex situ conditions, as long as they are also found in in situ conditions in the national territory, continental platforms, territorial waters or exclusive economic zones.
  - Traditional knowledge associated to genetic heritage, relevant to the conservation of biological diversity, the integrity of the country's genetic heritage and the use of its components
  - Access to and transfer of technology related to the conservation and utilization of biological diversity;
  - Economic exploitation of end product or reproductive material arising from access to genetic heritage or associated traditional knowledge.
  - Fair and equitable sharing of benefits derived from the economic exploitation of end product or reproductive material arising from access to genetic heritage and associated traditional knowledge, for the conservation and sustainable use of biodiversity;
  - International remittance of wholes or parts of living or dead organisms of animal, plant or microbial species, or any others, destined to provide access to genetic heritage; and
  - implementation of international treaties on genetic heritage or associated traditional knowledge approved and promulgated by the National Congress.



**Decree No. 8,772, of May 11, 2016:** which regulates Law 13,123/2015, and addresses access to genetic heritage, protection of and access to associated genetic heritage, and benefit-sharing for the conservation and sustainable use of biodiversity.

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

( X ) YES / ( ) NO

Art. 6 of Law 13,123/2015 creates, under the Ministry of the Environment, the Genetic Heritage Management Council - CGen, a collegiate responsible for deliberations, consultations, norms and appeals, responsible for coordinating the drafting and implementation of norms to coordinate the access to genetic heritage and associated traditional knowledge and the benefit-sharing.

The responsibilities of CGen are presented below:

COMPETENCE	DESCRIPTION
To Establish	technical norms; guidelines and criteria for drafting and enforcing benefit-sharing agreements; criteria for the creation of a databank to register information on genetic heritage and associated traditional knowledge; guidelines for the application of the resources destined for FNRB, related to benefit-sharing
To Monitor, in articulation with federal institutions or through partnerships with other institutions, activities of:	access and remittance of samples containing genetic heritage; and access to associated traditional knowledge
To deliberate on:	authorizations for access in legal Brazilian waters, continental platforms or exclusive economic areas; 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 databank.
To certify	a) the regularity of access to genetic heritage or associated traditional knowledge.
To register	inbound notifications of end products or reproductive material; and the presentation of benefit-sharing agreements.
To promote	a) debates and public hearings on the topics related to this Law.
To operate	a) as the high instance of appeal for decisions related to the accreditation of institutions and acts derived from the application of the Law

To create and maintain the relevant databases with	Records of access and remittance of genetic heritage or associated traditional knowledge; Authorizations of access and remittance of genetic heritage or associated traditional knowledge; The instruments and material transfer agreements; The ex situ collections of accredited institutions which include samples of genetic heritage; The notifications on end products or reproductive material; The benefit-sharing agreements; The certificates of regular access.
To inform	a) federal institutions for the protection of the rights of indigenous populations and traditional communities on the available records of access to associated traditional knowledge.
To approve	its internal regulations.

### 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

Article 3 of Law 13,123/2015 establishes that the access to the country's existing genetic heritage or associated traditional knowledge for purposes of research or technological development and economic exploitation of end product or reproductive material arising from the access can only be carried out following their registration, authorization or notification. The registration, however, is not prior to the inception of the research, unless in cases of international remittance, request of any intellectual property rights, commercialization of byproducts, publication of final or partial results in scientific media or means of communication, or notification of end product or reproductive material developed from the access.

The registry is a mandatory self-declaratory system which must be submitted to SisGen. It is important to note that the access to genetic heritage or associated traditional knowledge by foreign-based institutions can only be carried out when associated with a Brazilian national institution of technological and scientific research, whether public or private.

There are some exceptions, such as the case of article 13 of the Law, which requires prior authorization for access to genetic heritage or associated traditional knowledge in areas essential to the national security, which are subject to the approval of the Council of National Defense; and access to genetic heritage or associated traditional knowledge in Brazilian territorial waters, continental platform and exclusive economic zone, which are subject to the approval by the maritime authority. Differently from the registry, the authorization is an administrative act which allows, under specific conditions, the access to genetic heritage or associated traditional knowledge and the remittance 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

Chapter III, of Decree 7,882/2016, addresses associated traditional knowledge (ATK) and article 22 onwards address the registration procedures for access to ATK and genetic heritage;

**To access ATK, the basic procedure should be to:**

Observe if the ATK is of identifiable origin or not.

- if yes, the user must request the prior informed consent (PIC) with the ATK provider;
- if not, the benefit-sharing shall be monetary, to the value of 1% of the net revenue, in favor of FNRB

Besides, the means of access to ATK can be 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 PIC should be obtained as follows:**

- The user must observe the following guidelines to obtain prior informed consent:

Clarifications must be provided to the indigenous population, traditional community or traditional farmer on:

1. The social, cultural and environmental impacts expected to occur from the activity involving the access to associated traditional knowledge;
  2. The rights and responsibilities of each party in performing the activity and obtaining its results;
  3. The right of indigenous populations, traditional communities and traditional farmers to deny access to associated traditional knowledge.
- The preferred means of benefit-sharing, whether monetary or non-monetary, established in partnership with the indigenous populations, traditional community or traditional farmer, in relation to the economic exploitation; and
  - Respecting the rights of the indigenous population, traditional community and traditional farmer to eventually deny access to the associated traditional knowledge during the process of prior consent.

**Types of user:**

- If Brazilian citizen, they should proceed directly to the registration;
- If foreign organization, it is required that they enter a partnership with a national research institution before proceeding to the registration.

**Registration:**

- In order to obtain accreditation for accessing genetic heritage or associated traditional knowledge, the natural person or organization must complete the electronic form of SisGen (National System of Management of Genetic Heritage and Associated Traditional Knowledge)
- By completing the registration form of access and remittance, prior authorization and approval will be automatically requested from the Council of National Defense (National Security areas) or the Navy Command (territorial waters and continental platform), according to each case. The registry of access and remittance cannot be concluded without the agreement of these institutions.

- Once the form is completed, SisGen will automatically issue a certificate of registration of access

**Verification procedure:**

At this stage, the user might request the issuing of a certificate declaring that the respective registries of access and remittance, as well as the notification:

- Did not present evidence of irregularities during the verification process
- Were subjected to a verification process that was later dismissed.

**Purpose of access and benefit-sharing obligation:**

- Scientific research: no benefit-sharing obligation
- Technological development:
  - Byproducts: no benefit-sharing obligation
  - End product: requirement of end product notification.
    - If the technological development of end product has been carried out by traditional farmers and their cooperatives, micro-businesses, small businesses or individual entrepreneurs: no benefit-sharing obligation
    - For users that do not qualify in the category above, it should be noted whether the technological development is the main element that adds value to the product
      - If not, there is no benefit-sharing obligation
      - If yes, it should be noted if the ATK is of verifiable origin or not, and the benefit-sharing is mandatory.

**Means of benefit-sharing:**

- ATK of non-identifiable origin: the benefit-sharing must be in monetary form, to the value of 1% of the net revenue, to be paid to the FNRB.
- ATK of identifiable origin: in this case, the benefits must be shared both with the ATK provider and FNRB.
  - With the provider, the benefit-sharing can be negotiated freely, and it can be either in monetary or non-monetary form. In this case, the Benefit-Sharing Agreement (BSA) must be presented with the notification of the end product
  - The installment due by the user to the FNRB shall correspond to 0.5% of the annual net revenue or half of the value established in the sectorial agreement.

**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

Both the Law and the Decree provide that in order to request to the National Institute of Intellectual Property – INPI the regularization of patents requested during the validity of Provisional Measure No. 2,186-16 of 2001<sup>4</sup>, the applicant must present the certificate of registration or access authorization.

.....

4 This law came before the Law 13.123/2015 and the Decree 7.882/2016.

The Decree establishes that before requesting any intellectual property rights, it is necessary to register with SisGen. The user must update their records or notifications at least once a year to include the information related to the request of intellectual property rights or licensing of patents.

In order to make the notification of end product or reproductive material derived from access to genetic heritage or associated traditional knowledge, the electronic form of SisGen will request the protocol number of the request of intellectual property rights of the product or culture with the Ministry of Agriculture, Livestock and Food Supply, or INPI, or patent offices abroad.

Also, when requesting intellectual property rights, the user must inform if there was any access to genetic heritage or associated traditional knowledge, as well as if there is a registry of access under the terms of the Decree. If it is verified that no such registry exists or that it has been cancelled, Ibama or CGen will notify INPI so they can inform the applicant of the intellectual property rights to present the certificate of registry within 30 days, under penalty of closing the case of the request for intellectual property right.

Finally, if the user requesting intellectual property rights has economically exploited the end product or reproductive material, or published any final or partial results in scientific media or means of communication between November 17, 2015 and November 6, 2017, they must register the activities of access, remittance and shipping; and make a notification of end product or reproductive material developed from the access.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

There are no specific norms for that purpose. However, a technical note specifically related to that department has been approved in relation to exemptions of benefit-sharing obligations in cases where the genetic heritage component is not one of the main elements that add value to the product. It is the OT No. 2/2017.

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

( ) YES / ( X ) NO

There are no specific norms for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( X ) YES / ( ) NO

Yes, benefit-sharing is mandatory when there is access to genetic heritage or traditional knowledge associated to the genetic heritage.

The benefit-sharing from the access to associated traditional knowledge shall be made according to the dispositions listed under item 2.4

As for the benefit-sharing arising from access to genetic heritage, it should be carried out as follows:

- First, it must be observed if the genetic heritage (GH) to be accessed is found in in situ conditions, including domesticated species and spontaneous populations that have developed their own distinctive characteristics in the national territory, or kept in ex situ conditions, as long as they are also found in in situ conditions in the national territory, continental platforms, territorial waters or exclusive economic zones.
  - If the GH does not fit into any of these categories, there is no need for the user to register the access
  - If the GH to be accessed does fall into one of the categories described above, the user must proceed with the registration.
- After that, one must note the type of activity to be performed by the user, with the following activities requiring registration:
  - Access to genetic heritage or associated traditional knowledge in the country by national organization, either public or private, or natural persons.
  - Access to genetic heritage or associated traditional knowledge by foreign-based organization associated with national institution of technological and scientific research, whether public or private;
  - Access to genetic heritage or associated traditional knowledge performed abroad by national organization, either public or private, or natural persons;
  - International remittance of samples of genetic heritage for the purpose of access; and
  - Shipment of samples containing genetic heritage by a national organization, either public or private, with the purpose of providing services abroad as part of technological development or research.
- The Law and the Decree include a few exceptions to the obligations established in their dispositions, which can be found under article 4 of Law 13,123/2015 and articles 3 and 107 of Decree 7,882/2016.
- Types of user:
  - If Brazilian national, they should proceed directly to the registry
  - If foreign organization, they need to enter a partnership with a national research institution before proceeding to the registry
- Registry:
  - In order to register the access to genetic heritage or associated traditional knowledge, the national organization or natural person must complete the electronic form of SisGen (National System for the Management of Genetic Heritage and Associated Traditional Knowledge)
  - The completion of the registry of access to genetic heritage or associated traditional knowledge includes an automatic request of prior authorization and approval by the National Defense Council (National Security Area) or the Navy Command (legal waters and conti-

mental platform), according to each case. The registry of access and remittance cannot be concluded without the approval of these institutions.

- Once the form is completed, SisGen will automatically issue proof of registration of access. From that, the user can request a certificate of compliance with CGen.
- Verification procedure:
  - At this stage, the user might request the issuing of a certificate declaring that the respective registries of access and remittance, as well as the notification:
    - Did not present evidence of irregularities during the verification process
    - Were subjected to a verification process that was later dismissed.
- Purpose of access and benefit-sharing obligation:
  - Scientific research: no benefit-sharing obligation
  - Technological development:
  - Byproducts: no benefit-sharing obligation
  - End product: need of end product notification.
    - If this technological development of end product was made by traditional farmers and their cooperatives, micro-businesses, small businesses or individual entrepreneurs: no benefit-sharing obligation
    - For users that do not fit in the hypotheses mentioned above, it should be noted if the technological development is the main element that adds value to the product
      - If not, there is no benefit-sharing obligation
      - If yes, it should be noted if the ATK is of verifiable origin or not, and the benefit-sharing is mandatory.
- Main element that adds value to the product:
  - These are elements whose presence in the end product is essential to the existence of its functional characteristics or to create its market appeal:
    - Market appeal: reference to genetic heritage or associated traditional knowledge, its precedence or the distinctive features arising from it, related to a product, line of products or brand, in any means of visual or audio communication, including marketing campaigns, or highlights in the product's label; and
    - Functional characteristics: characteristics that determine the main purpose of the product, improve its action or broaden their list of usages.
- After all these stages, the benefit-sharing can be carried out in the following modalities:
  - Monetary: to the amount of 1% of the net revenue (or sector agreement), to be deposited in favor of FNRB. In this case it will be a decision of the user to make a benefit-sharing agreement (BSA) or to deposit it directly to the Fund.
  - Non-monetary: according to article 19, item II of Law 13,123/2017, a benefit-sharing agreement must be signed with the Union, plus:
    - 0.75% of the amount established for the monetary benefit-sharing in cases of:
      - Projects for the conservation or sustainable use of biodiversity or for the pro-

tection and maintenance of knowledge, innovations or practices of indigenous populations, traditional communities or traditional farmers, preferentially in the location where the species are found in situ or where the sample has been obtained in cases where the original location cannot be specified;

- Capacity-building of human resources on topics related to conservancy and the sustainable use of genetic heritage or associated traditional knowledge; and
- Free distribution of products in programs of social relevance.
- 1% for the following initiatives, among others:
  - Technology transfer
  - Availability of the product in public domain, without protection by intellectual property rights or technological restrictions; and
  - Licensing of products free of charge.
- Sector agreements to reduce the values of the benefit sharing:
  - It is a contractual act signed between the public power and the users of biodiversity to reduce the value of the benefit-sharing.
  - According to the requirements and procedures described under articles 56 to 69, the Union may sign a sector agreement with the users, allowing them to reduce the value of the monetary benefit-sharing up to 0.1% of the annual net revenue obtained from the economic exploitation of the end product or reproductive material derived from the access to genetic heritage or associated traditional knowledge of non-identifiable origin.
- The exemptions to the benefit-sharing obligations are listed under article 54 of Decree 7,882/2016.

## **2. 9. Does the current legislation establish procedures for the shipment of samples?**

( X ) YES / ( ) NO

For remittance, the user must obtain prior registration with SisGen observing the dispositions listed under items 2.4 and 2.8. In order to do that, it is necessary to sign a Material Transfer Agreement – MTA between the national organization or natural person and the foreign-based institution. It is also necessary to present the prior informed consent expressly authorizing the remittance in case of genetic heritage of local or creole traditional variation or locally adapted race or creole for access related to in non-agricultural activities, when applicable.

With the signature of the MTA, the receiver of the remittance abroad is obliged to:

- Partner with a Brazilian national institution of technological and scientific research;
- Register the technological development and research activity carried out with the object of the MTA;
- Register the technological development or research prior to requesting any intellectual property rights, or commercializing any byproducts, or publishing final or partial results in scientific media or means of communication, or the notification of end product or reproductive material developed from the access;



- Notify the SisGen and share the benefits arising from the economic exploitation of end product or reproductive material developed; and
- Obtain prior informed consent from the provider, when dealing with research or technological development related to traditional knowledge associated to the samples which are object of the MTA.

Once the form is completed, SisGen will automatically issue a proof of registry of the remittance, which is the working document to demonstrate that the user has provided the requested information, effectively establishing the beginning of the administrative verification process (which the user does not need to wait to be completed in order to proceed with the remittance)

The remittance can be effectively carried out, under the terms of the law, following the registry made prior to the remittance, or the request of intellectual property rights, or the commercialization of any byproducts, or publication of any final or partial results in scientific media or means of communication, or the notification of end products or reproductive material developed from the access. Besides the proof of registry of the remittance, the samples must be accompanied by the respective MTA to be regularly remitted.

It must be highlighted that, for the cases of article 13 of Law 13,123/2001, regarding access to genetic heritage or associated traditional knowledge in areas indispensable for national security (border zones and ocean islands), in Brazilian territorial waters, continental platform and exclusive economic zone, users wishing to make a remittance of material must identify all corporate board members of the company and associated institutions, according to their case, in addition to all already mentioned requirements. In the hypothesis that the corporate board is composed by other companies, the user must identify their respective corporate board members, until all individuals in the quality of shareholders or controllers have been identified. They must also obtain prior authorization and approval from the Council of National Defense or Navy Command, according to each case.

In addition, the “remittance” shall be considered “shipment of sample” in cases where the shipment of genetic heritage has the purpose of providing services abroad<sup>5</sup> as part of a research or technological development in which the user responsible for the sample has carried out the access in Brazil. As with the remittance, the shipment of samples must be registered with SisGen, although it is not necessary to do that in advance.

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<sup>5</sup> According to Decree 8,772/2016, the provision of services abroad is understood as the execution of tests or specialized technical activities performed by the partner institution of the national organization responsible for the access of hired by it, following payment or compensation.

## Websites Of Interest

### **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>

## Summary – Competent Authorities

Authority	Competence
Genetic Heritage Management Council	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.

## Bibliographical References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Brazil profile. Available in: <https://absch.cbd.int/countries/AL> Access in 09/11/2017.

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](http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2016/decreto/D8772.htm) Access in 09/11/2017.

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](http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Lei/L13123.htm) Acesso em 09/11/2017. Access in 09/11/2017.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Brazil profile. Available in: <https://www.cbd.int/countries/?country=al> 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.

IBAMA. Fiscalização Ambiental. Available in: [http://www.ibama.gov.br/index.php?option=com\\_content&view=article&id=825&Itemid=751#quemfiscaliza](http://www.ibama.gov.br/index.php?option=com_content&view=article&id=825&Itemid=751#quemfiscaliza) Access in 09/11/2017.

## 1. General Information

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

YES /  NO

Yes, Canada has been a Party to the Convention on Biological Diversity, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, Canada is not a party to the Nagoya Protocol.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

1 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>.

2 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>.

3 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 was not possible to identify during the survey an official inspection body specifically dedicated to monitoring access activities in the country, and neither was there evidence of application of fines.

**1.7 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

As mentioned in item 2.1, the country lacks the legal framework on access to genetic resources and associated traditional knowledge. Therefore, it was not possible to identify any sanctions against irregular access. However, as clarified by the National Focal Point, this does not mean that certain activities related to access with natural resources 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.

## 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

The country still lacks the legal framework on access to genetic resources and associated traditional knowledge. Therefore, at present there is no legal framework in Canada specifically related to ABS.

However, since 2004, the country has been engaging in a series of cross-sector and cross-government consultations, workshops and several other activities seeking to develop an ABS policy for all the Canadian territory. In 2005, Canada issued a document called: ABS Policies in Canada Outlining issues and problems. This was followed by a 2006 document called Guiding Principles and Features of ABS Policies in Canada (OGUAMANAN, 2009. p. 146).

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 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 peoples 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

As mentioned in item 2.1, the country does not have any legislation on access and benefit sharing, and neither does it have a national competent authority/institution.

## **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

As mentioned in item 2.1, the country still lacks the legal framework on access to genetic resources and associated traditional knowledge.

On the other hand, 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.

With regard to 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, requiring 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

As mentioned in item 2.1, the country still lacks the legal framework on access to genetic resources and associated traditional knowledge. However, as reported by the National Focal Point, there are several applicable procedures and guidance documents for access to the CTA:

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 (eg 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 /  NO

As mentioned in item 2.1, the country still lacks the legal framework on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for gaining access to genetic heritage in activities performed on behalf the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

As mentioned in item 2.1, the country still lacks the legal framework on access to genetic resources and associated traditional knowledge.

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.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country still lacks the legal framework on access to genetic resources and associated traditional knowledge.

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.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country still lacks the legal framework on access to genetic resources and associated traditional knowledge.

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.

### 3. Websites Of Interest

#### **National CHM**

<http://www.biodivcanada.ca>

#### **Canadian Biodiversity Information Facility**

<http://www.scib.gc.ca>

#### **National Environment Management Council**

<http://www.nemc.or.tz/>

### 4. Summary – Competent Authorities

As mentioned in item 2.3., Canada does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

##### **Mr. Basile van Havre**

ABS National Focal Point

+1 819 938 3935

[basile.vanhavre@canada.ca](mailto:basile.vanhavre@canada.ca)

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Director General, Domestic and International Biodiversity Policy

Canadian Wildlife Service

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Canada

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Canada profile. Disponível em: <https://absch.cbd.int/countries/CA> Acesso em 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Canada profile. Disponível em: <https://www.cbd.int/countries/?country=ca> Acesso em 18/10/2016.

Federal/Provincial/Territorial Working Group on Access and Benefit Sharing of Genetic Resources and Associated Traditional Knowledge (2005). **ABS Policies in Canada: Scoping the Questions and Issues**. Environment Canada, Ottawa. *Apud*: OGUAMANAM, Chidi. **Canada: Time to take access and benefit sharing over genetic resources seriously**. Canadá: HeinOnline, 2009. Disponível em: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2283254](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2283254) Acesso em 18/10/2016.

GOVERNMENT OF CANADA. **A Biodiversity Outcomes Framework for Canada**. Disponível em: <https://www.cbd.int/countries/?country=ca> Acesso em 18/10/2016.

GOVERNMENT OF CANADA. **Access to Genetic Resources and Benefit-sharing: Canadian Perspectives**. Environment Canada. Tokyo, 2007. Disponível em: [http://www.mabs.jp/archives/jba/pdf/007/5\\_seel.pdf](http://www.mabs.jp/archives/jba/pdf/007/5_seel.pdf). Acesso em 18/10/2016.

GOVERNMENT OF CANADA. **Access to Genetic Resources and Sharing of Benefits of their use in Canada: Opportunities for a New Policy Direction**. Disponível em: [http://www.biodiv-canada.ca/1AB19CC4-9C19-44B6-972B-42243654600B/accessing\\_genetic\\_e.pdf](http://www.biodiv-canada.ca/1AB19CC4-9C19-44B6-972B-42243654600B/accessing_genetic_e.pdf) Acesso em 18/10/2016.

GOVERNMENT OF CANADA. **Canada's 5th National Report to the Convention on Biological Diversity**. Disponível em: <https://www.cbd.int/countries/?country=ca> Acesso em 18/10/2016.

GOVERNMENT OF CANADA. **Northern Workshop on Access to Genetic Resources and Associated Traditional Knowledge and Benefit-Sharing**. Environment Canada. Whitehorse, 2005. Disponível em: <https://www.cbd.int/financial/bensharing/canada-workshop.pdf> Acesso em 18/10/2016.

SHARIFF, Nashina. **Access and Benefit-Sharing and the Nagoya Protocol**. Environment Canada, 2015. Disponível em: [http://www.landclaimscoalition.ca/assets/Nashina\\_Shariff.pdf](http://www.landclaimscoalition.ca/assets/Nashina_Shariff.pdf) Acesso em 18/10/2016. Acesso em 18/10/2016.



## 1. General Information

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

YES /  NO

Yes, Chile has been a Party to the CDB, by ratification, since Dec 28, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Chile has not signed and is not a party to the Nagoya Protocol.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in Chile.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

The country does not have a specific legislation regarding access to genetic heritage and associated traditional knowledge in the country.

However, it is important to emphasize that the country has the Industrial Property Law (Law 19.039), whose text had been reformulated, coordinated and systematized by the Decree with Force of Law No. 3 of March 9, 2006 (ID of the norm: 25078. The referred Decree, in its article 3, stipulates that the protection granted to industrial property rights regulated by it shall be granted while safeguarding and respecting both the biological and genetic heritage as well as the national traditional knowledge. It also emphasizes that the granting of industrial property rights which constitute protective elements that have been developed from material obtained from the referred heritage or the referred knowledge, shall be subject that this material has been acquired in accordance with the current legal system.

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

YES /  NO

No official competent institutions were found concerned with access and benefit-sharing under the terms 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 /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Although there is no law concerning access to genetic resources and associated traditional knowledge in the country, it is known that the Government has already entered into some access and benefit sharing agreements, but there is no template or contract models or standard definitions of benefit sharing, and each of them have been negotiated and outlined under the terms of the contract.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites of Interest

**National CHM:**

<http://www.mma.gob.cl/biodiversidad/1313/w3-channel.html>

**Ministry of Environment – Chile:**

<http://www.mma.gob.cl/1257/w3-channel.html>

## 4. Summary – Competent Authorities

As mentioned in item 2.3., Chile does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### Nagoya Protocol on Access and Benefit-sharing

#### Sr. Vicente Paeile Marambio

ABS National Focal Point  
+56 2 25735821  
vpaeile@mma.gob.cl

División de Recursos Naturales, Residuos y Evaluación de Riesgo  
Ministerio del Medio Ambiente  
San Martín 73  
Santiago

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Chile profile. Disponible em: <https://absch.cbd.int/countries/CL> Acceso em 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Chile profile. Disponible em: <https://www.cbd.int/countries/?country=cl> Acceso em 18/10/2016.

GOBIERNO DE CHILE. **Decreto con Fuerza de Ley nº 3. de 9 de marzo de 2006 (ID de la norma: 25078)**. Disponible em: <http://www.leychile.cl/Navegar?idNorma=5036> Acceso em 18/10/2016.

GOBIERNO DE CHILE. **Estrategia Nacional de Biodiversidad**. Comisión Nacional del Medio Ambiente. 2003. Disponible em: <https://www.cbd.int/countries/?country=cl> Acceso em 18/10/2016.

GOBIERNO DE CHILE. **Ley Nº 19.039 sobre Propiedad Industrial (Texto Refundido de 26 de enero de 2007, aprobado por Decreto con Fuerza de Ley Nº 30)**. Disponible em: <http://www.wipo.int/wipolex/en/details.jsp?id=5324> Acceso em 18/10/2016.

GOBIERNO DE CHILE. **Quinto Informe Nacional De Biodiversidad De Chile**. Ministerio del Medio Ambiente. 2014. Disponible em: <https://www.cbd.int/countries/?country=cl> Acceso em 18/10/2016.

MANZUR, Maria Isabel; DIAZ, Carolina Lasén. **ACCESO A RECURSOS GENÉTICOS: CHILE EN EL CONTEXTO MUNDIAL**. 2003. Disponible em: [http://www.inia.cl/recursosgeneticos/descargas/ Acceso\\_RRGG\\_Chile.pdf](http://www.inia.cl/recursosgeneticos/descargas/ Acceso_RRGG_Chile.pdf) . Acceso em 24/11/2016

# Colombia

## 1. General Information

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

YES /  NO

Yes, Colombia has been a Party to the CBD, by ratification, since Feb 26, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Colombia is a signatory (from Feb 2, 2011) but it is not a party to the Nagoya Protocol.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

Yes. Article 16 of Law 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, Bio-

.....  
1 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>.

2 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>.

3 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.

diversity and Ecosystem Resources is responsible for “enforcing preventive and punitive sanctions on matters under their competence”.

It is worth-reminding that, according to Article 16, item 14, the referred institution is responsible for “dealing with procedures related to requests for access to genetic resources, accepting or denying such requests, deciding on initial appeals and approving their corresponding contracts”.

Thus, Resolution No. 6,200 of 1997 established that the Office of the Vice-Minister is responsible for supervising and enforcing the conditions included in access contracts and the dispositions of Decision 391, as well as establishing the relevant monitoring and assessment mechanisms.

As for the records of fine application, no concrete cases were found during the survey.

### **1.7 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

As per 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 synthesized 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.

In Andean Resolution 391 there is no indication of value for the fines.

It is important to note that Article 16, item 16, of Law 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”, although there is no explicit indication or specification of which sanctions are those in the referred article.

## **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

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.

Domestically, the following legislation is applicable in Colombia regarding access to genetic resources and related affairs:

- Decree No. 1,687 of June 27, 1997 – establishes the responsibilities of the different departments of the Ministry of Environment;
- Decree 309 of February 25, 2000 – regulates scientific research on biological diversity;
- Decree No. 730 of March 14, 1997 – establishes the National Competent Authority on matters of access to genetic resources;
- Resolution 1,348 de 2014 – establishes the activities that configure access to genetic resources and its by-products for the due application of Andean Decision 381 of 1996 in Colombia;
- Decree 1,375 of June 27, 2013 – regulates biological collections<sup>4</sup>;
- Decree 1,376 of 2013 – regulates collection permits of wild species from the biological diversity for the purpose of non-commercial scientific research
- Law 99 of December 22, 1993 – Colombia’s General Environmental Law;
- Law 165 of November 9, 1994 – approves the Convention 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;
- 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.

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

( X ) YES / ( ) NO

Article 1 of Decision 391 of the Andean Pact defines as National Competent Authority:

*State entity or public institution appointed by each Member Country, 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 this common regime and to ensure their performance.*

In this sense, Article 50 establishes that the Member Countries of the Andean Community should establish a National Competent Authority, according to the capacities and attributions listed in

items ‘a’ to ‘p’ of this article. Furthermore, the set of directors from these National Competent Authorities (group formed of directors from each member country) shall assemble to compose the Andean Committee on Genetic Resources, described under subsection XI of article 51 of Resolution 391.

In agreement with the Andean Pact, Law 99 of 1993 establishes in Article 5, item 21, that it is the role of the Ministry of Environment and Sustainable Development:

*To regulate, under the terms of the law, the acquisition, use, management, investigation, import, export, commerce and distribution of genetic strains and species of wild flora and fauna; to regulate 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.*

More specifically, Decree 730 of 1997, in Article 1, establishes that the Ministry of Environment will act as the National Competent Authority under the terms and with the effects of Decision 391 of the Andean Community. In 2011, the objectives and the structure of the Ministry of Environment and Sustainable Development were modified by Law 3,570. It should be noted that the following institutions received responsibilities related to access and benefit sharing:

- 
- Sub-directorate of Education and Participation;
- 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);
- 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).

As for Resolution 620 of 1997, it delegates some functions of Decision 391 of the Commission of the Cartagena Agreement (Andean Pact), and establishes the internal procedures for processing requests for access to genetic resources and their by-products. From this legal instrument, the Office of the Vice-Minister for the Environment and the Legal Department received a number of functions, including:

Office of the Vice-Minister for the Environment	Legal Department
To evaluate access requests in the due term.	To receive access requests along with the relevant documents and information.
To issue a joint technical opinion with the legal department on the suitability or not of access requests	To offer an initial analysis of access requests to determine whether or not it is complete, and to request any missing information and documentation



To coordinate, supported by the legal department, the necessary steps for negotiating the signature of access contracts	To issue the order through which the access request to the genetic resources can be approved and the due procedures can be initiated.
To supervise and control the fulfillment of the conditions detailed in the access contracts and in the dispositions of Decision 391, and to establish the necessary mechanisms of monitoring and evaluation	To create and maintain up to date the Registry of Access to Genetic Resources and their by-products

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

YES / ( ) NO

Yes. Article 16 of Resolution 391 of the Andean Pact establishes that:

*All access procedures shall require the presentation, admittance, publication and approval of an application, the signing of a contract, the issuing and publication of the corresponding Resolution and the declarative registration of the acts connected with that access.*

Articles 26 and 30 of the aforementioned decision establish the procedures for requesting access authorizations. According to article 46, anyone who performs access activities without the respective authorization shall be liable for sanctions.

In the same lines as Article 16 of Resolution 391, Decree 309 of 2000, which sets out the regulations governing scientific research on biological diversity, establishes in Article 2 that any natural or legal persons wishing to develop a scientific research project on the Colombian biodiversity involving any activities of collection, recollection, capture, hunting, fishing or manipulation of biological resources within Colombian territory must obtain permission for the study.

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

( ) YES /  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 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.

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 of 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?**

YES /  NO

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 synthesized 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."

Decision 486/01, also 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. According to Article 1 of Resolution 66,200 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, for information only, 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for gaining access to genetic heritage in activities performed on behalf the perfume, personal hygiene and cosmetic industries.

## **2.7. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?**

( ) YES / ( X ) 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 in 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.

## **2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( X ) YES / ( ) NO

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”.

The only article of Andean Decision 1,391 that deals with the benefit-sharing requirement is article 35, which establishes as follows:

*Art. 35 – When access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of the contract, an annex stipulating the fair and equitable distribution of the profits from use of that component.*

*The annex shall be signed by the supplier of the intangible component and the applicant for the access. It may also be signed by the National Competent Authority, in accordance with the provisions of national law of the Member Country. If that annex is not signed by the National Competent Authority, it shall be subject to the suspensive condition referred to in Article 42 of this Decision. Failure to comply with the stipulations of the annex shall constitute grounds for the rescission and nullification of the access contract.*

Furthermore, 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 acknowledgment of rights or royalties owed to the country for the use of its genetic resources (article 9, item 11).

Although there is no express provision of form and values, or any specification of the applicability of benefit-sharing, on the website of the Ministry of Environment there is a list issued by the Directorate of Forests, Biodiversity and Ecosystem Resources of the projects that already have approved contracts of access to genetic resources in the country. It is important to highlight that, there are specific contracts for research within the cosmetic industry. The website also offers a model document for requesting access to the Colombian genetic resources.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

Decision 391 of the Andean Community does not mention the shipment of genetic resources, but there is one occasion, in the fourth complimentary disposition, in which it establishes that the health certificates supporting the exportation of genetic resources shall include, according to Decision 328 of the Commission, the following phrase: “Use as genetic resource NOT authorized”.

As for 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.

## 3. Websites Of Interest

### **National CHM**

<http://co.chm-cbd.net>

### **Instituto Humboldt**

<http://co.chm-cbd.net/es/>

### **Ministério do Meio Ambiente e Desenvolvimento Sustentável**

<https://www.minambiente.gov.co/index.php>

## 4. 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
Directorate of Forests, Biodiversity and Ecosystem Resources	Deal with procedures related to requests for access to genetic resources, accepting or denying such requests, deciding on initial appeals received and approving their corresponding contracts.

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Colombia profile. Disponível em: <https://absch.cbd.int/countries/CO> Acesso em 05/11/2016.

COMUNIDAD ANDINA. **Decisión N° 391 que establece el Régimen Común sobre Acceso a los Recursos Genéticos.** Disponível em: <http://www.wipo.int/wipolex/es/details.jsp?id=9446> Acesso em 18/10/2016.

COMUNIDAD ANDINA. **Decisión N° 486 que establece el Régimen Común sobre Propiedad Industrial.** Disponível em: <http://www.wipo.int/wipolex/es/details.jsp?id=9451> Acesso em 18/10/2016.

COMUNIDAD ANDINA. **Decisión N° 423 sobre Modificación de la Octava Disposición Transitoria de la Decisión 391 sobre Régimen Común sobre Acceso a los Recursos Genéticos.** Disponível em: <http://www.wipo.int/wipolex/es/details.jsp?id=9455> Acesso em 18/10/2016.

COMUNIDAD ANDINA. **Decisión N° 448 de 11 de Diciembre de 1998 - Modificación de la Octava Disposición Transitoria de la Decisión 391: Régimen Común sobre Acceso a los Recursos Genéticos.** Disponível em: <http://www.wipo.int/wipolex/es/details.jsp?id=9456> Acesso em 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Colombia profile. Disponível em: <https://www.cbd.int/countries/?country=co> Acesso em 05/11/2016.

GOBIERNO DE COLOMBIA. **Decreto N° 1.375 - Reglamenta las colecciones biológicas.** Disponível em: <https://www.ecolex.org/details/legislation/decreto-no-1375-reglamenta-las-colecciones-biologicas-lex-faoc125535/> Acesso em 05/11/2016.

GOBIERNO DE COLOMBIA. **Decreto N° 1.376 - Reglamenta el permiso de recolección de especímenes de especies silvestres de la diversidad biológica con fines de investigación científica no comercial.** Disponível em: <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-fines-de-investigacion-cientifica-no-comercial-lex-faoc125537/> Acesso em 05/11/2016.

GOBIERNO DE COLOMBIA. **Decreto N° 1.687 - Se fusionan unas dependencias del Ministerio del Medio Ambiente.** Disponível em: <https://www.ecolex.org/details/legislation/decreto-no-1687-se-fusionan-unas-dependencias-del-ministerio-del-medio-ambiente-lex-faoc024988/?q=Decreto+n%C2%BA+1.687+> Acesso em 05/11/2016.

GOBIERNO DE COLOMBIA. **Decreto N° 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.** Disponível em: <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=* Acceso em 05/11/2016.

GOBIERNO DE COLOMBIA. **Decreto N° 309 - Reglamenta la investigación científica sobre diversidad** biológica. Disponível em: <https://www.ecolex.org/details/legislation/decreto-no-309-reglamenta-la-investigacion-cientifica-sobre-diversidad-biologica-lex-faoc019644/?q=Decreto+309> Acceso em 05/11/2016.

GOBIERNO DE COLOMBIA. **Decreto N° 730 - Determina la autoridad nacional competente en materia de acceso a los recursos genéticos.** Disponível em: <https://www.ecolex.org/details/legislation/decreto-no-730-determina-la-autoridad-nacional-competente-en-materia-de-acceso-a-los-recursos-geneticos-lex-faoc024858/?q=Decreto+730+> Acceso em 05/11/2016.

GOBIERNO DE COLOMBIA. **Ley N° 165 De 1994 (Noviembre 9) Diario Oficial No. 41.589, de 9 de noviembre de 1994 Por medio de la cual se aprueba el “Convenio sobre la Diversidad Biológica”, hecho en Río de Janeiro el 5 de junio de 1992.** Disponível em: [http://www.minambiente.gov.co/images/BosquesBiodiversidadyServiciosEcosistemicos/pdf/Politica-Nacional-de-Biodiversidad/3355\\_ley\\_0165\\_091194.pdf](http://www.minambiente.gov.co/images/BosquesBiodiversidadyServiciosEcosistemicos/pdf/Politica-Nacional-de-Biodiversidad/3355_ley_0165_091194.pdf) Acceso em 05/11/2016.

GOBIERNO DE COLOMBIA. **Ley N° 99 - Crea el Ministerio del Medio ambiente y los recursos naturales renovables y se organiza el Sistema Nacional Ambiental (SINA).** Disponível em: [https://www.ecolex.org/details/legislation/ley-no-99-crea-el-ministerio-del-medio-ambiente-y-los-recursos-naturales-renovables-y-se-organiza-el-sistema-nacional-ambiental-sina-lex-faoc003962/?q=ley+n%C2%BA.+99&xcountry=Colombia&xdate\\_min=&xdate\\_max=&leg\\_type\\_of\\_document=Legislation](https://www.ecolex.org/details/legislation/ley-no-99-crea-el-ministerio-del-medio-ambiente-y-los-recursos-naturales-renovables-y-se-organiza-el-sistema-nacional-ambiental-sina-lex-faoc003962/?q=ley+n%C2%BA.+99&xcountry=Colombia&xdate_min=&xdate_max=&leg_type_of_document=Legislation) Acceso em 05/11/2016.

GOBIERNO DE COLOMBIA. **Resolución N° 1.348 De 14 De Agosto De 2014 Que Establece Las Actividades Que Configuran Acceso A Los Recursos Genéticos Y Sus Productos Derivados Para La Adecuada Aplicación De La Decisión 391 De 1996 De La Comisión De La Comunidad Andina En Colombia.** Disponível em: [http://legal.legis.com.co/document?obra=legcol&document=legcol\\_0868ecde3dde00c2e0530a01015100c2](http://legal.legis.com.co/document?obra=legcol&document=legcol_0868ecde3dde00c2e0530a01015100c2) Acceso em 05/11/2016.

GOBIERNO DE COLOMBIA. Resolución N° 620 - Procedimientos para los avalúos ordenados dentro del marco de la Ley N° 388 de 1997, Normas sobre planes de desarrollo municipal, compraventa y expropiación de bienes. Disponível em: [https://www.ecolex.org/details/legislation/resolucion-no-620-procedimientos-para-los-avaluos-ordenados-dentro-del-marco-de-la-ley-no-388-de-1997-normas-sobre-planes-de-desarrollo-municipal-compraventa-y-expropiacion-de-bienes-lex-faoc130737/?q=620&xcountry=Colombia&xdate\\_min=&xdate\\_max=](https://www.ecolex.org/details/legislation/resolucion-no-620-procedimientos-para-los-avaluos-ordenados-dentro-del-marco-de-la-ley-no-388-de-1997-normas-sobre-planes-de-desarrollo-municipal-compraventa-y-expropiacion-de-bienes-lex-faoc130737/?q=620&xcountry=Colombia&xdate_min=&xdate_max=) Acceso em 05/11/2016.

GOBIERNO DE COLOMBIA. **V Informe Nacional De Biodiversidad De Colombia Ante El Convenio De Diversidad Biológica.** Ministerio De Ambiente y Desarrollo Sostenible, 2014. Disponível em: <https://www.cbd.int/countries/?country=co> Acceso em 05/11/2016.

REPUBLICA DE COLOMBIA. **Política Nacional para la Gestión Integral de la Biodiversidad y sus Servicios Ecosistémicos (PNGIBSE)**. Ministerio De Ambiente y Desarrollo Sostenible. Disponible en: <https://www.cbd.int/countries/?country=co> Acceso em 05/11/2016.

## 1. General Information

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

YES /  NO

Yes, Costa Rica has been a Party to the Convention on Biological Diversity, by ratification, since Nov 24, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, Costa Rica is not a party to the Nagoya Protocol, but is signatory, since July 06, 2011.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.



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.

### **1.7 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

The offenses against Costa Rican 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.

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

( X ) YES / ( ) NO

The country has the following rules that regulate the activities related to access and benefit sharing:

- Act No. 7317, 1992 - Wildlife Conservation Act (Ley nº 7317, 1992 - Ley de Conservación de la Vida Silvestre);
- Law No. 7554, 1995 - Organic Law of the Environment (Ley Nº 7554, 1995 - Ley Orgánica del Ambiente);
- Law No. 7788, 1998 - Biodiversity Law (Ley Nº 7788, 1998 - Ley de Biodiversidad);
- Decree No. 31.514-MINAE, 2003 - General standards for Access to Genetic and Biochemical Elements and Resources of Biodiversity (Decreto Nº 31.514-MINAE, 2003 - Normas generales para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad);
- Decree No. 33.697-MINAE, 2007 - Regulation for Access to Genetic and Biochemical Elements and Resources of Biodiversity in ex situ conditions (Decreto nº 33.697-MINAE, 2007 - Reglamento para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad en condiciones ex situ);
- Law No. 8631, 2008 - Law on Protection of Plant Varieties (Ley nº 8631, 2008 - Ley de Protección de las Obtenciones Vegetales);
- 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 nº 34.958-MINAE-COMEX, 2008 – Reglamento al Artículo 80 de la Ley de Biodiversidad);
- Law No. 8,632-MINAE, 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);
- Decree No. 39.118-MINAE, 2015 - National Biodiversity Policy (Decreto Nº 39.118-MINAE, 2015 - Política Nacional de la 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 N° 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).

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 biodiversidade).

Finally, it should be noted that there is evidence that Decree No. 31,514-MINAE, 2003 can be amended. The draft of a Decree amending Decree No. 31.514-MINAE is available on the internet for public consultation, however no evidence has been found that said document has been approved, modified or rejected.

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

( X ) YES / ( ) NO

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:

- 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.
- 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, CONAGEBIO is renamed “Competent National Authority”. In addition, Article 5 establishes 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;
- Organize and maintain updated access request registration;
- 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

Yes, access to genetic and biochemical resources or traditional knowledge associated with these resources in the country can only be done from a request for access and the consequent receipt of an authorization from the Technical Office of CONAGEBIO, according to article 69 of Law No. 7788, 1998 - Biodiversity Law. In this sense, Article 63 provides that basic requirements for access are:

- Prior informed consent;
- The ratification of this consent by the Technical Office of CONAGEBIO;
- The terms of technology transfer and equitable sharing of benefits, where applicable, agreed in the authorizations, agreements and concessions, as well as the type of associated knowledge protection required by the representatives of the place where access will occur;
- Definition of how these activities will contribute to the conservation of species and ecosystems;
- The designation of a legal representative residing in the country, in the case of natural or legal persons domiciled outside the country.

The form, content of the applications, expiration date and characteristics are described in Section II "Permits of Access to the Elements of Biodiversity", and according to article 76 of this Section, the authorization applicant has an obligation to pay the System National Conservation Areas, indigenous territory or the private owner of the sample of the genetic resource to be accessed up to 10% of the value of scientific research and up to 50% of royalties.

With regard to the regulatory decree of the Biodiversity Law, Decree No. 31.514-MINAE, 2003 - General rules for Access to Genetic and Biochemical Elements and Resources of Biodiversity, the procedures for obtaining authorization, concession or access agreements to resources genetic and biochemical aspects of biodiversity are foreseen in section 1. In this sense, article 7 provides that there are 3 types of authorizations: basic research, bioprospecting and commercial economic exploitation. However, the content of the request form (item 1), technical guide (item 2), prior informed consent and mutually agreed conditions (item 3), basic research or bioprospection (item 4) and occasional or constant economic Article 9 of the Decree.

Finally, it is important to emphasize that access to ex situ genetic or biochemical resources has its own rules. Decree No. 33.697-MINAE, 2007 - Regulation for the Access to Genetic and Biochemical Elements and Resources of Biodiversity in ex situ conditions defines in its article 7 that the applicant must use the forms and documents described in articles 8 and 9 of Executive Decree No. 31514-MINAE. In addition, the applicant for access authorization must also undertake to comply with the code of conduct set out in Annex II of said decree.

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

YES /  NO

There are no specific procedures for access to associated traditional knowledge, except that an authorization must be obtained according to item 2.3. of this 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 /  NO

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 cultural 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

The country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

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.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

The fair distribution of the benefits and values denied by the use of Costa Rican 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" Law No. 7788, 1998 - Biodiversity Law. In this sense, Article 76 of this Section determines to the requesting party the payment 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 up to 10% of the value of scientific research and up to 50 % of royalties.

In the same sense, the decree regulating the Biodiversity Law, Decree No. 31.514-MINAE, 2003 - General Rules for Access to Genetic and Biochemical Elements and Resources of Biodiversity, establishes in article 9, item 3 the requirements of mutually agreed terms . The following are the main aspects related to benefit sharing:

- Agreed terms on the equitable sharing of economic, social, scientific, or spiritual environmental benefits, including the possibility of a short, medium and long term commercial profit of any product or by-product derived from the material accessed;

- Approximate estimation of the deadlines for the distribution of benefits;
- Benefit sharing of up to 10% of the research budget or bioprospecting.

The value of 10% is reinforced by item 4 of article 9, which further specifies that this percentage will be established according to the will of the Parties and should be deposited in a bank account or similar indicated by the provider. After the conclusion of the agreement, the Technical Office will give a deadline of 8 days for the researcher or bioprospector to make the deposit.

For cases of access for occasional or constant economic use, article 9, item 5, establishes that the party interested in accessing the genetic or biochemical resources must pay up to 50% of royalties obtained through commercial exploitation, in favor of the National System of conservation areas, local communities or indigenous peoples, rural owners, owners or responsible for the materials maintained in ex situ conditions and where the economic exploitation will materialize. If the applicant for the authorization of access is the owner, the value of up to 50% of royalties must be made in favor of CONAGEBIO

In addition, it is important to emphasize that access to ex situ genetic or biochemical resources has its own regulation. Decree No. 33.697-MINAE, 2007 - Regulation for the Access to Genetic and Biochemical Elements and Resources of Biodiversity in ex situ conditions, emphasizes in article 7 that, in cases where it is possible to determine the origin and origin of the materials that will be accessed from a collection established prior to the commencement of this decree, the benefits may be shared with the original providers thereof.

## **2. 9. Does the current legislation establish procedures for the shipment of samples?**

( X ) YES / ( ) NO

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.

On the other hand, article 10 of Decree 33.697-MINAE, 2007 - Regulation for the Access to Genetic and Biochemical Elements and Resources of Biodiversity in ex situ conditions, specifies that, in cases where there is a claim to refer the elements and genetic and biochemical resources kept in ex situ collections for the purpose of access abroad, the applicant for authorization and access must request a certificate of legal provenance from the Technical Office to accompany at any time the material to be sent, in the same terms of issued by article 19 of Executive Decree No. 31514-MINAE.

In addition, article 17 of Decree 33.697-MINAE, 2007, amended article 22 of Executive Decree No. 31514-MINAE, which established that it is the responsibility of the CONAGEBIO Technical Office to authorize agreements, agreements or material transfer agreements between national or foreign, when the transfer contemplates access to genetic and biochemical elements and resources of the Costa Rican biodiversity. The approval shall follow the provisions of article 10 of Executive



Decree No. 31514-MINAE, as well as articles 63, 64, 65, 69, 70 and 71 of the Biodiversity Law. Finally, it should be noted that Annex I to Decree 33.697-MINAE, 2007 provides a model of the Material Transfer Agreement.

### 3. Websites

**INBio - Instituto Nacional de Biodiversidad - Costa Rica:**

**Minae - Ministerio de Ambiente y Energía de Costa Rica:**

<http://www.minae.go.cr/index.php/es/>

**National CHM:**

<http://www.sinac.go.cr>

**CONAGEBIO:**

<http://www.conagebio.go.cr/Conagebio/public/>

### 4. 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.

### 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Costa Rica profile. Disponível em: <https://absch.cbd.int/countries/CR> Acesso em 22/08/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Costa Rica profile. Disponível em: <https://www.cbd.int/countries/?country=cr> Acesso em 22/08/2016.

COSTA RICA. **Decreto N° 31.514/MINAE - Normas para el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad.** Disponível em: <http://extwprlegs1.fao.org/docs/pdf/cos65121.pdf> Acesso em 22/08/2016.



COSTA RICA. **Decreto N° 33.106/MINAE - Crea el Programa Nacional de Corredores Biológicos: Estrategia de Conservación de la Biodiversidad.** Disponible em: <http://extwprlegs1.fao.org/docs/pdf/cos163437.pdf> Acceso em 22/08/2016.

COSTA RICA. **Decreto N° 33.697/MINAE - Reglamento para el acceso a los elementos y recursos genéticos y bioquímicos de la biodiversidad en condiciones ex situ.** Disponible em: <http://extwprlegs1.fao.org/docs/pdf/cos71597.pdf> Acceso em 22/08/2016.

COSTA RICA. **Decreto N° 34.781/MINAE - Modifica el Decreto N° 34.433/MINAE, Reglamento a la Ley de biodiversidad.** Disponible em: [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=](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=) Acceso em 22/08/2016.

COSTA RICA. **Decreto N° 39.118/MINAE - Política Nacional de la Biodiversidad.** Disponible em: <http://extwprlegs1.fao.org/docs/pdf/cos148813.pdf> Acceso em 22/08/2016.

COSTA RICA. **Decreto N° 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.** Disponible em: <http://extwprlegs1.fao.org/docs/pdf/cos163240.pdf> Acceso em 22/08/2016.

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. Disponible em: <https://www.cbd.int/countries/?country=cr> Acceso em 22/08/2016.

COSTA RICA. **Ley N° 7.788 - Ley de biodiversidad.** Disponible em: <http://extwprlegs1.fao.org/docs/pdf/cos13426S.pdf> Acceso em 22/08/2016.

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. Disponible em: <https://www.cbd.int/countries/?country=cr> Acceso em 22/08/2016.

COSTA RICA. **Ley N° 7.554 - Ley Orgánica del Medio Ambiente.** Disponible em: [https://www.ecolex.org/details/legislation/ley-no-7554-ley-organica-del-medio-ambiente-lex-faoc-007804/?q=Ley+Org%C3%A1nica+del+Ambiente&type=legislation&xcountry=Costa+Rica&xdate\\_min=&xdate\\_max=](https://www.ecolex.org/details/legislation/ley-no-7554-ley-organica-del-medio-ambiente-lex-faoc-007804/?q=Ley+Org%C3%A1nica+del+Ambiente&type=legislation&xcountry=Costa+Rica&xdate_min=&xdate_max=) Acceso em 22/08/2016.

## 1. General Information

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

YES /  NO

Yes, Ecuador has been a Party to the CBD, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, Ecuador is not a Party but it is a signatory to the Protocol since Apr 1st, 2011.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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 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>.

2 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>.

3 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 apply administrative sanctions according to national and community legislations;
- 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.

### **1.7 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

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 synthesized 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.

## **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

Domestically, the following legislation is applicable in Ecuador regarding access to genetic resources and related affairs:

- *Constitution of the Republic of Ecuador, of October 20, 2008;*
- *Decree No. 905* - This Regulation has as its object the establishment of 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.

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 or-

ganization 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

Domestically, article 7 of Decree 905 of 2011 establishes as the competent authority for enforcing the regulation on access to genetic resources the Ministry of the Environment.

Article 1 of Decision 391 of the Andean Pact defines as National Competent Authority:

*State entity or public institution appointed by each Member Country, 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 this common regime and to ensure their performance.*

In this sense, Article 50 establishes that the Member Countries of the Andean Community should establish a National Competent Authority, according to the capacities and attributions listed in items 'a' to 'p' of this article. Furthermore, the set of directors from these National Competent Authorities (group formed of directors from each member country) shall assemble to compose the Andean Committee on Genetic Resources, described under subsection XI of article 51 of Resolution 391.

In agreement with the Andean Pact, Law 99 of 1993 establishes in Article 5, item 21, that it is the role of the Ministry of Environment and Sustainable Development:

*To regulate, under the terms of the law, the acquisition, use, management, investigation, import, export, commerce and distribution of genetic strains and species of wild flora and fauna; to regulate 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.*

## **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

Yes. Article 16 of Resolution 391 of the Andean Pact establishes that:

All access procedures shall require the presentation, admittance, publication and approval of an application, the signing of a contract, the issuing and publication of the corresponding Resolution and the declarative registration of the acts connected with that access.

Articles 26 and 30 of the aforementioned decision establish the procedures for requesting access authorizations. According to article 46, anyone who performs access activities without the respective authorization shall be liable for sanctions.

Domestically, articles 12 to 16 of Decree 905 of 2011 establish the procedures for requesting the authorization that will be presented to the National Environmental Authority for accessing the genetic resources, which includes the signature of a Contract of Access to Genetic Resources for commercial purposes.

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

YES /  NO

Decree 905 of 2011 establishes, in its article 20, that for requesting access which includes associated traditional knowledge, 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 sign the Annex to the contract.

Resolution 391 of the Andean Community does not include any specific or differentiated procedures for accessing associated traditional knowledge, only establishing in its eighth transitory 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.

#### **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

Article 332 of the Constitution of Ecuador acknowledges 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.

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 synthesized products and associated intangible components, either obtained or developed through access activities. Furthermore, according to the third complemen-

tary 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES / (  ) NO

According to Decree No. 3,516, article 6, all scientific research on the fauna and flora to be carried out in National Natural Heritage areas by natural or legal persons, of national or foreign character, require an authorization issued by the appropriate Regional District. Outside of National Natural Heritage areas, no authorization for research is required, unless the respective project involves the collection of species or samples.

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

(  ) YES / (  ) 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 in 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.

## **2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

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”.

The only article of Andean Decision 1,391 that deals with the benefit-sharing requirement is article 35, which establishes as follows:

*Art. 35 – When access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of the contract, an annex stipulating the fair and equitable distribution of the profits from use of that component.*

*The annex shall be signed by the supplier of the intangible component and the applicant for the access. It may also be signed by the National Competent Authority, in accordance with the provisions of the national law of the Member Country. If that annex is not signed by the National Competent Authority, it shall be subject to the suspensive condition referred to in Article 42 of this Decision. Failure to comply with the stipulations of the annex shall constitute grounds for the rescission and nullification of the access contract.*

Article 30 of Decree 905 establishes that the contract of access to genetic resources must necessarily contain a clause related to benefit-sharing.

Considering 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.

## **2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

According to 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 Environment, which will only authorize their exportation if there is proof that the species come from an authorized tenure and management center.

Decision 391 of the Andean Community does not mention the shipment of genetic resources, but there is one occasion, in the fourth complimentary disposition, in which it establishes that the health certificates supporting the exportation of genetic resources shall include, according to Decision 328 of the Commission, the following phrase: “Use as genetic resource NOT authorized”.

### 3. Summary – Competent Authorities

Authority	Competence
Ministry of the Environment	Competent Authority responsible for the application of the regulation on access to genetic resources
National Directorate of Biodiversity (Ministry of the Environment)	Institution responsible for implementing the Public Registry of Applications on Access to Genetic Resources.
Ecuadorian Institute of Intellectual Property (IEPI)	To administrate the aspects of intellectual property covered by the Convention on Biological Diversity (Article 3 of the Intellectual Property Law)
Secretariat for Peoples, Social Movements and Citizen Participation	Responsible for coordinating with local communities the corresponding processes that allow the procurement of prior informed consent for accessing traditional knowledge associated to genetic resources.

### 4. References

BUSTAMANTE, Sebastián Ignacio Donoso. **Recursos Genéticos, Patentes de Invención y el ADPIC**. p. 122. Available at: [http://www.usfq.edu.ec/publicaciones/iurisDictio/archivo\\_de\\_contenidos/Documents/IurisDictio\\_11/Recursos\\_Geneticos.pdf](http://www.usfq.edu.ec/publicaciones/iurisDictio/archivo_de_contenidos/Documents/IurisDictio_11/Recursos_Geneticos.pdf) Access on Oct 25, 2016



# United States

## 1. General Information

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

YES /  NO

The country is not a Party to the Convention, but has signed it on July 4, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

The country is not a Party to the Protocol and neither has signed it.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

It was not possible to identify an official institution responsible for surveilling access and benefit-sharing and neither there is evidence of application of fines or of any legislation specifying cases of misconduct.

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, there is no legislation regulating the subject.

## 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

The United States does not have any valid and promulgated national legislation regarding access to genetic heritage and associated traditional knowledge, and neither do they have any bills dealing with these subjects at present.

However, according to information obtained from the country's National Focal Point, it was possible to identify specific regulations on the access to genetic heritage in the North-American National Parks:

- **National Park Omnibus Act of 1998** – Devolves to the Secretary the responsibility for administering 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 as to preserve them for future generations.
- **Management Policies of the National Park System 2006** – Whitepaper of the National Park System.
- **Director's Order (DO) #77-10: NPS Benefit Sharing, December 19, 2012** – This documents complements Management Policies NPS 2006 and is enhanced by the procedures and information contained in the Benefits Sharing-Handbook. There are no predated procedural guidelines on benefit-sharing.
- **Benefits-Sharing Handbook, September 29, 2014** – It is a complementary document to Director's Order (DO) #77-10.

For the record, it was identified that despite not having enforced any official legislation regulating access to the national genetic heritage, the 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. As a matter of fact, there are common whitepapers 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 /  NO

The competent institution responsible for issues related to the Nagoya Protocol and the Convention on Biological Diversity could not be identified through the official sources and official documents.

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

YES /  NO

As mentioned in item 2.1, no current administrative guidelines or national legislation regulating the subject could be identified.

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 /  NO

As mentioned in item 2.1, there is no legislation or administrative guidelines regulating the 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

As mentioned in item 2.1, there is no legislation or administrative guidelines regulating the subject. 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, there is no legislation or administrative guidelines regulating the subject.

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

YES /  NO

As mentioned in item 2.1, there is no legislation or administrative guidelines regulating the subject.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, there is no legislation or administrative guidelines regulating the subject. 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.

## 2.9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

As mentioned in item 2.1, there is no legislation or administrative guidelines regulating the subject.

## 3. Websites

### **Agricultural Research Service:**

<http://www.ars.usda.gov/main/main.htm>

### **US Environmental Protection Agency:**

<https://www3.epa.gov>

### **USDA Animal and Plant Health Inspection Service:**

<https://www.aphis.usda.gov/aphis/home>

### **Rainforest Partnership:**

<http://www.rainforestpartnership.org>

### **American Bird Conservancy:**

<https://abcbirds.org>

### **Precious Heritage\_The Status of Biodiversity in the United States \_NatureServe:**

<http://www.natureserve.org/biodiversity-science/publications/precious-heritage-status-biodiversity-united-states>

### **Biodiversity - National Wildlife Federation:**

<http://www.nwf.org/Eco-Schools-USA.aspx>

### **Priority Areas for Biodiversity Conservation in the USA:**

[http://www.biodiversitymapping.org/USA\\_priorities.htm](http://www.biodiversitymapping.org/USA_priorities.htm)

### **BGCI\_ Botanic Gardens Conservation International:**

<https://www.bgci.org>

## 4. Summary – Competent Authorities

There are no competent authorities specific to this subject. However, the country has instituted a National Focal Point (Article 13.1 of the Nagoya Protocol), which is the recognized competent authority according to the website of the Convention on Biological Diversity and the website of The Access and Benefit-Sharing Clearing-House Mechanism:

### **Nagoya Protocol on Access and Benefit-sharing**

#### **Ms. Stephanie Aktipis**

ABS National Focal Point

+1 202 647 4827

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[aktipiss@state.gov](mailto:aktipiss@state.gov)

Foreign Affairs Officer  
Office of Conservation and Water, Bureau of Oceans and International Environmental and Scientific Affairs  
United States Department of State  
HST Room 2657  
DC 20520  
Washington  
United States of America

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. United States profile. Disponível em: <https://absch.cbd.int/countries/US> Acesso em 31/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. United States profile. Disponível em: <https://www.cbd.int/countries/?country=us> Acesso em 31/10/2016.

UNITED STATES GOVERNMENT. **Benefits-Sharing Handbook**. Disponível em: <https://parkplanning.nps.gov/document.cfm?parkID=442&projectID=41624&documentID=56858> Acesso em 31/10/2016

UNITED STATES GOVERNMENT. **Director's Order (DO) #77-10: NPS Benefits Sharing , 19 de dezembro de 2012**. Disponível em: [https://www.nps.gov/policy/DOrders/DO\\_77-10.pdf](https://www.nps.gov/policy/DOrders/DO_77-10.pdf) Acesso em 31/10/2016

UNITED STATES GOVERNMENT. **Management Policies of the National Park System 2006**. Disponível em: <https://www.nps.gov/policy/mp2006.pdf> Acesso em 31/10/2016

UNITED STATES GOVERNMENT. **National Parks Omnibus Management Act Of 1998**. Disponível em: [https://www.nps.gov/gis/data\\_standards/omnibus\\_management\\_act.html](https://www.nps.gov/gis/data_standards/omnibus_management_act.html) Acesso em 31/10/2016

## 1. General Information

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

YES /  NO

Yes, Guatemala has been a party to the Convention on Biological Diversity, by ratification, since Oct 08, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Guatemala has been a party to the Nagoya Protocol since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

On March 30, 2016, the Access and Benefit-Sharing Clearing House website published the following Internationally Recognized Certificate of Conformity: “Access Agreement for Genetic Resources for Research in Mahogany (*Swietenia macrophylla* King) and Cedar (*Cedrella odorata* L.)” , unique identifier: ABSCH-IRCC-GT-206790-1.

Nationally, the authorization was issued on October 9, 2015 by the National Council of Protected Areas (Consejo Nacional de Áreas Protegidas) - CONAP through Resolution 02-19-2015, which approved the implementation of the non-commercial scientific research project “Evaluation of the effect of forest management on genetic diversity of Mahogany (*Swietenia macrophylla* King) and Cedar (*Cedrella odorata*) forest concessions in the Maya Biosphere Reserve “. The provider of prior consent in this case was the CONAP and the applicant “Del Valle University of Guatemala”.

The benefits derived from the use of the genetic resources of the species *Swietenia macrophylla* and *Cedrella odorata* L. between the parties:

1 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>.

2 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>.

- Full access to the project database;
- Ex situ monitoring in procedures, evaluation of the procedures to be carried out in the project with the purpose of verifying the quality of activities such as DNA extraction, amplification and sequencing;
- Capacity transfer;
- Access to scientific information relevant to the conservation and sustainable use of biological diversity;
- Disclosure of information
- Deposit of 3 copies of the survey.

**1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?**

( ) YES / ( X ) NO

No checkpoint communiqués were found in this country.

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

( ) YES / ( X ) NO

No official inspection body was mentioned, and there is no evidence of imposition of fines.

**1.7 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

No sanctions or fines for irregular access have been identified.

## 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

Although Guatemala has ratified the Nagoya Protocol, the country still lacks legal frameworks for access to genetic resources and associated traditional knowledge. At the moment, the country has the following norms:

- Decree No. 6-2014 - Approves the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of its use.
- Governance Agreement 171-2014 (Acuerdo Gubernativo número 1717-2014) - establishes the national focal point and the competent national authority.

However, according to Case 2606-2016 (Resolution of Unconstitutionality before approval of the

<sup>3</sup> 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.

Nagoya Protocol) (Expediente 2606-2016 (Resolución de Inconstitucionalidad ante aprobación de Protocolo de Nagoya)), the request by indigenous and traditional peoples 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 9, 2016 the provisional suspension of this Decree. No evidence has been identified that this temporary situation has changed.

In addition, the country has been moving to establish a legal framework on access and benefit sharing. In 2006, the Government conducted a study for the drafting of an ABS law entitled “Elements for the elaboration of a proposal for a law on access to genetic resources in Guatemala” (Technical Document No. 40 07-2006) (Elementos para la elaboración de una propuesta de ley em acceso a los recursos genéticos em Guatemala” (Documento Técnico n. 40 07-2006)), sponsored by GEF-UNDP. The ABS Guatemala Project was also formulated: Equitable protection and distribution of benefits derived from access to traditional knowledge linked to biological diversity, to promote conservation and sustainable use. With CONAP and UNEP funds as executing agency, this project lasted for 3 years, starting in March 2014, with an expected completion in March 2017.

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

YES /  NO

The CONAP - Technical Council for Protected Areas (Consejo Nacional de Areas Protected), in accordance with Article 1 of Governmental Agreement n. 171 of 2014, is the focal point and competent national authority 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?**

YES /  NO

As mentioned in item 2.1, the country does not have a law on access to genetic resources and associated traditional knowledge. It was not possible to identify in the legislation and documents researched specific rules for this purpose.

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

YES /  NO

As mentioned in item 2.1, the country does not have a law on access to genetic resources and associated traditional knowledge. It was not possible to identify in the legislation and documents researched specific rules for this 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?**

YES /  NO

None of the laws presented under item 2.1 mentions specific procedures for requesting patents.



**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for obtaining access to genetic heritage when performing activities on behalf the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

There are no specific norms for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have a law on access to genetic resources and associated traditional knowledge. It was not possible to identify in the legislation and documents researched specific rules for this purpose.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

No established procedures for the shipment of samples were identified in the relevant legislation.

### 3. Websites Of Interest

***Portal Nacional de Diversidad Biológica en Guatemala***

<http://www.chmguatemala.gob.gt/>

***Consejo Nacioal de Áreas Protegidas – CONAP***

<http://www.conap.gob.gt/>

<http://conap.online.fr/primer.htm>

***Ministerio de Ambiente y Recursos Naturales***

<http://www.marn.gob.gt/>

### 4. Summary – Competent Authorities

Authority	Competence
Consejo Nacioal de Áreas Protegidas – CONAP (National Council of Protected Areas)	In accordance with Article 1 of Governmental Agreement no. 171 of 2014 is the focal point and competent national authority for access and benefit-sharing.

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Guatemala profile. Disponível em: <https://absch.cbd.int/countries/GT> Acesso em 11/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Guatemala profile. Disponível em: <https://www.cbd.int/countries/?country=gt> Acesso em 11/11/2016.

GOBIERNO DE GUATEMALA. **Establishment of the Institutional Technical Unit from National Council of Protected Areas to support the management of access to genetic resources.** Disponível em: <https://absch.cbd.int/countries/GT> Acesso em 11/11/2016.

GOBIERNO DE GUATEMALA. **Estrategia Departamental De Diversidad Biológica De Huehuetenango 2014 Al 2018.** Consejo Nacional de Áreas Protegidas – CONAP; Mesa Departamental De Cambio Climático De Huehuetenango. 2014. Disponível em: <https://www.cbd.int/countries/?country=gt> Acesso em 11/11/2016.

GOBIERNO DE GUATEMALA. **Governmental Agreement 171-2014.** Disponível em: <https://absch.cbd.int/countries/GT> Acesso em 11/11/2016.

GOBIERNO DE GUATEMALA. **Legislative Decree 6-2014, approval of The Nagoya Protocol.** Disponível em: <https://absch.cbd.int/countries/GT> Acesso em 11/11/2016.

GOBIERNO DE GUATEMALA. **Política Nacional De Diversidad Biológica - Acuerdo Gubernativo 220-2011 / Estrategia Nacional De Diversidad Biológica Y Su Plan De Acción 2012-2022 - Resolución 01-16-2012 del CONAP.** Consejo Nacional de Áreas Protegidas – CONAP. La Década de la Vida y el Desarrollo. 112pp. Políticas, Programas y Proyectos No. 03 (01-2013). 2013. Disponível em: <https://www.cbd.int/countries/?country=gt> Acesso em 11/11/2016.

GOBIERNO DE GUATEMALA. **V Informe Nacional De Cumplimiento A Los Acuerdos Del Convenio Sobre La Diversidad Biológica.** Consejo Nacional de Áreas Protegidas – CONAP. Documento Técnico No. 3 - 2014. 2014. Disponível em: <https://www.cbd.int/countries/?country=gt> Acesso em 11/11/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since Oct 29, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Honduras is a Party to the Nagoya Protocol, having ratified it on Aug 12, 2013, and having become a party from Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

No official inspection body has been identified in the country.

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

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

YES /  NO

Although there is no legislation to access genetic heritage and associated traditional knowledge in the country, in contact with the National Focal Point, it was informed that recently, in accordance with Decree No. 0695-2016, the Department of Biodiversity, MIAMBIENTE, was officially appointed as National Competent Authority for CBD and 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 /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

There are no specific norms for gaining access to the genetic heritage in activities performed on behalf the perfume, personal hygiene and cosmetic industries.

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

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge, and there are no specific norms on the collection and access of exotic species either.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites Of Interest

***Secretaria de Energia, Recursos Naturais, Ambiente e Minas***

*<http://www.miambiente.gob.hn/>*

***CHM Honduras***

*<http://www.chmhonduras.org/>*

### 4. Summary – Competent Authorities

Autority	Competence
Secretariat of State for Energy, Natural Resources, Environment and Mines (MIAMBIENTE)	National Competent Authority for ABS

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Honduras profile. Disponível em: <https://absch.cbd.int/countries/HN> Acesso em 06/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Honduras profile. Disponível em: <https://www.cbd.int/countries/?country=hn> Acesso em 06/11/2016.

REPUBLICA DE HONDURAS. **Decreto N° 104/93 - Ley General del Medio Ambiente**. Disponível em: [https://www.ecolex.org/details/legislation/decreto-no-10493-ley-general-del-medio-ambiente-lex-faoc004880/?q=Decreto+N%C2%BA+104-93++Ley+General+del+Medio+Ambiente&type=legislation&xdate\\_min=&xdate\\_max=](https://www.ecolex.org/details/legislation/decreto-no-10493-ley-general-del-medio-ambiente-lex-faoc004880/?q=Decreto+N%C2%BA+104-93++Ley+General+del+Medio+Ambiente&type=legislation&xdate_min=&xdate_max=) Acesso em 06/11/2016.

REPUBLICA DE HONDURAS. **Estrategia Nacional de Biodiversidad y Plan de Acción**. Dirección General de Biodiversidad, Secretaría de Recursos Naturales y Ambiente. Disponível em: <https://www.cbd.int/countries/?country=hn> Acesso em 06/11/2016.

REPUBLICA DE HONDURAS. **V Informe Nacional de Biodiversidad**. Dirección General de Biodiversidad, Secretaría de Recursos Naturales y Ambiente. Disponível em: <https://www.cbd.int/countries/?country=hn> Acesso em 06/11/2016.

## 1. General Information

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

YES /  NO

Yes, Mexico has been a Party to the CBD, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Mexico has been a party to the Protocol since Oct 12, 2014, having ratified it on May 16, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

Yes, Mexico has an Internationally Recognized Certificate of Compliance, issued by the National Competent Authority (National Service of Seed Inspection and Certification. Secretary of Agriculture), issued on Jul 15, 2016. The certificate was issued to BioN2, Inc., an American company, for commercial and non-commercial purposes. The requirement of prior informed consent was respected, as well as the mutually agreed terms signed between this user and the providers. Further information is classified.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

1 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>.

2 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>.

3 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.

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

YES /  NO

In Mexico, the Secretariat of Environment, Natural Resources and Fisheries is the inspection institution responsible for the environment. No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in Mexico.

No concrete cases were found during the survey in relation to the application of fines.

**1.7 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

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, 2005, on chapter III, defines the offences, 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 that 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 cancelled without prejudice to the fulfillment of the obligations arising from access that are extended through time according to article 84.

## 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

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 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 N° 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.

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

( X ) YES / ( ) NO

Although there is not yet a law that directly addresses access to genetic heritage and associated traditional knowledge, the country has already made available three official institutions in the official "Access and Benefit-Sharing Clearing House" mechanism, which are:

- **General Directorate for Forestry and Soil Management of The Secretariat of Environment and Natural Resources** - this institution is responsible for issuing authorizations, certificates, information and documents, receiving notifications and reports, as well as exercising other acts of the authority regarding the application of legal provisions on the sustainable use, conservation, protection and restoration of forest resources and soils and to participate in formulating a policy on this subject. It also issues authorizations for compliance with applicable legal provisions for the collection and use of forest resources for scientific, commercial, research or biotechnological development purposes.
- **National Service of Seed Inspection and Certification of the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food** - responsible for coordinating international policies, strategies, actions and agreements on access, conservation and sustainable use of plant genetic resources.
- **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.

In addition to that, the Federal Law on Access and Utilization of Genetic Resources, of April 27, 2005, states, in articles 12 and 13, the Secretariat of Environment and Natural Resources as the

competent institution. Subsections I to XIX of the article specify in detail the competence of said body, among which stand out: to authorize access to genetic resources; sign agreements on access.

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

YES /  NO

The Federal Bill 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.

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 grant authorization to carry out scientific collection

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

YES /  NO

As explained under item 2.1, the country does not have any legislation on access and benefit sharing. The Federal Bill on Access and Utilization of Genetic Resources dated Apr 27, 2005 also does not present any specific procedures for access to associated 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 /  NO

There are no specific norms for patent applications from research and technological development that have made access.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for gaining access to genetic heritage in activities performed on behalf the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

The national regulations do not provide any specific procedures for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As explained under item 2.1, the country does not have any legislation on access and benefit sharing. Nevertheless, the Federal Law 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, with emphasis in 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.

### 2.9. Does the current legislation establish procedures for the shipment of samples?

( X ) YES / ( ) NO

The Regulation of the General law of Wildlife in its article No. 60 deals with the export of wildlife samples. To carry out such activity is required the authorization issued by the Secretariat of Environment and Natural Resources, the request must contain the following information: (1) export character (definitive or temporary); (2) period of stay abroad (in the case of temporary movements); (3) Indicate whether they are live animals, parts or derivatives, flora or others; (4) exit customs of the national territory; (5) country of destination, and (6) purpose of the movement.

## 3. WEBSITES OF INTEREST

### *Comisión Nacional para el Conocimiento y Uso de la Biodiversidad*

<http://www.biodiversidad.gob.mx>

### *Secretaría de Medio Ambiente y Recursos Naturales*

<http://www.semarnat.gob.mx>

## 4. Resumen - Autoridades Competentes

Authority	Competence
General Directorate for Forestry and Soil Management - Secretariat of Environment and Natural Resources for the Undersecretary of Management for Environmental Protection	Issue authorizations, certificates, information and documents, receive notifications and reports, as well as exercise other acts of the authority regarding the application of legal provisions on the sustainable use, conservation, protection and restoration of forest resources and soils
National Commission for the Development of Indigenous Peoples	Guide, coordinate, promote, support, encourage, monitor and evaluate 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.

National Service Seed Inspection and Certification - Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food	Coordinate international policies, strategies, actions and agreements on access, conservation and sustainable use of plant genetic resources.
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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Mexico profile. Disponível em: <https://absch.cbd.int/countries/MX> Acesso em 18/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Mexico profile. Disponível em: <https://www.cbd.int/countries/?country=mx> Acesso em 18/11/2016.

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. Disponível em: <https://www.cbd.int/countries/?country=mx> Acesso em 18/11/2016.

GOBIERNO DEL ESTADO DE MICHOACÁN. **Estrategia para la Conservación y Uso Sustentable de la Diversidad Biológica 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 Desarrollo Agropecuario – SEDAGRO. México, D.F., 2016. Disponível em: <https://www.cbd.int/countries/?country=mx> Acesso em 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. Disponível em: <https://www.cbd.int/countries/?country=mx> Acesso em 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. Disponível em: <https://www.cbd.int/countries/?country=mx> Acesso em 18/11/2016.

## 1. General Information

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

YES / (  ) NO

Yes, the country has been a Party to the CBD, by ratification, since Apr 17, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES / (  ) NO

Yes, the country has been a party to the Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

(  ) YES / (  ) NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoint communiqués were found in this country.

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

YES / (  ) NO

According to item 2.2. of this form, articles 4 and 5 of Executive Decree No. 25 of April 29, 2009 provide that the National Environmental Authority (ANAM) is the National Competent Authority, with responsibility for standardizing, regulating and controlling the access and use of genetic and/

1 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>.

2 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>.

3 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 biological resources. UNARGEN is the institution indicated in Articles 5 and 6 of Executive Decree No. 25 to issue authorizations and carry out activities related to access, issue certificates of origin or source of the genetic or biological resource, register the Material Transfer Agreements and Agreements of Prior Informed Consent, supervise the fulfillment of the commitments established in these authorizations and agreements, supervise the export of wild species of fauna and flora, supervise compliance with access contracts and benefit-sharing agreements, negotiate access contracts, among other functions described in the aforementioned articles.

**1.7 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

Article 49 of Executive Decree No. 25, of April 29, 2009, establishes the cases typified as contraventions and offences related to genetic heritage. Such actions shall be punished with the sanctions referred to in Article 50 of the same Decree, which are:

- Written warning;
- Fine imposed by ANAM, in accordance with the provisions of article 114 of Law 41 of 1998;
- Temporary or permanent sealing of the establishment or laboratory;
- Prohibition to contract with the Public Administration to obtain access to genetic and biochemical resources;
- Temporary or definitive cancellation of access permit.

Article 114 of Law 41 of 1998, indicated above, provides the values of fines, which will vary according to the institution that order 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).

## 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

The main legislation in the country dealing with this subject is Executive Decree No. 25, of April 29, 2009. In addition to this Decree, 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

Articles 4 and 5 of Executive Decree No. 25, of April 29, 2009 provide that the National Environmental Authority (ANAM) is the National Competent Authority, with the attribution of standardizing, regulating and controlling the access and use of genetic and/or biological resources. This competence is reinforced by the General Environmental Law No. 41, of July 1st, 1998 (General Environmental Law of the Republic of Panama), Article 71. ANAM's internal structure is established by Executive Decree No. 163, of Aug 22, 2006.

Article 5 creates the Genetic Resource Access Unit (UNARGEN), linked to the National Directorate of Protected Areas and Wildlife, ANAM. UNAGERN has its structure organized according to Resolution No. 204, of Apr 19, 2007.

In addition, UNARGEN is the institution indicated in Articles 5 and 6 of Executive Decree No. 25 to grant authorizations and carry out activities related to access, issue certificates of origin or source of the genetic or biological resource, register the Material Transfer Agreements and the Agreements of Prior Informed Consent, supervise the fulfillment of the commitments established by such authorizations and agreements, supervise the export of wild species of fauna and flora, supervise compliance with access contracts and benefit-sharing agreements, negotiate access contracts, among other functions described in the aforementioned articles.

Finally, it should be noted that UNARGEN and ANAM can count on the support of the Technical Advisory Group in the process of evaluating access requests, according to art. 11.

## **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

The Executive Decree No. 25 of 2009, establishes in its article 14 and 15 the need to request for



access to UNARGEN. Article 18 further determines that an Access Agreement shall be entered into between the State of Panama, duly represented by ANAM, and the access applicant. The requirements of such agreement are found in article 19.

In addition to the prior authorization and access agreement described above, it is important to notice that is a requirement to the application for access the presentation of the Prior Informed Consent (Consentimiento Libre Informado Previo - CLIP) of the provider of the genetic resource or traditional knowledge.

Finally, it is important to note that according to articles 26 and 28, CLIP submission is prior to the Access Agreement with the State of Panama, as well as in the case of a commercial research project or involving traditional knowledge, CLIP should contemplate the aspects of intellectual property rights.

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

YES /  NO

According to previous item 2.3, it is necessary an access authorization, access agreement, and CLIP so the user may utilize the associated traditional knowledge. Article 28 of Decree No. 25 of 2009 emphasizes that in the case of a commercial research project or involving traditional knowledge, the CLIP should contemplate aspects of intellectual property rights.

Although the associated traditional knowledge is dealt with separately from articles 34, 35 and 36, there is no specification of its own procedures, therefore, the only procedure verified is described above, article 28 of Decree No. 25 of 2009.

#### **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

According to items 2.3. and 2.4. of this form, Article 28 of Decree No. 25 of 2009 emphasizes that in the case of a commercial research project or involving traditional knowledge, the CLIP should contemplate aspects of intellectual property rights.

In addition to that, article 42, paragraph “c” of the same Decree states that “The Panamanian State reserves the right to grant mandatory licenses for patents granted in Panama, derived from investigations carried out with genetic or biological resources collected in the national territory or its derivatives, in accordance to the national interest, according to the law and to international norms.” 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

There are no specific norms for gaining access to genetic heritage in activities performed on behalf of the perfume, personal hygiene and cosmetic industries.

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

( ) YES / ( X ) NO

There are no specific norms for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( X ) YES / ( ) NO

Yes, the country requires the sharing of benefits in cases of access to genetic resources or associated traditional knowledge that have a commercial purpose. In this sense, in the Access Agreement itself, provisions should be made for the State of Panama to receive benefits, according to Article 19, paragraphs “a” and “b” of Executive Decree No. 25 of 2009.

According to Article 37, the resources arising from the Benefit Sharing Contracts shall be allocated to the Special Account for Access to Genetic and Biological Resources within the Wildlife Fund established by Law No. 24, of June 7, 1995. Article 38 specifies how the resources of the Fund may be used.

The Benefits Contract to be entered into with the State of Panama, through the General Administrator of ANAM, is regulated by Articles 39 to 44 of Executive Decree No. 25 of 2009. The following monetary commitments shall be part of the Contracts:

- a) Annual, negotiable royalties, not less than one percent (1%) of net sales.
- b) A payment at the beginning of the project, whose value shall be stipulated by the parties;
- c) Other payments, periodically or not, agreed by the parties.

Other commitments are stipulated in article 42, such as payment in the Special Account for Access to Genetic and Biological Resources, reservation of the right of the State of Panama to grant compulsory licenses on patents of invention, the participation of the State of Panama in all industrial or commercial contracts linked to the use of genetic or biological material and its derivatives, among others.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( X ) YES / ( ) NO

Bearing in mind that the “shipment” may have a different definition from that used by Brazil, and considering in this case that it will not always only mean the shipment to abroad, it should be clarified that Decree No. 25 of 2009 regulates the transfer of genetic material in the country, without specifying whether the transfer applies only within or outside the country. In this sense, it is necessary to apply for a transfer authorization, to which the supplier and the receiver of the material shall enter in a Material Transfer Agreement. Articles 29 to 33 deal on this subject.

### 3. Websites Of Interest

**National CHM:**

<http://www.chmpanama.gob.pa>

### 4. 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.
Access Unity to Genetic Resource (UNARGEN), linked to the National Directorate of Protected Areas and Wildlife, from the Environmental National Authority (ANAM)	UNARGEN is the institution indicated in Articles 5 and 6 of Executive Decree n° 25, to grant authorizations and carry out acts related to access, issue certificates of origin or source of the genetic or biological resource, register the Material Transfer Agreements and the Agreements Prior Informed Consent, to supervise the fulfillment of the commitments of such authorizations and agreements, to supervise the export of wild species of fauna and flora, to supervise compliance with access contracts and benefit contracts, to negotiate access contracts, among other functions described in the mentioned articles.

### 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Panama profile. Disponível em: <https://absch.cbd.int/countries/PA> Acesso em 17/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Panama profile. Disponível em: <https://www.cbd.int/countries/?country=pa> Acesso em 17/11/2016.

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.** Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=3397> Acesso em 17/11/2016.

REPÚBLICA DE PANAMÁ. **Decreto N° 122 - Política Nacional de Biodiversidad.** Disponível em: [https://www.ecolex.org/details/legislation/decreto-no-122-politica-nacional-de-biodiversidad-lex-faoc086717/?q=&type=legislation&xkeywords=biodiversity&xcountry=Panama&xdate\\_min=&xdate\\_max=](https://www.ecolex.org/details/legislation/decreto-no-122-politica-nacional-de-biodiversidad-lex-faoc086717/?q=&type=legislation&xkeywords=biodiversity&xcountry=Panama&xdate_min=&xdate_max=) Acesso em 17/11/2016.

REPÚBLICA DE PANAMÁ. **Decreto N° 163 - Organización y funciones de la Autoridad Nacional del Ambiente (ANAM).** Disponível em: [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=](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=) Acesso em 17/11/2016.

REPÚBLICA DE PANAMÁ. **Estrategia Nacional De Biodiversidad.** Autoridad Nacional Del Ambiente (Anam). Panamá, 2000. Disponível em: <https://www.cbd.int/countries/?country=pa> Acesso em 17/11/2016.

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.** Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=3400> Acesso em 17/11/2016.

REPÚBLICA DE PANAMÁ. **Ley N° 41 - Ley General de Ambiente.** Disponível em: [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=](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=) Acesso em 17/11/2016.

REPÚBLICA DE PANAMÁ. **Quinto Informe Nacional De Biodiversidad De Panamá Ante El Convenio Sobre Diversidad Biológica.** Autoridad Nacional Del Ambiente (Anam). Panamá, 2014. Disponível em: <https://www.cbd.int/countries/?country=pa> Acesso em 17/11/2016.

REPÚBLICA DE PANAMÁ. **Resolución N° 164 - Crea la Comisión Nacional de Biodiversidad.** Disponível em: [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=](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=) Acesso em 17/11/2016.

REPÚBLICA DE PANAMÁ. **Resolución N° 204 - Conformar la Unidad de Acceso al Recurso Genético.** Disponível em: [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=](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=) Acesso em 17/11/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the CBD, by ratification, since May 25, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

The country is not a Party to the Protocol and neither has signed it.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

However, a meeting of the Commission on Environment and Tourism of the Latin American Parliament (PARLATINO), held on May 14, 2015, resulted in a bill entitled Bill on Genetic Resources (Proyecto de Ley Marco sobre Recursos Genéticos).

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

YES /  NO

No official competent institutions were found concerning access and benefit-sharing under the terms 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 /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources. Moreover, the Bill on Genetic Resources within the Latin American Parliament does not include the need for prior authorization.

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

YES /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources. The Bill on Genetic Resources within the Latin American Parliament, in its article 20, establishes that the member-states, according to their national legislation, will determine the necessary conditions for requesting the prior informed consent required for accessing genetic resources in indigenous and traditional 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

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources. The Bill on Genetic Resources within the Latin American Parliament does not present any specific procedures for patent requests.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge. The Bill on Genetic Resources within the Latin American Parliament also does not present any specific procedures.

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

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge. The Bill on Genetic Resources within the Latin American Parliament also does not present any specific procedures.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites Of Interest

***Paraguay Biodiversidad***

<http://www.paraguaybio.com.py/>

***PyBio \_ Paraguay Biodiversidad***

<http://www.pybio.org/>

***Secretaria del Ambiente – SEAM***

<http://www.seam.gov.py/>

## 4. Summary – Competent Authorities

Conforme item 2.2., o país não possui uma autoridade competente instituída. No entanto, possui um Ponto Focal Nacional reconhecido no que tange ao Protocolo de Nagoya:

### **Convention on Biological Diversity**

#### **Sr.Lic. Darío Mandelburger**

CBD Primary NFP

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#### **Secretaría del Ambiente (SEAM)**

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Asunción

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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Paraguay profile. Disponível em: <https://absch.cbd.int/countries/PY> Acesso em 15/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Paraguay profile. Disponível em: <https://www.cbd.int/countries/?country=py> Acesso em 15/11/2016.

GOBIERNO DE PARAGUAY. **Estrategia Nacional y Plan de Acción para la Conservación de la Biodiversidad del Paraguay 2015-2020**. Secretaría del Ambiente. Asunción, 2016. Disponível em: <https://www.cbd.int/countries/?country=py> Acesso em 15/11/2016.

GOBIERNO DE PARAGUAY. **Quinto Informe Nacional al Convenio sobre la Diversidad Biológica Paraguay**. Secretaría del Ambiente. Asunción, 2016. Disponível em: <https://www.cbd.int/countries/?country=py> Acesso em 15/11/2016.

PARLATINO. **Proyecto de Ley Marco sobre Recursos Genéticos**. Comisión Permanente de Medio Ambiente y Turismo. 2015. Disponível em: <http://www.parlatino.org/proyecto-leyes-marcos> Acesso em 15/11/2016.

## 1. General Information

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

YES /  NO

Yes, Peru has been a Party to the Convention, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Peru has been a Party to the Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

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 similar to those performed by the CGEN in Brazil.

It was through this law that the crime of biopiracy has been 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

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<sup>1</sup> 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>.



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.

**1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> 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”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?**

( ) YES / ( X ) NO

No checkpoint communiqués were found in Peru.

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

( X ) YES / ( ) NO

Decree 003-2009 institutes as the inspection body the National Superintendence of Tax Administration – SUNAT, as well as the National Police and the National Authority, which will request, whenever necessary, the presentation of the access contract and of the authorization for the exportation or commercialization of end products.

**1.7 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

Decree 003-2009 deals with the applicable sanctions for accessing genetic resources in disagreement with the procedural rules, such as: the suspension or cancellation of access authorizations, the confiscation of the accessed material; fine of up to 1,000 (one thousand) Tax Units (according to the UIT decree, in the Spanish-language acronym), which is equivalent to approximately R\$4,000,000.00 (four million reais), according to the calculations detailed below.

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<sup>4</sup>, 150 UIT is equivalent to S/. 592,500.00 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 of slightly under R\$600,000.00 (six hundred thousand reais).

.....  
2 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>.

3 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.

4 Available at: <http://www.sunat.gob.pe/indicestzas/uit.html#>. Access on June 3, 2016.

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

YES /  NO

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
- Decree 003-2009 – Regulation on Access to Genetic Resources

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

YES /  NO

Here follows a summary of institutions and their competences, according to Supreme Decree No. 003-2009-MINAM:

- **Ministerio Del Ambiente - MINAM**

The regulatory agent on access to genetic resources is the Ministry of the Environment (MINAM). As such, it is the regulatory authority on the subject, with competence over the following aspects: political, legal and administrative.

- **Ministerio de la Producción - Viceministerio de Pesquería**

Article 14 delegates to the Ministry of Production – Vice-Ministry of Fisheries (PRODUTO – VMP) the role of Administration and Execution Authority (AAE) regarding access to genetic resources, molecules, blends and composites of natural molecules, including crude extracts and other by-products present in water species from marine and river sources. Such contents may be wholly or partially found in the sample.

- **Ministerio de Agricultura y Riego - Servicio Nacional Forestal y de Fauna Silvestre (MINAGRI-SERFOR)**

Article 14 delegates to the Ministry of Agriculture and Irrigation (MINAGRI) the role of Administration and Execution Authority (AAE) regarding access to genetic resources, molecules, blends and composites of natural molecules, including crude extracts and other by-products present in wild continental species, including amphibians and micro-organisms. Such contents may be wholly or

partially found in the sample. This institution also evaluates requests for access to genetic resources from wild relatives of cultivated species in coordination with INIA, the competent AAE for continental domesticated species.

- **Instituto Nacional de Innovación Agraria**

Article 14 delegates to the National Institute of Agricultural Innovation (INIA) the role of Administration and Execution Authority (AAE) regarding access to genetic resources, molecules, blends and composites of natural molecules, including crude extracts and other by-products present in continental domesticated or cultivated species. Such contents may be wholly or partially found in the sample.

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 authorization in order to obtain genetic resources?**

( X ) YES / ( ) NO

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 mandatory contents of the access request, the research project and the contracts are very similar to the administrative procedures of former Provisional Measure No. 2,186/2001 of Brazil, with the distinction that, in this case, 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.

Moreover, article 28 of Law 26,839 establishes the State as a party to this process and must participate in the procedures for accessing the Peruvian genetic resources.

The Administration and Execution Authority, as established in Article 15, will be the following national institutions, according to their field of activity: Ministry of Agriculture; National Institute of Agricultural Innovation; and Ministry of Production – Vice Ministry of Fisheries.

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

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 to the 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 much 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?**

YES /  NO

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. In the second complementary disposition, the requirement of presenting a usage license contract on the use of associated traditional knowledge is reiterated, 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

Regulation 003/2009 does not introduce any new information, only reinforcing that, as part of the procedure for requesting patent registrations, all industrial designs, vegetable varieties, medications, nutraceuticals, cosmetics and any similar products deriving from the access shall be presented along with the relevant contract and the certificate.

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

YES /  NO

There are no specific provisions on collection. The Andean Pact permeates the matter both in situ and ex situ situations, considering in situ the conditions where the genetic resources are found in their natural environments and ecosystems, or, in the case of cultivated or domesticated species or species that have escaped domestication, in environments where they have developed their specific characteristics; as for Ex Situ conditions, these are any genetic resources which are not found in in situ conditions.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

### **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 to payment obligations just for accessing genetic resources, let alone 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 cancellation 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)

## **2. 9. Does the current legislation establish procedures for the shipment of samples?**

( X ) YES / ( ) NO

Specifically in regard to outgoing genetic resources from Ex situ Conservation Centers for research purposes, a Material Transfer Agreement (MTA) is required, establishing the conditions and obligations related to the use of the sampled material. This agreement must also detail the conditions for the transfer to third-parties as well as the acknowledgement of its origin. However, if the shipment of the sample from the Ex situ Conservation Center is for commercial purposes, instead of the referred document, the parties must sign an access contract.

There are no express provisions on the commercialization of raw materials – which are sold by the local supplier.

### 3. Websites Of Interest

**Ministerio del Ambiente:**

<http://www.minam.gob.pe/>

**Iniciativa Andino Amazónica para la prevención de la biopiratería:**

<http://www.biopirateria.org/>

### 4. Summary – Competent Authorities

Authority	Competence
Ministry of the Environment - MINAM	The Regulation of Access to Genetic Resources (Supreme Decree No. 003-2009-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.
Ministry of Production – Vice-Ministry of Fisheries	The Regulation on Access to Genetic Resources, approved by Supreme Decree No. 003-2009-MINAM, establishes in Article 14 the Ministry of Production – Vice-Ministry of Fisheries (PRODUCTO - VMP) as the Administration and Execution Authority (AAE) regarding access to genetic resources, molecules, blends and composites of natural molecules, including crude extracts and other by-products present in water species from marine and river sources. Such contents may be wholly or partially found in the sample.
Ministry of Agriculture and Irrigation – National Forestry and Wildlife Service (MINAGRI-SERFOR)	The Regulation on Access to Genetic Resources, approved by Supreme Decree No. 003-2009-MINAM, establishes in Article 14 MINAGRI as the Administration and Execution Authority (AAE) regarding access to genetic resources, molecules, blends and composites of natural molecules, including crude extracts and other by-products present in wild continental species, including amphibians and micro-organisms. Such contents may be wholly or partially found in the sample. This institution also evaluates requests for access to genetic resources from wild relatives of cultivated species in coordination with INIA, the competent AAE for continental domesticated species.
National Institute of Agricultural Innovation	The Regulation on Access to Genetic Resources, approved by Supreme Decree No. 003-2009-MINAM, establishes in Article 14 INIA as the Administration and Execution Authority (AAE) regarding access to genetic resources, molecules, blends and composites of natural molecules, including crude extracts and other by-products present continental domesticated or cultivated species. Such contents may be wholly or partially found in the sample.



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.
National Focal Point	<p>Focal Point within the CBD: Ms. Liliam Ballon Sanchez de Amezaga Minister of the Diplomatic Service of the Republic of Peru lballon@ree.gob.pe</p> <p>Focal Point within the Nagoya Protocol: Mr. José Álvarez Alonso Director-General of Biological Diversity jalvarez@minam.gob.pe</p>

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Peru profile. Disponível em: <https://absch.cbd.int/countries/PE> Acesso em 14/11/2016.

ANDEAN COMUNITY. **Andean Decision nº 391 Establishing the Common Regime on Access to Genetic Resources (1996)**. Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=9446> Acesso em 15/11/2016.

ANDEAN COMUNITY. **Andean Decision nº 486 Establishing the Common Industrial Property Regime (2000)**. Disponível em <http://www.wipo.int/wipolex/en/details.jsp?id=9451> Acesso em 15/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Peru profile. Disponível em: <https://www.cbd.int/countries/?country=pe> Acesso em 14/11/2016.

GOBIERNO REGIONAL DE MADRE DE DIOS. **Estrategia Regional de Diversidad Biológica de Madre de Dios**. Instituto de Investigaciones de la Amazonía Peruana. Consejo Nacional del Ambiente – Secretaria Ejecutiva Regional de Madre de Dios. 2006. Disponível em: <https://www.cbd.int/countries/?country=pe> Acesso em 15/11/2016.

MINISTERIO DEL AMBIENTE – MINAM. **Política Nacional Del Perú Sobre Biodiversidad (Decreto Supremo Nº 012-2009-MINAM de 23 de Mayo de 2009)**. Disponível em <http://www4.congreso.gob.pe/comisiones/1997/ambiente/DISCURSO/bio.htm> Acesso em 15/11/2016.



REPÚBLICA DEL PERÚ. **Decreto Supremo nº 003-2009-MINAN Reglamento de Acceso a los Recursos Genéticos.** Disponible em: <https://absch.cbd.int/countries/PE> Acceso em 15/11/2016.

REPÚBLICA DEL PERÚ. **Decreto Supremo nº 029-2014 Ratifican el 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.** Disponible em: <https://absch.cbd.int/countries/PE> Acceso em 15/11/2016.

REPÚBLICA DEL PERÚ. **Decreto Supremo Nº 068/01/PCM - Reglamento de la Ley sobre conservación y aprovechamiento sostenible de la diversidad biológica.** Disponible em: <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/> Acceso em 15/11/2016.

REPÚBLICA DEL PERÚ. **Estrategia Nacional de Diversidad Biológica al 2021 y su Plan de Acción 2014-2018.** Ministerio del Ambiente - MINAM. Disponible em: <https://www.cbd.int/countries/?country=pe> Acceso em 15/11/2016.

REPÚBLICA DEL PERÚ. **Ley 28216, Ley de Protección al acceso a la diversidad biológica peruana y los conocimientos colectivos de los pueblos indígenas.** Disponible em: <https://absch.cbd.int/countries/PE> Acceso em 15/11/2016.

REPÚBLICA DEL PERÚ. **Ley Nº27811, Ley que establece el Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas vinculados a los Recursos Biológicos.** Disponible em: <https://absch.cbd.int/countries/PE> Acceso em 15/11/2016.

REPÚBLICA DEL PERÚ. **Ley Nº 28.611 - Ley General del Ambiente.** Disponible em: [https://www.ecolex.org/details/legislation/ley-no-28611-ley-general-del-ambiente-lex-faoc081742/?q=Ley+general&type=legislation&xcountry=Peru&xdate\\_min=&xdate\\_max=](https://www.ecolex.org/details/legislation/ley-no-28611-ley-general-del-ambiente-lex-faoc081742/?q=Ley+general&type=legislation&xcountry=Peru&xdate_min=&xdate_max=) Acceso em 15/11/2016.

REPÚBLICA DEL PERÚ. **V Informe Nacional Sobre La Aplicación Del Convenio Sobre La Diversidad Biológica: Perú (2010-2013).** Ministerio del Ambiente. Lima, 2010. Disponible em: <https://www.cbd.int/countries/?country=pe> Acceso em 15/11/2016.

# Dominican Republic

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since Feb 23, 1997.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Nagoya Protocol, by ratification, since Feb 11, 2015.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

According to ABSCH website, the Dominican Republic instituted 2 checkpoints: the Ministry of Higher Education, Science and Technology (MESCYT) and the National Office of Intellectual Property (ONAPI).

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

1 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>.

2 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>.

3 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 inspection bodies have been identified in the scope of access and benefit-sharing covered by the Nagoya Protocol.

**1.7 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

Article 65 of Law 333-15 (Sectoral Law on Biodiversity) provides for serious offenses committed against biodiversity. These include: misuse of biodiversity elements (item 1) and dissemination of content; publication or any other use, without proper authorization, of all information related to the genetic material confidential to the general public (item 2). The shortcomings considered to be very serious were established in article 66, with the items related to access and benefit sharing:

- Item 1 - access to biodiversity elements for unauthorized exploration and bioprospecting purposes;
- Item 2 - use biodiversity without or in disagreement with the authorization;
- Item 3 - Violate:
  - (a) the rights and obligations set out in the authorization for exploration or bioprospecting purposes;
  - (b) the provisions of the agreement granting access to genetic resources and fair and equitable sharing of benefits within the stipulated deadlines;

And to exploit biodiversity resources without corresponding authorization

- Item 10 - Conduct research on genetic resources or bioprospecting without authorization;
- Item 17 - facilitate access to biodiversity resources by third parties, without authorization.

According to item 67, these faults will be sanctioned according to article 167 of Law No.64-00 that creates the Secretary of State for Environment and Natural Resources, that is, the following sanctions may be applied by the Secretary of State for Environment and Resources Natural to the serious and very serious faults described above:

1. Fine corresponding to half (1/2) minimum wage up to three thousand (3,000) minimum salaries in force;
2. Limit or restrict activities that endanger the environment;
3. Loss or capture of objects, instruments, artifacts, vehicles, raw materials, products or articles that have been used or related to environmental damage;
4. Prohibition or temporary or provisional suspension of activities that generate environmental damage or risk. When applicable, the establishment where such activity is performed shall be closed in whole or in part.

On the other hand, the Regulations for the Investigation of Protected Areas and Biodiversity also provide for sanctions in its chapter XIV. These include the revocation of the investigation permit in cases of noncompliance with the aforementioned regulation, as well as the prohibition of conducting future investigations in Protected Areas and Biodiversity, for a period of ten years.

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

YES /  NO

Currently, the country has Law 333-15 (Sector Law on Biodiversity) that is not specific about access and benefit sharing, however stipulates several rights and obligations on the subject.

According to information provided by the National Focal Point established by the country, the Dominican Republic is in the process of elaborating ABS policy and its regulation through the National Biodiversity Committee. For the preparation of these instruments, Law 333-15 (Sector Law on Biodiversity) will be taken into account. Pending this regulation, the Regulation of Research on Protected Areas and Biodiversity is used.

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

YES /  NO

Law No. 333-15 (Sectoral Law on Biodiversity) provides in its article 12 that the Ministry of Environment and Natural Resources (Ministry of Environment and Natural Resources) is responsible for compliance with and application of the legal provisions contained in this law.

Already in the profile of the Dominican Republic on the ABSCH website, the country states that this body is the only competent national authority established to administer and regulate 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?**

YES /  NO

According to article 50 of Law 333-15 (Sectoral Law on Biodiversity), access to genetic resources and their derivatives, whether for scientific, technical or commercial research purposes, can only be done through a contract establishing the conditions of access, distribution benefits and intellectual property rights. This contract must be signed between the Ministry of Environment and Natural Resources and the one who wishes to access the genetic heritage.

In the Regulations for Research on Protected Areas and Biodiversity, the need for authorization from the Government of the Dominican Republic is mentioned at various times. Article 18 provides that both domestic and foreign legal entities may request authorization to conduct research activities; and Article 19 sets out the procedures for obtaining such authorization. Where research in the Dominican Republic is international, it must be accompanied by a national institution, in accordance with Article 30.

In addition, article 29 establishes that in the case of scientific research, as a condition for issuing the authorization, 0.5% of the cost of the project should be paid as a contribution to the monitoring and supervision of activities (in foreign projects, the value in the currency national currency shall be converted into dollars, according to the exchange rate in force at the time the authorization is issued). It is necessary to reinforce that this legal device speaks in procedural contribution

and not distribution of benefits.

Issues specifically related to access to genetic resources are outlined in Chapter XI of the Research Regulations for Protected Areas and Biodiversity. In this sense, Article 38 conditions research that implies access to genetic resources, including bioprospecting, to the prior informed consent procedure. Articles 39 and 40 also stipulate the need to conclude a Research Contract that provides for the conditions of the project and the distribution of benefits.

Finally, the models of forms and contracts are contemplated in the Annexes of the Regulation of Investigation of Protected Areas and Biodiversity, as follows:

- Annex I - proposal for investment
- Annex II - Summary Request Form for Research in Protected Areas and Biodiversity
- Annex III - model statement on knowledge of national legislation
- Annex IV - model of authorization to be issued by the Ministry of the Environment and Natural Resources
- Annex V - model contract for access to genetic resources in the Dominican Republic

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

YES /  NO

There are no specific procedures in the case of traditional knowledge, and the existing legislation mentions traditional knowledge with rare frequency: Article 51 of Law 333-15 (Sector Law on Biodiversity) reinforces the importance of participation and the interests of communities in the benefit-sharing contracts. Article 54 of this same law emphasizes that access to traditional knowledge and genetic resources should be governed by a specific regulation, confirming the understanding that there are no procedures in the field 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 /  NO

The current legislation does not stipulate specific procedures for the application of patents. Regarding intellectual property rights, Article 51 of Law 333-15 (Sectorial Law on Biodiversity) states that these rights must be provided for in the access contract. In addition, it will be the responsibility of the Ministry of the Environment to act as a mandatory body in the consultation on the protection of intellectual rights on biodiversity and associated traditional knowledge.

#### **2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

No specific rules were found for this purpose.

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

YES /  NO

No specific rules were found for this purpose.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As explained in item 2.1, Law No. 333-15 (Sectorial Law on Biodiversity) leaves much of its content for future regulation. Articles 49, 50 and 53 of this law only provide for the need to allocate benefits, not stipulating procedures, rules and values for such apportionment.

The Regulation of Research on Protected Areas and Biodiversity states in its article 40 that when scientific research arouses commercial interest, the benefits of commercial exploitation should be shared.

Annex V of the same Regulation, which deals with the contract model for access to genetic resources, deals with the allocation of benefits in its fifth clause. The model, however, does not stipulate a value, there is a percentage gap to be filled by the parties. However, in the sixth clause on "transfers to third parties", the model itself already establishes the 15% value of the negotiation of genetic resources or derived products transferred to be paid to the Ministry of the Environment. In addition, the party transferring the samples should ensure that the third party will share the benefits of marketing, industrialization, patents, and other forms of exploitation.

Finally, according to article 54, the other procedures and requirements on benefit sharing should be regulated through a specific regulation.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

There is no specific procedure for shipping samples. However, according to the Regulation of Investigation in Protected Areas and Biodiversity, Article 9, for the scientific research outside the territory of the Dominican Republic there is a need to make the deposit of samples of the biodiversity samples accessed at the National Museum of Natural History of Santo Domingo, or at the National Botanical Garden or other competent institution.

**3. Websites**

**National CHM**

<http://www.ambiente.gob.do>

## 4. Summary – Competent Authorities

Authority	Competence
Ministry of Environment and Natural Resources (Ministerio de Medio Ambiente y Recursos Naturales).	Administer and regulate access to genetic resources (Article 49 of Law 333-15). This is the only Competent National Authority established.

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Dominican Republic profile. Available in: <https://absch.cbd.int/countries/DO> Access in 07/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Dominican Republic profile. Available in: <https://www.cbd.int/countries/?country=do> Access in 07/11/2016.

REPÚBLICA DOMINICANA. **Estrategia nacional de conservación y uso Sostenible de la Biodiversidad (ENBPA)**. Ministerio de Medio Ambiente y Recursos Naturales. Santo Domingo, República Dominicana, 2011. Available in: <https://www.cbd.int/countries/?country=do> Access in 07/11/2016.

REPÚBLICA DOMINICANA. **Ley nº 333-15 de Biodiversidad**. Available in: <https://www.cbd.int/abs/submissions/Aichi16/Dominicanrepublic-law333-15-en.pdf> Access in 07/11/2016.

REPÚBLICA DOMINICANA. **Quinto Informe Nacional de Biodiversidad de la República Dominicana**. Ministerio de Medio Ambiente y Recursos Naturales. 80 pgs. Santo Domingo, República Dominicana, 2014. Available in: <https://www.cbd.int/countries/?country=do> Access in 07/11/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Feb 03, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.



**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. The country has benefit-sharing legislation only within the scope of the International Treaty on Plant Genetic Resources for Food and Agriculture (Tratado Internacional sobre Recursos Fitogenéticos para a Alimentação e Agricultura - TIRFAA).

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf**

**of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**3. Sites de Interesse**

**Nacional CHM**

<http://www.mvotma.gub.uy/biodiversidad-del-uruguay>

**4. Summary – Competent Authorities**

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**Emb. Fernando Marr**

ABS National Focal Point

+598 2902 1010 ext 2052

[medio.ambiente@mrree.gub.uy](mailto:medio.ambiente@mrree.gub.uy)

Director de Medio Ambiente (Political Focal Point)

Ministerio de Relaciones Exteriores

Colonia 1206, 2° piso

Montevideo

Uruguay

## 5. Referências Bibliográficas

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Uruguay profile. Disponível em: <https://absch.cbd.int/countries/UY> Access in: 05/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Uruguay profile. Disponível em: <https://www.cbd.int/countries/?country=uy> Acesso em 05/10/2016.

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. Disponível em: <https://www.cbd.int/countries/?country=uy> AAccess in 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**. Disponível em: <https://legislativo.parlamento.gub.uy/temporales/leytemp9534014.htm> Access in 05/10/2016.

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. Disponível em: <https://www.cbd.int/countries/?country=uy> Access in 05/10/2016.



Asia

## 1. General Information

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

YES /  NO

Yes, Bhutan has been a Party to the CBD, by ratification, since Nov 23, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Bhutan has been a Party to the Nagoya Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

No inspection body is indicated in the laws presented under item 2.1., nor there is any evidence of application of fines, apart from the legal provisions establishing that they may be applied.

1 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>.

2 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>.

3 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.

### 1.7 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

According to the Biodiversity Act of Bhutan 2003, chapter 5, section 43, are considered offences: (a) In-situ or ex-situ collection of genetic resources without an access permit; (b) Non-compliance of conditions for grant of access as provided in section 9; (c) Non-compliance of the conditions for benefit-sharing as provided in section 10; (d) Breach of confidentiality as provided in section 8; (e) Non-compliance with the traditional knowledge rights as provided in Chapter 4; (f) Failure to comply with any other provisions of this Act or Regulations.

The penalties are:

- A. Whoever: (a) Conducts in-situ or ex-situ collection of genetic resources without an access permit or (b) Fails to comply with or contravenes the provisions of Section 10 or Section 11; or (d) Fails to comply with or contravenes with Chapter 4 of the Act - Shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to 3 years, or with a fine which shall not be less than 2 years equivalent of the minimum daily wage rate, but which may extend to 6 years equivalent of the minimum daily wage rate provided in the Chathrim for wage rate and recruitment agencies and workman's compensation, 1994, or with both.
- B. The Authorized Agency shall take appropriate measures to provide for confiscation of such genetic resources collected in contravention of the provisions of this Act and impose liability on the person deemed guilty to pay damages.
- C. Whoever contravenes any of the provisions of this Act or rules and regulations issued there under, for which no penalty has been elsewhere provided under this Act, shall be punishable with imprisonment for a term which may extend to 3 months or with a fine which may extend to 6 months equivalent of minimum daily wage rate as provided in Chathrim for wage rate, recruitment agencies and workman compensation (1994).

## 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

- Biodiversity Act of Bhutan 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?**

YES /  NO

According to the Biodiversity Act of Bhutan 2003, chapter 6, section 51, the Competent Authority designated is the Minister of Agriculture of the RGOB. This competent authority, in turn, delegates certain tasks to the Authorized Agency.

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

YES /  NO

According to the Biodiversity Act of Bhutan 2003, section 5, the access covered by this Act shall be subject to the prior informed consent of the Competent Authority, being the Authorized Agency responsible for processing the applications and monitoring the permits granted.

According to section 6, the applicant shall submit an application for access to the Authorized Agency in accordance with section 7. If the Authorized Agency is satisfied that the application for access complies with the requirement under section 7, such an application may be referred to the Competent Authority to arrive at a decision to grant or refuse a permit.

For duly registered ex-situ collections, the regulations of this Act may establish special procedures for access authorization. Likewise, the requirements of this Act will be determined in a different way for non-commercial and commercial applications.

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

YES /  NO

According to the Biodiversity Act of Bhutan 2003, chapter 6, section 37 to 42: The applicant shall obtain prior informed consent of the owners of the traditional knowledge for use of traditional knowledge for a non-customary use. 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 applicant and the owners of the traditional knowledge enter into an authorization agreement, the owners of the traditional knowledge are deemed to have given their prior informed consent to the proposed use. A final copy must be provided to the competent authority, or the agreement will be considered null and void.

## **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

No specific legislation was found regarding patent requests.



**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

None of the laws presented under item 2.1 mention any specific procedures concerning the matter.

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

( ) YES / ( X ) NO

None of the laws presented under item 2.1 mention any specific procedures concerning the matter.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( X ) YES / ( ) NO

According to the Biodiversity Act of Bhutan 2003, section 10, the Competent Authority may grant access if one or more, when relevant, of the following minimum conditions for benefit-sharing are included in the Contract Agreement or Material Transfer Agreement to be signed between the applicant and the competent authority. These conditions may also be considered in any Contract Agreement or Material Transfer Agreement to be signed between the applicant and any other relevant stakeholder. They are:

- 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

In addition to the above, no information on values is specified.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( X ) YES / ( ) NO

According to the Biodiversity Act of Bhutan 2003, section 17, the export of certain samples (c.) depends on the authorization of the holder of the rights on such species.

In spite of the above, the Act does not describe the procedures.



### 3. Websites Of Interest

**NBC – National Biodiversity Centre, Bhutan:**

<http://www.nbc.gov.bt/about-nbc>

**Clearing House Mechanism of Bhutan:**

<http://www.biodiv.be/bhutan/introducation-chm>

### 4. Summary – Competent Authorities

Authority	Competence
Minister of Agriculture of RGOB	Responsible for matters related to genetic resources and associated traditional knowledge

### 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Bhutan profile. Disponível em: <https://absch.cbd.int/countries/BT> Access in 30/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Bhutan profile. Disponível em: <https://www.cbd.int/countries/?country=bt> Acesso em 30/10/2016.

GOVERNMENT OF BHUTAN. **National Biodiversity Strategies And Action Plan (NBSAP)**. Ministry of Agriculture and Forests. Thimphu, 2014. Disponível em: <https://www.cbd.int/countries/?country=bt> Access in 30/10/2016.

GOVERNMENT OF BHUTAN. **The Fifth National Report**. National Environment Commission Secretariat. Thimphu. Disponível em: <https://www.cbd.int/countries/?country=bt> Acesso em 30/10/2016.

GOVERNMENT OF BHUTAN. **The Biodiversity Act of Bhutan**. Disponível em: <http://www.biodiv.be/bhutan/legal-instruments/acts> Access in 30/10/2016.

GOVERNMENT OF BHUTAN. **Environment Assessment Act**. Disponível em: <http://www.biodiv.be/bhutan/legal-instruments/acts> Access in 30/10/2016.

GOVERNMENT OF BHUTAN. **Biodiversity Bill of Bhutan, 2016**. Disponível em: <http://www.nbc.gov.bt/wp-content/uploads/2016/03/Draft-Biodiversity-Bill-2016.pdf> Access in 30/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by accession, since May 10, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Apr 19, 2015.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

According to the CBD official website, the Cambodian competent authorities are:

- **H. E. Chay Samith** - responsible for genetic resources within the Protected Areas System.
- **Ms Somaly Chan** - responsible for genetic resources at the national level, coordination of policy development and implementation 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf**

**of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2. 9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**3. Websites**

***Clearing House Mechanism Cambodia***

*<http://www.chm.gdancp-moe.org>*

**4. Summary – Competent Authorities**

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

<b>Authority</b>	<b>Competence</b>
H.E. Chay Samith	Responsible for genetic resources within the Protected Areas System.
Ms Somaly Chan	Responsible for genetic resources at the national level, coordination of policy development and implementation of the Nagoya Protocol.

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Cambodia profile. Disponível em: <https://absch.cbd.int/countries/KH> Acesso em 03/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Cambodia profile. Disponível em: <https://www.cbd.int/countries/?country=kh> Acesso em 03/10/2016.

KINGDOM OF CAMBODIA. **National Biodiversity Strategy And Action Plan**. National Council for Sustainable Development. 2016. Disponível em: <https://www.cbd.int/countries/?country=kh> Acesso em 03/10/2016.

KINGDOM OF CAMBODIA. **The Fifth National Report To The Convention On Biological Diversity**. National Biodiversity Steering Committee. 2014. Disponível em: <https://www.cbd.int/countries/?country=kh> Acesso em 03/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Nov 19, 1996.

### Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Apr 25, 2017.

### Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites

**National CHM**

<http://www.qatarenv.org>

**Ministry of Municipality and Environment**

<http://www.mme.gov.qa/cui/index.dox?siteID=2>

### 4. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**Mr. Massoud Jar Allah Al-Marri**

ABS National Focal Point

+974 4420 7530

+974 4476 3676

[mjmmarri@mme.gov.qa](mailto:mjmmarri@mme.gov.qa)



Ministry of Municipality and Environment  
Doha  
Qatar

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Qatar profile. Disponível em: <https://absch.cbd.int/countries/QA> Acesso em 03/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Qatar profile. Disponível em: <https://www.cbd.int/countries/?country=qa> Acesso em 03/10/2016.

STATE OF QATAR. **Protected Area Action Plan 2008-2013**. Supreme Council for Environment and Natural Reserves (SCENR). Department of Wildlife Conservation. Doha, 2007. Disponível em: <https://www.cbd.int/countries/?country=qa> Acesso em 03/10/2016.

STATE OF QATAR. **Qatar National Biodiversity Strategy and Action Plan 2015-2025**. Ministry of Environment, 2014. Disponível em: <https://www.cbd.int/countries/?country=qa> Acesso em 03/10/2016.

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

YES /  NO

Yes, the country has been a Party to the CBD, by ratification, since Dec 5, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Kazakhstan has been a party to the Protocol since Sep 15, 2015, having acceded to it on Jun 17, 2015.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

In Kazakhstan, the Forestry and Wildlife Committee, linked to the Ministry of Agriculture of the Republic of Kazakhstan, is the environmental inspection institution. However, there is no information as to whether it is the institution responsible for inspecting access to genetic resources.

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

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

YES /  NO

Although the country does not have an access law indicating the competent authority, the profile of Kazakhstan on the official website of the CBD indicates the Forestry and Wildlife Committee of the Ministry of Agriculture as the focal point on the subject.

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

YES /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf**

**of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

There are no specific norms for obtaining access to genetic heritage in activities performed on behalf the perfume, personal hygiene and cosmetic industries.

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

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge, as well as there are no specific norms about collection and access of exotic species either.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**3. Websites Of Interest**

*Forestry and Fauna Committee of the Ministry of Agriculture of the Republic of Kazakhstan:*

*<http://fhc.kz/>*

**4. Summary – competent authorities**

As mentioned under item 2.3., Kazakhstan does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**Mr. Kairat Ustemirov**

ABS National Focal Point

+8 7172 749944, +8 7172 749014

*ustemirov64@mail.ru*

Vice Chairman

Committee of Forestry and Fauna

Ministry of Agriculture  
House of Ministries  
Orynbor Street 8  
010000  
Astana  
Kazakhstan

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Kazakhstan profile. Disponível em: <https://absch.cbd.int/countries/KZ> Acesso em 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Kazakhstan profile. Disponível em: <https://www.cbd.int/countries/?country=kz> Acesso em 18/10/2016.

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. Disponível em: <https://www.cbd.int/countries/?country=kz> Acesso em 18/10/2016.

REPUBLIC OF KAZAKHSTAN. **The Fifth National Report On Progress In Implementation Of The Convention On Biological Diversity.** Ministry Of Environment And Water Resources Of The Republic Of Kazakhstan. Disponível em: <https://www.cbd.int/countries/?country=kz> Acesso em 18/10/2016.

## 1. General Information

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

YES /  NO

Yes, the People's Republic of China has been a Party to the CBD, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the People's Republic of China has been a Party to the Protocol, by adhesion, since Sep 6, 2016.

### 1.3 Does the country have any officially recognized "checkpoints"<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

There is no indication of checkpoints for the People's Republic of China.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

There is no indication of Internationally Recognized Certificates of Compliance (IRCC).

### 1.5 Does the country have any officially recognized "checkpoint communiqués"<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

The country has not established recognized checkpoint communiqués.

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

YES /  NO

The country has no official inspection body. The Ministry of Agriculture and the Ministry of Environmental Protection have been working to implement a specific legislation on the access to .....

1 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>.

2 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>.

3 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. It should be noted that, in China, the State is the holder of all rights related to the genetic resources of plant species, and the notions of “property rights” only have a vague definition. Therefore, the lack of a national legislation on the matter poses a challenge to the activities of companies and individuals in the country.<sup>4</sup>

### **1.7 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

The People’s Republic of China has no specific legislation on the topic.

## **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

The country has no specific legislation on the subject. However, there are dispositions regulating access to genetic resources across the patent legislation of the country, as informed in item 2.5 of 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.

On the other hand, the “Biodiversity & Biosafety Law Research Programme”, 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, and the Project for Protection of Tibetan Medicine, developed in the Kangding County of the Sichuan Province, with the objective of protecting and promoting technologies related to medicinal planting, animal farming and pharmaceutical production and processing.<sup>5</sup>

In relation to the Aichi Targets, the 5th National Report on the Implementation of the Convention on Biological Diversity of 2015 establishes that, up to 2020, a system of access to genetic resources and benefit sharing shall be in place in China. As a matter of fact, the need for mechanisms and regulations on access and benefit sharing is covered under section V of the Report, items 5.1 ‘main issues’ and 5.2 ‘priority actions’ as one of the primordial initiatives towards biodiversity.

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

YES /  NO

4 Yiching, Song et al., 2016. Access and benefit sharing in participatory plant breeding in Southwest China. p. 22.

5 Medaglia, Jorge Cabrera et al., Overview of National and Regional Measures on Access and Benefit Sharing: challenges and opportunities in implementing the Nagoya protocol p. 63 - 64.

The country has no official institution regulating the subject.

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

YES /  NO

There is no legislation indicating the need for prior consent.

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

YES /  NO

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 Programme”, 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, and the Project for Protection of Tibetan Medicine, developed in the Kangding County of the Sichuan Province, with the objective of protecting and promoting technologies related to medicinal planting, animal farming and pharmaceutical production and processing.<sup>6</sup>

**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

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There is no legislation indicating specific procedures for the collection and/or access for these specific purposes.

6 Medaglia, Jorge Cabrera et al., Overview of National and Regional Measures on Access and Benefit Sharing: challenges and opportunities in implementing the Nagoya protocol p. 63 - 64.



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

YES /  NO

There is no legislation indicating the procedures for the collection of exotic species.

## 2.8 Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?

YES /  NO

There is no specific legislation on benefit-sharing. 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 in 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.<sup>7</sup>

Finally, for information only, the international organization called “World Intellectual Property Organization” (WIPO) publishes on their website some model contracts related to access and benefit-sharing within the Convention on Biological Diversity and the Nagoya Protocol. In this sense, it is possible to find a contract between Syngenta Crop Protection AG (user of genetic resource based in Basel, Switzerland) and the HUBEI Academy of Agricultural Sciences (supplier of genetic resource, located in Wuhan, China). The main objective of this contract, which entered into force in November 1997, is the discovery of natural products from micro-organisms for use as agricultural defenses or lead composites, aimed for commercial/industrial application. In relation to benefit-sharing, it has been carried out in the two modalities foreseen by the Nagoya Protocol, monetary and non-monetary, as follows: royalties (no specification of values) and the financing of a collection of samples, fermentation activities and prescreening in China, technology transfer and transfer of know-how to China, and the training of Chinese scientists and Swiss technicians.

## 2.9. Does the current legislation establish procedures for the shipment of samples?

YES /  NO

There is no legislation specifying specific procedures for the shipping of samples. However, the website Biodiversity Clearing -House Mechanism of China<sup>8</sup> informs that the country adopts a Material Transfer Agreement – MTA for exchanging germplasm with other countries or agriculture international organizations.

## 3. Websites Of Interest

### *National Clearing-house Mechanism:*

<http://english.biodiv.gov.cn/>

7 Id.

8 Benefit sharing of genetic resources. Available at: [http://english.biodiv.gov.cn/rdwt/201601/t20160112\\_325537.html](http://english.biodiv.gov.cn/rdwt/201601/t20160112_325537.html). Access on Oct 25, 2016.

**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/>

## 4. Summary – Competent Authorities

There are no competent authorities specifically for this subject. However, the country has instituted a National Focal Point (Article 13.1 of the Nagoya Protocol), which is the recognized responsible authority according to the website of the Convention on Biological Diversity and the website of The Access and Benefit-Sharing Clearing-House Mechanism

### Nagoya Protocol on Access and Benefit-sharing

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115 Xizhimennei Nanxiaojie  
100035  
Beijing  
China

## 5. Referências Bibliográficas

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. China profile. Disponível em: <https://absch.cbd.int/countries/CN> Acesso em 03/11/2016.

Biodiversity Clearing-House Mechanism of China. **Benefit sharing of genetic resources**. Disponível em: [http://english.biodiv.gov.cn/rdwt/201601/t20160112\\_325537.html](http://english.biodiv.gov.cn/rdwt/201601/t20160112_325537.html) Acesso em 03/11/2016.

CHINA. **China National Biodiversity Conservation Strategy and Action Plan (2011-2030)**. Disponível em: <https://www.cbd.int/countries/?country=cn> Acesso em 03/11/2016.

CHINA. **China's Fifth National Report on the Implementation of the Convention on Biological Diversity**. The Ministry of Environmental Protection of China. 2014. Disponível em: <https://www.cbd.int/countries/?country=cn> Acesso em 03/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. China profile. Disponível em: <https://www.cbd.int/countries/?country=cn> Acesso em 03/11/2016.

MEDAGLIA, Jorge Cabrera et al., CENTRE FOR INTERNATIONAL SUSTAINABLE DEVELOPMENT LAW – CISDL. **Overview Of National And Regional Measures On Access And Benefit 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). Disponível em: [http://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](http://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 03/11/2016.

REPUBLIC OF CHINA. **Implementing Regulations of the Patent Law of the People's Republic of China, of February 2010**. Disponível em: <http://www.wipo.int/edocs/lexdocs/laws/en/cn/cn078en.pdf> Acesso em 03/11/2016.

REPUBLIC OF CHINA. **Patent Law of the Republic of China, of December, 27, 2008**. Disponível em: <http://www.wipo.int/edocs/lexdocs/laws/en/cn/cn028en.pdf> Acesso em 03/11/2016.

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. Disponível em: <https://cgspace.cgiar.org/handle/10568/73323> Acesso em 03/11/2016

## 1. General Information

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

YES /  NO

Yes, South Korea has been a Party to the Convention, by ratification, since Jan 1st, 1995.

### 1.3 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, South Korea has been a Party to the Protocol, by ratification, since Aug 17, 2017.

The country has an ABS Research Support Center at the Korea Research Institute of Bioscience and Biotechnology, which provides guidance for research to ensure compliance with the ABS laws and regulations of other countries.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance<sup>2</sup>- IRCC under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

1 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>.

2 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>.

3 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 institution was identified in relation to access and benefit-sharing in this country.

**1.7 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

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.

## 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

Although it is not a dedicated legislation, the Act on The Conservation and Use of Biological Diversity, of 2012 (amended by Act No. 12459, Mar. 18, 2014), briefly addresses access and benefit-sharing.

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

YES /  NO

The legislation identified does not indicate the institutions responsible for authorizing, controlling and inspecting the access to genetic resources and traditional knowledge. However, the 5th National Report does mention some institutions and their competences:

- Ministry of Environment, Ministry of Oceans and Fisheries, Korean Intellectual Property Office, Rural Development Administration, Korea Forest Service: are responsible for protecting traditional knowledge, innovations and personalized knowledge.
- Ministry of Environment, Ministry of Science, ICT and Future Planning, Ministry of Foreign Affairs, Rural Development Administration, Korean Intellectual Property Office, Ministry of Oceans and Fisheries, Korea Forest Service, Ministry of Trade, Industry and Energy: are responsible for ensuring the fair and equitable sharing of benefits arising from 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

There is no clear mention to the requirement of prior authorization for the purposes of accessing genetic resources or traditional knowledge under the terms of the Nagoya Protocol.

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

YES /  NO

No legal provisions were identified on procedures for obtaining access to traditional knowledge. However, according to article 20 of the Act on The Conservation and Use of Biological Diversity, of 2012 (amended by Act No. 12459, Mar. 18, 2014), while seeking to promote the conservation and use of traditional knowledge, the Government shall establish policies for the research, protection and management of such 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 /  NO

No specifications on intellectual property rights have been identified in the applicable legislation.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

The applicable legislation does not provide any specific procedures on access for the purposes of research and technological development of cosmetics, products of personal hygiene and perfumes.

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

YES /  NO

There are no specific norms for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

The sharing of benefits arising from the use of biological resources is defined in article 19 of the Act on The Conservation and Use of Biological Diversity, of 2012 (amended by Act No. 12459, Mar. 18, 2014). However, there is no definition of value, and item I of article 19 only mentions that the sharing of benefits should be equitable between the resource user and the resource provider. According to item 3 of the same article, further rules and procedures shall be established in separate.

**2. 9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

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 will require official authorization.

### 3. Websites Of Interest

***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>*

### 4. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Republic of Korea profile. Disponível em: <https://absch.cbd.int/countries/KR> Acesso em 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Republic of Korea profile. Disponível em: <https://www.cbd.int/countries/?country=kr> Acesso em 18/10/2016.

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)**. Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=15653> Acesso em 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. Disponível em: <https://www.cbd.int/countries/?country=kr> Acesso em 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. Disponível em: <https://www.cbd.int/countries/?country=kr> Acesso em 18/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since May 10, 2000.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Dez 11, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.



**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 obtain genetic resources?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites

***Ministry of Environment and Water***

*<http://www.moccae.gov.ae/default.aspx>*

***Mohamed bin Zayed Species Conservation Fund***

*<http://www.speciesconservation.org/>*

### 4. Summary – competent authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**Ms. Hiba Obaid AlShehhi**

ABS National Focal Point

+971 4 214 8351

+971 4 214 8532

*[hodarwish@moew.gov.ae](mailto:hodarwish@moew.gov.ae)*

National Communication Coordinator  
Ministry of Climate Change and Environment  
P.O. Box 1509  
Dubai  
United Arab Emirates

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. United Arab Emirates profile. Available in: <https://absch.cbd.int/countries/AE> Access in 04/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. United Arab Emirates profile. Available in: <https://www.cbd.int/countries/?country=ae> Access in 04/10/2016.

UNITED ARAB EMIRATES. **5th National Report**. Ministry of Environment & Water. Available in: <https://www.cbd.int/countries/?country=eg> Access in 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 in 04/10/2016.

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

YES /  NO

Yes, India has been a Party to the Convention, by ratification, since May 19, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, India has been a Party to the Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

SIM /  NÃO

No checkpoints were found in this country

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

SIM /  NÃO

India has 46 IRCCs, according to the list in Annex 1 of this form.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

SIM /  NÃO

No checkpoint communiqués were identified in this country.

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

SIM /  NÃO

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.

1 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>.

2 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>.

3 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.

### **1.7 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 ) SIM / ( ) NÃO

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 offence, 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 offence or contravention under the aforementioned Act shall be deemed to be guilty of the offence or contravention.

## **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

The main laws related to this subject at national level are:

- 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

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 fulfil 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:

1. 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;
2. Any person or institution that seeks to apply for any Intellectual Property Rights, within or out-

- side India, related to research or biological information obtained from India;
3. 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;
  4. 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

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 /  NO

There are no specific procedures. 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?**

YES /  NO

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

It was not possible to identify in the legislation and other documents analyzed any specific procedures for that purpose.

#### **2.7. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?**

YES /  NO

It was not possible to identify in the legislation and other documents analyzed any specific procedures for that purpose.



## **2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES / (  ) NO

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 each the 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.

The Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 were recently created, and determined 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.

## **2.9. Does the current legislation establish procedures for the shipment of samples?**

YES / (  ) NO

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.

### 3. Websites Of Interest

**National CHM**

<http://envfor.nic.in/envis/envis.html>

**Ministry of Environment & Forests, Government of India**

<http://envfor.nic.in/>

**NBA - National Biodiversity Authority**

<http://nbaindia.org/>

### 4. Summary – Competent Authorities

Authority	Competence / Information
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.

### 5. Bibliographical References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. India profile. Disponível em: <https://absch.cbd.int/countries/IN> Acesso em 06/03/2017.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. India profile. Disponível em: <https://www.cbd.int/countries/?country=in> Acesso em 06/03/2017.

COSTA, Cíntia R.; PARANHO, Julia; VASCONCELLOS, Alexandre G. Brasil, Índia e China: o marco legal da biodiversidade e a proteção patentária no âmbito do sistema farmacêutico de inovação. Rio de Janeiro, 2015. 15 fls. Tese de Mestrado: Universidade Federal do Rio de Janeiro – UFRJ, Instituto de Economia. Disponível em: <http://bibliofarma.com/brasil-india-e-china-o-marco-legal-da-biodiversidade-e-a-protecao-patentaria-no-ambito-do-sistema-farmaceutico-de-inovacao/> Acesso em 06/03/2017.

GOVERNMENT OF INDIA. Biological Biodiversity Act, 2002. Disponível em: <https://absch.cbd.int/countries/IN> Acesso em 06/03/2017.

GOVERNMENT OF INDIA. Biological Biodiversity Rules, 2004. Disponível em: <https://absch.cbd.int/countries/IN> Acesso em 06/03/2017.

GOVERNMENT OF INDIA. Designation of institutions/organizations as National Repositories under Section 39 of the Biological Diversity Act, 2002. Disponível em: <https://absch.cbd.int/countries/IN> Acesso em 06/03/2017.

GOVERNMENT OF INDIA. Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014. Disponível em: <https://absch.cbd.int/countries/IN> Acesso em 06/03/2017

GOVERNMENT OF INDIA. India's Fifth National Report To The Convention On Biological Diversity - 2014. Ministry of Environment and Forests. New Delhi, 2014. Disponível em: <https://www.cbd.int/countries/?country=in> Acesso em 06/03/2017.

GOVERNMENT OF INDIA. National Biodiversity Action Plan (NBAP) – Addendum 2014 to NBAP 2008. Ministry of Environment, Forests & Climate Change. New Delhi, 2014. Disponível em: <https://www.cbd.int/countries/?country=in> Acesso em 06/03/2017.

GOVERNMENT OF INDIA. Notificaiton on exemption of crops listed in the Annex-I of the ITPGR-FA from the purview of the Section 3 and 4 of the Biological Diversity Act, 2002. Disponível em: <https://absch.cbd.int/countries/IN> Acesso em 06/03/2017.

GOVERNMENT OF INDIA. Notification on Guidelines for International Collaborative Research Projects under Section 5 of the Biological Diversity Act, 2002. Disponível em: <https://absch.cbd.int/countries/IN> Acesso em 06/03/2017.

GOVERNMENT OF INDIA. Notification under Section 40 of the Biological Diversity Act, 2002. Disponível em: <https://absch.cbd.int/countries/IN> Acesso em 06/03/2017.

NATIONAL BIODIVERSITY AUTHORITY. Draft Access Guidelines Issued By The National Biodiversity Authority Under Section 18(1) Of The Biological Diversity Act, 2002. 28 pages. Chennai, 2002. Disponível em: [http://nbaindia.org/uploaded/docs/Access\\_Guidelines.doc](http://nbaindia.org/uploaded/docs/Access_Guidelines.doc) Acesso em 06/03/2017.

NATIONAL BIODIVERSITY AUTHORITY. Draft Benefit Sharing Guidelines. 15 pages. Chennai, 2003. Disponível em: [http://nbaindia.org/uploaded/docs/Access\\_Guidelines.doc](http://nbaindia.org/uploaded/docs/Access_Guidelines.doc) Acesso em 06/03/2017.

NATIONAL BIODIVERSITY AUTHORITY. Peoples' Biodiversity Register (PBR). 16 pages. Disponível em: [http://nbaindia.org/uploaded/pdf/PPT\\_PBRs\\_Guidelines.pdf](http://nbaindia.org/uploaded/pdf/PPT_PBRs_Guidelines.pdf) Acesso em 06/03/2017.

NATIONAL BIODIVERSITY AUTHORITY. Peoples' Biodiversity Registers Guidelines. 18 pages. Disponível em: [http://nbaindia.org/uploaded/pdf/PPT\\_PBRs\\_Guidelines.pdf](http://nbaindia.org/uploaded/pdf/PPT_PBRs_Guidelines.pdf) Acesso em 06/03/2017.

## Annex I

Summary Table of Internationally Recognized Certificate of Compliance<sup>4</sup>:

PERMIT	DATE	SUMMARY
National: India/ NBA/App/9/701 ABSCH: ABSCH- IRCC-IN-207621-2	Issued on October 10, 2015	Application based on Form III to request prior approval of the invention titled "Extraction of vitamins and minerals from plant matter" to obtain intellectual property rights in India and USA. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, genetic resource and activities authorized.</li> </ul>
National: India/ NBA/App/592 ABSCH: ABSCH- IRCC-IN-208312-1	Issued on August 08, 2016 Valid until August 07, 2021	Application based on Form I to request permit to access resources from the Karnataka and Andhra Pradesh plants for research/bio-survey and bio-utilization with commercial purposes. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> <li>• Scope/species/traditional knowledge object of the authorization: parental lines of KBSH-41 sunflower hybrid viz., RHA 95 C1 (Male Parent), CMS 234 A (Female parent) e CMS 234 B (Sterility Maintainer line).</li> </ul>
National: India/ NBA/App/9/688 ABSCH: ABSCH- IRCC-IN-208311-1	Issued on August 04, 2016 Valid until August 03, 2019	Application based on Form I to request permit to access samples of soil and plant resources from Maharashtra to isolate and track micro-organisms for research /bio-survey and bio-utilization. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• Tre prior informed consent provider is the National Biodiversity Authority;</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> </ul>

4 Certificates updated up to June 13, 2017.

<p>National: India/ NBA/Apl/9/913 ABSCH: ABSCH- IRCC-IN-208310-1</p>	<p>Issued on May 27, 2016 Valid until May 26, 2021</p>	<p>Application based on Form I to request permit to access 4 plant species and 13 insects (pests) from Andhra Pradesh, Bihar, Chhattisgarh, Gujarat, Haryana, Jharkhand, Karnataka, Madhya Pradesh, Maharashtra, Odisha, Punjab, Rajasthan, Tamil Nadu, Telangana and Uttar Pradesh for research/bio-survey and bio-utilization with commercial purposes.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> </ul>
<p>National: India/ NBA/Apl/9/699 ABSCH: ABSCH- IRCC-IN-208309-1</p>	<p>Issued on January 19, 2016 Valid until January 18, 2019</p>	<p>Application based on Form I to request permit to access 6 species of Vanilla Sp. (Vanilla álbida, Vanilla grandiflora, Vanilla aphylla, Vanilla sanjappae, Vanilla walkeriae and Vanilla wightii), from Kerala for the research on the assessment of the genetic and phenotypical diversity within the genus.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Consent provider: National Biodiversity Authority</li> <li>• User of genetic resource: Centre de Cooperation Internationale en Recherche Agronomique pour le Development Academic or research institute (France)</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• No commercial purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> </ul>
<p>National: India/ NBA/Apl/9/586 ABSCH: ABSCH- IRCC-IN-208308-1</p>	<p>Issued on June 27, 2016 Valid until June 26, 2019</p>	<p>Application based on Form I to request permit to access 6 biological resources from Andhra Pradesh and Bangalore for research.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> <li>• User is committed to obtain prior authorization from NBA and sign a benefit-sharing agreement, if a potential for commercial exploitation arises from the research.</li> </ul>

PERMIT	DATE	SUMMARY
National: India/ NBA/Appl/9/680 ABSCH: ABSCH- IRCC-IN-208307-1	Issued on August 5, 2016 Valid until August 4, 2019	Application based on Form I to request permit to access soil and waste samples from Maharashtra for isolation of micro-organisms for research/bio-survey and bio-utilization. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The provider of prior informed consent is the National Biodiversity Authority</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> <li>• The user must make na advance payment to NBA according to the agreement signed between the parties.</li> </ul>
National: India/ NBA/Appl/9/854 ABSCH: ABSCH- IRCC-IN-208306-1	Issued on January 13, 2016 Valid until January 12, 2017	Application based on Form I to request permit to access species <i>Beauveria bassiana</i> obtained from the Directorate of Oilseeds Research, Andhra Pradesh for the development of a liquid bio-pesticide formula. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The provider of prior informed consent is the National Biodiversity Authority</li> <li>• User: Dhampur BioOrganics Ltd</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> <li>• The activity is authorized for commercial exploitation</li> <li>• The user is committed to paying benefit-sharing to NBA according to Regulation No. 4 of the Access and Benefit Sharing Regulations 2014, as the commercialization takes place.</li> </ul>
National: India/ NBA/Appl/9/759 ABSCH: ABSCH- IRCC-IN-208305-1	Issued on September 06, 2016 Valid until September 5, 2019	Application based on Form I to request permit to access biological resources from Kerala, Madhya, Pradesh and Temil Nadu for conducting research. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> <li>• The user is committed to requesting prior authorization from NBA and sign a benefit sharing agreement, if there is a commercial resulting from the investigation.</li> </ul>

<p>National: India/ NBA/9/App/895 ABSCH: ABSCH- IRCC-IN-208304-1</p>	<p>Issued on June 21, 2016 Valid until June 20, 2019</p>	<p>Application based on Form I to request permit to access plant species and micro-organisms from Telangana, Andhra Pradesh, Karnataka, Uttar Pradesh, Bihar, Chhattisgarh, Odisha and Jharkhand with the purpose of conducting research</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> </ul>
<p>National: India/ NBA/App/9/679 ABSCH: ABSCH- IRCC-IN-208303-1</p>	<p>Issued on August 5, 2016 Valid until August 4, 2019</p>	<p>Application based on Form I to request permit to access plant biomass from Maharashtra for research/bio-survey and bio-utilization.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The provider of prior informed consent is the National Biodiversity Authority</li> <li>• The following information were considered classified: user, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> <li>• The user must make an advance payment to NBA according to the agreement signed between the parties</li> </ul>
<p>National: India/ NBA/App/9/682 ABSCH: ABSCH- IRCC-IN-208302-1</p>	<p>Issued on August 4, 2016 Valid until August 3, 2019</p>	<p>Application based on Form I to request permit to access samples of soil waste and effluents from Maharashtra for isolation of micro-organisms for research/bio-survey and bio-utilization.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The provider of prior informed consent is the National Biodiversity Authority</li> <li>• The following information were considered classified: user, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> <li>• The user must make an advance payment to NBA according to the agreement signed between the parties.</li> </ul>



PERMIT	DATE	SUMMARY
National: India/ NBA/Apl/9/683 ABSCH: ABSCH- IRCC-IN-207611-2	Issued on June 1, 2015	<p>Application based on Form III to request permit for the invention titled "Preparation of anti-bacterial and anti-fungal medicines and their medical properties and development plan of Product 10 Plus" to obtain IP rights in India and the UK.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> <li>• The monetary benefit-sharing to the value of 0.2% over the annual gross sales</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee.</li> <li>• Form III to request prior approval of the invention titled "Extraction of vitamins and minerals from plant matter" to obtain intellectual property rights in India and USA.</li> </ul>
National: India/ NBA/Apl/9/640 ABSCH: ABSCH- IRCC-IN-207620-1	Issued on December 30, 2014	<p>Application based on Form III to request permit for the invention titled "Recombining master virus as vector of viral system" to obtain IP rights in India, China, Pakistan, EU, Australia, USA and South Africa.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Authorized user: National Agri-Food Biotechnology Institute</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• Biological resources: Wheat Dwarf India Virus, Ageratum yellow Leaf Curl Beta-satellite and Cotton Leaf Curl Burewala alphasatellite.</li> <li>• If the user commercializes the innovation/process/product, they are due to pay royalties of 3% over the highest sales price of the product sold or used for consumption.</li> <li>• In case of concession/licensing of the innovation /process /product to third parties for commercialization, the user shall pay 5% of the fees received for any given reason (including licensing fees and concession fees). They shall also pay the equivalent of 5% over the royalties received annually from the transferee/licensee, according to the terms of the agreement.</li> <li>• Alternatively to the description above, the transferee/licensee shall sign a tri-party agreement with the user and the NBA, with the objective of paying 5% of the full payment made to the licensor, as well as royalties equivalent to 5% of the highest sales price of the product sold and used for consumption, in favor of NBA.</li> </ul>

<p>National: India/ NBA/Apl/9/814 ABSCH: ABSCH- IRCC-IN-207619-1</p>	<p>Issued on January 13, 2016 Valid until January 12, 2017</p>	<p>Application based on Form I to request permit to interact with and collect information on medicinal plants from Tamil Nadu and Karnataka to better comprehend the epistemology of siddha medicine.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose.</li> </ul>
<p>National: India/ NBA/Apl/9/878 ABSCH: ABSCH- IRCC-IN-207618-1</p>	<p>Issued on July 20, 2016</p>	<p>Application based on Form III to request permit for the invention titled "Process for the preparation of active carbon particles from plant material" to obtain IP rights in India.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Authorized user: Dr V Muralikrishnan (natural person)</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: scope/species/traditional knowledge object of the permit, and use purpose</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee.</li> </ul>
<p>National: India/ NBA/Apl/9/691 ABSCH: ABSCH- IRCC-IN-207617-1</p>	<p>Issued on January 31, 2015</p>	<p>Application based on Form III to request permit for the invention titled "Extraction of Phyto-chemicals from plant material" to obtain IP rights in India and USA.</p> <p>Prior Informed Consent was obtained according to the legal requirements.</p> <p>Mutually agreed terms were signed between the parties.</p> <p>The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</p> <p>A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee.</p>
<p>National: India/ NBA/Apl/9/687 ABSCH: ABSCH- IRCC-IN-207616-1</p>	<p>Issued on September 22, 2015</p>	<p>Application based on Form III to request permit for the invention titled "NESTOGREN" to obtain IP rights in India.</p> <p>Prior Informed Consent was obtained according to the legal requirements.</p> <p>Mutually agreed terms were signed between the parties.</p> <p>The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit.</p> <p>This permit allows for commercial exploitation.</p> <p>A monetary benefit-sharing was established to the value of 0.1% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 4% over the remuneration received and 5% over the royalties received annually from the transferee/licensee.</p>

PERMIT	DATE	SUMMARY
National: India/ NBA/Appl/9/638 ABSCH: ABSCH- IRCC-IN-207614-1	Issued on November 20, 2014	<p>Application based on Form III to request permit for the invention titled "Use of two spoons of plant powder administered orally with tepid water three times a day, sulfur showers and sulfur ointment to applied over the skin in lesions that have a key role in curing hyper-keratinization and reducing psoriatic skin, as well as preventing the penetration of ultraviolet light rays from the sun through the total reflection and relieve of the dark chronic psoriatic skin with an absolutely non-steroid therapy" to obtain IP rights in India.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, scope/ species/traditional knowledge object of the permit, use purpose</li> <li>• If the user commercializes the innovation/process/product, they are due to pay royalties of 3% over the highest sales price of the product sold or used for consumption.</li> <li>• In case of concession/licensing of the innovation /process /product to third parties for commercialization, the user shall pay 5% of the fees received for any given reason (including licensing fees and concession fees). They shall also pay the equivalent of 5% over the royalties received annually from the transferee/licensee, according to the terms of the agreement.</li> <li>• Alternatively to the description above, the transferee/licensee shall sign a tri-party agreement with the user and the NBA, with the objective of paying 5% of the full payment made to the licensor, as well as royalties equivalent to 5% of the highest sales price of the product sold and used for consumption, in favor of NBA.</li> </ul>
National: India/ NBA/Appl/9/703 ABSCH: ABSCH- IRCC-IN-207613-1	Issued on July 6, 2015	<p>Application based on Form III to request permit for the invention titled "Fed-batch fermentation technique for the increased production of delta-endotoxin from Bacillus thuringiensis subspecies israelensis" to obtain IP rights in India.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Authorized user: Mr Chengalath Gopinathan (natural person)</li> <li>• This permit allows for commercial exploitation.</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee.</li> </ul>

<p>National: India/ NBA/App1/9/984 ABSCH: ABSCH- IRCC-IN-207612-1</p>	<p>Issued on July 26, 2016</p>	<p>Application based on Form III to request permit for the invention titled "Composition of new biological paints, extraction methods and their utilization" to obtain IP rights in India, USA, EU, Australia, Japan, China, Republic of Korea, Thailand, New Zealand, Sri Lanka, Malaysia, Singapore, Brazil, Taiwan, Indonesia, Mexico, Argentina, Chile, Peru, South Africa, Paraguay and Uruguay.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Authorized users: Dr Fathima Benazir (natural person) and Ms K Brinda (contact person)</li> <li>• Material and/or biological resources: new biological composition of paints comprising brazilein, brazilein extraction methods from the bark of Caesalpinia sappan and their uses</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: use purpose</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee.</li> </ul>
<p>National: India/ NBA/App1/9/664 ABSCH: ABSCH- IRCC-IN-206827-1</p>	<p>Issued on March 11, 2015</p>	<p>Application based on Form III to request permit for the invention titled "Garlic formulation and a process for preparing it for the treatment of diabetes" to obtain IP rights in India and USA.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee.</li> </ul>
<p>National: India/ NBA/App1/9/693 ABSCH: ABSCH- IRCC-IN-206826-1</p>	<p>Issued on January 31, 2015</p>	<p>Application based on Form III to request permit for the invention titled "Extraction of vitamin E from plant material" to obtain IP rights in India and USA.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee.</li> </ul>

PERMIT	DATE	SUMMARY
National: India/ NBA/Appl/9/789 ABSCH: ABSCH- IRCC-IN-206825-1	Issued on October 10, 2015 Valid until October 09, 2016	Application based on Form I to request permit to access filamentous fungi <i>Trichoderma harzianum</i> Th4d obtained from Andhra Pradesh for commercial use. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Authorized user: Dhampur BioOrganics Ltd</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The user is committed to paying benefit-sharing to the NBA according to Regulation No.4 of the Access and Benefit Sharing Regulations, 2014, as the commercialization takes place</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> </ul>
National: India/ NBA/Appl/9/708 ABSCH: ABSCH- IRCC-IN-206824-1	Issued on May 19, 2015	Application based on Form III to request permit for the invention titled "Effective herbal composite against Rhabdovirus and its preparation process" to obtain IP rights in India. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee</li> </ul>
National: India/ NBA/Appl/9/694 ABSCH: ABSCH- IRCC-IN-206823-1	Issued on August 19, 2015	Application based on Form III to request permit for the invention titled "Dry processed yellow mollusk meat" to obtain IP rights in India. IP rights will also be requested in USA, Japan, Australia, Belgium, Canada, China, Denmark, Finland, France, UK, Germany, Ireland, Hong Kong, Italy, Malaysia, New Zealand, Norway, Portugal, Russia, Singapore, Switzerland, Sri Lanka, Taiwan Thailand and Vietnam. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• The following information were considered classified: user, scope/species/traditional knowledge object of the permit</li> <li>• This permit allows for commercial exploitation.</li> <li>• A monetary benefit-sharing was established to the value of 0.5% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 4% over the remuneration received and 3% over the royalties received annually from the transferee/licensee.</li> </ul>

<p>National: India/ NBA/App/9/696 ABSCH: ABSCH- IRCC-IN-206822-1</p>	<p>Issued on August 28, 2015</p>	<p>Application based on Form III to request permit for the invention titled “Dry processed shrimp meat” to obtain IP rights in India, USA, Japan, Australia, Belgium, Canada, China, Denmark Finland, France, UK, Ireland, Hong Kong, Italy, Malaysia, New Zealand, Norway, Portugal, Russia, Singapore, Switzerland, Sri Lanka, Taiwan, Thailand and Vietnam.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• The following information were considered classified: user, scope/species/traditional knowledge object of the permit</li> <li>• This permit allows for commercial exploitation.</li> <li>• A monetary benefit-sharing was established to the value of 0.5% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 4% over the remuneration received and 3% over the royalties received annually from the transferee/licensee.</li> </ul>
<p>National: India/ NBA/App/9/836 ABSCH: ABSCH- IRCC-IN-206819-1</p>	<p>Issued on January 13, 2016</p>	<p>Application based on Form III to request permit for the invention on the increase of Estigmaterol and Hecogenina rates in in vitro cultures of Chlorophytum borivilianum root through polyploidy to obtain IP rights in India.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• A monetary benefit-sharing was established to the value of 0.5% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee.</li> <li>• For commercial exploitation of intellectual property, the user must obtain prior approval from NBA in order to access biological resources or traditional knowledge as raw material.</li> </ul>
<p>National: India/ NBA/App/9/601 ABSCH: ABSCH- IRCC-IN-206818-1</p>	<p>Issued on August 03, 2015 Valid until August 02, 2020</p>	<p>Application based on Form I to request permit to access and isolate green algae and cyanobacteria from the sea waters of Goa, Gujarat and Maharashtra to evaluate their commercial potential.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The user must make an advance payment to NBA according to the agreement signed between the parties</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource is not authorized. Prior authorization must be requested for such cases.</li> </ul>

PERMIT	DATE	SUMMARY
National: India/ NBA/Appl/9/882 ABSCH: ABSCH- IRCC-IN-206817-1	Issued on December 22, 2015	Application based on Form I to request permit to transfer the results of research on Bacillus thuringiensis isolates to M/s. Bioseed Research India, Hyderabad for the production of insect-resistant plant cultures. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The user shall pay the benefit-sharing of 3% over the amount received for the transference, in favor of NBA.</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource to third parties are not authorized. Prior authorization must be requested for such cases.</li> </ul>
National: India/ NBA/Appl/9/634 ABSCH: ABSCH- IRCC-IN-206816-1	Issued on August 16, 2015 Valid until August 15, 2018	Application based on Form I to request permit to access 2Ai cry gene isolated from Bacillus thuringiensis for the development of insect-resistant plants <ul style="list-style-type: none"> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource to third parties are not authorized. Prior authorization must be requested for such cases.</li> </ul>
National: India/ NBA/Appl/850 ABSCH: ABSCH- IRCC-IN-206815-1	Issued on January 19, 2016	Application based on Form III to request permit for the invention titled "Process for the preparation of neera syrup, a sweet sap obtained from palm trees, the Phoenix sylvestris species in particular" to obtain IP rights in India. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• Authorized users: Dr Balu Chopade Ananda (natural person) and Ms Suchitra Vishal Mokashi</li> <li>• The following information were considered classified: provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• A monetary benefit-sharing was established to the value of 0.5% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 4% over the remuneration received and 3% over the royalties received annually from the transferee/licensee.</li> </ul>



<p>National: India/ NBA/App1/9/745 ABSCH: ABSCH- IRCC-IN-206814-1</p>	<p>Issued on December 18, 2015</p>	<p>Application based on Form III to request permit for the invention titled "Macro-laricide activity of the Trachyspermum amii fruit starch" to obtain IP rights in India.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Authorized users: Dr Balu Chopade Ananda (natural person) and Ms Suchitra Vishal Mokashi</li> <li>• Mutually agreed terms were signed between the parties</li> <li>• This permit allows for commercial exploitation.</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee</li> </ul>
<p>National: India/ NBA/App1/9/732 ABSCH: ABSCH- IRCC-IN-206813-1</p>	<p>Issued on December 18, 2015</p>	<p>Application based on Form III to request permit for the invention titled "Process for the preparation of alcohol from damaged rice grains" to obtain IP rights in India.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee</li> </ul>
<p>National: India/ NBA/App1/9/803 ABSCH: ABSCH- IRCC-IN-206812-1</p>	<p>Issued on November 23, 2015</p>	<p>Application based on Form III to request permit for the invention titled "Process of hyperproduction of catalase from new extremophilic Geobacillus extremocatsoochus bacteria and its MTCC 5873 strain" to obtain IP rights in India.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• Authorized users: Punjabi University</li> <li>• This permit allows for commercial exploitation.</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee</li> </ul>



PERMIT	DATE	SUMMARY
National: India/ NBA/Appl/9/608 ABSCH: ABSCH- IRCC-IN-206811-1	Issued on July 08, 2015	Application based on Form III to request permit for the invention titled "Fruit containing confectionery" to obtain IP rights in India. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• Authorized users: Mr Ashok Prabhakar Gade</li> <li>• Activity/Genetic resource: banana (<i>Musa acuminata</i>)</li> <li>• This permit allows for commercial exploitation.</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee</li> </ul>
National: India/ NBA/Appl/9/790 ABSCH: ABSCH- IRCC-IN-206810-1	Issued on January 19, 2016	Application based on Form III to request permit for the invention titled "Process of extraction of bioactive composites showing anti-cancerous properties from <i>Lentinus tuberregium</i> " to obtain IP rights in India. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Authorized users: University of Madras</li> <li>• This permit allows for commercial exploitation.</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee</li> </ul>
National: India/ NBA/Appl/9/700 ABSCH: ABSCH- IRCC-IN-206809-1	Issued on July 02, 2015 Valid until July 01, 2017	Application based on Form I to request permit to access species of Formicidae, Coleoptera, Hemiptera, Anura and Apoda obtained from Maharashtra for research purposes. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Authorized users: Mr Christopher John Thorpe-Dixon</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• This permit is for non-commercial purposes only</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource to third parties are not authorized. Prior authorization must be requested for such cases.</li> </ul>

<p>National: India/ NBA/App1/9/722 ABSCH: ABSCH- IRCC-IN-206808-1</p>	<p>Issued on September 21, 2015 Valid until September 20, 2018</p>	<p>Application based on Form I to request permit to access infected leaves, plant stalk and Zea mays sheath obtained from Andhra Pradesh, Bihar, Karnataka and Telangana to identify breeds of pathogenic agents that cause damage in hybrid precursors.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource to third parties are not authorized. Prior authorization must be requested for such cases.</li> </ul>
<p>National: India/ NBA/App1/9/631 ABSCH: ABSCH- IRCC-IN-206807-1</p>	<p>Issued on November 16, 2015 Valid until November 15, 2020</p>	<p>Application based on Form I to request permit to access Lepidoptera shingidae nocturne butterflies obtained from Karnataka, Odisha, Kerala, Andhra Pradesh, Gujarat, Himachal Pradesh, West Bengal, Arunachal Pradesh, Meghalaya, Mizoram, Rajasthan, Chhattisgarh, Uttar Pradesh and Madhya Pradesh for research purposes.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Authorized users: (1) Ekologike Centrum Orlov, o.p.s Sphingidae Museum and (2) Dr Manjunatha H B.</li> <li>• This permit is for non-commercial purposes only</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• Activities/genetic resources: access to the Lepdoptera order of the Sphingidae family of nocturne butterflies and the Scarabaeoidea, Buprestidae and Cerambycidae super families</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource to third parties are not authorized. Prior authorization must be requested for such cases.</li> </ul>
<p>National: India/ NBA/App1/9/593 ABSCH: ABSCH- IRCC-IN-206806-1</p>	<p>Issued on March 06, 2015</p>	<p>Application based on Form III to request permit for the invention titled "Process and formulation of ayurvedic medical capsules and pills" to obtain IP rights in India.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Authorized users: Mr Nilesh Madhusudan Pagedar</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• This permit allows for commercial exploitation.</li> <li>• Bioresource utilized: "Castor leaves powder and cow milk"</li> <li>• If the user commercializes the innovation/process/product, they are due to pay royalties of 3% over the highest sales price of the product sold or used for consumption.</li> <li>• In case of concession/licensing of the innovation /process /product to third parties for commercialization, the user shall pay 5% of the fees received for any given reason (including licensing fees and concession fees). They shall also pay the equivalent of 5% over the royalties received annually from the transferee/licensee, according to the terms of the agreement.</li> <li>• Alternatively to the description above, the transferee/licensee shall sign a tri-party agreement with the user and the NBA, with the objective of paying 5% of the full payment made to the licensor, as well as royalties equivalent to 5% of the highest sales price of the product sold and used for consumption, in favor of NBA.</li> </ul>

PERMIT	DATE	SUMMARY
National: India/ NBA/Appl/9/584 ABSCH: ABSCH- IRCC-IN-206805-1	Issued on January 12, 2016 Valid until January 11, 2019	Application based on Form I to request permit to access two biological resources from Tamil Nadu and Rajasthan for research purposes. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource to third parties are not authorized. Prior authorization must be requested for such cases.</li> <li>• The user must make an advance payment to NBA according to the agreement signed between the parties.</li> </ul>
National: India/ NBA/Appl/9/583 ABSCH: ABSCH- IRCC-IN-206804-1	Issued on January 12, 2016 Valid until January 11, 2019	Application based on Form I to request permit to access nine biological resources from Karnataka and Kerala for research purposes. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource to third parties are not authorized. Prior authorization must be requested for such cases.</li> <li>• The user must make an advance payment to NBA according to the agreement signed between the parties.</li> </ul>
National: India/ NBA/Appl/9/582 ABSCH: ABSCH- IRCC-IN-206803-1	Issued on January 12, 2016 Valid until January 11, 2019	Application based on Form I to request permit to access seven biological resources from Karnataka and Kerala for research purposes. <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: user, provider, scope/species/traditional knowledge object of the permit, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource to third parties are not authorized. Prior authorization must be requested for such cases.</li> <li>• The user must make an advance payment to NBA according to the agreement signed between the parties.</li> </ul>

<p>National: India/ NBA/App/9/719 ABSCH: ABSCH- IRCC-IN-206802-1</p>	<p>Issued on October 26, 2015</p>	<p>Application based on Form III to request permit for the invention titled "Process for the preparation of storable insecticide formula using a combination of microorganisms" to obtain IP rights in India.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• Provider of prior consent: National Biodiversity Authority</li> <li>• Authorized user: Directorate of Oilseeds Research</li> <li>• This permit allows for commercial exploitation.</li> <li>• Activities/genetic resources: Bacillus thuringiensis var. kurstaki (DOR Bt 127 ) e Beauveria bassiana (isolate ITCC 4513).</li> <li>• A monetary benefit-sharing was established to the value of 0.2% over the annual gross sales from the factory, State tax deducted. If the process/product/innovation developed from the patent arising from the access is given/licensed to third parties for commercialization, the user shall pay to NBA the value of 3% over the remuneration received and 2% over the royalties received annually from the transferee/licensee</li> </ul>
<p>National: India/ NBA/App/9/684 ABSCH: ABSCH- IRCC-IN-204353-1</p>	<p>Issued on March 27, 2015 Valid until March 26, 2018</p>	<p>Application based on Form I to request permit to access ethno-medical knowledge from the Siddi community in Gujarat, for research purposes.</p> <ul style="list-style-type: none"> <li>• Prior Informed Consent was obtained according to the legal requirements.</li> <li>• Authorized user: Ms Seema Solanki</li> <li>• Mutually agreed terms were signed between the parties.</li> <li>• The following information were considered classified: provider, use purpose</li> <li>• The acquisition of intellectual property rights and the transfer (wholly or partly) of the accessed biological resource to third parties are not authorized. Prior authorization must be requested for such cases.</li> </ul>

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since Nov 21, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Nagoya Protocol, by ratification, since Oct 12, 2014 .

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the 5th National Report under the CBD, the country is working on a draft of the National Act on Genetic Resources to regulate the issue of genetic resources, conservation, sustainable use and procedures for access to these resources.

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf**

### **of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### **2.7. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### **2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### **2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## **3. Websites**

### ***National Clearing-house Mechanism***

*<http://www.menlh.go.id>*

## **4. Summary – Competent Authorities**

As mentioned in item 2.2., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### **Nagoya Protocol on Access and Benefit-sharing**

#### **Mr. Bambang Hendroyono**

ABS National Focal Point

+62 21 5734818

*[nfpcbd@menlhk.go.id](mailto:nfpcbd@menlhk.go.id)*

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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Indonesia profile. Disponível em: <https://absch.cbd.int/countries/ID> Access on 11/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Indonesia profile. Disponível em: <https://www.cbd.int/countries/?country=id> A Access on 11/11/2016.

REPUBLIC OF INDONESIA. **Indonesian Biodiversity Strategy and Action Plan - National Document**. The National Development Planning Agency (BAPPENAS). 2003. Disponível em: <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 Control and Climate Change. 2014. Disponível em: <https://www.cbd.int/countries/?country=id> Access on 11/11/2016.



## 1. General Information

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

YES /  NO

Yes, Israel has been a Party to the CBD, by ratification, since Nov 5, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

The country is not a Party to the Protocol and neither has signed it.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

It was not possible to identify an official institution responsible for inspecting access and benefit-sharing and neither there is evidence of application of fines or of any legislation specifying cases of misconduct.

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 1.6, there is no legislation regulating the subject.

## 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

Israel does not have any valid and promulgated national legislation regarding access to genetic heritage and associated traditional knowledge, and neither does it have any bills dealing with these subjects at present.

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

YES /  NO

As mentioned in item 2.1, no current administrative guidelines or national legislation regulating the subject could be identified.

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

YES /  NO

As mentioned in item 2.1, no current administrative guidelines or national legislation regulating the subject could be identified.

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

YES /  NO

As mentioned in item 2.1, there are no administrative guidelines or legislation regulating the 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 development involving the access?**

YES /  NO

As mentioned in item 2.1, there are no administrative guidelines or legislation regulating the subject.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, there are no administrative guidelines or legislation regulating the subject.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, there are no administrative guidelines or legislation regulating the subject.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, there are no administrative guidelines or legislation regulating the subject.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, there are no administrative guidelines or legislation regulating the subject.

### 3. Websites Of Interest

*Israel Ministry of Foreign Affairs*

*<http://mfa.gov.il/>*

### 4. Summary – Competent Authorities

There are no official competent authorities specific to this subject. However, the country has instituted a National Focal Point (Article 13.1 of the Nagoya Protocol), which is the recognized responsible authority according to the website of the Convention on Biological Diversity and the website of The Access and Benefit-Sharing Clearing-House Mechanism:

#### **Nagoya Protocol on Access and Benefit-sharing**

**Dr. Simon Nemptov**

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ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Israel profile. Disponível em: <https://absch.cbd.int/countries/IL> Acesso em 08/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Israel profile. Disponível em: <https://www.cbd.int/countries/?country=il> Acesso em 08/11/2016.

STATE OF ISRAEL. **Fifth National Report to the United Nations Convention on Biological Diversity**. Ministry of Environmental Protection. 2016. Disponível em: <https://www.cbd.int/countries/?country=il> Acesso em 08/11/2016.

STATE OF ISRAEL. **Israel's National Biodiversity Plan**. Ministry of Environmental Protection. 2010. Disponível em: <https://www.cbd.int/countries/?country=il> Acesso em 08/11/2016.

## 1. General Information

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

YES /  NO

Yes, Japan has been a Party to the Convention, by acceptance, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Japan has been a Party to the Protocol, by ratification, since Aug 20, 2017.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.4 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

No competent institutions responsible for inspecting access and benefit-sharing were found in this country. Similarly, there are no records of fine application, or any specific legislation clarifying which activities are considered to be irregular in the country.

1 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>.

2 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>.

3 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.

### 1.7 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

As per item 2.1, there are no administrative guidelines or any legislation regulating the subject.

## 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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge. The website of the Japanese Ministry of the Environment<sup>4</sup> affirms 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, the Ministry of Economy, Trade and Industry – METI and the Japan Bioindustry Association – JBA have developed a Guidebook of Access to Genetic Resources for Users in Japan (second edition). This guidebook clarifies the procedures and frequently asked questions on obtaining access to genetic resources in countries that are a party 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.

### 2.3. Does the current legislation or any ongoing bills identify the competent institution?

YES /  NO

From the official sources, there is no indication that Japan has an official competent institution in place for matters related to access and benefit sharing within the Nagoya Protocol and the Convention on Biological Diversity.

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

YES /  NO

As per item 2.1, no legislation or administrative guidelines were found on the existence of laws regulating the subject. 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.

.....  
4 Available at: <https://www.env.go.jp/en/nature/biodiv/abs/index.html>

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

( ) YES / ( X ) NO

As per item 2.1, no legislation or administrative guidelines were found on the existence of laws regulating the subject. 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.

**2.6. 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

As per item 2.1, no legislation or administrative guidelines were found on the existence of laws regulating the subject.

**2.7. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As per item 2.1, no legislation or administrative guidelines were found on the existence of laws regulating the subject.

*Please note that collecting and/or importing plants, animals, microorganisms or other biological materials may be subject to existing regulations (e.g. regulations regarding protected areas, endangered species, quarantine) and agreement with land/specimen owners.*

*Please ask Ranger Offices for detailed information about required procedures under the Natural Parks Law of Japan. When you could not specify the Ranger Office in charge of the National Park area where you are planning to access the specimens, please contact the Regional Environmental Office in charge of the area.*

*Contact information of Ranger offices and Regional Environmental Offices is available at:*

*It is also advisable to contact municipal and/or prefectural government offices where you are going to obtain plants and/or animals, as they might regulate the places or the species to protect.*

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

( ) YES / ( X ) NO

As per item 2.1, no legislation or administrative guidelines were found on the existence of laws regulating the subject.

**2.12. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As per item 2.1, no legislation or administrative guidelines were found on the existence of laws regulating the subject.

**2. 13. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As per item 2.1, there is no legislation or administrative guidelines regulating the subject.

### 3. Websites Of Interest

***Biodiversity Center of Japan (National CHM):***

*[http://www.biodic.go.jp/index\\_e.html](http://www.biodic.go.jp/index_e.html)*

***Ministry of the Environment, Government of Japan:***

*<http://www.env.go.jp/en/>*

***National Institute for Environmental Studies, Japan:***

*<http://www.nies.go.jp/>*

### 4. Summary – Competent Authorities

As per item 2.3, no information was found regarding the competent authorities, but the country has instituted a National Focal Point recognized by the official website of the Convention on Biological Diversity and the website of The Access and Benefit-Sharing Clearing-House (ABSCH).

***Nagoya Protocol on Access and Benefit-sharing***

***Ms. Kaori Tsujita***

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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Japan profile. Disponível em: <https://absch.cbd.int/countries/JP> Acesso em 10/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Japan profile. Disponível em: <https://www.cbd.int/countries/?country=jp> Acesso em 10/10/2016.

GOVERNMENT OF JAPAN. *Basic Act on Biodiversity*. Disponível em: [https://www.ecolex.org/details/legislation/basic-act-on-biodiversity-lex-faoc100101/?q=Basic+Act+on+Biodiversity&type=legislation&xkeywords=biodiversity&xcountry=Japan&xdate\\_min=&xdate\\_max=](https://www.ecolex.org/details/legislation/basic-act-on-biodiversity-lex-faoc100101/?q=Basic+Act+on+Biodiversity&type=legislation&xkeywords=biodiversity&xcountry=Japan&xdate_min=&xdate_max=) Acesso em 10/10/2016.

GOVERNMENT OF JAPAN. **Fifth National Report of Japan to the Convention on Biological Diversity**. Ministry of the Environment. 2014. Disponível em: <https://www.cbd.int/countries/?country=jp> Acesso em 10/10/2016.

GOVERNMENT OF JAPAN. **The National Biodiversity Strategy of Japan 2012-2020 -Roadmap towards the Establishment of an Enriching Society in Harmony with Nature**. Ministry of the Environment. 2012. Disponível em: <https://www.cbd.int/countries/?country=jp> Acesso em 10/10/2016.

**Guidelines for access to genetic resources and the fair and equitable sharing of benefits arising from their utilization. s/a**. Ministry of Finance, Ministry of Education, Culture, Sports, Science and Technology Ministry of Health, Labour and Welfare, Ministry of Agriculture, Forestry and Fisheries, Ministry of Economy, Trade and Industry, Ministry of the Environment. Disponível em: Acesso em 19/05/2017.

MINISTRY OF ECONOMY, TRADE AND INDUSTRY – METI; and JAPAN BIOINDUSTRY ASSOCIATION – JBA. **Guidebook of Access to Genetic Resources for Users in Japan**. 2 ed. Research Institute of Biological Resources - Japan Bioindustry Association – JBA. 2012. Disponível em: [http://www.jba.or.jp/pc/en/library/pdf/2012\\_guideline\\_access\\_e.pdf](http://www.jba.or.jp/pc/en/library/pdf/2012_guideline_access_e.pdf) Acesso em 10/10/2016.

MINISTRY OF THE ENVIRONMENT. **Outline of Guidelines (draft) for Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization**. Nature Conservation Bureau, Ministry of the Environment. 2017. Disponível em: Acesso em 19/05/2017.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Feb 10, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 obtain genetic resources?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

**Mr. Raed Bani Hani**

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Director  
Nature Protection Directorate  
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11941  
Amman  
Jordan

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Jordan profile. Available in: <https://absch.cbd.int/countries/JO> Access in 06/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Jordan profile. Available in: <https://www.cbd.int/countries/?country=jo> Access in 05/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since Oct 31, 2002.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Nagoya Protocol, by accession, since Aug 30, 2017 .

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

LEGAL INFORMATION

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

YES /  NO

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 /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites

***Environment Public Authority***

<https://www.epa.org.kw/index.php>

***Kuwait Legal Information Network***

<http://www.gcc-legal.org/CountryHome.aspx?country=1>

### 4. Summary – Competent Authorities

As mentioned in item 2.2., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

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Kuwait

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Kuwait profile. Disponível em: <https://absch.cbd.int/countries/KW> Acesso em 07/06/2017.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Kuwait profile. Disponível em: <https://www.cbd.int/countries/?country=kw> Acesso em 07/06/2017.

STATE OF KUWAIT. **Fifth National Report on the implementation of the Convention of Biological Diversity**. Environment Public Authority – EPA. 2014. Disponível em: <https://www.cbd.int/countries/?country=kw> Acesso em 07/06/2017.

STATE OF KUWAIT. **Patent Law No. 71 of 2013**. Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=15423> Acesso em 07/06/2017.

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. Disponível em: <https://www.cbd.int/countries/?country=kw> Acesso em 07/06/2017.

## 1. General information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by accession, since Dez 19, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 obtain genetic resources?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Lao People’s Democratic Republic profile. Available in: <https://absch.cbd.int/countries/LA> Access in 06/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Lao People’s Democratic Republic profile. Available in: <https://www.cbd.int/countries/?country=la> Access in 06/10/2016.

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 in 06/10/2016.

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 in 06/10/2016.

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 in 06/10/2016.

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

YES /  NO

Yes, Malaysia has been a Party to the CBD, by ratification, since Sep 22, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

The country is not a Party to the Protocol and neither has signed it.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No Internationally Recognized Certificates of Compliance (IRCC) were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

Malaysia still does not have any legislation on genetic resources and associated traditional knowledge and, therefore, it is not possible to specify the competent institutions responsible for inspecting access and benefit sharing, or to identify any cases of application of fines.

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 1.9, the country still does not have any legislation on this subject, and thus there is no existing legislation to clarify which conducts are considered to be irregular in the country, also making it impossible to determine the applicable sanctions or the value of fines.

## 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

The country does not have any valid and promulgated legislation on the matter, but it was possible to identify the existence of a bill called 'Draft Access to Biological Resources and Benefit Sharing Law of 2013'.

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

YES /  NO

The referred Bill designates in its article 7 the Ministry of Natural Resources and Environment as the national competent institution.

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

YES /  NO

The Bill differentiates the types of access between access for commercial and potential for commercial use and access for non-commercial use. For both cases a proper permit is required. Article 12 (1) states that any person who intends to access a biological resource or associated traditional knowledge for commercial or potential commercial purposes shall apply for a permit; and the same is required for non-commercial purposes under to article 14 (1). The permit request shall be submitted to the competent authority, which, in turn, will decide on the issuing of a license.

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

YES /  NO

As mentioned under item 2.3, the Bill states, under articles 12 (1) and 14(1), that any person who intends to access biological resources or associated traditional knowledge must apply for a permit with the competent authority, which, in turn, will decide on the issuing of a license.

In addition, the Bill establishes in its article 18(1) the requirement that applicants shall obtain prior informed consent, and enter into a fair and equitable benefit-sharing agreement with the relevant indigenous and local communities for accessing biological resources in lands to which they have a right established by law, and for any associated traditional knowledge held by such 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 /  NO

The Bill states in Article 26(1) that no person shall apply for a patent on a biological resource or associated traditional knowledge without the authorization of the National Competent Authority.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific procedures for the collection and/or access for research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

There are no specific norms for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

According to article 17 of the Bill, a Benefit Sharing Agreement must be signed between the supplier of the resources and the applicant of the permit to access the genetic resources for commercial or potential commercial purposes. The applicant may be obliged by the competent authority or the resources supplier to pay a percentage of any monetary payments arising from the benefit-sharing agreement to a trust fund that may be established by the Federal Government or the State Government.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

No established procedures for the shipment of samples were identified.

### 3. Websites Of Interest

***Malaysia Biodiversity Information System- MyBIS:***

*<http://www.mybis.gov.my>*

***Official Portal of Malaysia Department of Agriculture:***

*<http://www.doa.gov.my/web/guest/lain-lain-bahasa>*

***Department of Environment: Ministry of Natural Resources Environment:***

*<http://www.doe.gov.my/portalv1/en/>*

***Official Website of the Department of Wildlife and National Parks (DWNP) Peninsular Malaysia:***

*<http://www.wildlife.gov.my/index.php/ms/>*



**Official Portal Ministry of Natural Resources and Environment:**

<http://www.nre.gov.my/en-my/Pages/default.aspx>

**Malaysian Biological Diversity Clearing House Mechanism (CHM) – Home**

<http://www.chm.frim.gov.my/>

## 4. Summary – Competent Authorities

According to item 2.3., Malaysia does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### Nagoya Protocol on Access and Benefit-sharing

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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Malaysia profile. Disponível em: <https://absch.cbd.int/countries/MY> Acesso em 16/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Malaysia profile. Disponível em: <https://www.cbd.int/countries/?country=my> Acesso em 16/10/2016.

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. Disponível em: <https://www.cbd.int/countries/?country=my> Acesso em 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. Disponível em: <http://www.tfbc.frim.gov.my/Press%20Release.pdf> Acesso em 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. Disponível em: <https://www.cbd.int/countries/?country=my> Acesso em 16/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Dez 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Out 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

The country does not have a specific law to regulate access to the genetic heritage and associated traditional knowledge of 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.

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 2. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

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Director

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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Mongolia profile. Available in: <https://absch.cbd.int/countries/MD> Access in 07/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Republic of Mongolia profile. Available in: <https://www.cbd.int/countries/?country=md> Access in 07/10/2016.

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 in 07/10/2016.

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 in 07/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Feb 23, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since ratification Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.4 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

2.9. Does the current legislation establish procedures for the shipment of samples?

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites

#### **National CHM**

<http://www.myanmarchm.gov.mm/>

### 4. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

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Environmental Conservation Department

Ministry of Natural Resources and Environmental Conservation



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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Myanmar profile. Available in: <https://absch.cbd.int/countries/MM> Access in 08/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Republic of Myanmar profile. Available in: <https://www.cbd.int/countries/?country=mm> Access in 08/10/2016.

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 in 08/10/2016.

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 in 08/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Oct 24, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Feb 21, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in the country. According to the Fifth National Report (Progress on CDB Strategic Plan 2010-2020 and Aichi Biodiversity Targets), the country already has a draft Pakistan Access and Benefit Sharing Act 2012.

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

( ) YES / ( X ) NO

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 obtain genetic resources?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf**

**of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2. 9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**3. Summary – Competent Authorities**

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**Mr. Syed Mahmood Nasir**

ABS National Focal Point

+92 51 924 55 89

+92 51 924 55 90

*igf@ccd.gov.pk*

*igf.moenv@gmail.com*

Inspector General (Forests)  
Ministry of Climate Change  
5th Floor, LG & RD Complex  
Sector G 5/2  
Islamabad  
Pakistan

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Pakistan profile. Available in: <https://absch.cbd.int/countries/PK> Access in 13/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Pakistan profile. Available in: <https://www.cbd.int/countries/?country=pk> Access in 13/11/2016.

GOVERNMENT OF PAKISTAN. **Biodiversity Action Plan Pakistan**. IUCN/WWF. World Bank/GEF. 1999. Available in: <https://www.cbd.int/countries/?country=pk> Access in 13/11/2016.

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 in 13/11/2016.

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by accession, since Nov 04, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Nagoya Protocol, by accession, since Sep 13, 2015.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

No inspection bodies have been identified in the scope of access and benefit-sharing covered by the Nagoya Protocol.

1 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>.

2 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>.

3 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.

### **1.7 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

There is no indication of sanctions, Article 17 of Law No. 166 “On the Protection of Traditional Knowledge”, 2007, only defines that the use of traditional knowledge in commercial production without the conclusion of agreements with holders of traditional knowledge that the law, will be considered as illegal use of traditional knowledge.

## **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

The 5th National Report on Biodiversity Conservation in Kyrgyzstan states 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).

On the other hand, the country has rules on access to traditional knowledge, including the traditional knowledge associated with genetic resources, they are:

- Law No. 166 “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 on Fees for Registration and the Right to Use Traditional Knowledge

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

YES /  NO

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. This the Authorized State Body will receive the requests for traditional knowledge registration.

Regarding genetic resources, Kyrgyzstan’s 5th National Report on Biodiversity Conservation, while lacking standards on the subject, 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 /  NO

According to item 2.1, the country does not have specific legislation on access to genetic resources. On the other hand, the Kyrgyzstan's 5th National Report on Biodiversity Conservation states 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?**

YES /  NO

As explained in item 2.1, the country has only access to associated traditional knowledge, Law No. 166 "On the Protection of Traditional Knowledge", 2007. Article 14 of this standard states that traditional knowledge may be used by person who does not hold this knowledge as long as it has an agreement with the holder of the traditional knowledge registered with the Authorized State Body. This agreement shall provide for the conditions of use, term and payments, and shall be recorded in the Authorized State Body.

**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

Law No. 166 "On the Protection of Traditional Knowledge", 2007 defines in article 8 the conditions for patents originating from traditional knowledge. The source and source of knowledge should be indicated.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific rules for this purpose.

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

YES /  NO

There are no specific rules for this purpose.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Yes, the sharing of benefits in the case of access to knowledge was covered by Articles 14 and 16 of Law No. 166 "On the Protection of Traditional Knowledge", 2007. There is no stipulation of value, this and other issues must be stipulated in an agreement between the user and the traditional knowledge holder. These articles also provide for the establishment of a Fund for the conservation



and development of legal communities, which may receive the values of agreements between the user and the holder of traditional knowledge, at a minimum percentage of 20%.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

There are no specific rules for this purpose.

## 3. Websites

No related websites were found.

## 4. Summary – Competent Authorities

According to item 2.2., The country does not have an established competent authority. However, it has a recognized National Focal Point for the Nagoya Protocol:

### **Nagoya Protocol on Access and Benefit-sharing**

#### **Ms. Cholpon Alibakieva**

ABS National Focal Point

*min-eco@elcat.kg*

Chief Specialist

Department of International Cooperation

State Agency on Environment Protection and Forestry

228, Toktogul Street

720001 Bishkek

Kyrgyzstan

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Kyrgyzstan profile. Available in: <https://absch.cbd.int/countries/KG> Access in 21/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Kyrgyzstan profile. Available in: <https://www.cbd.int/countries/?country=kg> Access in 21/11/2016.

KYRGYZSTAN. **Biodiversity conservation priorities of the Kyrgyz Republic till 2024.** Available in: <https://www.cbd.int/countries/?country=kg> Access in 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 in: <https://www.cbd.int/countries/?country=kg> Access in 21/11/2016.

KYRGYZSTAN. **Law n° 166 On the Protection of Traditional Knowledge, 2007**. Available in: <http://www.wipo.int/wipolex/en/details.jsp?id=5571> Access in 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=](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 in 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 in 21/11/2016.

KYRGYZSTAN. **Order of the Government of the Kyrgyz Republic in Compliance with the Law ‘On Protection of Traditional Knowledge’**. Available in: <http://www.wipo.int/wipolex/en/details.jsp?id=11577> Access in 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 in 21/11/2016.

# Syrian Arab Republic

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since April 03, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

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

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

### **1.7 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

As mentioned in item 2.1, after extensive searches, it was not possible to identify an easy-to-read English version of Act No. 20 on the Protection and Exchange of Plant Genetic Resources (2003). The present study was elaborated through the search mechanism by secondary sources.

## **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

According to the bibliography consulted, the country has a current norm on access and benefit sharing, namely Act No. 20 on the Protection and Exchange of Plant Genetic Resources (2003). However, after exhaustive searches, it was not possible to identify a version in a more universal language of this standard.

On the other hand, 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?**

( X ) YES / ( ) NO

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 obtain genetic resources?**

( - ) YES / ( - ) NO

As mentioned in item 2.1, after extensive searches, it was not possible to identify an easy-to-read English version of Act No. 20 on the Protection and Exchange of Plant Genetic Resources (2003). The present study was elaborated through the search mechanism by secondary sources.

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

( - ) YES / ( - ) NO

As mentioned in item 2.1, after extensive searches, it was not possible to identify an easy-to-read English version of Act No. 20 on the Protection and Exchange of Plant Genetic Resources (2003). The present study was elaborated through the search mechanism by secondary sources.

**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

As mentioned in item 2.1, after extensive searches, it was not possible to identify an easy-to-read English version of Act No. 20 on the Protection and Exchange of Plant Genetic Resources (2003). The present study was elaborated through the search mechanism by secondary sources.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( - ) YES / ( - ) NO

As mentioned in item 2.1, after extensive searches, it was not possible to identify an easy-to-read English version of Act No. 20 on the Protection and Exchange of Plant Genetic Resources (2003). The present study was elaborated through the search mechanism by secondary sources.

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

( - ) YES / ( - ) NO

As mentioned in item 2.1, after extensive searches, it was not possible to identify an easy-to-read English version of Act No. 20 on the Protection and Exchange of Plant Genetic Resources (2003). The present study was elaborated through the search mechanism by secondary sources.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( - ) YES / ( - ) NO

As mentioned in item 2.1, after extensive searches, it was not possible to identify an easy-to-read English version of Act No. 20 on the Protection and Exchange of Plant Genetic Resources (2003). The present study was elaborated through the search mechanism by secondary sources.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( - ) YES / ( - ) NO

As mentioned in item 2.1, after extensive searches, it was not possible to identify an easy-to-read English version of Act No. 20 on the Protection and Exchange of Plant Genetic Resources (2003). The present study was elaborated through the search mechanism by secondary sources.

### 3. Websites

No relevant ABS sites have been identified in the country.

### 4. Summary – Competent Authorities

Authority	Competence
Ministry Of State for Environment Affiars (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 Agriculatural 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.

### 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Syrian Arab Republic profile. Available in: <https://absch.cbd.int/countries/SY> Access in 08/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Syrian Arab Republic profile. Available in: <https://www.cbd.int/countries/?country=sy> Access in 08/11/2016.

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](http://www.fkphillips.com/?page_id=39) Access in 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 in 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 in 08/11/2016.

# Thailand

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since Jan 29, 2004.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, the country is not a party to the Nagoya Protocol.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

.....  
1 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>.

2 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>.

3 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.

**1.7 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

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in Thai language version.

## 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

The National Committee on Conservation and Utilization of Biological Diversity Regulation on the Criteria and Methods of the Access to Biological Resources and Sharing of Benefits Arising from Biological Resources BE 2554 (2011), adopted on January 11, 2011 and published on March 4 2011 is the specific legislation responsible for regulating ABS in Thailand<sup>4</sup>.

However, the bibliography studied states that this legislation has several legal gaps, including issues related to the relationship between the private sector and the government, procedures for proper sharing of benefits, among other issues important to the implementation of ABS rules under the Nagoya Protocol<sup>5</sup>.

In addition, it was not possible to find an accessible version on the internet, it is available only in the Thai language version, thus prejudicing the conclusion of the present study.

Finally, it is worth noting that the country still has the Act on Promotion and Protection of Traditional Thai Medicinal Intelligence, BE 2542 which regulates specific issues related to access to medicinal knowledge of traditional Thai communities, not being an ABS standard, however fulfills the role of protecting the traditional medicinal knowledge of these communities.

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

( - ) YES / ( - ) NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in Thai language version.

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

( - ) YES / ( - ) NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates

4 SOUTHEAST Asia Regional Capacity Building on Access and Benefit Sharing Thailand. Disponível em: <[http://abs.aseanbiodiversity.org/index.php?option=com\\_content&view=article&id=13:thailand&catid=9:participatingcountries&Itemid=101](http://abs.aseanbiodiversity.org/index.php?option=com_content&view=article&id=13:thailand&catid=9:participatingcountries&Itemid=101)>. Acesso em: 27 out. 2016.

5 Master Plan for Integrated Biodiversity Management B.E. 2558 – 2564 (2015-2021). Thailand: Office Of Natural Resources And Environmental Policy And Planning, 2015. 10 p. Disponível em: <<https://www.cbd.int/doc/world/th/th-nbsap-v4-en.pdf>>. Acesso em: 24 maio 2017.



access and benefit sharing in the country. It is available only in Thai language version.

On the other hand, it is known from the publication by the Office of Natural Resources and Environmental Policy and Planning, available on the Internet in English, that it is necessary to request from the NCBD (National Committee on Conservation and Utilization of Biological Diversity) access to the genetic resource or traditional knowledge of the country. In addition, the authorized person must also enter into a contract of access and benefit sharing with the competent government agency.

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

( - ) YES / ( - ) NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in Thai language version.

On the other hand, the Act on Promotion and Protection of Traditional Thai Medicinal Intelligence, BE 2542, establishes that research, development or development of new drug formulas for commercial exploitation with traditional national authorization as well as paying fees.

#### **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

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in Thai language version.

#### **2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( - ) YES / ( - ) NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in Thai language version.

#### **2.7. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?**

( - ) YES / ( - ) NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in Thai language version.

#### **2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( - ) YES / ( - ) NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in Thai language version.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( - ) YES / ( - ) NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in Thai language version.

## 3. Websites

### **National CHM**

<http://chm-thai.onep.go.th>

### **Ministry of Natural Resources and Environment**

<http://www.warehouse.mnre.go.th/portal>

## 4. Summary – Competent Authorities

According to item 2.2, the country does not have an established competent authority. However, it has a recognized National Focal Point for the Nagoya Protocol

### **Nagoya Protocol on Access and Benefit-sharing**

#### **Ms Sommawan Sukprasert**

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#### **Biodiversity Division**

Office of Natural Resources and Environmental Policy and Planning

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#### **Mrs. Pattarin Sanghaisuk**

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#### **Biodiversity Division**

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Thailand

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Thailand profile. Disponível em: <https://absch.cbd.int/countries/TH> Acesso em 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Thailand profile. Disponível em: <https://www.cbd.int/countries/?country=th> Acesso em 18/10/2016.

OFFICE OF NATURAL RESOURCES AND ENVIRONMENTAL POLICY AND PLANNING. **Access and Benefit-Sharing**. Ministry of Natural Resources and Environment. 28 pages. Bangkok, 2014. Disponível em: <http://chm-thai.onep.go.th/chm/ABS/Documents/Nagoya/ACCESS%20Eng.pdf> Acesso em 24/05/2017.

THAILAND. **Master Plan for Integrated Biodiversity Management B.E. 2558 – 2564 (2015-2021)**. Office of Natural Resources and Environmental Policy and Planning. Ministry of Natural Resources and Environment. Disponível em: <https://www.cbd.int/countries/?country=th> Acesso em 18/10/2016.

THAILAND. **Protection and Promotion of Traditional Thai Medecinal Intelligence Act, B.E. 2542 (1999)**. Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=5790> Acesso em 24/05/2017.

THAILAND. **Thailand National Report on the Implementation of the Convention on Biological Diversity**. Office of Natural Resources and Environmental Policy and Planning. Ministry of Natural Resources and Environment. Disponível em: <https://www.cbd.int/countries/?country=th> Acesso em 18/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by accession, since Jan 27, 1998.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

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

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in the Russian language version.

## 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

According to the Fifth National Report on Preservation of Biodiversity of the Republic of Tajikistan, the Law "On Genetic Resources of Plants (August 1st, 2012, No. 892)" is the national norm responsible for regulating collection, preservation, research and rational use of plant genetic resources. However, it is known that this standard is not specific to ABS, nor was it possible to find an accessible version on the internet, it is only available in the Russian language version, thus prejudicing the conclusion of the present study.

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

YES /  NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in the Russian language version.

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

YES /  NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in the Russian language version.

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

YES /  NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in the Russian language version.

**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

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in the Russian language version.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( - ) YES / ( - ) NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in the Russian language version.

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

( - ) YES / ( - ) NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in the Russian language version.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( - ) YES / ( - ) NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in the Russian language version.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( - ) YES / ( - ) NO

As stated in item 2.1, it was not possible to find an accessible version of the norm that regulates access and benefit sharing in the country. It is available only in the Russian language version.

### 3. Websites

No websites related to ABS have been identified in the country.

### 4. Summary – competent authorities

As mentioned in item 2.2., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**Mr. Neimatullo Safarov**

ABS National Focal Point

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Head  
National Biodiversity and Biosafety Center  
47 Shevchenko street  
734025  
Dushanbe  
Tajikistan

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Tajikistan profile. Disponível em: <https://absch.cbd.int/countries/TJ> Acesso em 21/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Tajikistan profile. Disponível em: <https://www.cbd.int/countries/?country=tj> Acesso em 21/11/2016.

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); Global Ecological Fund (GEF). 2014. Disponível em: <https://www.cbd.int/countries/?country=tj> Acesso em 21/11/2016.

REPUBLIC OF TAJIKISTAN. **National Strategy and Action Plan for Biodiversity Conservation Until 2020**. Global Ecological Fund (GEF). 2016. Disponível em: <https://www.cbd.int/countries/?country=tj> Acesso em 21/11/2016.

REPUBLIC OF TAJIKISTAN. **Law No. 892 “On collection, conservation and rational management of genetic resources of cultivated plants”**. Disponível em: [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=](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=) Acesso em 21/11/2016.

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since May 15, 1997.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, the country is not a party to the Nagoya Protocol and neither is signatory.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.



### 1.7 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

As stated in item 2.1, the country does not have a law on access to genetic resources and associated traditional knowledge.

## 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

Turkey does not have specific ABS legislation. According to the 5th National Report presented to the CBD and the document prepared by the Union for Ethical BioTrade (UEBT) "ABS in Turkey"<sup>4</sup>, certain specific issues related to access, research and development with genetic resources are regulated by more than one standard, namely:

- Regulation on Collection, Conservation and Utilisation of Plant Genetic Resources (No. 21316, 1992) Law on Protection of Breeder's Rights of New Plant Varieties (Law No 5042, 2004)
- Seed Law (Law No. 5553, 2006).
- Regulation on Registration of Plant Varieties (2008)
- Regulation on use and export of fish genetic resources for research (No 29 381, 2015)
- Regulation on the Collection, Production and Exportation of Natural Flower Bulbs (No. 22371, 1995)
- Law ratifying the International Treaty for Plant Genetic Resources for Food and Agriculture (Law No 5414, 2006)
- Regulation on Utilisation and Export of the Native Domestic Animal Genetic Resources (No. 28418, 2012)

On the other hand, the above legislation is not easily accessible or is not available in languages other than Turkish. In addition, the legislation found and studied has been shown to be more related to research on species in general and the right of seed breeders, rather than the access and benefit-sharing covered by the Nagoya Protocol.

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

YES /  NO

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

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<sup>4</sup> ABS IN TURKEY. Amsterdam, Holanda: [s.n.], 2016. 2 p. Disponível em: <[http://ethicalbiotrade.org/dl/Turkey%20ABS%20fact%20sheet\\_FINAL.pdf](http://ethicalbiotrade.org/dl/Turkey%20ABS%20fact%20sheet_FINAL.pdf)>. Acesso em: 18 out. 2016.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites

#### **National CHM**

<http://www.cbd.gov.tr>

#### **Republic of Turkey Ministry of Food, Agriculture and Livestock**

<http://www.tarim.gov.tr/Sayfalar/EN/AnaSayfa.aspx>

#### **TC Ministry of Forestry and Water Affairs**

<http://www.ormansu.gov.tr/osb/AnaSayfa.aspx?sflang=tr>

### 4. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

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Director General

General Directorate of Agricultural Research and Policies

Ministry of Food Agriculture and Livestock

P.K. 51, Yenimahalle

Ankara

Turkey

### 5. Referências Bibliográficas

**ABS IN TURKEY.** Amsterdam, Holanda: [s.n.], 2016. 2 p. Disponível em: [http://ethicalbiotrading.org/dl/Turkey%20ABS%20fact%20sheet\\_FINAL.pdf](http://ethicalbiotrading.org/dl/Turkey%20ABS%20fact%20sheet_FINAL.pdf) Acesso em 18/10/2016.

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Turkey profile. Disponível em: <https://absch.cbd.int/countries/TR> Acesso em 15/06/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Turkey profile. Disponível em: <https://www.cbd.int/countries/?country=tr> Acesso em 15/06/2016

REPUBLIC OF TURKEY. **The National Biological Diversity Strategy And Action Plan.** Ministry of Forestry And Water Affairs, General Directorate of Nature Conservation and National Parks; Department of Nature Conservation, National Focal Point of Convention on Biological Diversity. Disponível em: <https://www.cbd.int/countries/?country=tr> Acesso em 15/06/2016

REPUBLIC OF TURKEY. **UN Convention on Biological Diversity Fifth National Report.** Ministry of Forestry And Water Affairs. General Directorate of Nature Conservation and National Parks. Disponível em: <https://www.cbd.int/countries/?country=tr> Acesso em 15/06/2016

## 1. General information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since Feb 14, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

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

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

### **1.7 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

No sanctions were found to punish harmful or irregular acts regarding access to genetic resources. The Biodiversity Law, 2008 only prohibits in its article 7, item 8, illegal access of genetic resources of species in listed as threatened of great importance and rare priority for legal protection.

## **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

The country has two standards that, while not specific to access and benefit sharing, have comprehensive chapters with rights and obligations to users and providers of genetic resources and traditional knowledge for research and development purposes. Are they:

- Biodiversity Law, 2008 (Law No. 20/2008/QH12)
- Decree No. 65/2010/ND-CP of June 11, 2010

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

YES /  NO

The Biodiversity Law, 2008, establishes the various actors responsible for managing the genetic resources of the country, and the State is responsible for the uniform management of all genetic resources in the Vietnamese territory. In addition, the State should divide this competence among other organizations and individuals as follows:

- Conservation area management units and organizations duly designated to manage conservation areas should have responsibility under the genetic resources in those conservation areas;
- Heads of biodiversity conservation facilities, scientific research and technological development institutions, and establishments for the storage or preservation of genetic resources should manage their own genetic resources;
- Organizations, families and individuals designated to manage or use land, forests or aquatic resources must manage the genetic resources assigned to them for management or use;
- The Popular Committees will manage genetic resources in their localities, except in the cases specified above.

Under the terms of article 18 of the Decree entitled Decree No. 65/2010/ND-CP of June 11, 2010, in the case of licenses for access to genetic resources, the following shall be responsible: (a) the Ministry of Natural Resources and the Environment, when dealing of permits for access to genetic resources of species defined as “priority for protection”; and (b) the Popular Committees for other cases.

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

YES /  NO

Viet Nam's legislation establishes a system of documents and licenses necessary for access to genetic resources in the country. In this sense, Biodiversity Law, 2008 establishes in the article 57 the following procedures, in the form and order arranged below:

- Registration of access to genetic resources;
- Enter into a written agreement on access to genetic resources and benefit sharing with organizations, families or individuals designated to manage the genetic resources accessed;
- Apply for a license to access genetic resources.
- Notwithstanding these procedures, the Government may also specify other procedures.

Regarding the requirements to receive such a license, article 59 of the same standard prescribes that the registration of a license to access genetic resources must be made with a competent state management agency and the dossier of the license application must contain, in addition to the document access agreement and distribution of benefits duly signed. Licenses may not be granted in the case of access to genetic resources of species in threat, rare or priority species lists for protection (unless specifically authorized by the competent organ), as well as when the use of the genetic resource is a threat to humans human, environment, security, defense or national interest.

In addition, Decree No. 65120101ND • CP of June 11, 2010 requires in its article 18 that the registration of access to genetic resources that precedes the signing of the contract of access and distribution of benefits and the request for a license is made to the People's Committee of the locality that owns the genetic resource. The Popular Committee will still be responsible for certifying the said contract.

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

YES /  NO

Vietnam's ABS legislation did not establish specific procedures in the case of traditional knowledge and has a single one, namely Article 64 of the Biodiversity Law, 2008. This legal provision strengthens the State's protection of traditional knowledge rights associated with genetic resources, as well as defining the Ministry of Science and Technology as the primary responsibility, in the joint coordination of ministries and relevant ministerial agencies, on the procedures for registering copyright of this 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 /  NO

No legal provision was found for this purpose.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

No legal provision was found for this purpose.

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

YES /  NO

No legal provision was found for this purpose.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Benefit-sharing is mandatory in Vietnam and is considered a principle for biodiversity conservation and sustainable development. In this sense, 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.

Article 56, however, stipulates that organizations, families and individuals designated to manage genetic resources shall have the right to receive a sharing of 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 (a) may be 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.

However, the forms of benefit sharing were only established in 2010, in art. 19 of Decree No. 65120101ND • CP of June 11, 2010, these being:

- Division of research and development results, and results of commercial production and profits realized with the commercialization of these products from access to genetic resources;
- Cooperation in the research and development of genetic resources, and scientific and technical information on genetic resources;
  - Transfer of technologies developed on genetic patrimony with suppliers of genetic resources;
  - Training and training on research and development of genetic resources;



- Contributions to local economic development, and the development of public activities and support to poverty reduction;
- Breakdown of benefits in cash or similar;
- Other forms established in written agreements and access licenses to genetic resources; and
- Intellectual property right of creations resulting from access to genetic resources.

The benefits to be allocated should be determined in the licensing procedure, as well as established by contract between the parties involved, however, the amount may not be less than 30% of the total benefits converted into money.

### 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

There is no specific procedure for cases of sample remes of Vietnamese genetic heritage. 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 Viet Nam, provided that they are not on the list banned species.

## 2. Websites

No relevant websites were found.

## 3. Summary – Competent Authorities

Authority	Competence
State of Vietnam	Responsible for managing all genetic resources in the Vietnamese territory uniformly.
Management units of conservation areas and organizations duly designated to manage conservation areas.	Conservation area management units and organizations duly designated to manage conservation areas should be held accountable under genetic resources in those conservation areas
Heads of biodiversity conservation facilities, scientific research and technological development institutions, and establishments for the storage or preservation of genetic resources	They should manage their own genetic resources
Organizations, families and individuals designated to manage or use land, forests or aquatic resources	They must manage the genetic resources assigned to them for management or use
Popular Committees	The Popular Committees will manage genetic resources in their localities, except in the cases specified above. They are also responsible for granting the remaining licenses and registration of access.

Ministry of Natural Resources and Environment	It has the power to grant licenses in the case of licenses to access genetic resources of species defined as "priority for protection.
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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Viet Nam profile. Disponível em: <https://absch.cbd.int/countries/VN> Acesso em 17/06/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Viet Nam profile. Disponível em: <https://www.cbd.int/countries/?country=vn> Acesso em 17/06/2016.

VIETNAM. **Biodiversity Law (2008)**. Disponível em: <https://absch.cbd.int/countries/VN> Acesso em 17/06/2016.

VIETNAM. **Decree No. 651 2010 ND-CP of June 11, 2010**. Disponível em: <http://extwprlegs1.fao.org/docs/pdf/vie98415.pdf> Acesso em 17/06/2016.

VIETNAM. **Decree On The Management Of Access To Genetic Resources And The Sharing of Benefits Arising From Their Utilization**. Disponível em: <https://absch.cbd.int/countries/VN> Acesso em 17/06/2016.

VIETNAM. **Vietnam National Biodiversity Strategy to 2020, vision to 2030**. Ministry Of Natural Resources And Environment. Disponível em: <https://www.cbd.int/countries/?country=vn> Acesso em 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. Disponível em: <https://www.cbd.int/countries/?country=vn> Acesso em 17/06/2016.



Europe

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

YES /  NO

Yes, Albania has been a Party to the CBD, by acceding, since Apr 5, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Albania has been a Party to the Protocol, by acceding, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

According to article 2, item 2, of Law 37 of 2013, which altered article 49 of Law 9,587 of July 20, 2006 (which included provisions on genetic resources), the following institutions are responsible

1 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>.

2 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>.

3 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 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.

Fines are defined according to item 1.7, but no concrete cases were found during this inquiry.

### **1.7 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

Yes, breaches and sanctions are defined under article 54 of Law No. 9,587 of July 20, 2006. The value for the fines were initially determined according to item 3 of article 54, and would vary, depending on the infraction, from 300,000 to 500,000 Leke.

However, law 37 of 2013 changed some dispositions of law 9,587 of 2006, including the above-mentioned information, 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, while others will have values from 10,000 to 300,000 Leke.

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.

Article 3 of law 37 of 2013 also 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 seizure of the biological material and the tools employed in carrying out the illegal activities.

## **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

Although the country does not have any specific laws on the subject, the law of protection of the national biodiversity, Law No. 9,587 of July 20, 2006, establishes detailed procedures and obligations related to access and benefit-sharing. However, Law 37 of 2013 changed some dispositions of the aforementioned law 9,587 of 2006. In relation to ABS, it changed article 49 of the said law, related to the value of the fines. Finally, through Law No. 113/2012, the country officially became a Party to the Nagoya Protocol.

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

YES /  NO

The National Competent Authority of Albania is the Directorate of Biodiversity and Protected Areas at the Ministry of the Environment of Albania, 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 /  NO

The activities that explore or use the biological diversity of Albania require a license, according to article 41 of Law No. 9,587 of July 20, 2006. According to item 3 of the said article, the approval of such license will depend on the user of biodiversity obtaining prior consent from the government or the owner of the assets, as well as establishing a benefit-sharing regime. 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 /  NO

Although there are no specific procedures, article 45 reinforces the necessity of prior informed consent and the right of communities to obtaining 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 /  NO

None of the laws presented under item 2.1 mentions specific procedures for requesting patents.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for obtaining access to genetic heritage in activities performed on behalf the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

There are no specific norms for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

Article 42, item 2, d) and article 43, item 2, c) of Law No. 9,587 of July 20, 2006 establishes the requirement of benefit-sharing. However, the referred law does not provide any specific provisions on how benefit-sharing shall occur.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned under item 4, article 41 of Law No. 9,587 of July 20, 2006, a material transfer agreement is required.

### 3. Websites Of Interest

**National CHM:**

<http://nfp-al.eionet.eu.int>

**Ministry of Environment**

<http://www.moe.gov.al>

### 4. Summary – Competent Authorities

Authority	Competence
Directorate of Biodiversity and Protected Areas at the Ministry of the Environment of Albania	Responsible for all issues related to genetic resources.

### 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Albania profile. Disponível em: < <https://absch.cbd.int/countries/AL> > Access in 11/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Albania profile. Disponível em: < <https://www.cbd.int/countries/?country=al> > Access in 11/11/2016.

GOVERNMENT OF ALBANIA. **Document of Strategic Policies for the Protection of Biodiversity in Albania**. Government of Albania (GoA). Tirana, December, 2015. Disponível em: < <https://www.cbd.int/countries/?country=al> > Access in 18/10/2016.

GOVERNMENT OF ALBANIA. **Fifth National Report Of Albania To The United Nations Convention On Biological Diversity (CDB)**. Albania. May, 2014. Disponível em: < <https://www.cbd.int/countries/?country=al> > Access in 11/11/2016.

GOVERNMENT OF ALBANIA. **Law No. 9587 of 2006 on Biodiversity Protection**. Disponível em: < <http://www.ecolex.org/details/legislation/law-no-9587-on-biodiversity-protection-lex-fa-oc067304/> > Access in 11/11/2016.

GOVERNMENT OF ALBANIA. **Law No. 37/2013 For Some Changes And Additions To Law No. 9587, 2006 “On Protecting Biodiversity”**. Disponível em: < <http://faolex.fao.org/docs/texts/alb132097.doc> > Access in 11/11/2016.

GOVERNMENT OF ALBANIA. **Law No 113/2012 on the Accession**. Disponível em: < <https://absch.cbd.int/database/record/ABSCH-MSR-AL-207101> > Access in 11/11/2016.

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

YES /  NO

Yes, Germany has been a Party to the CBD, by ratification, since Mar 21, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Germany has been a Party to the Nagoya Protocol, by ratification, since July 20, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

The following checkpoints were identified:

- Federal Agency for Nature Conservation
- German Patent and Trade Mark Office

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance<sup>2</sup>- IRCC under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in Germany.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in Germany.

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

YES /  NO

According to article 9 of EU Regulation No. 511/2014, the national competent authorities of each

1 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>.

2 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>.

3 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.



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.

In this sense, the Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No. 511/2014 establishes that it is the responsibility of the Federal Agency for Nature Conservation to execute the control activities mentioned in article of EU Regulation No. 511/2014.

### **1.7 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

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).

In this sense, the Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No. 511/2014 establishes in its article 4 that the breaches described in items 1 and 2 may suffer penalty of an administrative fine of 50,000 EUR. Furthermore, according to information obtained through the National Focal Point, the German law provides that regulatory fines may exceed the financial benefit that an author obtained (i.e. € 50,000 may, at first, be exceeded ad infinitum).

## **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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in Germany. Notwithstanding, 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.

On the other hand, in the quality of 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 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.

Lastly, according to clarifications obtained from the National Focal Point, this EU legislation deals exclusively with the compliance of the Member States with the Nagoya Protocol, which means that each State need to draw up its own rules on access and benefit sharing. In the case of Germany, the country has decided not to implement any specific legislation on ABS, thus obtaining Prior Informed Consent and signing of the Mutually Agreed Terms are not necessary for access to genetic resources in situ.

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

YES /  NO

Only one National Competent Authority is indicated in Germany's web page on The Access and Benefit-Sharing Clearing-House of CBD, which is the Federal Agency for Nature Conservation. Its responsibilities cover all aspects of genetic resources within EU Regulation No. 511/2014 and EU Execution Regulation 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 /  NO

As explained in item 2.1, Germany does not have any legislation regulating access. For that reason, there is no need for prior consent.

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 /  NO

As explained in item 2.1, Germany does not have any legislation regulating access.

In relation to the European Union, the 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?**

YES /  NO

As explained in item 2.1, 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.

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As explained in item 2.1, Germany does not have any legislation regulating access.

As for the European Union, Article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them. At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

( ) YES / ( X ) NO

As explained in item 2.1, Germany does not have any legislation regulating access.

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.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As explained in item 2.1, Germany does not have any legislation regulating access.

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-counties 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.

### 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

No procedures for the shipment of samples were identified in the norms covered by this analysis.

## 3. Websites Of Interest

### National CHM

<https://abs.bfn.de>

### Federal Ministry for the Environment, Nature Conservation and Nuclear Safety

<http://www.bmu.de/english/nature/current/aktuell/3836.php>

### The German Federal Nature Conservation Agency (BfN)

<http://www.bfn.de>

### Federal Environment Agency

<http://www.umweltbundesamt.de/>

### The Federal Ministry for Economic Cooperation and Development

<http://www.bmz.de/en/issues/Environment>

### The Economics of Ecosystems and Biodiversity

<http://www.teebweb.org/>

## 4. Summary – Competent Authorities

Authority	Competence
Federal Agency for Nature Conservation	Its responsibilities cover all aspects of genetic resources, within EU Regulation No. 511/2014 and EU Execution Regulation No. 2015/1866.

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Germany profile. Disponível em: < <https://absch.cbd.int/countries/DE> > Access in 18/10/2016.

BERTRAM, Verena. **The implementation of the Nagoya Protocol in Germany**. Taylor Wessing. Synapse, Law for Life Sciences. January, 2016. Disponível em: < <https://united-kingdom.taylorwessing.com/synapse/ti-nagoya-germany.html> > Access in 11/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Germany profile. Disponível em: < <https://www.cbd.int/countries/?country=de> > 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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 11/11/2016.

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 Utilisation in the Union.** Disponível em: < <https://absch.cbd.int/database/record/ABSCH-MSR-DE-208044> > Access in 11/11/2016.

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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 11/11/2016.

GOVERNMENT OF GERMANY. **Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No. 511/2014.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-207328> Access in 11/11/2016.

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. Disponível em: < <https://www.cbd.int/countries/?country=al> > Access in 18/10/2016.

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. Disponível em: < <https://www.cbd.int/countries/?country=al> > Access in 18/10/2016.

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. Disponível em: < <https://www.bfn.de/fileadmin/MDB/documents/skript126.pdf> > Access in 11/11/2016.

## 1. General Information

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

YES /  NO

Yes, Austria has been a Party to the Convention on Biological Diversity, by ratification, since Nov 16, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Austria is neither a party nor a signatory to the Nagoya Protocol.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in Austria.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in Austria.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in Austria.

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

YES /  NO

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

1 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>.

2 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>.

3 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 institution responsible for inspecting access to genetic resources, probably due to the fact that Austria has no specific legislation regulating the subject.

### **1.7 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

As explained in item 2.1, Austria does not have any legislation on access and benefit sharing. For that reason, no information on the imposition of sanctions could be found.

However, 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).

## **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

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

On the other hand, in the quality of 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



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?**

( ) YES / ( X ) NO

No competent institution was identified in relation to access and benefit-sharing in this 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

As explained in item 2.1, Austria does not have any legislation regulating access.

Within the European Union, of which Austria 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. A Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?**

( ) YES / ( X ) NO

As explained in item 2.1, Austria does not have any legislation regulating access.

In relation to the European Union, the legislation 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?**

YES /  NO

As explained in item 2.1, Austria does not have any legislation regulating access.

In relation to the European Union, although the topic 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As explained in item 2.1, Austria does not have any legislation regulating access.

As for the European Union, through article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them.

At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

YES /  NO

As explained in item 2.1, Austria does not have any legislation regulating access. Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As explained in item 2.1, Austria does not have any legislation regulating access.

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.

### **2. 9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

No procedures for the shipment of samples were identified in the norms covered by this analysis.

## **3. Websites Of Interest**

### ***National CHM:***

*<http://at.chm-cbd.net>*

### ***Federal Ministry for Agriculture, Forestry, Environment and Water Management:***

*<http://www.lebensministerium.at>*

## **4. Summary – Competent Authorities**

According to item 2.3., Austria does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### **Nagoya Protocol on Access and Benefit-sharing**

#### **Ms. Andrea H. Nouak**

ABS National Focal Point

+43 1 71100 611616

*[andrea.nouak@bmlfuw.gv.at](mailto:andrea.nouak@bmlfuw.gv.at)*

Division I/9 - International Environmental Affairs

Federal Ministry of Agriculture, Forestry, Environment and Water Management

Stubenbastei 5

A-1010

Vienna

Austria

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Austria profile. Disponível em: <https://absch.cbd.int/countries/AT> Access in 04/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Austria profile. Disponível em: <https://www.cbd.int/countries/?country=at> Access in 04/11/2016.

GOVERNMENT OF AUSTRIA. **Fifth National Report Of Austria: Convention on Biological Diversity.** Umweltbundesamt (Environmental Protection Agency). Vienna, 2014. Disponível em: <https://www.cbd.int/countries/?country=at> Access in 04/11/2016.

GOVERNMENT OF AUSTRIA. **Biodiversity Strategy Austria 2020+.** Federal Ministry of Agriculture, Forestry, Environment and Water Management. Vienna, December, 2014 Disponível em: <<https://www.cbd.int/countries/?country=at>> Access in 04/11/2016.

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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 11/11/2016 Access in 04/11/2016.

# Belgium

## 1. General Information

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

YES /  NO

Yes, Belgium has been a Party to the Convention on Biological Diversity, by ratification, since Feb 20, 1997.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Belgium has been a Party to the Nagoya Protocol, by ratification, since Nov 7, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in Belgium.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in Belgium.

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

YES /  NO

According to information obtained by the National Focal Point, the country has not yet designated an inspection body in the context of ABS.

1 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>.

2 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>.

3 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.

### **1.7 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

As explained in item 2.1, Belgium does not have any legislation on access and benefit sharing.

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).

## **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

There is no specific legislation regarding access to genetic resources and associated traditional knowledge in Belgium.

On the other hand, in the quality of 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 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?**

( ) YES / ( X ) NO

No official competent institution was identified in relation to access and benefit-sharing in this 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

As explained in item 2.1, Belgium does not have any legislation regulating access. For that reason, there is no need for prior consent.

Within the European Union, of which Belgium 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

As explained in item 2.1, Belgium does not have any legislation regulating access.

In relation to the European Union, the legislation does not foresee specific procedures for access to 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?**

YES /  NO

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

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As explained in item 2.1, Belgium does not have any legislation regulating access.

As for the European Union, through article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them.

Currently, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

YES /  NO

As explained in item 2.1, Belgium does not have any legislation regulating access. Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As explained in item 2.1, Belgium does not have any legislation regulating access.

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.

### **2. 9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

No procedures for the shipment of samples were identified in the norms covered by this analysis.

## **3. Websites Of Interest**

### **National CHM:**

<http://www.biodiv.be>

### **Biosafety website:**

<http://www.biosafety.be/bch/bch.html>

### **Royal Belgian Institute of Natural Sciences:**

<http://www.naturalsciences.be>

### **News Bulletin of the CBD National Focal Point:**

<http://www.naturalsciences.be/institute/structure/biodiv/actual/newsbulletin>

### **Ministry of Foreign Affairs, Foreign Trade and Development:**

<http://diplomatie.belgium.be/en/policy/>

### **Belgian Development Cooperation Agency:**

<http://www.btcctb.org/?sLangCode=EN>

## **4. Summary – Competent Authorities**

As per item 2.3., the European Union does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### **Nagoya Protocol on Access and Benefit-sharing**

#### **Ms. Salima Kempnaer**

ABS National Focal Point

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[cbd-abs@naturalsciences.be](mailto:cbd-abs@naturalsciences.be)

General Directorate (DG5) Environment  
Federal Public Service (FPS) Health, Food Chain Security and Environment  
DG5 Environment, Place Victor Horta 40  
bte 10, Bloc 11, 2me étage  
B-1060  
Brussels  
Belgium

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Belgium profile. Disponível em: <https://absch.cbd.int/countries/BE> Access in 04/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Belgium profile. Disponível em: <https://www.cbd.int/countries/?country=be> Access in 04/11/2016.

COOLSAET, Brendan; DEDEURWAERDERE, Tom; PITSEYS, John; and BATUR, Fulya. **Study for the implementation in Belgium of the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity.** Centre for Philosophy of Law Université catholique de Louvain. March, 2013. Disponível em: < <http://www.biodiv.be/implementation/cross-cutting-issues/abs/20130321-final-report-np-abs-be.pdf> > Access in 04/11/2016.

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. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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. Disponível em: <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. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 11/11/2016 Access in 04/11/2016.

GOVERNMENT OF BELGIUM. **Biodiversity 2020, Update of Belgium's National Strategy.** Inter-ministerial Conference for the Environment. Brussels, November, 2013 Disponível em: < <https://www.cbd.int/countries/?country=at> > Access in 04/11/2016.

GOVERNMENT OF BELGIUM. **Fifth National Report of Belgium to the Convention on Biological Diversity.** Brussels, 2014. Disponível em: <https://www.cbd.int/countries/?country=at> Access in 04/11/2016.

PEETERS, Marc; FRANKLIN, Anne; VAN GOETHEM, Jackie L. (eds). **Biodiversity in Belgium.** Royal Belgium Institute of Natural Science. Brussels, 2003. Disponível em: <http://www.biodiv.be/biodiversity/bib/implementation/docs/books/bib> Access in 04/11/2016.

# Belarus

## 1. General Information

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

YES / (  ) NO

Yes, Belarus has been a Party to the Convention on Biological Diversity, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES / (  ) NO

Yes, Belarus has been a party to the Protocol, by accession, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES / (  ) NO

The country has the following checkpoint:

The National Coordination Centre for Access to Genetic Resources and Benefit Sharing. It is the responsibility of this checkpoint to ensure compliance to the Nagoya Protocol in the Republic of Belarus, by monitoring and promoting transparency on the use of the country’s genetic resources.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

(  ) YES / (  ) NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoint communiqués were found in this country.

1 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>.

2 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>.

3 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.

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

YES /  NO

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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge. According to information obtained through the Belarusian National Focal Point, harmonization of the national legal framework with the terms of the Nagoya Protocol will begin this year through the Global ABS Project funded by the Global Environmental Facility - GEF.

## 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

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 Center 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 Center 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?**

YES /  NO

The country has established two national competent authorities. The first of them, the National Coordination Centre for Access to Genetic Resources and Benefit Sharing, has the responsibility to ensure compliance with the Nagoya Protocol in the Republic of Belarus through the appropriate measures of monitoring and increased transparency on the use of genetic resources. All of its responsibilities are described in Resolution No. 933, of Oct 2014, from the Council of Ministers of the Republic of Belarus.

The other competent authority is the Ministry of Natural Resources and Environmental Protection, which bears the responsibility of implementing the Nagoya Protocol in Belarus.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any specific legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any specific legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any specific legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any specific legislation on access to genetic resources and associated traditional knowledge. 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.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As indicated in item 2.1, the country does not have any specific legislation on the matter, and, therefore, the Benefit-Sharing obligation has not been established in the country.

However, it should be noted that the country has ratified the Nagoya Protocol, which provides for the Benefit-Sharing obligation. In addition, 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.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

No established procedures for the shipment of samples were identified.

### 3. Websites Of Interest

**National CHM:**

<http://www.biodiv.by>

**National co-ordination centre for access to genetic resources and benefit-sharing checkpoint for monitoring:**

<http://abs.igc.by/en/>

## 4. Summary – Competent Authorities

Authority	Competence
The National Coordination Centre for Access to Genetic Resources and Benefit Sharing	Ensure compliance to the Nagoya Protocol in the Republic of Belarus through the appropriate measures of monitoring and increased transparency concerning the use of genetic resources. One of the main objectives of the Center consists in determining the conditions of access to the country's genetic resources, including the distribution of benefits arising from the use of such resources.
Ministry of Natural Resources and Environment Protection.	Responsible for implementing the Nagoya Protocol in Belarus

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Belarus profile. Disponível em: <https://absch.cbd.int/countries/BY> Access in 30/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Belarus profile. Disponível em: <https://www.cbd.int/countries/?country=by> Access in 30/10/2016.

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. Disponível em: <https://www.cbd.int/countries/?country=by> Access in 30/10/2016.

REPUBLIC OF BELARUS. **Fifth National Report.** Government of Belarus. Minsk, 2015. Disponível em: <https://www.cbd.int/countries/?country=by> Access in 30/10/2016.

REPUBLIC OF BELARUS. **Decree of the President of the Republic of Belarus “On Accession of the Republic of Belarus to the International Treaty”.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-BY-204260> Access in 30/10/2016.

REPUBLIC OF BELARUS. **Decree of the President of the Republic of Belarus “On Accession of the Republic of Belarus to the International Treaty”.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-BY-201806> Access in 30/10/2016.

REPUBLIC OF BELARUS. **National Coordination Centre on Access to Genetic Resources Issues and Benefit Sharing (ABS NCC).** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-BY-202255> Access in 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**

**Benefit-Sharing” of 1 October 2014, N933.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-BY-202243> Access in 30/10/2016.

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 Benefit-Sharing and Regulations for the Checkpoint of Monitoring the Utilization of Genetic Resources”.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-BY-202445> Access in 30/10/2016.



# Bulgaria

## 1. General Information

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

YES /  NO

Yes, Bulgaria has been a Party to the Convention on Biological Diversity, by ratification, since Jul 16, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Bulgaria has been a Party to the Nagoya Protocol, by ratification, since Nov 9, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance- IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in Bulgaria.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in Bulgaria.

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

YES /  NO

According to information obtained with the National Focal Point, the competent authorities that apply the control over users of genetic resources are those described in article 115, paragraph 1

1 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>.

2 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>.

3 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.

(18) and article 118, paragraph 4 (1 and 2), Biological Diversity Act - BDA.

In addition, the same clarifies that until the moment they are not applied to the users who seek access to genetic resources Bulgarian or that use genetic resources in the territory of the country.

### **1.7 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

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 BDA (Biological Diversity Act). According to these articles, for violation of 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).

## **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

At present, the main issues of access and benefit sharing are set out in Article 66 of the Biological Diversity Act - BDA, however, the National Focal Point reported that it is expected that by the end of 2017, Article 66 should be regulated and published.

In this sense, the Bulgarian Biological Diversity Act (2000) sets out some provisions related to access and benefit sharing in the country that may be used as a basis for the creation of a specific legislation. 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.

On the other hand, in the quality of 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 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?

YES / (  ) NO

Competent authorities that receive applications and grant permits to access genetic resources, as well as perform control over users, are stipulated in art. 115, paragraph 1 (17), and art. 118, paragraphs 2 and 3, of the BDA, including the Ministry of Environment and Water; Ministry of Agriculture and Forestry; Ministry of Regional Development and Public Works; and other state organs and their divisions, as well as the municipal ones.

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

YES / (  ) NO

According to item 2.3., 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.

Within the European Union, of which Bulgaria 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 /  NO

No specific procedures were found concerning the access to traditional knowledge associated to genetic resources, and the country does not have any specific legislation on the subject, as informed in item 2.1.

In relation to the European Union, the legislation does not foresee any 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?**

YES /  NO

In liaison 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.

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As explained under item 2.1, Bulgaria does not have any legislation on access and benefit sharing. As for the European Union, Article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them. At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

YES /  NO

The existing legislation does not regulate ABS issues in the case of exotic species. According to information obtained from the National Focal Point, the future regulation on ABS also does not provide special procedures for collecting and accessing exotic species

Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

According to item 2.3., 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. 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 N°. 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 mem-

ber-counties 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.

In contact with the National Focal Point, it was informed that before the end of 2017 it is expected that the regulation referred to in art. 66.6 of the BDA, which will bring new procedures, including on benefit sharing.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

No specific procedures for the shipment of samples were identified in the norms analyzed.

### National CHM:

<http://chm.moew.government.bg>

### Ministry of Environment and Waters:

<http://www.online.bg/politics/who/govern/comin/ministries/menviron.htm>

## 3. Websites of interest

## 4. Summary – Competent Authorities

According to item 2.3., Bulgaria does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### Nagoya Protocol on Access and Benefit-sharing

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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Bulgaria profile. Disponível em: <https://absch.cbd.int/countries/BG> Access in 18/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Bulgaria profile. Disponível em: <https://www.cbd.int/countries/?country=bg> Access in 18/11/2016.

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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016.

REPUBLIC OF BULGARIA. **Biological Diversity Act 2002.** <http://www.wipo.int/edocs/lexdocs/laws/en/bg/bg038en.pdf> Access in 18/11/2016.

REPUBLIC OF BULGARIA. **Fifth National Report 2009 – 2013 - Convention On Biological Diversity. Ministry Of Environment And Water.** Sofia, 2008. Disponível em: <https://www.cbd.int/countries/?country=bg> Access in 18/11/2016.

REPUBLIC OF BULGARIA. **Report on the National Biodiversity Conservation Plan for 1999-2004 & National Biodiversity Conservation Plan for 2005-2010.** Ministry Of Environment And Water. Sofia, 2005. Disponível em: <https://www.cbd.int/countries/?country=bg> Access in 18/11/2016.

## 1. General Information

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

YES /  NO

Yes, Croatia has been a Party to the CBD, by ratification, since Jan 5, 1997.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Dec 1st, 2015.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

According to the country’s profile on the ABSCH website, the National Competent Authority of Croatia is the Ministry of Environmental and Nature Protection, which includes among the competences listed on the website the responsibility to be one of the country’s checkpoints under the terms of Article 17 of the Nagoya Protocol. Although the text alludes to the idea that there are other checkpoints, this has been the only institution officially identified.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in Croatia.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in Croatia.

1 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>.

2 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>.

3 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.



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

YES /  NO

There is no official inspection body specifically responsible for inspecting the access to genetic resources.

As an organization, the European Union does not have any 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 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.

### **1.7 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

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);

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).

## 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

The following legislation was identified in relation to access and benefit-sharing in this country:

- Nature Protection Act (2013) Reg. No.: 71-05-03/1-13-2, in articles 88 to 98, disposes on access to genetic resources in the country.
- Furthermore, in the quality of 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 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?

YES /  NO

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. Accordingly, 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 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.

The country's profile on the ABSCH website indicates as the National Competent Authority the Ministry of Environment and Nature Protection. The following are some competences of this institution:

- 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

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.

On the other hand, despite the details transcribed above, article 98 states that the all other requirements on access, issuing of permits, conditions for the transfer of genetic material and benefit sharing must be regulated by the Government.

Within the European Union, of which Croatia is a member, the requirement of prior authorization to access genetic resources and traditional knowledge was not 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. As per 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 regulations on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and that 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

The national legislation does not mention the access to traditional knowledge.

In relation to the European Union, the legislation 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?**

( ) YES / ( X ) NO

The national legislation does not mention the issue of intellectual property rights.

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

There are no specific procedures for the collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries.

As for the European Union, Article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them. At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

YES /  NO

There are no specific norms for the collection and access of exotic species.

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

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 above 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.

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-counties 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.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

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 reminds that the form of this procedure shall be regulated by the Government.

### 3. Websites of interest

#### **Croatia – Biodiversity System of Europe:**

<http://biodiversity.europa.eu/mtr/countries/croatia>

### 4 Summary – Competent Authorities

Authority	Competence
Ministry of Environmental and Nature Protection	<ul style="list-style-type: none"> <li>• Implementation of the Nagoya Protocol.</li> <li>• Issuing of permits for access to the genetic resources of native wildlife species located in situ;</li> <li>• Establishing requirements to ensure the sharing of benefits arising from the utilization of genetic material;</li> <li>• Authority to negotiate and sign contracts with potential users;</li> <li>• Responsible for receiving information on the transfer of genetic material to third parties;</li> <li>• This Ministry shall be one of the checkpoints under the terms of article 17.º of the Nagoya Protocol.</li> </ul>

### 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Croatia profile. Disponível em: <https://absch.cbd.int/countries/HR> Access in 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Croatia profile. Disponível em: <https://www.cbd.int/countries/?country=hr> 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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 11/11/2016

REPUBLIC OF CROATIA. **Fifth National Report of the Republic of Croatia to the Convention on Biological Diversity.** Disponível em: <https://www.cbd.int/countries/?country=hr> Access in 18/10/2016.

REPUBLIC OF CROATIA. **Nature Protection Act (2003) No. 01-081- 03-3243/2.** Disponível em: <http://www.ecolex.org/details/legislation/nature-protection-law-lex-faoc049067/> Access in 18/10/2016.

REPUBLIC OF CROATIA. **Nature Protection Act (Official Gazette No 80/2013).** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-HR-206385> Access in 18/10/2016.

REPUBLIC OF CROATIA. **Strategy And Action Plan For The Protection Of Biological And Landscape Diversity Of The Republic Of Croatia.** Disponível em: <https://www.cbd.int/countries/?country=hr> Access in 18/10/2016.

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

YES /  NO

Yes, Denmark has been a Party to the CBD, by ratification, since Mar 21, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by approval, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

The country has as checkpoint 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.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance- IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found either for Denmark or the European Union.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found either for Denmark or the European Union.

1 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>.

2 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>.

3 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.



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

( X ) YES / ( ) NO

The Danish Nature Agency, 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, 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.

**Act 1375 of 2012 (Act on Sharing Benefits Arising from the Utilization of Genetic Resources)**

7. The Danish Minister for the Environment must monitor and ensure compliance with this Act and regulations issued in accordance with this Act.

No concrete cases were found during the survey in relation to the application of fines.

**1.7 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

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 of 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 offence was committed intentionally or with gross negligence and, as a result of the offence, 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.

## 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

The country has the following legislation:

- 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)

On the other hand, in the quality of regional organization, the European Union - of which Denmark 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 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?**

YES /  NO

The second article of the Executive Order (of Oct 6, 2014) on the Entry into Force of Act 1375 dated 2012, states that the Danish Nature 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. This checkpoint is also responsible for the ad hoc and scheduled monitoring of users of genetic resources and traditional knowledge associated with 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

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, merely stipulating in 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.

Within the European Union, of which Denmark 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

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 cannot violate the law of the country where the traditional knowledge has been accessed.

In relation to the European Union, the 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?**

( ) YES / ( X ) NO

There are no specific provisions related to intellectual property in the country's national legislation regarding access to genetic heritage and associated traditional knowledge.

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As for the European Union, Article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them. At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

YES /  NO

There are no specific norms for the collection and access of exotic species. Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  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 Act does not present any procedures, rules or values related to the said benefit-sharing.

On the other hand, 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.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

No specific procedures for the shipment of samples were identified in the norms covered by this analysis.

### 3. Websites of interest

**National CHM:**

<http://at.chm-cbd.net>

**Danish Environmental Protection Agency:**

<http://www.mst.dk/>

**Ministry of Environment:**

<http://www.mim.dk/eng/Topics>

**Danish Forest and Nature Agency:**

<http://www.sns.dk>

**Ministry of Foreign Affairs: Development Policy Section:**

<http://www.um.dk/en/menu/DevelopmentPolicy/DanishDevelopmentPolicy>

**Naturstyrelsen - Udnyttelse af genetiske ressourcer og ABS protokollen:**

<http://naturstyrelsen.dk/naturbeskyttelse/biodiversitet/hvordan-bevarer-vi-biodiversiteten/globalt-2020-maal/abs-protokol/>

### 4. 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.

### 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Denmark profile. Disponível em: <https://absch.cbd.int/countries/DK> Access in 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Denmark profile. Disponível em: <https://www.cbd.int/countries/?country=dk> Access in 18/10/2016.

DANISH GOVERNMENT. **5th Danish Country Report To the Convention on Biological Diversity.** Danish Ministry of the Environment. Nature Agency. 2014. Disponível em: <https://www.cbd.int/countries/?country=dk> Access in 18/10/2016.

DANISH GOVERNMENT. **Act on sharing information for the use of genetic resources (No. 1375 of 2012).** Disponível em: <http://www.ecolex.org/details/legislation/act-on-sharing-information-for-the-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. Disponível em: <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.* Disponível em: <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-fa-oc137585/?> 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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016

GOVERNMENT OF GREENLAND. **The Fifth National Report Greenland.** Ministry of Environment and Nature, Government of Greenland. 2014. Disponível em: <https://www.cbd.int/countries/?country=dk> Access in 18/10/2016.

## 1. General Information

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

YES / (  ) NO

Yes, Slovakia has been a Party to the Convention on Biological Diversity, by approval, since Nov 23, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES / (  ) NO

Yes, Slovakia has been a Party to the Protocol, by accession, since Mar 8, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES / (  ) NO

The following checkpoints have been identified:

- 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 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.

<sup>1</sup> 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>.



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<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?**

( ) YES / ( X ) NO

No IRCCs were found in Slovakia. It should be noted that Slovakia has only compliance legislation, ie legislation is concerned with ensuring compliance with other internal and external laws. Access (under the Nagoya Protocol) to all of the country’s genetic resources is free, so it means that IRCCs will not be published.

**1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?**

( ) YES / ( X ) NO

No checkpoint communiqués were found in Slovakia.

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

( X ) YES / ( ) NO

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, being the supervisory body of the Ministry of the Environment.

**1.7 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

As explained under item 2.1, Slovakia does not have any legislation on access and benefit sharing.

.....  
2 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>.

3 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.



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).

## 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

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.

In addition, as a Member-State of the European Union, the following shall also apply:

- 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

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

( X ) YES / ( ) NO

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

As explained under item 2.1, Slovakia does not have any legislation regulating access. For that reason, there is no need for prior consent.

Within the European Union, of which Slovakia 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

As explained under item 2.1, Slovakia does not have any legislation regulating access.

In relation to the European Union, the 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?**

( ) YES / ( X ) NO

There are no specific provisions related to intellectual property in the country's national legislation regarding access to genetic heritage and associated traditional knowledge.

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

As explained under item 2.1, Slovakia does not have any legislation regulating access.

As for the European Union, Article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as "best practices" a set of procedures, tool or mechanisms developed and supervised by them. At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

( ) YES / ( X ) NO

As explained under item 2.1, Slovakia does not have any legislation regulating access. The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As explained under item 2.1, Slovakia does not have any legislation regulating access.

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-counties 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.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

No procedures for the shipment of samples were identified in the norms covered by this analysis.

## 3. Websites of Interest

### National CHM:

<http://www.fns.uniba.sk/zp/biod>

### Slovak Environmental Agency:

<http://www.sazp.sk/public/index/index.php>

## 4. Summary – competent authorities

Authority	Competence
Ministry of Environment	Only national competent institution for topics related to genetic resources.

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Slovakia profile. Disponível em: <https://absch.cbd.int/countries/SK> Access in 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Slovakia profile. Disponível em: <https://www.cbd.int/countries/?country=sk> 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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016.

SLOVAK REPUBLIC. **Act. No. 263/2015 Col. on competences in area of the access to genetic resources and sharing of benefits arising from its utilization.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-SK-207103> Access in 18/10/2016.

SLOVAK REPUBLIC. **Fifth National Report On The Implementation Of The Convention On Biological Diversity In The Slovak Republic.** Disponível em: <https://www.cbd.int/countries/?country=sk> Access in 18/10/2016.

SLOVAK REPUBLIC. **Updated National Strategy for the Protection of Biodiversity to 2020.** 2014. Disponível em: <https://www.cbd.int/countries/?country=sk> Access in 18/10/2016.

## 1. General Information

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

YES /  NO

Yes, Spain has been a Party to the Convention on Biological Diversity, by ratification, since Mar 21, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Spain has been a Party to the Nagoya Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

Yes, Spain has two IRCCs, issued by the Competent National Authority (Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente):

- The first issued on April 21, 2017, treats the identification of the person favored by the certificate with confidentiality; however, it is known that the use is for non-commercial purposes and prior informed consent has been respected. As the National Focal Point points out, the object or genetic resources covered by the permit or its equivalent are ant species *Myrmica rubra*, *Linepithema humile* and *Lasius neglectus* being studied in the context of their collective behavior in defense against pathogens.
- The second issued on June 15, 2017, treats with confidentiality the identification of the favored by the certificate, however, it is known that the use is for non-commercial purposes and prior informed consent has been respected. The object or genetic resources covered by the permit

1 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>.

2 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>.

or its equivalent are the species of *Cardiocondyla obscurior* ant being studied in the context of its collective behavior in defense against pathogens.

**1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?**

YES /  NO

No checkpoint communiqués were found either for Spain or the European Union.

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

YES /  NO

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, as the focal point of the Nagoya Protocol, 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.

**1.7 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

Furthermore, art. 19 of Royal Decree 124/2017 provides forecasts on 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 it 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.

.....  
3 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, 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).

## 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

- 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

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

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. For both the competent authority is the Dirección General de Calidad y Evaluación Ambiental y Medio Natural del Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente.

### **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

Article 71, item 2, of Law 42/2007, provides that a access authorization will be issued as proof of obtaining prior informed consent and if mutually agreed conditions have been established.

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 a 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. A Does the current legislation or any ongoing bills provide specific procedures for access to Associated Traditional Knowledge?**

(  ) YES / (  ) NO

Neither Law 42/2007 and the Royal Draft Decree provides the need for benefit sharing and access authorization request as well for the access to genetic heritage.

In relation to the European Union, the 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?**

(  ) YES / (  ) NO

Royal Decree 124/2017, in its article 14.3, provides forecasts 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 prejudice 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.

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

No specific procedure has been identified in national legislation. In the meantime, the procedures established under Articles 6 and 7 of Royal Decree 124/2017 would apply to access to Spanish genetic resources for their use (research and development) in all relevant sectors, including perfumes, personal hygiene or cosmetics.

As for the European Union, Article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them.

At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

YES /  NO

Royal Decree 124/2017 only deals with issues related to ABS in general, which does not exempt users from complying with other norms applicable to their specific cases. In this sense, in the case of invasive alien species, Royal Decree 630/2013, of August 2, regulates the Spanish catalog of invasive alien species.

Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

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 whose 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-counties 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.

## **2. 9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

No specific procedures for the shipment of samples were identified in the norms covered by this analysis.

## **3. Websites Of Interest**

### ***Ministry of Agriculture, Food and Environment***

*<http://www.mma.es>*

### ***World Tourism Organization***

*<http://www.world-tourism.org>*

## **4. Summary – Competent Authorities**

As mentioned in item 2.3, it is not clear which institution is the competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the

Nagoya Protocol:

## Nagoya Protocol on Access and Benefit-sharing

### Mr. Miguel Aymerich

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Dirección General de Calidad y Evaluación Ambiental y Medio Natural  
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## 5. Referências Bibliográficas

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Spain profile. Disponível em: <https://absch.cbd.int/countries/ES> Access in 18/10/2016.

CANDEIRA, Alejandro Lago; GADEA, Daniel Serrano. **El conocimiento tradicional y la biodiversidad en el marco internacional: El CDB y el Protocolo de Nagoya. El Inventario Español de Conocimientos Tradicionales en la Ley 42/2007.** Ministerio De Medio Ambiente y Medio Rural y Marino. Gobierno de España. Disponível em: [https://drive.google.com/drive/folders/0B7Oc-xow\\_yaeYTVxbDZCZUZwcnM](https://drive.google.com/drive/folders/0B7Oc-xow_yaeYTVxbDZCZUZwcnM) Access in 18/10/2016

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Spain profile. Disponível em: <https://www.cbd.int/countries/?country=es> 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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 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.** Disponible em: [https://www.boe.es/diario\\_boe/txt.php?id=BOE-A-2014-8817](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.** Disponible em: <https://absch.cbd.int/database/record/ABSCH-MSR-ES-204413> Access in 18/10/2016.

GOBIERNO DE ESPAÑA. **Quinto Informe Nacional Sobre La Diversidad Biológica.** 2014. Disponible em: <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.** Disponible em: <https://www.boe.es/boe/dias/2017/03/14/pdfs/BOE-A-2017-2743.pdf> Access in 18/10/2016.

## 1. General Information

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

YES /  NO

Yes, Finland has been a Party to the Convention, by acceptance, since Oct 25, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Finland has been a Party to the Protocol, by acceptance, since Sept 1st, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

Yes, Finland has two checkpoints. The Natural Resources Institute Finland and the Finnish Environment Institute, which are federal institutions with similar responsibilities. As informed on the official website of The Access and Benefit-Sharing Clearing-House Mechanism of CBD, these federal entities were designated as the National Competent Authorities as determined in article 17 of the Nagoya 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.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under

1 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>.

2 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>.

3 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 terms of Article 17, 1(a) of the Nagoya Protocol?**

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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.

**1.7 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

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.

## 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

Finland has the following legislation regarding access to genetic heritage and associated traditional knowledge, apart from the existing regulations within the European Union:

**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.

The European Union - of which Finland 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** - relates to measures concerning the compliance of users with 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 Regulation of Execution 2015/1866, of October 13, 2015** - establishes the execution norms of EU Regulation No. 511/2014 of the European Parliament and Council in relation to the registry of collections, the monitoring of compliance by the users and good practices.

**Guidance 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 users' compliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.**

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

( X ) YES / ( ) NO

The Act on the Implementation of the Nagoya Protocol to the Convention on Biological Diversity institutes the general direction and supervision of this law as a responsibility of the Ministry of the Environment according to Section 10. As for section 11, it establishes as the national focal points The Natural Resources Institute Finland and the Finnish Environment Institute.

The Natural Resources Institute Finland is 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. As for the Finnish Environment Institute, it deals with 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 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.

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

YES /  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.

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

YES /  NO

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 databank 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 databank 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 /  NO

Although the theme is not covered by the legislation mentioned under item 2.1., within intellectual property law, there is the European Parliament Resolution of January 15, 2013 on aspects of the development of intellectual property rights in matters of genetic resources: impact on poverty-reduction in developing countries (2012/2135(INI)). This resolution does not establish 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

Finland's legislation does not provide any specific procedures.

As for the European Union, through article 8 of Regulation 511/2014 it authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as "best practices" a set of procedures, tools or mechanisms developed and supervised by them.

At present, sector-specific guidelines are being established, such as for the cosmetic, pharmaceutical, biotechnological sectors, and others.

### **2.7. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?**

YES /  NO

None of the laws presented under item 2.1 mentions any specific procedures for collection and access of exotic species.

### **2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

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 to the possibility of requesting benefit-sharing, there is no additional information in terms of its procedures, rules and values.

### **2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

No procedures for the shipment of samples were identified in the norms covered by this analysis.

## **3. Websites Of Interest**

### ***National CHM***

<http://www.biodiversity.fi>

### ***Finnish Environment Institute***

<http://www.syke.fi/en-us>

### ***Ministry for Foreign Affairs of Finland, Development Policy***

<http://formin.finland.fi/Public/default.aspx?nodeid=15316&contentlan=2&culture=en-us>

### ***Ministry for Foreign Affairs of Finland, Human Rights (Rights of the indigenous peoples, the Saami people)***

<http://formin.finland.fi/Public/default.aspx?nodeid=15630&contentlan=2&culture=en-us>

**The Saami Parliament**

<http://www.samediggi.fi/index.php?lang=english>

**Joint website of Finland's environmental administration (in Finnish)**

<http://www.environment.fi>

**Ministry of Agriculture and Forestry:**

<http://mmm.fi/en/frontpage>

**Luke – Natural Resource Institute:**

<https://www.luke.fi/en/luke-3/>

#### 4. Summary – Competent Authorities

Authority	Competence
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	Deals with any other genetic resources and the associated traditional knowledge of local communities related to such resources.

#### 5. Referências Bibliográficas

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Finland profile. Disponível em: <https://absch.cbd.int/countries/FI> Access in 05/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Finland profile. Disponível em: <https://www.cbd.int/countries/?country=fi> Access in 05/11/2016.

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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016.

**FINLAND. Act on the Implementation of the Nagoya protocol to the Convention on Biological Diversity (Finnish).** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-FI-207673> Access in 04/11/2016.

**FINLAND. Fifth National Report To The Convention On Biological Diversity Finland.** Disponível em: <https://www.cbd.int/countries/?country=fi> Access in 05/11/2016.

**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’.** Disponível em: <https://www.cbd.int/countries/?country=fi> Access in 05/11/2016.

**FINLAND. Implementation of the Convention on Biological Diversity’s Programme of Work on Protected Areas.** Disponível em: <https://www.cbd.int/countries/?country=fi> Access in 05/11/2016.

**FINLAND. Implementation of the Convention on Biological Diversity’s Programme of Work on Protected Areas.** Disponível em: <https://www.cbd.int/countries/?country=fi> Access in 05/11/2016.

**FINLAND. Saving Nature for People National action plan for the conservation and sustainable use of biodiversity in Finland 2013–2020.** Disponível em: <https://www.cbd.int/countries/?country=fi> Access in 05/11/2016.

## 1. General Information

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

YES /  NO

Yes, France has been a Party to the CBD, by ratification, since Sept 29, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, France has been a Party to the Protocol, by ratification, since Nov 29, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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 a responsibility of: officials responsible 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.

### **1.7 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

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:

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 increase up to 1 million Euro in cases where commercial use is identified.

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.

## **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

The main French legislation that regulate ABS Activities is LOI No. 2016-1087 of Aug 8, 2016, pour la reconquête de la biodiversité, de la nature et des paysages, the so-called Biodiversity Law (Loi Biodiversité).

It is important to highlight that the website “French Biodiversity Clearing House Mechanism”<sup>4</sup> 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.

4 <http://biodiv.mnhn.fr/info/mise-en-oeuvre-du-protocole-sur-l-acces-et-le-partage-des-avantages>

As for the dependent territories, one should note 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 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.

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

YES / (  ) NO

The “Agence française pour la biodiversité” (French Agency for Biodiversity) was created by article 21 of LOI n° 20161087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages. It should be highlighted that one of the main roles of this agency is 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?**

YES / (  ) NO

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 a 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:



- The Parties fail to sign a benefit-sharing agreement;
- The benefit-sharing proposed by the user does not correspond to their technical and financial capabilities;
- The activity or its application has a potential of negatively impacting the 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?**

YES / (  ) NO

The dispositions concerning traditional knowledge associated to genetic resources are listed under article 37 of the Biodiversity Law, as well as other key ABS-related issues. 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 as 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?**

YES / (  ) NO

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

(  ) YES / (  ) NO

It was not possible to identify in the legislation and other documents analyzed any specific procedures for that purpose.

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

YES /  NO

It was not possible to identify in the legislation and other documents analyzed any specific procedures for that purpose.

## 2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?

YES /  NO

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 – although it does not specify any specific values or procedures:

- *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 detail these practices establishes actions 1-5 as priority, and therefore it can be understood that there is a preference for non-monetary benefit-sharing.

Finally, a benefit-sharing agreement template can be established according to the terms of article L. 412-1-9.

## 2.9. Does the current legislation establish procedures for the shipment of samples?

YES /  NO

It was not possible to identify in the legislation and the other documents analyzed any specific procedures for that purpose. 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.

## 3. Websites Of Interest

### **National CHM**

<http://biodiv.mnhn.fr/>

### **Ministry of Ecology, Energy, Sustainable Development and Energy**

<http://www.developpement-durable.gouv.fr/>

**Fondation for Research on Biodiversity**

<http://www.fondationbiodiversite.fr/en/>

**Agence française pour la biodiversité**

<http://www.afbiodiversite.fr/>

#### 4. Summary – Competent Authorities

Authority	Competence
Ministry of Ecology, Energy, Sustainable Development and Energy	National Competent Authority for environment-related issues.
French Agency for Biodiversity	National Competent Authority for access and use of genetic resources and associated traditional knowledge.

#### 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. France profile. Disponível em: <https://absch.cbd.int/countries/FR> Access in 17/03/2017.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. France profile. Disponível em: <https://www.cbd.int/countries/?country=fr> Access in 17/03/2017.

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> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016

FRANCE. **Loi n° 2016-1087 du 8 août 2016 pour la reconquête de la biodiversité, de la nature et des paysages.** Disponível em: <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=* Access in 17/03/2017.

FRANCE. **Loi n° 2006-436 relative aux parcs nationaux, aux parcs naturels marins et aux parcs naturels régionaux.** Disponible en: *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=* . Access in 17/03/2017.

FRANCE. **Ségolène Royal, Ministre de l'écologie présente le cinquième rapport national de la France à la Convention sur la Diversité Biologique.** 2014. Disponible en: *https://www.cbd.int/countries/?country=fr* Access in 17/03/2017.

FRANCE. **Stratégie nationale pour la biodiversité 2011-2020.** 2011. Disponible en: *https://www.cbd.int/countries/?country=fr* Access in 17/03/2017.

# Netherlands

## 1. General Information

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

YES /  NO

Yes, the Netherlands has been a Party to the Convention on Biological Diversity, by acceptance, since Oct 10, 1994.

### Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the Netherlands has been a Party to the Nagoya Protocol, by acceptance, since Nov 17, 2016.

### Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in the Netherlands.

### Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in the Netherlands.

### Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in the Netherlands.

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

YES /  NO

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

1 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>.

2 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>.

3 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 Netherlands Food Safety Authority (Nederlandse Voedsel- en Warenautoriteit) appointed by decision of the Minister for Economic Affairs from March 31, 2016; (b) the Minister 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.

### **1.7 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

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.

## **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

The Netherlands have the following legislation regarding access to genetic heritage and associated traditional knowledge:

- **Rules for implementation of the Nagoya Protocol (Nagoya Protocol Implementation Act) Bill** - 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.

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. According to information obtained through contact with the National Focal Point, 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 the access to genetic resources occurring in the Netherlands in national legislation (Section 6.2.1 Of The Explanatory Memorandum accompanying the Nagoya Protocol (Implementation) Act).

- **Decision from the Minister of Economic Affairs, March 31, 2016** - appoints supervisors and focal points for the implementation of the Nagoya Protocol.

The European Union - of which the Netherlands 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 Council, of April 16, 2014 - related to measures dealing with the user's compliance with the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from its use within the Union.
- EU Regulation of Execution 2015/1866, of October 13, 2015 - establishes the execution norms of EU Regulation No. 511/2014 of the European Parliament and Council in relation to the registry of collections, the monitoring of users' compliance and good practices.
- Baseline Document on the scope of application and the obligations resulting from EU Regulation 511/2014 of the European Parliament and Council in relation to measures dealing with users' 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 such regulations were drafted with the objective of assisting European Union countries in the creation of their own national norms; 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

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 /  NO

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.

Within the European Union, of which the Netherlands is a member, the requirement of prior authorization to access genetic resources and traditional knowledge was not 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. As per 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 regulations on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and that 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 European Union’s legislation.

Through articles 4 and 7 of Regulation 511/2014, the European Union imposes obligations to the users of genetic resources and associated traditional knowledge. As per article 4 of this documents, users are obliged to carry out due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation and, in this case, also the legislation of the organization pursuant to 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 due 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

None of the laws presented under item 2.1 mentions any specific procedures for accessing Associated Traditional Knowledge.

In relation to the European Union, the legislation does not foresee specific procedures for access to 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?**

( ) YES / ( X ) NO

None of the laws presented under item 2.1 include any information on patent requests.

In relation to the European Union, although the theme is not covered by the legislation mentioned in item 2.1., within the intellectual property law, there is the European Parliament Resolution of January 15, 2013 on aspects of the development of intellectual property rights in matters of 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

None of the laws presented under item 2.1 include any information on access for research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries

As for the European Union, article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as "best practices" a set of procedures, tools or mechanisms developed and supervised by them. At present, sector-specific guidelines are being established, such as for the cosmetic, pharmaceutical, biotechnological sectors, and others.

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

( ) YES / ( X ) NO

None of the laws presented under item 2.1 mentions specific procedures for collection and access of exotic species. Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

## 2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?

( ) YES / ( X ) NO

None of the laws presented under item 2.1 mention the requirement of benefit-sharing.

However, 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-counties have sovereign ownership rights, such as the sharing of benefits resulting from the use of genetic resources and traditional knowledge associated to them. In this context, the obligations of users of genetic resources and traditional knowledge include the carrying out of due diligence in order to guarantee compliance with the applicable legislation or regulations on matters of access and benefit-sharing.

## 2.9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

No procedures for the shipment of samples were identified in the norms covered by this analysis.

## 3. Websites Of Interest

### *Biodiversity-CHM.NL - Information, activities, people and policy:*

<http://en.biodiversiteit.nl/>

### *Ministry of Development Cooperation*

<http://www.minbuza.nl/en/themes>

### *Ministry of Foreign Affairs*

<https://www.government.nl/ministries/ministry-of-foreign-affairs#ref-minbuza>

### *Nature and biodiversity*

<https://www.government.nl/topics/nature-and-biodiversity>

### *Center for genetic Resourcer (ABS Focal Point - Wageningen UR)*

[www.absfocalpoint.nl](http://www.absfocalpoint.nl)

## 4. Summary – Competent Authorities

Authority	Competence
Ms. Kim van Seeters, Ministry of Economic Affairs.	National competent authority on access and benefit-sharing under the terms of article 13, second paragraph, of the Nagoya Protocol and competent authority responsible for the application of EU regulations on genetic resources.
Netherlands Food Safety Authority (Nederlandse Voedsel- en Warenautoriteit)	Responsible for enforcing the Nagoya Protocol Implementation Act
Ministry of Security and Justice	Responsible for the surveillance, under the terms of article 17 of the Economic Offences Act, aimed at detecting or identifying the offenses defined under the terms of the Nagoya Protocol Implementation Act.

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Netherlands profile. Disponível em: <https://absch.cbd.int/countries/NL> Access in 06/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Netherlands profile. Disponível em: <https://www.cbd.int/countries/?country=nl> Access in 06/11/2016.

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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016.

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. Disponível em: <https://www.cbd.int/countries/?country=nl> Access in 06/11/2016.

NETHERLANDS. **Convention on Biological Diversity Fifth National Report of the Kingdom of the Netherlands.** Ministry of Economic Affairs. Disponível em: <https://www.cbd.int/countries/?country=nl> Access in 06/11/2016.

NETHERLANDS. **Nagoya Protocol (Implementation) Act.** Disponível em: <https://absch.cbd.int/countries/NL> Access in 06/11/2016.

NETHERLANDS. **Nature Policy Plan The Caribbean Netherlands 2013-2017.** Disponível em: <https://www.cbd.int/countries/?country=nl> Access in 06/11/2016.

NETHERLANDS. **The Natural Way Forward Government Vision 2014.** Ministry of Economic Affairs. Disponível em: <https://www.cbd.int/countries/?country=nl> Access in 06/11/2016.

### 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 25, 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 Oct 12, 2014.

### 1.3 Does the country have any officially recognized "checkpoints"<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

( X ) YES / ( ) NO

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 traditional 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.

.....  
<sup>1</sup> 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<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?**

YES /  NO

No IRCCs were found in Hungary.

**1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?**

YES /  NO

No checkpoint communiqués were found in Hungary.

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

YES /  NO

The specific bodies for control and inspection of access and benefit sharing are the checkpoints described in item 1.3, however, according to information obtained from the National Focal Point, so far no fine has been imposed for irregular ABS activities.

**1.7 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

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).

## 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

The following legislation was identified in this country:

- 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.

2 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>.

3 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.

In addition to that, as a State-member of the European Union, the following shall apply:

- 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?**

YES /  NO

The responsible institution for all matters related to genetic resources in Hungary is the National Inspectorate for Environment, Nature and Water.

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

YES /  NO

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.

Within the European Union, of which Hungary 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

The current legislation does not establish any specific procedures for access to associated traditional knowledge.

In relation to the European Union, the 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?**

( ) YES / ( X ) NO

There are no specific provisions related to intellectual property in the country's national legislation regarding access to genetic heritage and associated traditional knowledge.

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

There are no specific provisions related to intellectual property in the country's national legislation regarding access to genetic heritage and associated traditional knowledge.



As for the European Union, Article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them. At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

YES /  NO

Both the Hungarian and European laws do not provide any specific procedures for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

The national legislation does not expressly provide for benefit sharing obligations, but the 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.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

No specific procedures concerning the subject were identified in Hungary.

**3. Websites Of Interest**

**National CHM**

<http://www.biodiv.hu/>

**Ministry of Rural Development**

<http://www.kormany.hu/hu/foldmuvelesugyi-miniszterium>

**4. Summary – competent authorities**

Authority	Competence
National Inspectorate for Environment, Nature and Water.	National institution responsible for the use of genetic resources.



## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Hungary profile. Disponível em: <https://absch.cbd.int/countries/HU> Access in 07/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Hungary profile. Disponível em: <https://www.cbd.int/countries/?country=hu> Access in 07/11/2016.

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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016.

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.** Disponível em: <https://absch.cbd.int/countries/HU> Access in 04/11/2016.

HUNGARY. **Fifth National Report to the Convention on Biological Diversity - Hungary.** Disponível em: <https://www.cbd.int/countries/?country=hu> Access in 04/11/2016.

HUNGARY. **National Strategy for the Conservation of Biodiversity in 2015-2020.** Disponível em: <https://www.cbd.int/countries/?country=hu> Access in 04/11/2016.

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.** Disponível em: <https://absch.cbd.int/countries/HU> Access in 04/11/2016.

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

YES /  NO

Yes, Italy has been a Party to the CBD, by ratification, since Jul 14, 1994.

**1.2 Is the country a Party to the Nagoya Protocol?**

YES /  NO

No, Italy is not a Party, but is a signatory to the Nagoya Protocol since Jun 23, 2011.

**1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?**

YES /  NO

No checkpoints were found in Italy.

**1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?**

YES /  NO

No IRCCs were found in Italy.

**1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?**

YES /  NO

No checkpoint communiqués were found in Italy.

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

YES /  NO

None of the laws presented under item 2.1 mention any inspections bodies. Also, there is no evidence of imposition of fines apart from the legal provisions establishing that they may be applied.

1 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>.

2 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>.

3 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.

### 1.7 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

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

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).

## 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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in Italy, but there are two laws that cover 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.

- 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.

In the quality of regional organization, the European Union - of which Italy 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 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?**

( ) YES / ( X ) NO

No competent institution was identified in relation to access and benefit-sharing in this 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

As explained under item 2.1, Italy does not have any legislation regulating access. For that reason, there is no need for prior consent.

Within the European Union, of which Italy 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 /  NO

As explained under item 2.1, Italy does not have any legislation regulating access.

In relation to the European Union, the 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?**

YES /  NO

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.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As explained under item 2.1, Italy does not have any legislation regulating access.

As for the European Union, Article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them. At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

YES /  NO

None of the laws presented under item 2.1 mention any specific procedures for the collection and access of exotic species. Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

## 2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?

YES /  NO

Although there is no national law on Access and Benefit Sharing, 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 this resources, as the community was 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-counties 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.

## 2.9. Does the current legislation establish procedures for the shipment of samples?

YES /  NO

No specific procedures for the shipment of samples were identified in the norms covered by this analysis.

## 3. Websites Of Interest

### *Ministero Dell'Ambiente e della Tutela del Territorio e del Mare*

<http://www.minambiente.it/>

### *ISPRA – Istituto Superiore per la Protezione e la Ricerca Ambientale:*

<http://www.isprambiente.gov.it/it/temi/biodiversita/le-domande-piu-frequenti-sulla-biodiversita>

### *MIPAAF – Ministero delle politiche agricole alimentary e forestali*

<https://www.politicheagricole.it>

### *IPOGEA - Traditional Knowledge Research Center*

<http://www.ipogea.org/site2/index.php/it/home>

## 4. Summary – Competent Authorities

According to item 2.3., Italy does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

## Nagoya Protocol on Access and Benefit-sharing

### Mr. Oliviero Montanaro

ABS National Focal Point

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Head of Unit for International Issues

Directorate General for Nature and Sea Protection

Ministry of the Environment, Land and Sea

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Italy

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Italy profile. Disponível em: <https://absch.cbd.int/countries/IT> Access in 12/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Italy profile. Disponível em: <https://www.cbd.int/countries/?country=it> Access in 12/10/2016.

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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016

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)**. Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=13123> Access in 12/10/2016.

ITALY. **Italian National Biodiversity Strategy**. Ministero dell'Ambiente e della Tutela del Territorio e del Mare – MATTM. Disponível em: <https://www.cbd.int/countries/?country=it> Access in 12/10/2016.

ITALY. **Italy's Fifth National Report To The Convention On Biological Diversity (2009-2013)**. Ministry for the Environment, Land and Sea. Disponível em: <https://www.cbd.int/countries/?country=it> Access in 12/10/2016.

ITALY. **La Strategia Nazionale per la Biodiversità**. Ministero dell'Ambiente e della Tutela del Territorio e del Mare – MATTM. Disponível em: <https://www.cbd.int/countries/?country=it> Access in 12/10/2016.

ITALY. **Legge Regionale N. 26 Del 14-10-2008 Regione Basilicata**. Disponível em: [http://www.regione.basilicata.it/giunta/files/docs/DOCUMENT\\_FILE\\_304418.pdf](http://www.regione.basilicata.it/giunta/files/docs/DOCUMENT_FILE_304418.pdf) Access in 12/10/2016.

ITALY. **Mid-term review of the National Biodiversity Strategy to 2020**. Disponível em: <https://www.cbd.int/countries/?country=it> Access in 12/10/2016.



# Luxembourg

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the CBD, by ratification, since Aug 7, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country ratified the Nagoya Protocol on October 25, 2016, and it will become effective from Jan 23, 2017.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

No official inspection body was identified in the country, and it neither has any legislation on access and benefit-sharing.

.....  
1 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>.

2 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>.

3 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.

**1.7 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

As explained in item 2.1, Luxembourg does not have any legislation on access and benefit sharing. 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 the member-countries should establish the applicable rules and sanctions to anyone breaching the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”, respectively).

## 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

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

On the other hand, in the quality of regional organization, the European Union - of which Luxembourg 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 dealing with user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from its use within the Union.
- EU Regulation of Execution 2015/1866, of October 13, 2015 - establishes the execution norms of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, monitoring of compliance by the users and good practices.
- Baseline Document 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 the compliance of users 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 such regulations were drafted with the objective of assisting European Union countries in the creation of their own national norms; 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?**

YES /  NO

No official competent institutions were found concerned with access and benefit-sharing under the terms 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 /  NO

As explained in item 2.1, Luxembourg does not have any legislation regulating access. For that reason, there is no need for prior consent.

Within the European Union, of which Luxembourg 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. As per 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 regulations on access and benefit-sharing of the supplier country listed as a Party to the Nagoya Protocol and which thus 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 European Union’s legislation.

Through articles 4 and 7 of Regulation 511/2014, the European Union imposes obligations to the users of genetic resources and associated traditional knowledge. As per 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 regulating 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 at least twenty years after the period of utilization. According to article 7, all beneficiaries using genetic resources and associated traditional knowledge are required by the Member-States of the European Union to declare due diligence in the activities performed.

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

YES /  NO

As explained in item 2.1, Luxembourg does not have any legislation regulating access.

In relation to the European Union, the legislation does not foresee any specific procedures for access to associated traditional knowledge; however, all rights of holders of traditional knowledge associated to the 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?**

YES /  NO

There are no specific provisions related to intellectual property in the country's national legislation regarding access to genetic heritage and associated traditional knowledge.

In relation to the European Union, although the theme is not covered by the legislation mentioned under item 2.1., within the intellectual property law, there is the European Parliament Resolution of January 15, 2013 on aspects of the development of intellectual property rights in matters of 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As explained in item 2.1, Luxembourg does not have any legislation regulating access.

As for the European Union, through article 8 of Regulation 511/2014, it authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as "best practices" a set of procedures, tools or mechanisms developed and supervised by them.

At present, sector-specific guidelines are being established, such as for the cosmetic, pharmaceutical, biotechnological sectors, and others.

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

YES /  NO

As explained in item 2.1, Luxembourg does not have any legislation regulating access. Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As explained in item 2.1, Luxembourg does not have any legislation regulating access.

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 for the sharing of benefits resulting from

the use of genetic resources and the traditional knowledge associated to them. 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 on matters of access and benefit-sharing.

### **2. 9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

No procedures for the shipment of samples were identified in the norms covered by this analysis.

## **3. Websites of Interest**

### ***National CHM***

*<http://www.mev.etat.lu>*

### ***Luxembourg Agency for Development Cooperation***

*<http://www.lux-development.lu/agence.lasso>*

## **4. Summary – Competent Authorities**

As mentioned in item 2.3., Luxembourg does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### **Nagoya Protocol on Access and Benefit-sharing**

#### **Mr. Laurent Schley**

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ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Luxembourg profile. Disponible em: <https://absch.cbd.int/countries/LU> Access in 20/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Luxembourg profile. Disponible em: <https://www.cbd.int/countries/?country=lu> Access in 20/11/2016.

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.** Disponible em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponible em: <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.** Disponible em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016

LUXEMBOURG. **Cinquieme Rapport National Du Luxembourg A La Convention Sur La Diversite Biologique.** Ministere Du Developpement Durable Et Des Infrastructures – Departement De L'environnement. 2015. Disponible em: <https://www.cbd.int/countries/?country=lu> Access in 20/11/2016.

LUXEMBOURG. **Plan National Concernant la Protection de la Nature 2017 – 2021.** Ministère du Développement durable et des Infrastructures. Département de l'Environnement. 2017. Disponible em: <https://www.cbd.int/countries/?country=lu> Access in 13/04/2017.

LUXEMBOURG. **Plan National Pour La Protection De La Nature (PNPN): Rapport Final (Avant-Projet).** Ministère de l'Environnement. 2007. Disponible em: <https://www.cbd.int/countries/?country=lu> Access in 20/11/2016.

## 1. General Information

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

YES / (  ) NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since March 29, 2001.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES / (  ) NO

Yes, the country has been a party to the Nagoya Protocol, by accession, since March 01, 2017 .

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES / (  ) NO

Yes, the country has set up a checkpoint, namely the Plant Health Directorate, which also acts as the competent authority. It is responsible for managing information on access to genetic resources, Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), and Internationally Recognized Certificate of Conformity (IRCC).

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

(  ) YES / (  ) NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoint communiqués were found in this country.

1 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>.

2 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>.

3 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.

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

YES / (  ) NO

The Act "Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization Regulations, 2016" states in rule 15 that the competent authority, or any other entity duly authorized by the competent authority, may carry out inspections.

**1.7 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

Yes, administrative fines may be imposed, as per rule 14, of the "Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization Regulations, 2016" rule. The offenses against the supervising agent are contained in rule 19, and the other types of infractions are described in rule 22, (1). The values of fines are found in rule 22, (2):

- A) In the case of a first violation, a fine of not less than eight hundred euros (800 euros), but not exceeding € 4,658.75;
- B) In the event of a repeat 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.

## 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

At the national level, the country has the standard entitled "Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization Regulations, 2016" (Legal Notice, 379 of 2016 - Environment Protection Act). In addition, 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.

On the other hand, in the quality of 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 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

In accordance with the initial provisions of the Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization Regulations, 2016, the competent authority is the Director of the body called Plant Health Services. Rule 4 indicates as the authority of that authority the application of the Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization Regulations, 2016, the Council Regulation and the Nagoya Protocol.

The Director of Plant Health Services is also responsible for granting access to genetic resources through prior informed consent, the issuance of IRCCs, the performance of the functions of the Member State pursuant to Article 5 of the Council Regulation and advise on the applicable procedures and measures Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization Regulations, 2016 “and the Council Regulation.

In addition, it provides that the following assisting authorities shall participate in granting access to genetic resources through prior informed consent:

- The Environment and Wildlife Authority Authority as set forth in the Environmental Protection Act, with the exception of birds protected under the provisions of the Wild Bird Conservation Regulation;
- The Ministry of Fisheries and Aquaculture, as provided for in the Fisheries Conservation and Management Law.

Finally, rule 11 defines that an advisory committee called the Access to Benefit Sharing Advisory Committee, composed of 11 members, should be created to assist and advise the competent authority in the application of legal norms and other matters relating to the matter.

## **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

Rule 5 of Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization Regulations 2016 indicates that access to genetic resources requires the prior informed consent of the competent authority 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 consent.

Within the European Union, of which Austria 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.

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

( X ) YES / ( ) NO

According to Rule 6 of Access to Genetic Resources and the Fair and Equitable Sharing of Benefits from their Utilization Regulations, 2016, 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.

In relation to the European Union, the legislation 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?**

( ) YES / ( X ) NO

The country does not have any legislation on access to genetic resources and associated traditional knowledge.

In relation to the European Union, although the topic 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

The country does not have any legislation on access to genetic resources and associated traditional knowledge.

As for the European Union, through article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them.

At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

( ) YES / ( X ) NO

The country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( X ) YES / ( ) NO

Rule 5 (3) of the Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization Regulations 2016 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-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.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

The country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 3. Websites

### **National CHM**

<http://www.mepa.org.mt/biodiversity>

### **Ministry for resources and rural affairs**

<http://vafd.gov.mt/home>

### **Plant Health Directorate**

<http://planthealth.gov.mt>

### **Environmental and Resources Authority – ERA**

<http://era.org.mt/en/Themes/Pages/Welcome.aspx>

## 4. Summary – Competent Authorities

Authority	Competence/Informations
Plant Health Services	It is responsible for managing information on access to genetic resources, Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), and Internationally Recognized Certificate of Conformity (IRCC).

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Malta profile. Disponível em <https://absch.cbd.int/countries/MT> Access in 21/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Malta profile. Disponível em : <https://www.cbd.int/countries/?country=mt> Access in 21/11/2016.

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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016.

REPUBLIC OF MALTA. **Fifth National Report on the Implementation of the Convention on Biological Diversity.** Malta Environment and Planning Authority. 2014. Disponível em: <https://www.cbd.int/countries/?country=mt> Access in 21/11/2016.

REPUBLIC OF MALTA. **Legal Notice 379 of 2016 - Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations, 2016.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-MT-208508> Access in 10/03/2017.

REPUBLIC OF MALTA. **Malta's National Biodiversity Strategy and Action Plan 2012-2020.** Ministry for Tourism, Culture and the Environment. Disponível em: <https://www.cbd.int/countries/?country=mt> Access in 21/11/2016.

## 1. General information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Jan 18, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Nov 21, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites

**National CHM**

<http://bsapm.moldnet.md>

### 4. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**Ms. Veronica Josu**

ABS National Focal Point

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Head of Natural Resources and Biodiversity Department

**Ministry of Agriculture, Regional Development and Environment**

9, Constantin Tanase Str.

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Chisinau

Republic of Moldova



## Ministry of Agriculture, Regional Development and Environment

ABS Competent National Authorities

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9 Str. Constantin Tanase

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Republic of Moldova

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Republic of Moldova profile. Disponivel em: <https://absch.cbd.int/countries/MD> Access in 07/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Republic of Moldova profile. Disponivel em: <https://www.cbd.int/countries/?country=md> Access in 06/10/2016.

REPUBLIC OF MOLDOVA. **Decision n° 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 in 06/10/2016.

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 Resources and Biodiversity Division; “ Biodiversity” Office. Chisinau, 2013. Available in: <https://www.cbd.int/countries/?country=md> Access in 06/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Nagoya Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

The Norwegian legislation establishes a supervisory institution. According to article 63 of the Nature Diversity Act, the Royal Norwegian Ministry of Climate and Environment shall oversee the

1 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>.

2 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>.

3 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.

state of the natural environment and monitor compliance with the dispositions set out in the Act - which, in articles 57 to 61, regulates access and benefit-sharing in the country. In addition, article 64 of the same act establishes that the supervisory authority or the police shall be given free access to any properties where activities that may have an impact on the biological diversity are being carried out.

No concrete cases were found during the survey in relation to the application of fines.

### **1.7 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

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 authority 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.

## **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

The Nature Diversity Act of July 1, 2009, the Marine Resources Act, the Patents Act and the Plant Variety Act make up the Norwegian legal framework for ABS. It should be noted that many of the provisions on the subject are general, leaving much of their content for future regulation.

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;
- Patents Act Act no. 09, of December 15, 1967 (updated with last amendment in 2013);
- Regulations relating to the protection of traditional knowledge associated with genetic material, having entered into membership since January 1, 2017.
- Marine Resources Act
- Plant Variety Act

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

( X ) YES / ( ) NO

Norway is a constitutional monarchy, with a parliamentary system of government. In this sense, the Nature Diversity Act states, in its article 62, that the King is the highest authority under the referred law, and may designate a special institution as the administrative authority for any particular themes.

The country's profile on the ABSCH website states that the Royal Norwegian Ministry of Climate and Environment is the National Competent Authority for any 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 obtain genetic resources?**

YES /  NO

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 exploration, 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?**

YES /  NO

The Nature Diversity Act was amended in June 2013 to include in this legal instrument some specific provisions related to associated traditional knowledge. Such an amendment was necessary 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 (Royal Decree of 25.November 2016) 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?**

YES /  NO

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), which 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 so require.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

There are no specific norms for obtaining access to genetic heritage in activities performed on behalf the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

There are no specific norms for the collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

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, let alone its compulsoriness.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

No specific procedures for the shipment of samples were identified.

## 3. Websites Of Interest

### **National CHM**

[http://chm-root.eea.europa.eu/chm\\_no](http://chm-root.eea.europa.eu/chm_no)

<http://www.miljo.no>

### **Ministry of Climate and the Environment**

<http://odin.dep.no/md/engelsk/bn.html>

### **Norwegian Environment Agency**

[www.miljodirektoratet.no](http://www.miljodirektoratet.no)

### **Directorate for nature management**

<http://www.dirnat.no>

### **Ministry of Foreign Affairs: International Development Programme**

[http://www.regjeringen.no/en/dep/ud/selected-topics/development\\_cooperation.html?id=1159](http://www.regjeringen.no/en/dep/ud/selected-topics/development_cooperation.html?id=1159)

## Summary – Competent Authorities

Authority	Competence
Royal Norwegian Ministry of Climate and Environment	National Competent Authority on ABS

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Norway profile. Disponível em: <https://absch.cbd.int/countries/NO> Access in 18/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Norway profile. Disponível em: <https://www.cbd.int/countries/?country=no> Access in 18/11/2016.

NORWEGIAN GOVERNMENT. **Marine Resources Act**. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-NO-208517> Access in 18/11/2016.

NORWEGIAN GOVERNMENT. **Nature Diversity Act Chapter VII Access to genetic material**. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-NO-203981> Access in 18/11/2016.

NORWEGIAN GOVERNMENT. **Norway's Fifth National Report to the Convention on Biological Diversity**. Ministry of Climate and Environment. Disponível em: <https://www.cbd.int/countries/?country=no> Access in 18/11/2016.

NORWEGIAN GOVERNMENT. **Norway's national biodiversity action plan**. Ministry of Climate and Environment. Disponível em: <https://www.cbd.int/countries/?country=no> Access in 18/11/2016.

NORWEGIAN GOVERNMENT. **Norwegian Patents Act (Act no. 09 of 15 December 1967)**. Disponível em: <http://www.wipo.int/edocs/lexdocs/laws/en/no/no107en.pdf> Access in 18/11/2016.

NORWEGIAN GOVERNMENT. **Regulation on traditional knowledge associated with genetic material**. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-NO-208516> Access in 18/11/2016.

NORWEGIAN GOVERNMENT. **Traditional knowledge associated with genetic resources**. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-NO-203982> Access in 18/11/2016.

## 1. General Information

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

YES /  NO

Yes, Poland has been a Party to the CBD, by ratification, since Apr 17, 1996.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, Poland is not a Party but is a signatory to the Nagoya Protocol since Sept 20, 2011.

### 1.3 Does the country have any officially recognized “checkpoints” under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

According to the National Focal Point, the Minister of the Environment is the only one checkpoint established in Poland.

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

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués” under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

According to the Act of Jul 19, 2016, Art. 3: 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 n°511/2014, the provincial inspector advises the user to take the corrective measures referred to in this instrument, and establishes a deadline for its execution.

### 1.7 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

The Act of July 19, 2016, 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. Will be subject to a fine to the amount of 5,000 zł to 50,000 zł. Article 12 Maintenance of genetic resource 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 zł to 50,000 zł. 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 zł to 100,000 zł. Article 14 Any person who did not submit a due diligence declaration, will be fined to the amount of 1,000 zł to 10,000 zł. 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 zł to 50,000 zł.

Still according to the Act of Jul 19, 2016, Art. 19 states that the pecuniary sanctions must be payed 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 The pecuniary sanctions may not be imposed after 5 years from the date on which the offence was identified.

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

( X ) YES / ( ) NO

Poland have the following legislation regarding access to genetic heritage and associated traditional knowledge:

- Act of Jul 19, 2016 - Deals access and benefit sharing. Establishing norms and sanctions based on the EU Regulation 511/2014.

In addition to that, in the quality of regional organization, the European Union - of which Poland 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.
- Commission on Implementation\_EU - Guide on the scope of essential applications and obligations of EU Regulation n° 511/2014.
- 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 com-

pliance to the Nagoya Protocol and access to genetic resources and the fair and equitable benefit-sharing deriving from their use within the Union.

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

YES /  NO

According to the Act of Jul 19, 2016, Art. 3: The national authority referred to in article 6th, paragraph 1<sup>o</sup>, of EU Regulation n° 511/2014 is the Minister of the Environment, except when it concerns user control and collection registration, these subjects being dealt with by the Inspectorate for Environmental Protection.

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

YES /  NO

The Act of Jul 19, 2016 adopts, in its Art. 1<sup>o</sup>, the provisions of EU Regulation n° 511/2014. In turn, the Regulation within the European Union does not clearly define the need for prior authorization to access genetic resources and traditional knowledge, 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 /  NO

The Polish legislation does not provide any specific procedures for access to the Associated Traditional Knowledge.

In relation to the European Union, the 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?**

( ) YES / ( X ) NO

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

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

( ) YES / ( X ) NO

According to article 10 of the Act of Jul 19, 2016, the chief-inspector of Environmental Protection works according to the Minister of the Environment in terms of examining recognition applications as “best practices” referred in Art. 8th, paragraph 1°, of the EU Regulation n°511/2014, being able to decide to amend or update a recognized practice.

As for the European Union, Article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them.

At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

( ) YES / ( X ) NO

The Act of Jul 19, 2016 does not present any specific procedures for the collection and access of exotic species. Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

## 2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?

YES /  NO

The Act of Jul 19, 2016 adopts, in its Art. EU Regulation No. 511/2014 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-counties 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.

## 2.9. Does the current legislation establish procedures for the shipment of samples?

YES /  NO

No procedures for the shipment of samples were identified in the norms covered by this analysis.

## 3. Websites Of Interest

### **Clearing House Mechanism Poland:**

<http://biodiv.gdos.gov.pl/>

### **Ministry of the Environment:**

<https://www.mos.gov.pl/en>

### **National CHM**

<http://biodiv.mos.gov.pl>

### **Polish Global Taxonomy Initiative**

<http://www.gti-polska.pl>

## 4. Summary – Competent Authorities

Authority	Competence
Ministry of the Environment	Responsible for applying Regulation n° 511/.
Inspectorate for Environmental Protection.	Responsible for user inspection and collection registration.

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Poland profile. Disponível em: <https://absch.cbd.int/countries/PL> Access in 10/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Poland profile. Disponível em: <https://www.cbd.int/countries/?country=pl> Access in 10/11/2016.

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))**. Disponível em: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2013-0007+0+DOC+XML+V0//EN> Access in 04/11/2016.

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**. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union**. Disponível em: <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**. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016

POLAND. **Fifth National Report On The Implementation Of The Convention On Biological Diversity**. Warsaw, 2014. Disponível em: <https://www.cbd.int/countries/?country=pl> Access in 10/11/2016.

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”**. Disponível em: <https://www.cbd.int/countries/?country=pl> Access in 10/11/2016.

POLAND. **The law of July 19, 2016 on access to genetic resources and the distribution of benefits from their use**. Disponível em: <http://dziennikustaw.gov.pl/du/2016/1340> Access in 10/11/2016.0

## 1. General Information

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

YES /  NO

Yes, Portugal has been a Party to the Convention on Biological Diversity, by ratification, since Mar 21, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, Portugal is not a Party, but is a signatory to the Nagoya Protocol since Sept 20, 2011.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

The country does not have an inspection body and it does not have any specific legislation on access and Benefit-Sharing either. In contact with the National Focal Point, it was informed that

1 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>.

2 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>.

3 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.

Chapter IV of Regional Legislative Decree no. 9/2012/A, of March 20, of the Autonomous Region of the Azores, under the heading “Inspection” process instruction and application of sanctions, among other predictions.

### **1.7 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

As explained in item 2.1, Portugal does not have any legislation on access and benefit sharing. 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).

## **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

According to clarifications obtained from the National Focal Point, the Autonomous Region of the Azores has ABS legislation, namely:

- Regional Legislative Decree No. 9/2012 / A of March 20 (Decreto Legislativo Regional N.º 9/2012/A de 20 de março): establishes the legal regime for access and use of natural resources of the Autonomous Region of the Azores, regarding:
  1. access to natural resources for scientific purposes, including biological and genetic resources, their by-products and by-products, air, water, minerals and soil;
  2. the transfer of natural resources collected or accessed for scientific purposes;
  3. the fair and equitable sharing of benefits arising from the use of natural resources collected and / or accessed for scientific purposes.
- Regional Regulatory Decree No. 20/2012 / A of November 5 (Decreto Regulamentar Regional N.º 20/2012/A de 5 de novembro): develops and regulates the legal regime for access and use of the natural resources of the Autonomous Region of the Azores for scientific purposes.
- On the other hand, in the quality of regional organization, the European Union - of which Portugal 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 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?**

YES / (  ) NO

According to the official website of the CBD, the only National Competent Authority of Portugal is the Institute for Nature Conservation and Forests, which is the institution responsible for all genetic resources.

In addition, Regional Regulatory Decree No. 20/2012 / A, of November 5, which develops and regulates the legal regime for access and use of the natural resources of the Autonomous Region of the Azores for scientific purposes, also the entities responsible for issuing of their licenses or authorizations.

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

(  ) YES / (  ) NO

In contact with the National Focal Point, it was informed that, except for the regional legislation referred to in item 2.1, in fact, there is no legislation or national regulatory requirements arising from the Nagoya Protocol for access to genetic resources.

For the Autonomous Region of the Azores, it is based on article 7 of Regional Legislative Decree no. 9/2012 / A, of March 20, which provides the following:

*“Access to natural resources for scientific purposes is done by prior informed consent.”*



In this context, Article 4 of Regional Regulatory Decree No. 20/2012 / A, of November 5, provides that:

*“Prior informed consent constitutes the administrative procedure that ensures that access to or sampling of natural resources for scientific purposes is carried out in accordance with the standards defined by this law.”*

Within the European Union, of which Portugal 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

As explained in item 2.1, Portugal does not have any legislation regulating access.

In relation to the European Union, the legislation 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?**

( ) YES / ( X ) NO

There are no specific provisions related to intellectual property in the country's legislation regarding access to genetic heritage and associated traditional knowledge.

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.

Furthermore, as regards the use of pathogens, reference is made to the penultimate paragraph of Article 4 of Regulation 511/2014 whereby "In the absence of prior informed consent obtained in a timely manner and mutually agreed terms, and until an agreement with the supplier country, no exclusive rights of any kind may be claimed by the user in relation to developments achieved through the use of such pathogens. "

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As explained in item 2.1, Portugal does not have any legislation regulating access.

As for the European Union, through article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as "best practices" a set of procedures, tool or mechanisms developed and supervised by them.

At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

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

YES /  NO

As explained in item 2.1, Portugal does not have any legislation regulating access. Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

In contact with the National Focal Point, it was informed that Chapter III of Regional Legislative Decree no. 9/2012 / A of March 20, of the Autonomous Region of the Azores, under the heading "Fair and equitable sharing of benefits" provides for the terms of the fair and equitable sharing of benefits arising from the use of the natural resources sampled and / or accessed for scientific purposes.

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.

### 2.9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

No procedures for the shipment of samples were identified in the norms covered by this analysis.

## 3. Websites Of Interest

**Instituto da Conservação da Natureza e das Florestas – ICNF**

<http://www.icnf.pt/portal>

**Agência Portuguesa do Ambiente**

<http://www.apambiente.pt/>

**Portal do Ambiente e do Cidadão**

<http://ambiente.maiadigital.pt/>

**Governo Regional dos Açores – Ciência e Tecnologia**

<http://www.azores.gov.pt/Gra/CTacores>

**Comissão Europeia**

[http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation\\_en.htm](http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm)

## 4. Summary – Competent Authorities

Authority	Competence
Institute for Nature Conservation and Forests - ICNF	Responsible for all genetic resources.

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Portugal profile. Disponível em: <https://absch.cbd.int/countries/PT> Access in 10/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Portugal profile. Disponível em: <https://www.cbd.int/countries/?country=pt> Access in 10/11/2016.

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))**. Disponível em: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2013-0007+0+DOC+XML+V0//EN> Access in 04/11/2016.

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))**. Disponível em: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2013-0007+0+DOC+XML+V0//EN> Access in 04/11/2016.

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**. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union**. Disponível em: <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**. Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016

PORTUGAL. **5º Relatório Nacional à Convenção Sobre a Diversidade Biológica**. Instituto da Conservação da Natureza e das Florestas, I. P. 2015 Disponível em: <https://www.cbd.int/countries/?country=pt> Access in 10/11/2016.

PORTUGAL. **Estratégia Nacional de Conservação da Natureza e da Biodiversidade**. Ministério do Ambiente e do Ordenamento do Território. 2001. Disponível em: <https://www.cbd.int/countries/?country=pt> Access in 10/11/2016.

REGIÃO AUTÓNOMA DOS AÇORES. **Decreto Legislativo Regional n.º 9/2012/A**. Disponível em: <https://dre.pt/web/guest/pesquisa/-/search/553632/details/maximized>, Access in 08/06/2017.

REGIÃO AUTÓNOMA DOS AÇORES. **Decreto Regulamentar Regional n.º 20/2012/A**. Disponível em: <https://dre.pt/web/guest/pesquisa/-/search/191518/details/maximized>, Access in 08/06/2017.

# United Kingdom

## 1. General Information

### 1.1 Is the sovereign state a signatory to the Convention on Biological Diversity?

YES /  NO

Yes, the UK has been a Party to the Convention on Biological Diversity, by ratification, since Sep 1st, 1994.

### 1.2 Is the sovereign state a Party to the Nagoya Protocol?

YES /  NO

Yes, the UK has been a party to the Nagoya Protocol, by ratification, since May 22, 2016.

### 1.3 Does the sovereign state have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

The UK has only one checkpoint, which is:

Regulatory Delivery: responsible for requests of due diligence from the users of genetic heritage and for the monitoring of user compliance. This checkpoint also has competence to take the necessary measures to ensure that the users of genetic resources and traditional knowledge in the United Kingdom comply with the applicable legal obligations.

### 1.4 Does the sovereign state have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

In contact with the National Focal Point, it was informed that this situation does not apply to the United Kingdom, since it does not have access legislation, therefore, would not be able to grant an IRCC, which is the function of the provider country.

### 1.5 Does the sovereign state have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in the United Kingdom.

1 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>.

2 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>.

3 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.

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

( X ) YES / ( ) NO

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 measure to ensure that the users of genetic resources and traditional knowledge within the United Kingdom comply to 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.

**1.7 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

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 offences and penalties. Some offences 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 offence.

## 2. Legal information

**2.1. Does the sovereign state already have valid and promulgated legislation on access to genetic heritage and associated traditional knowledge?**

( X ) YES / ( ) NO

The United Kingdom has only one specific legislation, Regulation No. 821 of 2015 (The Nagoya Protocol (Compliance) Regulations 2015 No. 821), which covers regulations for compliance with the Nagoya Protocol and with the following European Union norms:

- 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.

In contact with the National Focal Point, it was informed that regulations implementing user compliance obligations are established at EU level. The EU regime is comprehensive and very specific in many respects, for example the annexes to Implementing Regulation (EU) 2015/1866. EU rules still require national rules to implement them properly (to appoint authorities and implement enforcement measures), but this is not related to their broad and broad nature. EU rules only concern user compliance. Access is decided at national level by the Member States, some of them, such as France and Spain, have decided to put access regimes in place; others, such as the United Kingdom, have not.

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

YES /  NO

Under the Regulatory Delivery, the Department for Business, Energy & Industrial Strategy is responsible for all matters related to genetic resources in the country.

In addition, Regulation No. 821 of 2015 (The Nagoya Protocol (Compliance) Regulations 2015 No. 821) stipulates that the Secretary of State will also have competence to act as the competent authority, and have the responsibility to inspect and enforce that the users of biodiversity and traditional knowledge comply with the applicable legislation.

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

YES /  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. Within the European Union, of which the United Kingdom 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 /  NO

The country's current legislation does not establish any specific procedures for access to Associated Traditional Knowledge.

In relation to the European Union, the 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?**

YES /  NO

There are no specific provisions related to intellectual property in the country's national legislation regarding access to genetic heritage and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As informed, the United Kingdom does not foresee any specific procedures for these purposes.

As for the European Union, Article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as "best practices" a set of procedures, tool or mechanisms developed and supervised by them.

At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.



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

( ) YES / ( X ) NO

The country does not have any specific legislation on the topic. Likewise, the European Union legislation does not provide any specific procedures for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) 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-counties 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.

**2.13. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

No specific procedures for the shipment of samples were identified in the norms covered by this analysis.

**3. Websites Of Interest**

***Department for Environment, Food and Rural Affairs (Defra)***

<https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs>

***National CHM***

<http://uk.chm-cbd.net/>

***Regulatory Delivery***

<https://www.gov.uk/guidance/abs>

**4. Summary – Competent Authorities**

Authority	Competence
The Regulatory Delivery, Department for Business, Energy & Industrial Strategy.	Responsible for all matters related to genetic resources in the country.

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. United Kingdom of Great Britain and Northern Ireland profile. Disponível em: <https://absch.cbd.int/countries/GB> Access in 13/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. United Kingdom of Great Britain and Northern Ireland profile. Disponível em: <https://www.cbd.int/countries/?country=gb> Access in 13/11/2016.

ENGLAND. **Biodiversity 2020: A strategy for England’s wildlife and ecosystem services.** Department for Environment, Food and Rural Affairs. Disponível em: <https://www.cbd.int/countries/?country=gb> Access in 13/11/2016.

NORTHERN IRELAND. **A Biodiversity Strategy for Northern Ireland to 2020.** Department of the Environment, 2015. Disponível em: <https://www.cbd.int/countries/?country=gb> Access in 13/11/2016.

SCOTTISH GOVERNMENT. **2020 Challenge for Scotland’s Biodiversity - A Strategy for the conservation and enhancement of biodiversity in Scotland.** Edinburgh, 2013. Disponível em: <https://www.cbd.int/countries/?country=gb> Access in 13/11/2016.

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. Disponível em: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/415474/nagoya-consult-sum-resp.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/415474/nagoya-consult-sum-resp.pdf) Access in 13/11/2016.

UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND. **Fifth National Report to the United Nations Convention on Biological Diversity: United Kingdom.** Peterborough: JNCC, 2014. Disponível em: <https://www.cbd.int/countries/?country=gb> Access in 13/11/2016.

UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND. **The Nagoya Protocol (Compliance) Regulations 2015 No. 821.** Disponível em: <https://absch.cbd.int/countries/GB> Access in 13/11/2016.

WALES. **The Nature Recovery Plan for Wales Setting the course for 2020 and beyond.** 2015. Disponível em: <https://www.cbd.int/countries/?country=gb> Access in 13/11/2016.

# Czech Republic

## 1. General Information

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

YES /  NO

Yes, Czech Republic has been a Party to the CDB, by approval, since Mar 3rd, 1994.

### 1.2. Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Czech Republic has been a Party to the Nagoya Protocol, by ratification, since Aug 4, 2016.

### 1.3. Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4. Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in Czech Republic.

### 1.5. Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in Czech Republic.

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

YES /  NO

The country does not have an inspection body, just as the country has no specific legislation on access and Benefit-Sharing.

1 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>.

2 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>.

3 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.

### **1.7 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

As explained in item 2.1, the country does not have any legislation on access and benefit sharing. 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 the member-countries should establish the applicable rules and sanctions to anyone breaching the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”, respectively).

## **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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in Czech Republic. In contact with the National Focal Point on matters of the Nagoya Protocol has confirmed the absence of a specific legislation on the subject.

On the other hand, in the quality of regional organization, the European Union - of which Czech Republic 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 dealing with user compliance to the Nagoya Protocol in relation to access to genetic resources and the fair and equitable benefit-sharing deriving from its use within the Union.
- EU Regulation of Execution 2015/1866, of October 13, 2015 - establishes the execution norms of EU Regulation No. 511/2014 of the European Parliament and the Council in relation to the registry of collections, monitoring of compliance by the users and good practices.
- Baseline Document 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 the compliance of users 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 such regulations were drafted with the objective of assisting European Union countries in the creation of their own national norms; 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?**

YES /  NO

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 /  NO

As explained in item 2.1, Czech Republic does not have any legislation regulating access. For that reason, there is no need for prior consent.

Within the European Union, of which Czech Republic is a member, the requirement of prior authorization to access genetic resources and traditional knowledge was not 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. As per 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 regulations on access and benefit-sharing of the supplier country listed as a Party to the Nagoya Protocol and which thus 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 European Union’s legislation.

Through articles 4 and 7 of Regulation 511/2014, the European Union imposes obligations to the users of genetic resources and associated traditional knowledge. As per 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 regulating 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 at least twenty years after the period of utilization. According to article 7, all beneficiaries using genetic resources and associated traditional knowledge are required by the Member-States of the European Union to declare due diligence in the activities performed.

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

YES /  NO

As explained in item 2.1, Czech Republic does not have any legislation regulating access.

In relation to the European Union, the legislation does not foresee any specific procedures for access to associated traditional knowledge; however, all rights of holders of traditional knowledge associated to the 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?**

YES /  NO

There are no specific provisions related to intellectual property in the country's national legislation regarding access to genetic heritage and associated traditional knowledge.

In relation to the European Union, although the theme is not covered by the legislation mentioned under item 2.1., within the intellectual property law, there is the European Parliament Resolution of January 15, 2013 on aspects of the development of intellectual property rights in matters of 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As explained in item 2.1, Czech Republic does not have any legislation regulating access.

As for the European Union, through article 8 of Regulation 511/2014, it authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as "best practices" a set of procedures, tools or mechanisms developed and supervised by them.

At present, sector-specific guidelines are being established, such as for the cosmetic, pharmaceutical, biotechnological sectors, and others.

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

YES /  NO

As explained in item 2.1, Czech Republic does not have any legislation regulating access. Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As explained in item 2.1, Czech Republic does not have any legislation regulating access.

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 mem-

ber-counties have sovereign ownership rights, such as for the sharing of benefits resulting from the use of genetic resources and the traditional knowledge associated to them. 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 on matters of access and benefit-sharing.

## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( ) YES / ( X ) NO

No procedures for the shipment of samples were identified in the norms covered by this analysis.

## 3. Websites Of Interest

### *Clearing-House Mechanism of the Convention on Biological Diversity*

<http://chm.nature.cz/en/>

### *Ministry of Environment of the Czech Republic*

<http://www.mzp.cz/en>

### *Nature Conservation Agency of the Czech Republic*

<http://www.ochranaprirody.cz/en/>

## 4. Summary – Competent Authorities

Authority	Competence
Ministry of the Environment	Federal Institution responsible for all matters related to genetic resources in Czech Republic.

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Czech Republic profile. Disponível em: <https://absch.cbd.int/countries/CZ> Access in 13/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Czech Republic profile. Disponível em: <https://www.cbd.int/countries/?country=cz> Access in 13/11/2016.

CZECH REPUBLIC. **National Biodiversity Strategy of the Czech Republic 2016–2025**. Ministry of the Environment. Prague, 2016. Disponível em: <https://www.cbd.int/countries/?country=cz> Access in 13/11/2016.

CZECH REPUBLIC. **The Fifth National Report of the Czech Republic to the Convention on Biological Diversity**. Ministry of the Environment. 2014. Disponível em: <https://www.cbd.int/countries/?country=cz> Access in 13/11/2016.

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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016.



## 1. General Information

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

YES /  NO

Yes, Russia has been a Party to the Convention, by ratification, since Jul 4, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

The country is neither a Party nor a signatory to the Nagoya Protocol.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

It was not possible to identify an official institution responsible for inspecting access and benefit-sharing and neither there is evidence of application of fines or of any legislation specifying cases of misconduct.

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, there is no legislation regulating the subject.

## 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

Russia does not have any valid and promulgated national legislation regarding access to genetic heritage and associated traditional knowledge, and neither does it have any bills dealing with these subjects at present. However, according to the 5th National Report, the country is in the process of adopting a legal system to regulate access and benefit sharing within its territory.

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

YES /  NO

The competent institution responsible for issues related to the Nagoya Protocol and the Convention on Biological Diversity could not be identified through the official sources and official documents.

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

YES /  NO

As mentioned in item 2.1, no current administrative guidelines or national legislation regulating the subject could be identified.

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

YES /  NO

As mentioned in item 2.1, there is no legislation or administrative guidelines regulating the 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

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, there is no legislation or administrative guidelines regulating the subject.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, there is no legislation or administrative guidelines regulating the subject.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, there is no legislation or administrative guidelines regulating the subject.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, there is no legislation or administrative guidelines regulating the subject.

### 3. Websites Of Interest

***The Convention on Biological Diversity. Clearing [Clearing House Mechanism]:***

*<http://biodat.ru/>*

***BioDat:***

*<http://biodat.ru/>*

***REC\_Biodiversity:***

*[http://education.rec.org/ru/en/biodiversity/in\\_russia/index.shtml](http://education.rec.org/ru/en/biodiversity/in_russia/index.shtml)*

### 4. Summary – Competent Authorities

There are no official competent authorities specific to this subject. However, the country has instituted a National Focal Point (Article 13.1 of the Nagoya Protocol), which is the recognized responsible authority according to the website of the Convention on Biological Diversity and the website of The Access and Benefit-Sharing Clearing-House Mechanism:

#### Convention on Biological Diversity

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## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Russian Federation profile. Disponível em: <https://absch.cbd.int/countries/RU> Access in 15/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Russian Federation profile. Disponível em: <https://www.cbd.int/countries/?country=ru> Access in 15/10/2016.

RUSSIAN FEDERATION. **Fifth National Report “Biodiversity Conservation In Russian Federation”**. Ministry of Natural Resources and Ecology Russian Federation. Moscow, 2014. Disponível em: <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. Disponível em: <https://www.cbd.int/countries/?country=ru> Access in 15/10/2016.

## 1. General Information

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

YES /  NO

Yes, Sweden has been a Party to the CDB, by ratification, since Mar 16, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, Sweden has been a Party to the Nagoya Protocol, by ratification, since Dec 7, 2016.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

The checkpoint identified is the Swedish Environmental Protection Agency. Its responsibilities are the following:

- To receive declarations of due diligence from users undertaking research and development activities in Sweden with focus on two specific aspects: research financing and product commercialization.
- To submit the declarations of due diligence as checkpoint communiqués to the ABS Clearing House
- If necessary, to apply 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<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in Sweden.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

1 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>.

2 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>.

3 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 checkpoint communiqués were found in Sweden.

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

YES /  NO

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.

**1.7 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

As explained in item 2.1, Sweden does not have any legislation on access and benefit sharing.

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 the regulations on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and which requires prior informed consent.

In these terms, article 11 of the same regulation establishes that the member-countries should establish the applicable rules and sanctions to anyone breaching the obligations contained in articles 4 and 7 of the regulations (“user conformity” and “monitoring of user conformity”, respectively).

## 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

No specific legislation was found regarding access to genetic heritage and associated traditional knowledge in Sweden. Without prejudice to the above, although norm Förordning (2016:858) om användning av genetiska resurser och traditionell kunskap om sådana resurser does not establish any specific procedures or obligations on access and benefit sharing to the users of biodiversity, it formalizes the implementation of the European Union legislation described below, while also establishing some responsibilities to be undertaken by the National Competent Authority.

In an email exchange, the country’s focal point on issues related to the Nagoya Protocol has confirmed the absence of a specific legislation on the subject.

On the other hand, in the quality of regional organization, the European Union - of which Sweden 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 users' compliance with the Nagoya Protocol in relation to access to genetic resources and the fair and equitable sharing of the benefits deriving from their use within the Union.
- EU Regulation of Execution 2015/1866, of October 13, 2015 - establishes the execution norms 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.
- Baseline Document 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 concerning user compliance within the Nagoya Protocol on 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 drafted with the objective of assisting European Union countries in the creation of their own national norms; therefore, these dispositions 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?**

YES /  NO

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 /  NO

As explained in item 2.1, Sweden does not have any legislation regulating access. For that reason, there is no need for prior consent.

Within the European Union, of which Sweden is a member, the requirement of prior authorization to access genetic resources and traditional knowledge was not 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. As per 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 regulation on access and benefit-sharing of the supplier country that is a Party to the Nagoya Protocol and that 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 European Union's legislation.

Through articles 4 and 7 of Regulation 511/2014, the European Union imposes obligations to the users of genetic resources and associated traditional knowledge. As per article 4 of this documents, users are obliged to carry out due diligence in order to ensure that genetic resources and associated traditional knowledge have been accessed in compliance with the national legislation and, in

this case, also the legislation of the organization pursuant to 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 due diligences have been carried out.

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

YES /  NO

As explained in item 2.1, Sweden does not have any legislation regulating access.

In relation to the European Union, the legislation does not foresee any specific procedures for access to associated traditional knowledge; however, all rights of holders of traditional knowledge associated to the 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?**

YES /  NO

There are no specific provisions related to intellectual property in the country's national legislation regarding access to genetic heritage and associated traditional knowledge.

In relation to the European Union, although the theme is not covered by the legislation mentioned under item 2.1., within the intellectual property law, there is the European Parliament Resolution of January 15, 2013 on aspects of the development of intellectual property rights in matters of 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As explained in item 2.1, Sweden does not have any legislation regulating access.

As for the European Union, through article 8 of Regulation 511/2014, it authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as "best practices" a set of procedures, tools or mechanisms developed and supervised by them.



At present, sector-specific guidelines are being established, such as for the cosmetic, pharmaceutical, biotechnological sectors, and others.

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

YES /  NO

As explained in item 2.1, Sweden does not have any legislation regulating access. Likewise, the European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

### 2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?

YES /  NO

As explained in item 2.1, Sweden does not have any legislation regulating access.

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-counties have sovereign ownership rights, such as for the sharing of benefits resulting from the use of genetic resources and the traditional knowledge associated to them. 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 on matters of access and benefit-sharing.

### 2.9. Does the current legislation establish procedures for the shipment of samples?

YES /  NO

No procedures for the shipment of samples were identified in the norms covered by this analysis.

## 3. Websites Of Interest

*Swedish Environmental Protection Agency (Agência Sueca de Proteção Ambiental)*

<http://www.swedishepa.se>

## 4. Summary – Competent Authorities

Authority	Competence
Swedish Environmental Protection Agency	Institution responsible for all matters related to genetic resources in Sweden.

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Sweden profile. Disponível em: <https://absch.cbd.int/countries/SE> Access in 17/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Sweden profile. Disponível em: <https://www.cbd.int/countries/?country=se> Access in 17/10/2016.

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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union.** Disponível em: <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.** Disponível em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016.

SWEDEN. **A Swedish strategy for biodiversity and ecosystem services.** Swedish Environmental Protection Agency 2013. Disponível em: <https://www.cbd.int/countries/?country=se> Access in 17/10/2016.

SWEDEN. **Fifth National Report to the Convention on Biological Diversity.** Swedish Environmental Protection Agency. Disponível em: <https://www.cbd.int/countries/?country=se> Access in 17/10/2016.

SWEDEN. **Ordinance on Environmental Sanction Charges (2012:259).** Disponível em: <https://absch.cbd.int/countries/SE> Access in 17/10/2016.

SWEDEN. **Ordinance on Use of Genetic Resources and Traditional Knowledge (2016:858).** Disponível em: <https://absch.cbd.int/countries/SE> Access in 17/10/2016.

SWEDEN. **The Swedish Environmental Code.** Disponível em: <https://absch.cbd.int/countries/SE> Access in 17/10/2016.

# Switzerland

## 1. General Information

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

YES / (  ) NO

Yes, Switzerland has been a Party to the CBD, by ratification, since Feb 19, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES / (  ) NO

Yes, Switzerland has been a Party to the Nagoya Protocol, by ratification, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES / (  ) NO

Switzerland has two checkpoints, as follows:

- Federal Office for the Environment – functions as a centralized checkpoint according to Article 17 of the Nagoya Protocol. Any person utilizing genetic resources, or benefiting directly from their utilization, must notify the FOEN on their compliance with the due diligence requirement before obtaining any commercialization permits or, if such a permit is not required, prior to the commercialization of the products developed from the utilization of the genetic resources. In addition to that, this checkpoint is responsible for publishing certain information on the notification and forwarding information to the supplier country or to the ABS-CH, as appropriate.
- Swiss Federal Institute of Intellectual Property - federal agency responsible for matters related to intellectual property in Switzerland. Within the scope of genetic resources and associated traditional knowledge, it is responsible for implementing the dissemination of information required by the source of the genetic resources and associated traditional knowledge in any patents applications.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance- IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

(  ) YES / (  ) NO

No IRCCs were found in Switzerland.

1 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>.

2 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”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?**

YES /  NO

No checkpoint communiqués were found in Switzerland.

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

YES /  NO

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)
2. Immunologic therapeutic products for veterinary use and (2) Food products, additives, processing agents - Federal Food Safety and Veterinary Office (FSVO)
3. Plant production, (2) plant propagating material for all other uses, (3) fertilizers, (4) food products - Federal Office for Agriculture (FOAG)
4. Biocides and Chemical Products - Federal Office of Public Health (FOPH)
5. Plant propagation material exclusive for forestry use and (2) other products - FOEN

There is no evidence of imposition of fines apart from the legal provisions establishing that they may be applied.

**1.7 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

According to the Federal Act on the Protection of Nature and Cultural Heritage, within the scope of access and benefit sharing:

*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.*

## 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

<sup>3</sup> 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.

- 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

According to the Decree on the Nagoya Protocol, article 10, and the official website of the CBD, the National Competent Authority is the Federal Office for the Environment, which is the competent authority and the focal point 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?**

( X ) YES / ( ) NO

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.

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

( X ) YES / ( ) NO

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?**

YES /  NO

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

None of the laws presented under item 2.1 mention any specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries.

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

YES /  NO

According to the Federal Act on the Protection of Nature and Cultural Heritage, Art. 23<sup>1</sup>: 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.

### 2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?

YES /  NO

According to the Federal Act on the Protection of Nature and Cultural Heritage, Art. 23<sup>n1</sup>: 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.

### 2.9. Does the current legislation establish procedures for the shipment of samples?

YES /  NO

No procedures for the 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.

## 3. Websites Of Interest

**SIB - Swiss Information System Biodiversity:**

<http://www.sib.admin.ch/en/index.html>

**FOEN - Federal Office for the Environment**

<http://www.bafu.admin.ch/index.html?lang=en>

**DETEC - Federal Department of the Environment, Transport, Energy and Communications:**

<https://www.uvek.admin.ch/uvek/en/home.html>

## 4. Summary – Competent Authorities

Authority	Competence
FOEN - Federal Office for the Environment	Responsible for all genetic resources.

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Switzerland profile. Disponível em: <https://absch.cbd.int/countries/CH> Access in 17/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Switzerland profile. Disponível em: <https://www.cbd.int/countries/?country=ch> Access in 17/10/2016.

KRAUS, Daniel; RÜSSLI, Markus. **Study on Access and Benefit Sharing User Measures in the Swiss Legal Order**. Federal Office for the Environment (FOEN). 48 p. Berne: Swiss InformationSystem Biodiversity (SIB), 2009. Disponível em: <http://www.sib.admin.ch/en/documentation/publications-addressing-biodiversity/2009/abs-user-measures-in-the-swiss-legal-order/> Access in 17/10/2016.

SWITZERLAND. **Federal Act on Patents for Inventions (Patents Act, PatA) of 25 June 1954**. Disponível em: <https://absch.cbd.int/countries/CH> Access in 17/10/2016.

SWITZERLAND. **Federal Act on the Protection of Nature and Cultural Heritage (NCHA)**. Disponível em: <https://absch.cbd.int/countries/CH> Access in 17/10/2016.

SWITZERLAND. **Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Ordinance, NagO)**. Disponível em: <https://absch.cbd.int/countries/CH> Access in 17/10/2016.

SWITZERLAND. **Swiss Biodiversity Strategy**. Federal Office for the Environment (FOEN). 2012. Disponível em: <https://www.cbd.int/countries/?country=ch> Access in 17/10/2016.

SWITZERLAND. **Switzerland's Fifth National Report under the Convention on Biological Diversity**. Federal Office for the Environment (FOEN). Bern, 2014. Disponível em: <https://www.cbd.int/countries/?country=ch> Access in 17/10/2016.



# Ukraine

## 1. General Information

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

YES /  NO

Yes, Ukraine has been a Party to the CBD, by ratification, since May 8, 1995.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

The country is not a signatory to the Nagoya Protocol.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in Ukraine.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in Ukraine.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

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

YES /  NO

No official competent institutions were found concerning access and benefit-sharing under the terms 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 /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned under item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Websites Of Interest

***Ministry of Ecology and Natural Resources:***

*<http://eng.menr.gov.ua/>*

### 4. Summary – Competent Authorities

As mentioned under item 2.3., Ukraine does not have any official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

**Nagoya Protocol on Access and Benefit-sharing**

**Mr. Sergiy Gubar**

ABS National Focal Point

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Kyiv

Ukraine

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Ukraine profile. Disponível em: <https://absch.cbd.int/countries/UA> Access in 19/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Ukraine profile. Disponível em: <https://www.cbd.int/countries/?country=ua> Access in 19/10/2016.

UKRAINE. **Fifth National Report Of Ukraine To The Convention On Biological Diversity**. Disponível em: <https://www.cbd.int/countries/?country=ua> Access in 19/10/2016.

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))**. Disponível em: <https://www.cbd.int/countries/?country=ua> Access in 19/10/2016.

# European Union

## 1. General Information

### 1.1 Is the organization a signatory to the Convention on Biological Diversity?

( X ) YES / ( ) NO

Yes, it has been a Party to the Convention on Biological Diversity, by approval, since Mar 21, 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 will be a responsibility of the Organization and its Member-States to decide on their respective responsibilities for meeting the obligations established in these instruments, being prohibited that both (the Organization and its State-Members) make simultaneous use of the rights established by the Convention or the pertaining protocol.

### 1.2 Is the organization a Party to the Nagoya Protocol?

( X ) YES / ( ) NO

The European Union approved the Nagoya Protocol in May 16, 2014 and became a Party in Oct 12, 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.

**1.3 Does the organization have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?**

YES /  NO

No checkpoints were found for the European Union.

**1.4 Does the organization have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?**

YES /  NO

No IRCCs were found for the European Union.

**1.5 Does the organization have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?**

YES /  NO

No checkpoint communiqués were found for the European Union.

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

YES /  NO

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 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.

**1.7 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

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

1 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>.

2 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>.

3 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.

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).

## 2. Legal Information

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

YES /  NO

In the quality of regional organization, the European Union has established 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 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?

YES /  NO

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 /  NO

From this inquiry, 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 /  NO

The European legislation 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?**

YES /  NO

Although the topic 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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO



Article 8 of Regulation 511/2014 authorizes associations of users or other stakeholders to submit a request to the European Union Commission in order to acknowledge as “best practices” a set of procedures, tool or mechanisms developed and supervised by them.

At present, sector-specific guidelines are being outlined, such as for the cosmetic, pharmaceutical and biotechnological industries, among others.

### **2.7. Does the current legislation or any ongoing bills also provide procedures for collection and access of exotic species?**

YES /  NO

The European Union legislation on access and benefit-sharing does not provide any specific procedures for collection and access of exotic species.

### **2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

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-counties 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.

### **2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

No specific procedures for the shipment of samples were identified in the norms covered by this analysis.

## **3. Websites of interest**

### ***National CHM***

*<http://biodiversity.europa.eu/>*

### ***Coastal Wiki***

*<http://www.coastalwiki.org/>*

## **4. Summary – Competent Authorities**

According to item 2.3., the European Union does not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

## Nagoya Protocol on Access and Benefit-sharing

**Ms. Alicja Kozłowska**

ABS National Focal Point

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Desk Officer for ABS, Unit E2

Global Sustainability, Trade & Multilateral Agreements,

DG Environment

European Commission

Office BU9 3/124

1049

Brussels

Belgium

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. European Union profile. Disponible em: <https://absch.cbd.int/countries/EU> Access in 03/11/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. European Union profile. Disponible em: <https://www.cbd.int/countries/?country=eur> Access in 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. Disponible em: <https://www.cbd.int/countries/?country=eu> Access in 03/11/2016.

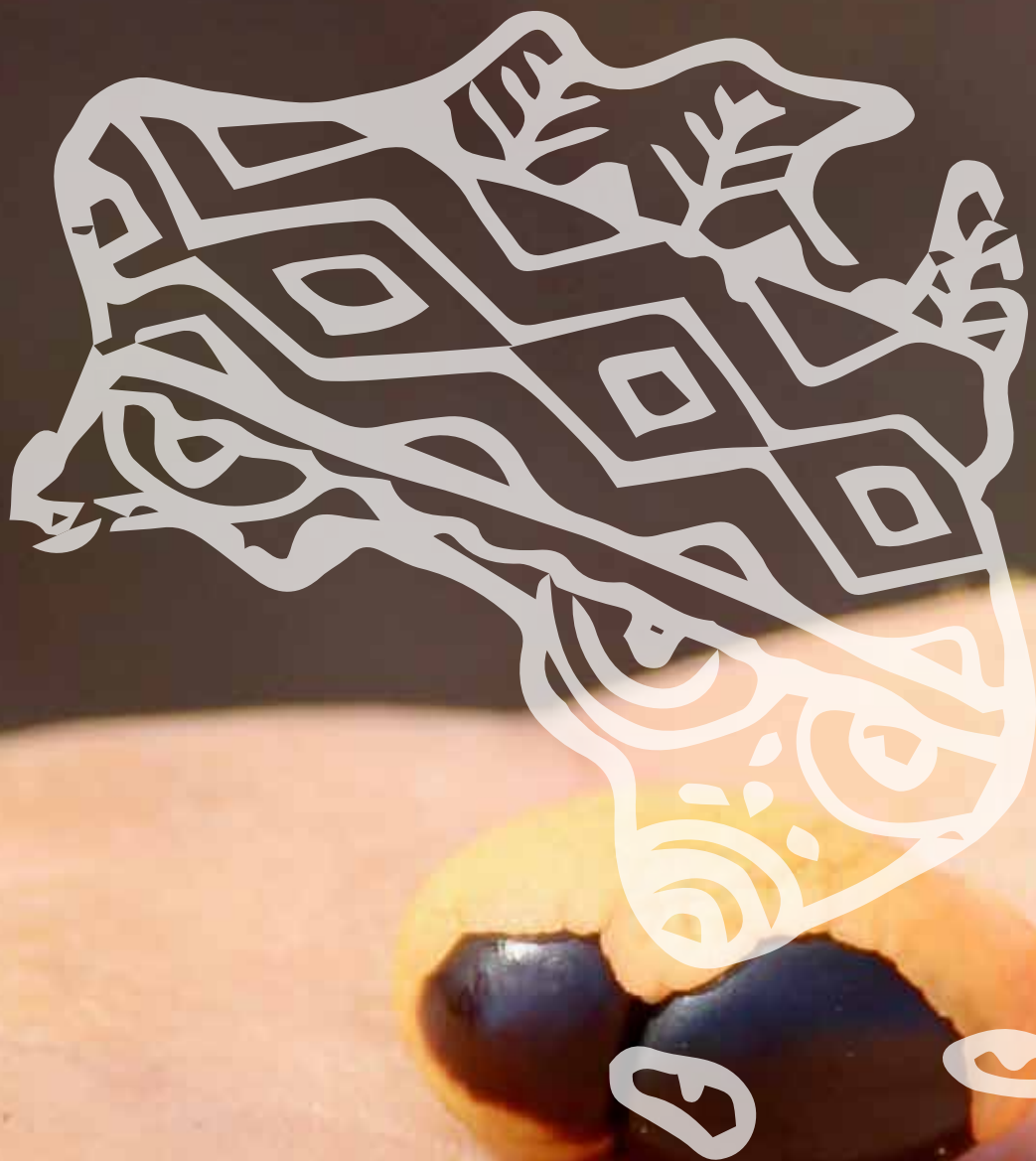
EUROPEAN COMMISSION. **Fifth Report Of The European Union To The Convention On Biological Diversity**. 2014. Disponible em: <https://www.cbd.int/countries/?country=eu> Access in 03/11/2016.

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**. Disponible em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-204508> Access in 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 Utilisation in the Union**. Disponible em: <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**. Disponible em: <https://absch.cbd.int/database/record/ABSCH-MSR-DE-201808> Access in 04/11/2016

# Oceania



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

YES /  NO

Yes, Australia has been a Party to the Convention, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

No, Australia is not a Party to the Protocol, but it has been a signatory country since Jan 20, 2012.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

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.

### **1.7 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

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<sup>4</sup>. 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.

## **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

At federal level (Commonwealth areas), the country has two major laws regarding access and benefit sharing:

- Environment Protection and Biodiversity Conservation Act (1999).
- Environmental Protection and Biodiversity Conservation Regulations 2000.

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<sup>5</sup>; 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/state level, two following norms are the most relevant ones:

4 "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>

5 Source: <http://www.environment.gov.au/topics/science-and-research/australias-biological-resources/access-biological-resources-states-and>

**Queensland:**

- Biodiscovery Act 2004

**Northern Territory:**

- Biological Resources Act 2014

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

( X ) YES / ( ) NO

Australia has its own specific institutions for each given region. In order to gain authorized access to 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.

To any other areas, at federal level and for other territories, the official website of the Department lists the following national competent authorities<sup>6</sup> (for more information, see table under item 4):

**Federal Level (Australian Government):**

Protected Area Policy and Biodiscovery Section  
- Department of Sustainability, Environment,  
Water, Population and Communities

**Australian Capital Territory:**

Natural Environment and Resource  
Management - Environment and Sustainable  
Development Directorate

**New South Wales:**

Principal Policy Officer, Natural Environment  
and Resource Management - NSW Department  
of Premier and Cabinet

**Queensland:**

Office of Biotechnology and Therapeutic  
Medicines and Devices - Department of  
Employment, Economic Development and  
Innovation

**South Australia:**

Science Resource Centre, Client Services - De-  
partment of Environment and Natural Resources

**Tasmania:**

Department of Primary Industries, Parks, Water  
and Environment

**Victoria:**

Biodiversity Policy and Programs - Department  
of Sustainability and Environment

**Western Australia:**

Science, Innovation and Business Division, De-  
partment of Commerce - Government of Wes-  
tern Australia

6 <http://www.environment.gov.au/topics/science-and-research/australias-biological-resources/nagoya-protocol-convention-biological-0>

### **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

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 1.7 of this document.

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 worth noting 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 deal specifically with permits for access to biological resources. On its turn, Part 18 addresses authorization fees.

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.

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

( X ) YES / ( ) NO

The issue of indigenous peoples is addressed differently, since there are special procedures in place with regard to 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 devel-**



**opments involving the access?**

YES /  NO

In the legislation and the other documents analyzed it was not possible to identify any specific procedures for requesting patents from research and technological developments arising from the access.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

It was not possible to identify in the legislation and the other documents analyzed any specific norms for that purpose.

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

YES /  NO

It was not possible to identify in the legislation and the other documents analyzed any specific norms for that purpose, although the Environment Protection And Biodiversity Conservation Act 1999, Part 13, Division 2, Subdivision B, deals with permits for activities with migratory species.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

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 Resources Act 2014.

**2. 9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

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).



### 3. Websites of Interest

***National Clearing-house Mechanism***

<http://www.environment.gov.au/biodiversity>

***World Agroforestry Centre***

<http://www.worldagroforestrycentre.org/>

***The Australian Development Gateway - Water and Sanitation***

<http://www.developmentgateway.com.au/jahia/Jahia/lang/en/pid/9>

***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/>

### 4. Summary – Competent Authorities

Authority	Competence/Information
Great Barrier Reef Marine Park Authority	According to the Environment Protection and Biodiversity Conservation Act (1999) and the Environmental Protection and Biodiversity Conservation Regulations 2000, it is the institution responsible for the access to genetic heritage in Australia and the Great Barrier Reef.
Australian Government Antarctic Division	According to the Environment Protection and Biodiversity Conservation Act (1999) and the Environmental Protection and Biodiversity Conservation Regulations 2000, it is the institution responsible for the access to Australia's genetic heritage in the area claimed by Australia in Antarctica.
Department of Sustainability, Environment, Water, Population and Communities	Competence within "Commonwealth areas". Key contact: Ben Phillips Director Protected Area Policy and Biodiscovery Section Department of Sustainability, Environment, Water, Population and Communities GPO Box 787 Canberra ACT 2601 Australia Tel: +61 2 6274 2528 Fax: +61 2 6274 2309 Email: <a href="mailto:grm@environment.gov.au">grm@environment.gov.au</a>

<p>Natural Environment and Resource Management Environment and Sustainable Development Directorate</p>	<p>Competence over Australian Capital Territory Key contact Ian Baird Principal Policy Officer, Natural Environment and Resource Management Environment and Sustainable Development Directorate GPO Box 158 Canberra ACT 2601 Australia Tel: +61 2 6207 2336 Fax: +61 2 6207 6084 Email: Ian.Baird@act.gov.au</p>
<p>NSW Department of Premier and Cabinet</p>	<p>Competence over New South Wales Key contact Ian Hunter Executive Director Strategic Policy and Communications Group NSW Department of Premier and Cabinet GPO Box 5341 Sydney NSW 2001 Australia Tel: +61 2 9228 3498 Email: Ian.Hunter@dpc.nsw.gov.au</p>
<p>Department of Employment, Economic Development and Innovation</p>	<p>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 Level 10, 111 George Street, Brisbane QLD 4000 Australia  Tel: +61 7 3227 8617 Fax: +61 7 3225 8754 Email: sue.coke@deedi.qld.gov.au</p>
<p>Department of Environment and Natural Resources</p>	<p>Competence over South Australia Key contact Research Permits Officer Science Resource Centre Client Services Department of Environment and Natural Resources GPO Box 1047 Adelaide SA 5001 Australia Tel: +61 8 8222 9435 Fax: +61 8 8124 4661 Email: DENRresearchpermits@sa.gov.au</p>
<p>Department of Primary Industries, Parks, Water and Environment</p>	<p>Competence over Tasmania Key contact Brooke Craven Manager, Policy Branch, Policy and Projects Group Department of Primary Industries, Parks, Water and Environment GPO BOX 44 Hobart Tasmania 7001 Australia Tel: +61 3 6233 6218 Fax: +61 3 6233 0865 Email: brooke.craven@dpipwe.tas.gov.au</p>

Department of Sustainability and Environment	Competence over Victoria Key contact Director Biodiversity Policy and Programs Department of Sustainability and Environment PO Box 500 East Melbourne VIC 3002 Australia Phone: 136 186; +61 3 5332 5000 Fax: 03 5332 5050 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 1 Adelaide Terrace East Perth WA 6004 Australia Tel: +61 8 9263 8022 Fax: +61 8 9263 8100 Email: howard.shawcross@commerce.wa.gov.au

## 5. Bibliographical References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Australia profile. Disponível em: <https://absch.cbd.int/countries/AU> Acesso em 18/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Australia profile. Disponível em: <https://www.cbd.int/countries/?country=au> Acesso em 18/10/2016.

GOVERNMENT OF AUSTRALIA. **Australia's fifth National Report to the Convention on Biological Diversity**. Department of Environment. Australian Government. Canberra. 2014. Disponível em: <https://www.cbd.int/countries/?country=au> Acesso em 18/10/2016.

GOVERNMENT OF AUSTRALIA. **Biodiscovery Act 2004**. State of Queensland. Disponível em: < <https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/B/BiodiscovA04.pdf> > Acesso em 18/10/2016.

GOVERNMENT OF AUSTRALIA. **Biological Resources Act 2014**. Northern Territory. Disponível em: < [https://legislation.nt.gov.au/Pages/~//link.aspx?\\_id=7C3FA89ED742451592672A1DDB-C5A87F&\\_z=z](https://legislation.nt.gov.au/Pages/~//link.aspx?_id=7C3FA89ED742451592672A1DDB-C5A87F&_z=z) > Acesso em 18/10/2016.

GOVERNMENT OF AUSTRALIA. **Department of the Environment**. Disponível em: <http://www.environment.gov.au/> Acesso em 18/10/2016.

GOVERNMENT OF AUSTRALIA. **Environment Protection and Biodiversity Conservation Act (1999)**. Disponível em: <http://www.environment.gov.au/epbc> Acesso em 18/10/2016 Acesso em 18/10/2016.

GOVERNMENT OF AUSTRALIA. **Environmental Protection and Biodiversity Conservation Regulations (2000)**. Disponível em: <https://www.legislation.gov.au/Series/F2000B00190> Acesso em 18/10/2016.

GOVERNMENT OF AUSTRALIA. **Native Title Act 1993**. Disponível em: < <https://www.legislation.gov.au/Details/C2016C00748> > Acesso em 18/10/2016.

GOVERNMENT OF AUSTRALIA. **National Objectives and Targets for Biodiversity Conservation 2001–2005**. Department of the Environment and Heritage, Australian Government. Canberra, 2001. Disponível em: <https://www.cbd.int/countries/?country=au> Acesso em 18/10/2016.

## 1. General Information

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

YES / (  ) NO

Yes, the country has been a Party to the Protocol, by ratification, since Dez 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES / (  ) NO

Yes, the country has been a party to the Protocol, by accession, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

(  ) YES / (  ) NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoint communiqués were found in this country.

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

(  ) YES / (  ) NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

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

YES /  NO

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 obtain genetic resources?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

#### Nagoya Protocol on Access and Benefit-sharing

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Fiji

### 4. Websites

***Biodiversity Clearing House Mechanism Fiji***

<https://chmfiji.wordpress.com/>

***Ministry of Local Government, Housing and Environment***

<http://www.fiji.gov.fj/Government-Directory/Ministries-and-Department/Ministry-of-Local-Government,-Urban-Dev,-Housing-.aspx>

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Fiji profile. Available in: <https://absch.cbd.int/countries/FJ> Access in 05/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Fiji profile. Available in: <https://www.cbd.int/countries/?country=fj> Access in 05/10/2016.

**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 05/10/2016.

**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 05/10/2016.

**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 05/10/2016.



# Marshall Islands

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Dec 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by accession, since Jan 8, 2015.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

( ) YES / ( X ) NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the Marshall Islands do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

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Marshall Islands

## 4. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Fiji profile. Available in: <https://absch.cbd.int/countries/FJ> Access in 05/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Fiji profile. Available in: <https://www.cbd.int/countries/?country=fj> Access in 05/10/2016.

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 05/10/2016.  
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 05/10/2016.

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 05/10/2016

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Protocol, by ratification, since Set 18, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

Yes, the country has been a party to the Protocol, by ratification, since Out 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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

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

YES /  NO

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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

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ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Micronesia (Federated States of) profile. Available in: <https://absch.cbd.int/countries/MF> Access in 06/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Micronesia (Federated States of) profile. Available in: <https://www.cbd.int/countries/?country=mf> Access in 06/10/2016.

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 06/10/2016.

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 06/10/2016.



## 1. General Information

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

YES / (  ) NO

Yes, the country has been a Party to the Protocol, by ratification, since May 10, 1994.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES / (  ) NO

Yes, the country has been a party to the Protocol, by accession, since Oct 12, 2014.

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

(  ) YES / (  ) NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

(  ) YES / (  ) NO

No checkpoint communiqués were found in this country.

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

(  ) YES / (  ) NO

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

1 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>.

2 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>.

3 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.

**1.7 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

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

## 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

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 /  NO

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 obtain genetic resources?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated 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 /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.6. Does the current legislation or any ongoing bills provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

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

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

**2.9. Does the current legislation establish procedures for the shipment of samples?**

YES /  NO

As mentioned in item 2.1, the country does not have any legislation on access to genetic resources and associated traditional knowledge.

### 3. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

#### **Nagoya Protocol on Access and Benefit-sharing**

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Chief Executive Officer

Ministry of Natural Resources and Environment

Private Bag, MNRE

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### 4. Websites

*Ministry of Natural Resource and Environment*

*<http://www.mnre.gov.ws/>*

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Samoa profile. Available in: <https://absch.cbd.int/countries/WS> Access in 06/10/2016.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Samoa profile. Available in: <https://www.cbd.int/countries/?country=ws> Access in 06/10/2016.

SAMOA. **Samoa's 5th National Report 2014 to the Convention on Biological Diversity**. Pacific Social and Environment Safeguards Consult (PSES), Division of Environment & Conservation (DEC), Ministry of Natural Resources and Environment (MNRE). Available in: <https://www.cbd.int/countries/?country=ws> Access in 06/10/2016.

SAMOA. **Samoa's National Biodiversity Strategy and Action Plan (NBSAP) 2015 – 2020**. Ministry of Natural Resources and Environment. Available in: <https://www.cbd.int/countries/?country=ws> Access in 06/10/2016.

## 1. General Information

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

YES /  NO

Yes, the country has been a Party to the Convention on Biological Diversity, by ratification, since Dez 29, 1993.

### 1.2 Is the country a Party to the Nagoya Protocol?

YES /  NO

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

### 1.3 Does the country have any officially recognized “checkpoints”<sup>1</sup> under the terms of Article 17, 1(a), (i) of the Nagoya Protocol?

YES /  NO

No checkpoints were found in this country.

### 1.4 Does the country have an Internationally Recognized Certificate of Compliance - IRCC<sup>2</sup> under the terms of Article 17 of the Nagoya Protocol?

YES /  NO

No IRCCs were found in this country.

### 1.5 Does the country have any officially recognized “checkpoint communiqués”<sup>3</sup> under the terms of Article 17, 1(a) of the Nagoya Protocol?

YES /  NO

No checkpoint communiqués were found in this country.

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

YES /  NO

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

1 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>.

2 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>.

3 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.

### 1.7 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

Article 32 of the Environmental Management and Conservation Act, No. 12 of 2002 provides that the following actions shall be punished with a fine not exceeding 1,000,000 VT or imprisonment for a period not exceeding 2 years, or both:

- 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;
- Violate any law related to the protection of native flora and fauna of Vanuatu.

## 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

The Environmental Management and Conservation Act, No. 12 of 2002 devotes legislation on conservation, sustainable development and environmental management in Vanuatu. Part 4 “Biodiversity and Protected Areas” of this standard regulates activities understood as “bioprospecting”. The country also has the Patents Act n. 2 of 2003, which in its part number 12 (Article 47) provides for the registration of a patent involving indigenous knowledge. Already the question about traditional knowledge registration is covered by the Design Act no. 3 of 2003.

Finally, it is known that there are bills to regulate some subjects related to ABS, namely<sup>4</sup>:

- 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?

YES / (  ) NO

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

4 .....  
SUMMARY Report of Nagoya Protocol Workshop. Port Vila, Vanuatu Cultural Centre: [s.n.], 2015. Disponível em: <[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](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)>. Acesso em: 18 out. 2016.

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

As already explained in item 1.7., 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

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?**

YES /  NO

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 provide specific procedures for collection and/or access in research and technological development activities performed on behalf of the perfume, personal hygiene and cosmetic industries?**

YES /  NO

No legal provision was found for this purpose.

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

YES /  NO

No legal provision was found for this purpose.

**2.8. Is Benefit-Sharing mandatory? What are the applicable procedures, rules and values?**

YES /  NO

The main rule regulating access to genetic resources in the country, which Environmental Management and Conservation Act, No. 12 of 2002, is unclear about the need to share the benefits of exploiting the genetic resource 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.

Por outro lado, segundo o *Patents Act n° 2 of 2003*, artigo 47, item 3, b, e 4 “c”, fazem menção à repartição de benefícios, sem, no entanto, especificar procedimentos, regras ou valores. Dessa forma, uma patente de invenção oriunda ou que incorpore elementos de conhecimento indígena não poderá ser registrada se o solicitante não tenha celebrado um acordo com os detentores destes conhecimentos, que preveja o pagamento pelo solicitante ao detentor de parcela equitativa dos benefícios percebidos com a exploração da patente.



## 2. 9. Does the current legislation establish procedures for the shipment of samples?

( X ) YES / ( ) NO

As already explained in item 1.7., The authorization for bioprospecting is necessary, being punishable in case of export or attempt to export any specimen obtained in the exploration of biodiversity without the proper authorization of bioprospecting. Therefore, it is understood that the consignment originates or for access purposes requires authorization.

## 3. Websites

No relevant websites were found.

## 4. Summary – Competent Authorities

As mentioned in item 2.3., the country do not have an official competent authority. However, it has a National Focal Point recognized by the Convention on Biological Diversity in relation to the Nagoya Protocol:

### Nagoya Protocol on Access and Benefit-sharing

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Department of Environmental Protection and Conservation

Ministry of Climate Change Adaptation, Meteorology and Geo-Hazards, Environment, Energy and Disaster Management

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Port Vila

Vanuatu

## 5. References

ACCESS AND BENEFIT-SHARING CLEARING-HOUSE – ABSCH. Country Profiles. Vanuatu profile. Disponível em: <https://absch.cbd.int/countries/VU> Acesso em 07/04/2017.

CONVENTION OF BIOLOGICAL DIVERSITY - CBD. Country Profiles. Vanuatu profile. Disponível em: <https://www.cbd.int/countries/?country=vu> Acesso em 07/04/2017.

**SUMMARY Report of Nagoya Protocol Workshop. Port Vila, Vanuatu Cultural Centre:** [s.n.], 2015. Report compiled by the organizing committee. Vanuatu, 2015. Disponível em: [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](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) Acesso em 18/10/2016.

VANUATU. **Environmental Management and Conservation Act 2002 (Cap. 283).** Disponível em: [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=](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=) Acesso em 07/04/2017.

VANUATU. **Fifth National Report – Country Report to the Conference of the Parties on the Convention on Biological Diversity.** Department of Environmental Protection and Conservation. Disponível em: <https://www.cbd.int/countries/?country=vu> Acesso em 07/04/2017.

VANUATU. **Patents Act No. 2 of 2003.** Disponível em: <http://www.wipo.int/wipolex/en/details.jsp?id=10727> Acesso em 07/04/2017.

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. Disponível em: <https://www.cbd.int/countries/?country=vu> Acesso em 07/04/2017.

## *About Natura*

One of the leading businesses in the area of perfume, cosmetics and personal hygiene in Brazil, Natura is dedicated, since its foundation in 1969, to adding value to all of its relationship network. In 2014, as a recognition of the evolution of its commitment to match economic development with the promotion of social and environmental wellness, Natura became the largest company in the world to achieve certification as a B-Corporation.

The Natura brand is present in countries of Latin America such as Argentina, Bolivia, Chile, Colombia, Mexico and Peru, and also in France.

Through a differentiated business model that is coherent with its view of a sustainable world, Natura acts to add increasing value to all of its stakeholders and relationship networks.

Its reason for existing is to create and commercialize products and services that promote wellness and wellbeing.



# About GSS Sustainability

**GSS Sustainability and Bioinnovation** is a Brazilian company with representatives in Curitiba (PR), São Paulo (SP) and Brasília, formed by professionals with national and international experience involving biodiversity, climate change and corporate sustainability.

The GSS Team gathers knowledge acquired from activities with a variety of companies of the public and private sector, providing its clients with strategic thinking and competitive capacity aligned with the current challenges and opportunities. We believe in our role and therefore the coherence between discourse and action is the fundamental premise of GSS.

## *Management Strategies for the sustainable use of biodiversity*

- Advice on Best-practices in Benefit-Sharing and in the relationship with local communities.
- Support in the construction of a Benefit-Sharing Policy
- Field activities aimed at managing the use of biodiversity, monitoring projects and assessing indicators
- Surveying of inputs, raw materials and local communities with a potential for providing genetic resources
- Participative development of community protocols.
- Community development, strengthening of local associations and cooperatives and other field activities.

## *Diagnosis and assessment of risks on the use of biodiversity*

- Risk assessment of the activities involved in the use of the ingredients in the company's products. Both passive and preventive.
- Assessment of inputs from biodiversity for the identification of their center of origin and existing applicable national or international legislation.
- Assessment of inputs, ingredients, raw materials and bibliographical references from suppliers seeking to identify access to associated traditional knowledge

## *Registration process and regularization with the SisGen*

- Development of activities and strategies related to the use of biodiversity – Access to genetic heritage and associated traditional knowledge
- Compliance, in the scope of Law 13,123/2015, of projects and processes registered or approved under Provisional Measure 2,186/2001.
- Regularization of activities undertaken in disagreement with Provisional Measure 2,186/01 under the terms of the new Law on Biodiversity.
- Registration and notification of researches and products developed under the new Law on Biodiversity.

## *Mediation and monitoring of Benefit-Sharing Projects through the Showcase of Environmental Projects – VBIO*



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## *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. Due to this the time limit for this research ended in November 2016.

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.

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









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