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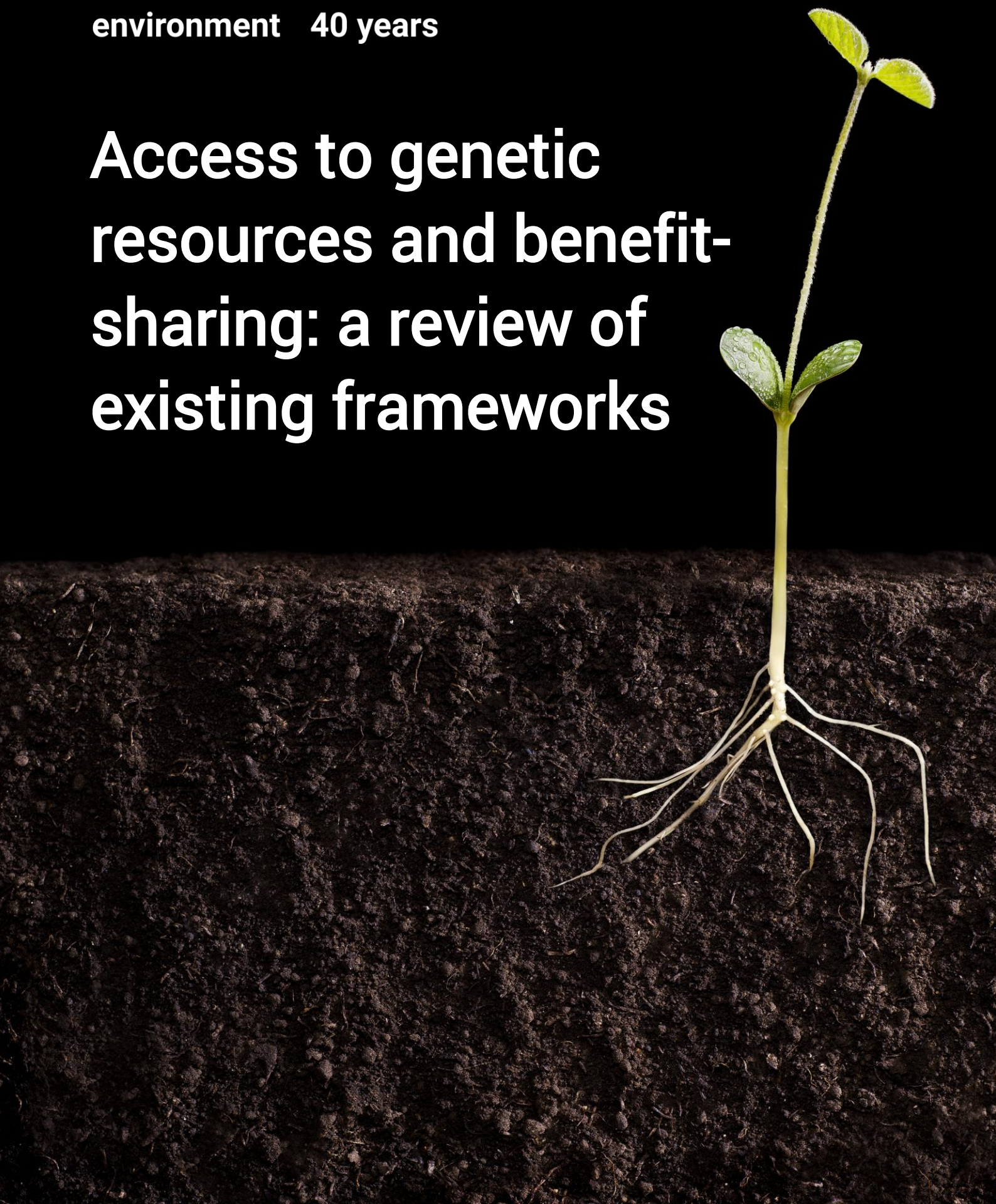
Access to genetic resources and benefit-sharing: a review of existing frameworks



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Acronyms and abbreviations

ABS	Access and benefit-sharing
ABSCH	Access and Benefit-Sharing Clearing-House
Anvisa	National Health Surveillance Agency, Brazil
BABS	Regulations on Bio-Prospecting, Access and Benefit-Sharing, South Africa
BMC	Biodiversity Management Committee, India
CAN	Andean Community (Comunidad Andina)
CBD	Convention on Biological Diversity (The Convention)
CENSI	National Institute of Intercultural Health, Peru
CGen	Genetic Heritage Management Council, Brazil
CNPq	Platform of the National Council for Scientific and Technological Development, Brazil
CONAM	National Council for the Environment, Peru
CONCYTEC	National Council for Science, Technology and Technological Innovation (Consejo Nacional de Ciencia, Tecnología e Innovación Tecnológica), Peru
Consea	National Council for Food and Nutrition Security, Brazil
CTNBio	National Technical Biosafety Commission, Brazil
DIGEMID	General Directorate for Medicines, Supplies and Drugs (Dirección General de Medicamentos, Insumos y Drogas), Peru
DIGESA	General Directorate of Environmental Health and Food Safety (Dirección General de Salud Ambiental e Inocuidad Alimentaria), Peru
EU	European Union
FNRB	National Fund for Benefit-Sharing (Fundo Nacional para a Repartição de Benefícios), Brazil
FONAM	National Environment Fund (Fondo Nacional Ambiental), Colombia
IBAMA	Brazilian Institute for the Environment and Natural Resources
IEPI	The Ecuadorian Institute of Intellectual Property, Ecuador
INABIO	National Institute of Biodiversity (Instituto Nacional de Biodiversidad), Ecuador
INDECOPI	National Institute for the Defence of Competition and the Protection of Intellectual Property (Instituto Nacional de Defensa de la Competencia y Protección de la Propiedad Intelectual), Peru
INIA	National Institute of Agricultural Innovation (Instituto Nacional de Innovación Agraria), Peru
INPI	National Institute of Industrial Property, Brazil
INRENA	National Institute of Natural Resources, Peru
IPPN	Peruvian Institute of Natural Producers, Peru
IRCC	Internationally Recognised Certificate of Compliance
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
JFMC	Joint Forest Management Committee, India
MAT	Mutually agreed terms

MINAM	Ministry of Environment of Peru
MINCETUR	Ministry of International Trade and Tourism, Peru
NBA	National Biodiversity Authority, India
NEMBA	National Environmental Management Biodiversity Act, South Africa
NIKSO	National Indigenous Knowledge Systems Office, South Africa
NITE	National Institute of Technology and Evaluation, Japan
PBR	People's Biodiversity Registers, India
PIC	Prior informed consent
PIPF	Pandemic Influenza Preparedness Framework
PRODUCE	Ministry of Production, Peru
PROMPEX	Commission for the Promotion of Exports, Peru
SBB	State Biodiversity Board, India
SENADI	National Service of Intellectual Rights, Ecuador
SENESCYT	Secretariat for Higher Education, Science, Technology and Innovation, Ecuador
SERFOR	National Forestry and Wild Fauna Service (Servicio Nacional Forestal y de Fauna Silvestre), Peru
Siscomex	Integrated Foreign Trade System, Brazil
SisGen	National system for the management of genetic heritage and associated traditional knowledge, Brazil
SNIIC	National System of Cultural Information and Indicators, Brazil
SPDA	Peruvian Society of Environmental Law, Peru
SUNAT	Superintendencia Nacional de Administración Tributaria, Peru
The Nagoya Protocol or The Protocol	The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights

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Executive Summary

Genetic resources are used for commercial and non-commercial purposes in a variety of sectors and by a number of users. Considering the importance of genetic resources and associated traditional knowledge, and recognising that their utilisation has been essential for many years, the Convention on Biological Diversity and later on the Nagoya Protocol on access and benefit-sharing constitute some of the key international instruments in regulating this subject matter.

The entry into force of the Nagoya Protocol in 2012 triggered the development or adjustment of national access and benefit-sharing frameworks across the globe. The Protocol expands on the obligations on access and benefit-sharing included in the Convention, to effectively establish an international access and benefit-sharing regime that provides legal certainty, clarity and transparency. It currently has 109 Parties[1], and a few other countries have deposited their instruments of ratification and will become full Parties shortly. Others, are analysing the implications of ratification. In this context, the present report provides an overview of policy and legal frameworks on access to genetic resources and benefit-sharing in Brazil, Colombia, Ecuador, the European Union, India, Japan, Peru, and South Africa.

The analysed cases show a variety of instruments and approaches to regulate access and benefit-sharing. The main difference is that while most of the reviewed frameworks have access measures in place, others have been developed around user compliance measures. Further, most of the reviewed frameworks include specific situations that are exempted from the benefit-sharing obligation.

In terms of how these frameworks address the implementation of benefit-sharing, again some key differences can be identified. While some provide a thorough description of the applicable benefit-sharing mechanism, this is not spelled out in detail in others and the analysis is made by the national authorities on a case-by-case basis. It is however worth noting that various countries are currently in the process of developing more detailed processes to ensure benefit-sharing arising out of the utilisation of genetic resources.

The key challenges that countries have so far experienced in implementing these frameworks as well as the areas of work that they are further developing, could be useful for others when developing and implementing their ABS frameworks. In addition, considering that new instruments and issues of relevance to access and benefit-sharing regimes are being considered by governments in different international fora, seeing how some of these aspects are being taken up in legal and policy frameworks could help a range of stakeholders to better understand their implications for their activities.

[1] As of 30 October 2018, based on information available on the website of the Protocol https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml

1 Introduction

Access and benefit-sharing (ABS) is not a new issue in the environmental agenda. Furthermore, it has gained increasing attention in the last few decades. Countries are highly interdependent both in terms of genetic resources as well as the associated traditional knowledge. This interdependency is mainly materialised through the regular flow of those resources from one country to the other in order for their utilisation in various sectors. Genetic resources are used for commercial and non-commercial purposes in a variety of sectors and by a number of users (Greiber et al., 2012; Laird & Wynberg, 2008).

The Convention on Biological Diversity (CBD) pursues: (i) the conservation of biological diversity, (ii) the sustainable use of its components and (iii) the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.[2] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity (The Nagoya Protocol) entered into force in 2014, progresses implementation of the third objective.

The provisions of the Protocol reflect the need for countries to set up rules and procedures on access to genetic resources to be implemented domestically (South Centre, 2015). Although the exchange of material takes place on a regular basis, the operationalization of access and benefit-sharing mechanisms is practically and technically complex and, consequently, governments are trying to identify tools and mechanisms that can ease the process in a cost-effective manner.

Capitalising on the experience from an increasing number of access and benefit-sharing measures designed and implemented in different countries, even those existing prior to the entry into force of the Nagoya Protocol, can therefore strengthen the development and implementation of access and benefit-sharing measures. In this context, the report pursues the following main objectives:

(i) To provide an up-to-date overview of selected national, and as appropriate regional, policy and legal frameworks on access to genetic resources and benefit-sharing

(ii) To contribute to the promotion of South-South cooperation on these issues in order to advance the access and benefit-sharing agenda.

The structure of the report aims to respond to these two objectives. Following a brief description of the methodology used (section 2), an overview of access and benefit-sharing at the global level is presented (section 3). Section 4 systematises information of the access and benefit-sharing regimes from Brazil, Colombia, Ecuador, the European Union (EU)[3], India, Japan, Peru, and South Africa, providing an overview of the domestic frameworks in place. Based on this information, section 5 presents an overview of some key elements identified in the case studies, including a simple comparative analysis. The last part of the section includes a brief summary of key next steps and prospects for the future based on the work that is underway at the domestic level in the covered case studies.

[2] Convention on Biological Diversity, Article 1

[3] Only the ABS framework of the European Union, and not those from individual Member States, has been reviewed.

2 Methodology

The study was developed through a desk-based literature review, focusing on the access and benefit-sharing regimes of Brazil, Colombia, Ecuador, the European Union, India, Japan, Peru, and South Africa. It should be noted that only the access and benefit-sharing framework of the European Union, and not those from individual Member States, has been reviewed. With the exception of the European Union, which is a regional organisation, all the other analysed case studies are countries. For ease of reference, the generic reference to case study *countries* in the report also includes the European Union.

The selection of the studied cases was done following a series of key criteria, with the ultimate goal of presenting a variety of frameworks. In particular, the following criteria were considered:

- Frameworks of provider and user countries in different regions of the world, with an emphasis on provider countries given the potential of the report to be used as a source of information to foster South-South cooperation;
- Consideration of megadiverse countries;
- Parties and non-Parties to the Nagoya Protocol; and
- Recent developments and/or work underway to revise policy and legal frameworks.

The technical report was developed in two phases. Firstly, given the broad scope of issues related to access and benefit-sharing and the multiple interlinkages that could be made, a list of questions with key areas to be covered within the scope of the study was developed. Based on that, two tables were developed to gather relevant information. The first one was used to identify key access and benefit-sharing legislative, policy and administrative measures for each country/regional organization; and then, a second table was developed for each case study. The latter is the one included in section 4 of this report.

In principle, the same template was used for each case study. However, in order to better represent specific features of some of the analysed cases, slight modifications were undertaken in some of them.

The report was developed following a thorough review process. For each case study, country reviewers were identified, mostly through requests sent to the access and benefit-sharing national focal points published in the Access and Benefit-Sharing Clearing-House (ABSCH). In some cases, additional reviewers were identified later on to complement the information or to fill specific gaps that had been acknowledged during the development of the report.

Reviewers provided inputs at various stages during the drafting process regarding the individual case study countries.

3 Access and benefit-sharing at the global level: a snapshot

The adoption and entry into force of the Convention on Biological Diversity (the Convention) was a significant milestone as it implied a paradigm change in terms of international environmental governance. With the recognition of the principle of sovereignty of States over their natural resources, genetic resources moved from being considered common heritage of mankind, therefore freely available, to being governed nationally.[4]
Furthermore, the fair and equitable sharing of benefits arising out of the utilisation of genetic resources was established as one of the objectives of the Convention. It therefore introduced the need for Parties to take legislative, administrative or policy measures with the aim of sharing in a fair and equitable manner the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Party providing such resources.[5] The Convention further stipulates for access to genetic resources be subject to prior informed consent and for mutually agreed terms to be established.[6]
Despite the provisions in the Convention, the international community considered that more efforts were necessary to advance the implementation of the benefit-sharing objective. There were some concerns over the misappropriation of genetic resources and associated traditional knowledge.
Consequently, negotiations were initiated that led to the development of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity (The Nagoya Protocol or The Protocol).
The Nagoya Protocol, which entered into force on 12 October 2014, aims to ensure the fair and equitable sharing of the benefits arising from the utilisation of genetic resources.[7] Its membership has grown continuously since the entry into force. It currently has 109 Parties[8], and a few other countries have deposited their instruments of ratification and will become full Parties shortly. Others, are analysing the implications of ratification.
The Protocol expands on the obligations on access and benefit-sharing included in the Convention, to effectively establish an international access and benefit-sharing regime that provides legal certainty, clarity and transparency. In brief, the Protocol requires that Parties take legislative, administrative or policy measures to ensure that benefits arising from the utilisation of genetic resources and associated traditional knowledge are shared in a fair and equitable way, based on mutually agreed terms.[9] Furthermore, Parties need to take measures to ensure that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.[10]
An important characteristic of the Protocol is that some of the agreed language is vague. This therefore provides governments with policy space to refine the details and find the most adequate way to regulate access and benefit-sharing in accordance with their circumstances (South Centre, 2015).

[4] Convention on Biological Diversity, Article 15
[5] Convention on Biological Diversity, Article 15.7
[6] Convention on Biological Diversity, Article 15 (paragraphs 4 and 5)
[7] Nagoya Protocol, Article 1
[8] As of 30 October 2018, based on information available on the website of the Protocol https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml
[9] Nagoya Protocol, Article 5
[10] Nagoya Protocol, Articles 6 and 7

Besides the importance of the Convention on Biological Diversity and the Nagoya Protocol, global governance of genetic resources goes beyond these international instruments. Some of the other agreements that are part of the global regime on genetic resources include the International Treaty on Plant Genetic Resources for Food and Agriculture and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization. These agreements regulate different aspects that relate to access and benefit-sharing.

The International Treaty pursues "the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security"[11]. Its objective makes the links to the Nagoya Protocol very obvious. Further, the Protocol specifically acknowledges the fundamental role of the International Treaty and recalls the Multilateral System of Access and Benefit-sharing established under it. In turn, the TRIPS Agreement, which establishes minimum standards of protection and of intellectual property, deals with patentability of living organisms. Looking at the relationship between intellectual property and biodiversity, regulated differently in diverse countries, is essential to understand the implementation of access and benefit-sharing regimes. As a result, Parties to these agreements also consider their provisions when designing their access and benefit-sharing frameworks.

Also at the regional level, specific legal frameworks have been developed to deal with access to genetic resources and benefit-sharing. One key example of this type of regional arrangements is the regime developed by the Andean Community.[12] Another one, looked into more detail in this study, relates to the European Union. While the Andean Community access regime has been developed prior to the Nagoya Protocol being adopted, the European Union's framework as developed in response to that international instrument. In different ways, but they both entail a series of obligations that need to be implemented nationally by their respective Member States. In addition, the ABS framework under the Andean Community aims to bridge the relationship between intellectual property rights rules and biodiversity (Helfer, 2009).

Lastly, it should be noted that new instruments and issues of relevance to access and benefit-sharing regimes are being considered by governments in different fora. One of these includes the work carried out by the World Intellectual Property Organisation with the objective of reaching an agreement on an international legal instrument(s) relating to intellectual property and the protection of genetic resources, traditional knowledge and traditional cultural expressions. Further, the outcome of current deliberations taking place under the Convention on Biological Diversity and the Nagoya Protocol relating to digital sequence information, or under the Protocol on specialised access and benefit-sharing instruments, could result in countries taking further action at the domestic level.

Without intention of being exhaustive, the agreements referred to above give an indication of the complexity that applies to the design and implementation of access and benefit-sharing frameworks. It makes also clear that there are opportunities for cooperation not only at the global level, but likewise domestically.

[11] International Treaty on Plant Genetic Resources for Food and Agriculture, Article 1

[12] The Member States of the Andean Community are Bolivia, Colombia, Ecuador and Peru.

4 Overview of selected access and benefit-sharing frameworks

This section presents an overview of legislation relevant to access and benefit-sharing in Brazil, Colombia, Ecuador, the European Union, India, Japan, Peru and South Africa, with a view to gain understanding on scope and key measures being implemented. The review focused in particular on the following issues:

- Key terms defined in the legislation (e.g. utilisation, genetic resources)
- Objectives and scope of the legislation
- Approaches for governance of genetic resources
- Key requirements for access to genetic resources and/or associated traditional knowledge
- Mechanisms for sharing benefits derived from the utilisation of genetic resources and/or traditional knowledge
- The institutional arrangements established for implementation and enforcement of the domestic legislation, as well as monitoring mechanisms developed to track the utilisation of genetic resources and/or traditional knowledge
- The relationship between domestic access and benefit-sharing legislation and intellectual property rights (focusing on patents).

Details of the information identified in the ABS measures in place in each of the case study countries are included in the tables that follow.

4.1 Brazil

- Brazil has not yet ratified the Nagoya Protocol. However, its ABS legislation is at the forefront with respect to many of the dimensions covered by such instrument.
- Law 13.123, adopted in 2015, and its regulating Decree 8772 of 2016, are the main legal instruments regulating access and benefit-sharing in Brazil. The emphasis of the legislation is on access to genetic heritage and associated traditional knowledge; with the aim of ensuring benefits arising out of their economic exploitation are shared in a fair and equitable way.

1. Definition of key terms	
a) Definition of access to genetic resources and associated traditional knowledge	Access to genetic heritage: Research or technological development carried out on a genetic heritage sample.[13] Access to associated traditional knowledge: Research or technological development carried out on traditional knowledge associated with genetic heritage that facilitates access to genetic heritage even when obtained from secondary sources as fairs, publications, inventories, films, scientific articles, registries, and other forms of systematization and registry of associated traditional knowledge.[14]
b) Definition of collection	Neither Law 13.123 nor Decree 8722 of 2016 define the term "collection".
c) Definition of utilisation of genetic resources and the associated traditional knowledge	The term "utilisation" is neither used nor defined in the Brazilian ABS legal framework. Instead, the legislation defines the following terms, which are included in the definition that the Nagoya Protocol provides for "utilisation"[15]: • Research: theoretical or experimental activity, carried out on genetic heritage or associated traditional knowledge with the objective of producing new knowledge, by systematic knowledge construction process which generates and tests hypotheses and theories, describes and interprets the foundations of observable phenomena and facts. • Technological development: systematic work on genetic heritage or associated traditional knowledge, based on existing procedures, obtained by research or by practical experience, carried out with the objective to develop new materials, products or devices, perfecting or developing new processes for economic exploitation.

[13] Law 13.123, Article 2, point VIII
[14] Law 13.123, Article 2, point IX
[15] In accordance with the Nagoya Protocol, "*utilisation of genetic resources* means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention" (Article 2)

d) Definition of bioprospecting	Not defined in the ABS legislation in place
e) Others definitions of relevance? E.g. biological resources, in situ conservation; indigenous species; benefit-sharing, derivative; genetic resources; genetic material	**Genetic heritage**: information of genetic origin from plant, animal, microbial or other species, including substances derived from the metabolism of living organisms.[16] Even though **derivatives** are not defined within the legislation in place, they are covered. In particular, the scope of the definition of genetic heritage account for them by indicating "substances derived from the metabolism of living organisms" are included. **Associated traditional knowledge**: information or practice of an indigenous population, traditional community or traditional farmer, in relation to the properties or uses (direct or indirect) associated to genetic heritage.[17] **Associated traditional knowledge of unidentified origin**: associated traditional knowledge for which its origin cannot be linked to, at least one, indigenous people, traditional community or traditional farmer.[18]

2. General information	
a) To whom do genetic resources belong? Are these considered private goods, goods of common use by the population, public goods or do they belong to the State, etc.?	Brazilian genetic heritage is considered a collective good, of use by the Brazilian people.[19] Law 13.123 also stipulates that access to genetic heritage or associated traditional knowledge will be carried out without prejudice to the rights of material, or immaterial, property that affect the genetic heritage or associated traditional knowledge accessed, or the place of its occurrence.[20]
b) Does the legislation provide any indication on when it is considered that species have developed their own characteristics, i.e. distinctive properties, to start being considered a genetic resource of that country?	In accordance with Law 13.123, *in situ* conditions entail the "conditions in which genetic heritage exist in their natural ecosystems or habitats, and, in the case of domesticated or cultivated species, includes those forming spontaneous populations in the surroundings where they have naturally developed their distinctive properties".[21] When plant and animal species are introduced in the country, they will only be considered genetic heritage found in *in situ* conditions in the

[16] Law 13.123, Article 2, point I
[17] Law 13.123, Article 2, point II
[18] Law 13.123, Article 2, point III
[19] Law 13.123, Article 1, point I
[20] Law 13.123, Article 1, point I and paragraph 1
[21] Law 13.123, Article 2, point XXV

	national territory when they form spontaneous populations that have acquired their own distinctive properties in the country.[22] Besides the mentioned references, the legislation provides no criteria relating to when it could be considered that species developed their own characteristics. In the context of the Genetic Heritage Management Council (CGen), a thematic group to deal with this subject matter has been established in August 2017.[23]
c) Objective of the ABS legislation	The objective of Law 13.123 is to provide for access to genetic heritage, for protection and access to associated traditional knowledge, and for benefit-sharing for conservation and sustainable use of biodiversity.
d) Scope of the legislation – does it refer to all genetic resources or only to a subset (e.g. genetic resources for food and agriculture)? Are there any exemptions of genetic resources that fall outside of the scope (e.g. human genetic resources)?	Both Law 13.123 and Decree 8772 clarify the scope of the Brazilian ABS framework. In particular, Law 13.123 regulates: • Access to Brazilian genetic heritage and to associated traditional knowledge, found in *in situ* conditions, including domesticated species and spontaneous populations, or kept in *ex situ* conditions, as long as found in *in situ* conditions within the national territory, on the continental shelf, on territorial waters, or in the exclusive economic zone • Access to and transfer of technology for the conservation and utilisation of biological diversity • Economic exploitation of finished products or reproductive material originating from access to genetic heritage or associated traditional knowledge • Fair and equitable benefit-sharing arising out of the economic exploitation of finished products or reproductive material resulting from access to genetic heritage or associated traditional knowledge, for conservation and sustainable use of biodiversity • Shipment abroad of living or non-living organisms or parts thereof of plants and animals, microbial species, or any other species The following activities are subject to ABS requirements: access to genetic heritage or associated traditional knowledge; shipment abroad of genetic heritage; and economic exploitation of finished products or reproductive material arising from access to genetic heritage or associated traditional knowledge.

[22] Decree 8772, Article 1, paragraph 3
[23] See http://www.mma.gov.br/images/arquivo/80043/deliberacoes/del-23-cgen.pdf

	The legal framework indicates specific circumstances under which genetic heritage can be considered as *of the country*. In particular, it refers to: • Microorganisms that have been isolated from substrates from the national territory, territorial sea, exclusive economic zone or continental shelf[24] • Plant and animal species introduced into the country will only be considered genetic heritage found in *in situ* conditions in the national territory when they had developed spontaneous populations that have acquired their own distinctive properties in the country[25] • A variety originating from species introduced into the national territory is considered genetic heritage found in *in situ* conditions when such variety has genetic diversity developed or adapted by indigenous populations, traditional communities or traditional farmers, including natural selection combined with human selection in the local environment, which is not substantially similar to commercial varieties[26] Regarding the temporal scope, the following applies: • For shipment abroad of genetic heritage, any research or technological development activity taking place after 17 November 2015, regardless of its start date, is considered as access for which Law 13.123 is applicable[27] • For activities that took place between 30 June 2000[28] and 17 November 2015, the legislation stipulates that users need to accommodate the requirements to be consistent with the current legal framework if the following activities were involved: access to genetic heritage and associated traditional knowledge; and economic exploitation of finished products or reproductive material resulting from access to genetic heritage or associated traditional knowledge[29] Exemptions:

[24] Law 13.123, Article 2, Single paragraph
[25] Decree 8772, Article 1, paragraph 3
[26] Decree 8772, Article 1, paragraph 4
[27] Decree 8772, Article 2
[28] It is worth noting that the date 30 June 2000 relates to the first version of the previous ABS framework (i.e. Provisional Measure 2.186-16/2001, revoked by Law 13.123/2018), under which it was already necessary to comply with certain access requirements such as prior informed consent. For example, those submitting patent applications relating to access to Brazilian genetic heritage or associated traditional knowledge that had taken place after 30 June 2000 needed to disclose the origin of such resources in the application (Genetic Heritage Governing Council, Resolution 23 of 2006, later on replaced by Resolution 34 of 2009).
[29] Decree 8772, Article 2, paragraph 2; and Article 103

	• Human genetic heritage[30] • Microorganisms, when they were isolated from substrates that are not in the national territory, the territorial sea, the exclusive economic zone or the continental shelf; and when the regularity of its importation can be proved[31] • Access to genetic heritage and associated traditional knowledge is prohibited for practices that are harmful to the environment, cultural reproduction and human health, and for the development of biological and chemical weapons[32] • Regarding the temporal scope, access to genetic heritage or associated traditional knowledge concluded before 30 June 2000, and the economic exploitation of finished products or reproductive material arising from it are not subject to ABS requirements.[33] However, at the request of the competent authority, a user must provide the required information to prove all the steps concluded for the access even if carried out before of that date[34] • Access to genetic heritage or associated traditional knowledge by foreign natural persons is prohibited, and the shipment abroad of genetic heritage samples depends on signing the material transfer agreement as provided by the CGen.[35] It is worth noting that access to genetic heritage or associated traditional knowledge by a foreign legal person that works in collaboration with a national public or private research institution is regulated and hence needs to be registered in accordance with the legislation in place.[36] The same applies when a national, public or private, natural or legal person accesses genetic heritage or associated traditional knowledge abroad.[37]
e) Is ABS regulated at the national or subnational level? To what extent does the national government share competencies with subnational entities?	In Brazil, ABS is regulated at the national level. The national government is responsible for the management, control and oversight of activities relating to access to Brazilian genetic heritage

[30] Law 13.123, Article 4
[31] Decree 8772 of 2016, Article 1
[32] Law 13.123, Article 5
[33] Decree 8772, Article 3
[34] Decree 8772, Article 3, paragraphs 1-5
[35] Law 13.123, Article 11
[36] Law 13.123, Article 12, point II
[37] Law 13.123, Article 12, point II

	and associated traditional knowledge; either for research or technological development, or for commercial exploitation.[38]

3. Access to genetic resources and associated traditional knowledge	
a) According to the legislation, is access to genetic resources and/or associated traditional knowledge subject to prior informed consent (PIC)?	The legislation does not provide for specific procedures relating to obtaining prior informed consent for the access to **genetic heritage**. In this respect, access to genetic heritage is subject to registration in the national system for the management of genetic heritage and associated traditional knowledge (SisGen). Access to genetic heritage of local traditional or native varieties, or locally adapted or native breeds for agricultural activities encompasses access to traditional knowledge associated with a non-identifiable origin of the variety or breed. It does not depend on prior consent from the indigenous community, the traditional community or farmer who breeds, develops, holds or conserves the variety or the breed.[39] Access to **associated traditional knowledge** is subject to PIC only when it refers to traditional knowledge of *identifiable origin*. Evidence of prior informed consent may occur at the discretion of the indigenous population, traditional community or traditional farmer, through the signature of prior consent term; audio-visual record of consent; opinion of the competent official body; or membership as provided for in the Community Protocol. In turn, access to associated traditional knowledge of *non-identifiable origin* is not subject to PIC. [40] As indicated above, associated traditional knowledge of non-identifiable origin refers to associated traditional knowledge for which its origin cannot be linked to at least one indigenous people, traditional community or traditional farmer.[41]
b) Does the legislation establish rules/procedures for requiring and establishing mutually agreed terms (MAT)?	In Brazil, **benefit-sharing agreements** are equivalent to mutually agreed terms. The CGen under the Ministry of Environment, is responsible for establishing guidelines and criteria for the preparation and compliance of the Benefit-sharing agreement.[42] The **Benefit-Sharing Agreement** should clearly indicate that the parties to the agreement, for the case of economic exploitation of a finished product or reproductive material originating from access to genetic heritage or

[38] Law 13.123, Article 3, single paragraph
[39] Law 13.123, Article 9
[40] Law 13.123, Article 9
[41] Law 13.123, Article 2, point III
[42] Law 13.123, Article 6

	associated traditional knowledge of *unidentified origin*, are: the Federal Government, represented by the Ministry of Environment, and the user. In the case of economic exploitation of a finished product or reproductive material originating from an access to associated traditional knowledge of *identified origin*, the parties are the provider of the associated traditional knowledge and the user. [43] With respect to traditional knowledge of *identified origin* associated with genetic heritage, the user and the provider will freely negotiate the terms and conditions for access as well as those relating to the benefit-sharing agreement.
c) Does the legislation set out criteria for the approval and involvement of indigenous and local communities for access to genetic resources and associated traditional knowledge?	The government recognizes the right of indigenous communities, traditional communities and traditional agriculturists to participate in decision-making at the national level about issues relating to the conservation and sustainable use of their traditional knowledge associated to the genetic heritage of the country.[44] Indigenous populations, traditional communities and traditional farmers who create, develop, maintain or conserve associated traditional knowledge **are guaranteed the right to participate** in decision-making processes on issues related to access to associated traditional knowledge and the sharing of benefits arising from such access.[45] In particular, they participate in the CGen and in the Management Committee of the National Fund for Benefit-Sharing (Fundo Nacional para a Repartição de Benefícios - FNRB). Indigenous populations, traditional communities and traditional farmers are assured participation of at least 40% (shared with the academic and business sectors) in the CGen.[46] The CGen Plenary includes in its composition nine representatives of civil society, one of which is appointed by representatives of indigenous populations and organizations.[47] Furthermore, the Steering Committee of the FNRB also includes a representative of the indigenous population, traditional community or traditional farmer appointed by the National Council for Food and Nutrition Security – Consea.[48]

[43] Law 13.123, Article 25
[44] Law 13.123, Article 8
[45] Law 13.123, Article 8
[46] Law 13.123, Article 6
[47] Decree 8772, Article 7
[48] Decree 8772, Article 97

	Access to associated traditional knowledge of identifiable origin is conditional on obtaining prior informed consent (see PIC above).[49] The indigenous population, traditional community or traditional farmer **may deny consent** to access their associated traditional knowledge of identifiable origin.[50] Finally, is it worth noting that the CGen has recently established a Sectoral Committee of indigenous populations, traditional communities and traditional farmers that are holders of traditional knowledge associated to genetic heritage. This Committee is aimed at discussing issues relating to access and benefit-sharing for that sector.[51]
d) Does the legislation address any changes of intent in the utilisation of accessed genetic resources? (e.g. initially accessed for non-commercial research and then changing their utilisation to commercial)	The legislation indicates that when there is a change in the genetic heritage or traditional knowledge accessed, or when there is a change related to the purpose of the access, the user must complete a new registration.[52]
e) Does the legislation consider any simplified measures on access for non-commercial research purposes; or for cases of present or imminent emergencies that threaten or damage human, animal or plant health?	Regarding health, the Ministry of Environment and the Ministry of Health will regulate, through a joint ordinance, a simplified procedure for shipping of genetic heritage related to an Emergency Situation of National Importance, referred to in Decree 7616 of 2011.[53]
f) Are there any specific provisions/piece of law related to genetic resources for food and agriculture?	Under the Brazilian ABS framework, there are no differences between the different subsectors relating to genetic resources for food and agriculture.[54] Access to genetic heritage of local traditional or native varieties, or a locally adapted or native breed constitutes access to unidentifiable associated traditional knowledge that gave origin to the variety or breed. Therefore access does not require PIC from indigenous peoples, traditional community or traditional farmer that breeds, develops, holds and conserves the variety or breed.[55] The Ministries of Agriculture, Livestock and Supply, and the Special Secretariat for

[49] Law 13.123, Article 8
[50] Law 13.123, Article 13
[51] See http://www.mma.gov.br/images/arquivo/80043/deliberacoes/del-4-cgen.pdf
[52] Decree 8772, Article 22, paragraph 5
[53] Decree 8772, Article 115
[54] See submission from Brazil to Commission of Genetic Resources for Food and Agriculture (2018), available at http://www.fao.org/3/a-bt993e.pdf (page 3)
[55] Law 13.123, Article 9, paragraph 3

	Family Agriculture and Agrarian Development[56] will develop and release the list of "local traditional or native varieties or a locally adapted or native breed".[57] Concerning benefits arising from the economic exploitation of products that result from access to genetic heritage or associated traditional knowledge for agricultural activities, these are to be shared on the commercialisation of reproductive material.[58]

4. Benefit-sharing	
a) What triggers benefit-sharing? Does any utilisation of genetic resources create a benefit-sharing obligation, even if it does not add value to the product or market?	In accordance with the Brazilian legislation, benefits arising out of the **economic exploitation of finished products or reproductive material** that result from access to genetic heritage of species found in *in situ* conditions or to associated traditional knowledge are to be shared in a fair and equitable way. Importantly, this is also the case **when products are produced outside of Brazil**. The condition for triggering benefit-sharing obligations in the case of a finished product is that the genetic heritage or associated traditional knowledge **must be one of the key elements of adding value to the product**.[59] This is defined as elements whose presence in the finished product determine its functional features[60] or its marketing appeal[61].[62] In brief, the triggering event for the benefit-sharing obligation is the economic exploitation of a finished product and, for agricultural activities, the benefit-sharing obligation lies at the final point in the production chain of reproductive materials.

[56] After the decree was published, the Ministry of Rural Development turned into a Special Secretariat. As a result, this competence, initially intended for the Ministry of Rural Development, is now competence of the Special Secretariat for Family Agriculture and Agrarian Development.
[57] Law 13.123, Article 114
[58] Law 13.123, Article 18
[59] Law 13.123, Article 17
[60] Defined as characteristics that determine the main purposes, improve the product or extend its list of purposes (Decree 8772, Article 43, paragraph 3)
[61] Refers to genetic heritage or associated traditional knowledge, their origin or their resulting differential distinctions, related to a product, line of product or brand in any visual or audible means of communication, including marketing campaigns or highlight on the product label (Decree 8772, Article 43, paragraph 3)
[62] Law 13.123, Article 2, XVIII

<table>
<tr><td>b) Does the national legislation exempt benefit-sharing arising from any particular utilisation (research and development), even if the CBD support the sharing of the benefits arising from such activities?</td><td>Under the Brazilian ABS framework, the following situations or actors are exempted from the benefit-sharing obligation:
Exchange and dissemination of genetic heritage and associated traditional knowledge practiced by indigenous populations, traditional community or traditional farmer among themselves for their own benefit and based on their uses, customs and traditions[63]
Manufacturers of intermediate products and developers of processes from access to genetic heritage and associated traditional knowledge along the production chain[64]
Licensing, transferring or permitting any use of intellectual property rights related to a finished product, process, or reproductive material arising from access to genetic heritage or associated traditional knowledge by third parties[65]
Micro-businesses, small businesses, micro individual entrepreneurs, and traditional farmers and their cooperatives with annual gross revenue equal to or lower than the upper limit established in the applicable national legislation[66]
Economic exploitation of finished products or reproductive material arising from access to genetic heritage of species introduced to the national territory by human action, even if domesticated. This exemption does not apply to those species that developed spontaneous populations with distinctive properties acquired in the country; and to local traditional variety or landrace, or locally adapted breed or creole breed.[67]
Importantly, sharing the benefits resulting from exploiting finished products or reproductive material arising from access to associated traditional knowledge exempts the user from sharing benefits related to genetic heritage.[68]</td></tr>
<tr><td>c) How does the national legislation define the amount to be paid as benefit-sharing? Does it establish a fixed percentage for benefit-sharing?</td><td>The Brazilian ABS legislation is quite detailed in terms of how to calculate the amount to be shared as part of the benefit-sharing obligations, including on the different situations in which benefit-sharing is involved.<table><tr><td>Genetic heritage</td><td>• When monetary benefit-sharing is chosen as modality for the distribution of benefits arising from the economic exploitation of</td></tr></table></td></tr>
</table>

[63] Law 13.123, Article 8, paragraph 4
[64] Law 13.123, Article 17, paragraph 2
[65] Law 13.123, Article 17, paragraph 4
[66] Law 13.123, Article 17, paragraph 5
[67] Law 13.123, Article 18, paragraph 3
[68] Law 13.123, Article 25, paragraph 3

		a finished product or reproductive material originating from access to the genetic heritage, the legislation stipulates a benefit-sharing amount corresponding to **1% (one percent) of the annual net revenue obtained from such economic exploitation**.[69] The full amount should be deposited in the FNRB. • With respect to **non-monetary** benefit-sharing, the amount can vary between 0.75 and 1% of the annual net revenue. For some of the modalities specified in the legislation, the amount needs to equal 75% of the amount that relates to monetary benefit-sharing. Therefore, 0.75% of the annual net revenue obtained from such economic exploitation is applicable for those cases.[70] For the others, the amount remains as 1% of the annual net revenue obtained from the economic exploitation. For non-monetary modalities, benefit-sharing is operationalised through a benefit-sharing agreement concluded with the Federal Government, represented by the Ministry of Environment.[71]
	Associated traditional knowledge of *identifiable* origin	When a finished product or reproductive material is the result of access to associated traditional knowledge of *identifiable origin*, the benefit-sharing component has two parts: 1. The provider of the knowledge has the right to receive benefits through a Benefit-Sharing Agreement and therefore, as indicated under item 4.d) above, the legislation stipulates that the benefit-sharing agreement is to be negotiated between the user and the provider in a fair and equitable way including the type and duration of benefits to be accrued.[72] Both the modality and the amount are defined during the negotiation of the benefit-sharing agreement and

[69] Law 13.123, Article 20

[70] Law 13.123, Article 22. The 0.75% applies to projects for conservation or sustainable use of biodiversity, or for protection and maintenance of knowledge, innovations, or practices of indigenous peoples, traditional communities or traditional farmers; capacity building of human resources in topics related to the conservation and sustainable use of genetic heritage or associated traditional knowledge; and distribution of products free of charge in social programs (Law 13.123, Article 19, point II, items a, e and f).

[71] Decree 8772, Article 50, point II

[72] Law 13.123, Article 24

	in accordance with the terms of the free prior informed consent already granted by the community, with no specific amounts being defined in the legislation. 2. In addition, given that it is assumed that traditional knowledge can be shared by more than one community, the Brazilian ABS system requires that monetary benefit-sharing also takes place. The amount to be deposited to the FNRB corresponds to 0.5% of the annual net revenue obtained from economic exploitation of finished products or reproductive material arising from access to associated traditional knowledge of identifiable origin.[73] The funds are to be used to invest in projects and activities that would benefit traditional knowledge holders, and to contribute to the preservation of traditional knowledge.
Associated traditional knowledge of *unidentifiable* origin	When the finished product or reproductive material results from access to the associated traditional knowledge where there is no way to link its origin to at least one indigenous population, traditional community, or traditional farmer, the benefits arising from using such knowledge must be monetary, and they need to be deposited directly in the FNRB. In these cases, the amount needs to equal 1% of the annual net revenue resulting from the economic exploitation of a finished product or reproductive material.

Finally, with regard to monetary benefit-sharing derived from access to genetic heritage or associated traditional knowledge of *unidentifiable* origin, it is worth noting that the legislation gives provisions to guarantee the competitiveness of the sector in cases where the application of the 1% (one percent) share of the annual net income may result in material damage or threat of material damage. In these cases, the government can, at the request of a minimum percentage of companies from the interested productive sector, enter into a *sectoral agreement* to allow for the reduction the value of the monetary benefit-sharing. The minimum possible benefit-sharing amount equals 0.1% of the annual net revenue obtained from the economic

[73] Law 13.123, Article 24, paragraph 3

	exploitation of the finished product or from the reproductive material derived from access to the genetic heritage or associated traditional knowledge.[74] When a **finished product or reproductive material is the result of different accessions**, these will not be considered cumulatively for the calculation of benefit-sharing.[75] The sharing of benefits resulting from exploiting finished products or reproductive material arising from access to associated traditional knowledge exempts the user from sharing benefits related to genetic heritage.[76] Concerning the calculation of the benefit-sharing amount for situations where the **finished products or reproductive material have been produced outside Brazil**, the Ministry of Environment can request supportive information to the manufacturer of the finished product or producer of the reproductive material, or to another representative of the foreign producer situated in the Brazilian territory (such as importer, subsidiary companies, commercial representatives).[77]
d) Who should pay for the benefits to be shared (the one who carries out access to/utilisation of genetic resources and the associated traditional knowledge, the one who undertakes the economic exploitation, or both)?	The manufacturer of the finished product or the producer of the reproductive material are *exclusively* subject to benefit-sharing regardless of who would have previously accessed the resources.[78] Regarding agricultural activities, the responsibility of sharing benefits lies on the producer in charge of the last link in the productive chain of reproductive material, thus exempting other links within the chain.[79] In the case of economic exploitation of reproductive material originating from access to genetic heritage or associated traditional knowledge related to agricultural activities, but intended exclusively for the generation of finished products in productive chains that do *not* involve agricultural activity, benefit-sharing will occur only over the economic exploitation of the finished product.[80] The economic exploitation of finished products or reproductive material derived from access to genetic resources of species that have been introduced into the national territory by human
e) Where within the production chain rests the obligation to pay benefits? ○ supplier of raw material, ○ intermediary, ○ final product ready for commercialisation, or ○ all	

[74] Law 13.123, Article 20
[75] Law 13.123, Article 17, paragraph 3
[76] Law 13.123, Article 25, paragraph 3
[77] Decree 8772, Article 46
[78] Law 13.123, Article 17, paragraph 1; and Decree 8772, Article 44
[79] Decree, Article 44, paragraph 1
[80] Decree, Article 44, paragraph 3

	action, even if domesticated, are exempted from the distribution of benefits. This does not apply to introduced species that develop spontaneous populations that have acquired distinctive characteristics in the country, and to a local traditional or native variety or locally adapted or native breed.[81]
f) Is there anyone else that needs to share benefits? For example, non-commercial research, commercial research, intellectual property rights licensing, the whole value chain of an industry or the one with the greater added value?	No. As indicated under item 4.c), the following are specifically exempt from benefit-sharing: • Intermediate manufacturers or developers throughout the production chain • Third party licensing, transfer or permit procedures of intellectual property rights on the finished product, process or reproductive material coming from access to genetic resources or associated traditional knowledge[82] • Microenterprises, small businesses, individual micro-entrepreneurs[83] • Traditional farmers and their cooperatives, with annual gross revenue equal to or less than the maximum limit established by the legislation in place.[84]
g) Does the legislation provide an indication of what can constitute (monetary and non-monetary) benefits to be shared?	The legislation stipulates that benefit-sharing can take place both in monetary and non-monetary modalities. The latter includes, among others: projects aimed at conservation and sustainable use; technology transfer: availability of a product in the public domain not involving intellectual property protection; capacity development relating to conservation and sustainable use of genetic heritage and associated traditional knowledge; and free distribution of products as part of social programmes.[85] Importantly, for economic exploitation of a finished product or reproductive material arising out of the access to genetic heritage the user can choose between either monetary or non-monetary benefit-sharing. When the economic exploitation relates to access to associated traditional knowledge of unknown origin, benefit-sharing can only be monetary.[86]
h) Are there any specific provisions on how benefit-sharing should be dealt with respect to traditional knowledge hold by indigenous peoples and local communities?	Yes. See details in item f) below.

[81] Law 13.123, Article 18
[82] Law 13.123, Article 17, paragraph 4
[83] Law 13.123, Article 17, Paragraph 5
[84] Law 13.123, Article 17, Paragraph 5
[85] Law 13.123, Article 19
[86] Decree 8772, Article 47

i) Does the national legislation consider benefit-sharing arising from the utilisation of traditional knowledge for those cases in which it was accessed from secondary sources (publications, registries, databases, inventories, etc.), or when it is not possible to identify the peoples or communities that hold it?	Access to associated traditional knowledge in Brazil includes traditional knowledge obtained from secondary sources such as fairs, publications, inventories, films, scientific articles, registers and other forms of systematization and registration of associated traditional knowledge.[87] Furthermore, as mentioned above, benefit-sharing has to take place also when associated traditional knowledge is from unidentified origin. In these cases, the National Fund for the Distribution of Benefits will receive the benefit-sharing amount.

5. Monitoring and reporting	
a) What are the designated checkpoints? What are their functions and responsibilities? How do they work?	Given that Brazil has not yet ratified the Nagoya Protocol, it has not designated any checkpoints in that context. However, the Genetic Heritage Management Council (CGen) and other agencies act as checkpoints for the verification of compliance with the procedures established in accordance with the national legislation. The checkpoints at the national level are the following: • Genetic Heritage Management Council (CGen) – responsible for monitoring compliance relating to access to genetic heritage or associated traditional knowledge; shipment abroad of genetic heritage samples; and economic exploitation of finished product or reproductive material arising from the access to genetic heritage or associated traditional knowledge[88] • The patent office, National Institute of Industrial Property (INPI), verifies that intellectual property rights' applicants have complied with the ABS legislation[89] • Furthermore, other agencies listed under item d) below with a role in relation to tracking access to and utilisation of genetic heritage and associated traditional knowledge can potentially be considered as checkpoints. For this purpose, specific administrative procedures will be established.
b) What are the reporting requirements? Who is responsible for reporting?	Either the manufacturer of the finished product or the producer of the reproductive material are responsible for providing information, on an annual basis, relating to economic exploitation of each relevant finished product or reproductive material (based on benefit-sharing obligation as stated under 4.g).

[87] Law 13.123, Article 2, point IX
[88] Law 13.123, Article 6
[89] Law 13.123, Article 47

c) How can access to/utilisation of genetic resources and associated traditional knowledge be tracked? Has the country developed any particular method/mechanism to monitor the access and utilisation of genetic resources and/or associated traditional knowledge?	
d) Does the country have any monitoring systems for patent databases, registries of products resulting from access, and scientific publications so to identify activities that are not in compliance with the domestic legislation of the country where the access took place and with the Nagoya Protocol?	Yes. The Genetic Heritage Governing Council is responsible for maintaining a system that tracks activities related to access to genetic heritage or associated traditional knowledge, including activities related to economic exploitation.[90] The Brazilian tracking system builds on linkages to a number of databases such as those dealing with: 1. Protection and registration of cultivars, seeds and seedlings, agricultural products, establishments and inputs, information on the international transit of agricultural products and inputs (Ministry of Agriculture, Livestock and Supply); 2. import and export registration under the Integrated Foreign Trade System (Siscomex); 3. information on curricula, research groups, institutions registered in the Lattes Platform of the National Council for Scientific and Technological Development (CNPq); 4. information on research and commercial release of genetically modified organisms and derivatives, from the National Technical Biosafety Commission (CTNBio, under the Ministry of Science, Technology and Innovation); 5. registration of products (National Health Surveillance Agency, Anvisa); 6. concession of intellectual property rights (National Institute of Industrial Property, INPI); 7. national registry of social information (Ministry of Social Development); and 8. information on cultural heritage within the National System of Cultural Information and Indicators (SNIIC, under the Ministry of Culture).[91] Given that the databases are administered by different governmental agencies, the legislation in place allows for the establishment of the necessary arrangements to access the relevant information from them.[92] Furthermore, the national system of genetic heritage and associated traditional knowledge system (SisGen), created through Decree 8772/2016 and recently

[90] Decree 8772, Article 5
[91] Decree 8772, Article 5, paragraph 1
[92] Decree 8772, Article 5, paragraph 2

	released on 6 November 2017[93], will be the system through which to gather information relating to: access to genetic heritage and associated traditional knowledge; shipment abroad of samples; authorizations granted for access and shipment; institutions in which *ex situ* collections are maintained; and finished products or reproductive material.[94]

6. Compliance	
a) What are the competent authorities in charge of enforcement of the ABS legislation? Is compliance implemented in a centralised way (a single responsible body) or is it decentralised (several bodies with different competences)? What measures have been adopted to integrate/coordinate the actions of the bodies responsible for enforcing ABS rules at the national level? How to promote the integration/coordination of the various bodies responsible for enforcing ABS rules?	The Genetic Heritage Governing Council, established under the auspices of the Ministry of Environment, is responsible for coordinating the elaboration and implementation of policies for the management of access to genetic heritage and associated traditional knowledge and benefit-sharing. It consists of representatives of agencies and entities of the federal public administration that have competence over the various actions covered by Law 13.123. The maximum member participation is 60%; civil society makes up the remaining 40% of its members.[95] Other agencies with responsibility for monitoring compliance with ABS provisions include the National Security Council and the Navy Command (regarding shipment abroad)[96], the Ministry of Agriculture, Livestock and Supply or the National Institute of Industrial Property (INPI) (regarding plant varieties or other intellectual property rights respectively)[97], and the Brazilian Institute for the Environment and Natural Resources (IBAMA). Cooperation amongst the institutions that host the databases upon which the tracking system relies remains a crucial aspect in terms of monitoring of legal compliance. To foster cooperation among these institutions and to enable access to the relevant information that they gather, the ABS legislation allows for the establishment of the necessary arrangements.[98] This has been facilitated by the use of information and communication technologies; most of the databases are now electronically available. Moreover, both the SisGen and the tracking system are being designed as integrated systems, able to communicate with the rest of the databases indicated under item 4.d) above.
b) What measures have already been adopted to promote the effective monitoring of legal compliance?	

[93] Genetic Heritage Governing Council Executive Secretariat, Ordinance 1, October 2017
[94] Decree 8772, Article 20
[95] Law 13.123, Article 6
[96] Decree 8772, Articles 27-29
[97] Decree 8772, Article 29
[98] Decree 8772, Article 5, paragraph 2

	In accordance with the legislation, CGen's responsibility for monitoring activities of access and shipment of samples containing genetic heritage, and access to associated traditional knowledge, can be done in collaboration with federal bodies, or by agreement with other institutions.[99] Both the CGen and the management committee of the National Fund for Benefit-Sharing represent multiple bodies and institutions (government and civil society). This supports political articulation and dialogue between all parties involved.
c) Are there any measures foreseen in the national legislation to ensure benefit-sharing when access and utilisation of genetic resources and associated traditional knowledge occur outside the jurisdiction of the country where the access took place, especially when it is in a country that is not a Party to the Nagoya Protocol or when the user is based in a country that is not a Party?	If the finished product or the reproductive material has not been produced in Brazil, the importer, subsidiary, affiliate, or commercial representative of the foreign producer in the national territory or in the territory of countries with which Brazil has an agreement, responds jointly with the manufacturer of the finished product or the reproductive material for the sharing of benefits.[100]

7. Intellectual property rights (focusing on patents)	
a) How does the country deal with patentability of living organisms found in nature and of its components, such as DNA, molecules and metabolites?	In accordance with Industrial Patent Law 9279, living organisms or parts thereof are not patentable subject matter in Brazil, with the exception of transgenic microorganisms that meet the three requirements of patentability (novelty, inventive activity and industrial application), and which are not mere discovery. For the purposes of this Law, transgenic microorganisms are organisms, except plants or animals or parts thereof, which express, through direct human intervention in their genetic makeup, a characteristic not normally attainable by the species under natural conditions.[101]
b) Do patent applications include disclosure of origin among the requirements that need to be filled in by the applicant? Is it a mandatory or optional element? Is it only	Grant of any intellectual property right of a final product or reproductive material resulting from genetic heritage or associated traditional knowledge depends on registration or approval in accordance with the procedures established through Law 13.123.[102]

[99] Law 13.123, Article 6
[100] Law 13.123, Article 17
[101] Law 9279, Article 18
[102] Law 13.123, Article 47

related to genetic resources or also to the associated traditional knowledge?	

8. Supporting instruments for the implementation of ABS legislation	
a) Does the legislation consider the development of community protocols related to access to traditional knowledge associated with genetic resources? If so, has the country developed them so far?	Article 9 of Law 13.123 states that the confirmation of prior informed consent can be up to the criteria of the indigenous population, traditional community or traditional farmer and can be regulated through accession in accordance with community protocols. [103] The National Fund for Benefit-Sharing (Fundo Nacional para a Repartição de Benefícios – FRNB) can support projects and activities related to the development of community protocols.[104] Some examples of community protocols in the country are: the Protocolo Comunitário Biocultural das Raizeiras do Cerrado[105] and the Protocolo Comunitário do Arquipélago do Bailique in collaboration with the Amazon Working Group (Grupo de Trabalho Amazônico)[106]. This last group has created, in collaboration with CGen, a booklet "Methodology for Community Protocols".[107]
b) Has the country developed any guidelines, codes of conduct, best practices or standards related to the implementation of their ABS legislation? If so, which ones?	Yes. The legislation is quite recent and therefore the institutional arrangements and means to facilitate its implementation are being established gradually. A sourcebook targeted at traditional communities is already available[108] and a handbook for SisGen users has also been released.[109] Additional handbooks and guidelines are being developed, for example relating to the negotiation of benefit-sharing agreements, and the implementation of community protocols. Some of this material will be released soon.
c) Does the legislation include any model contractual clauses/standard agreement to be used for exchange of materials and establishment of MAT?	While not included in the Law or in the decree, the CGen has been working on the development of a standard material transfer agreement and model contractual clauses. For example, in 2016 the CGen approved the minimum content that needs to be contained in material transfer agreements[110] required to register shipment of genetic heritage.[111]

[103] Law 13.123, Article 9
[104] Decree 8.772, Article 100, Paragraph 2
[105] https://www.cbd.int/financial/micro/brazil-cerrado-raizeiras.pdf
[106] http://www.gta.org.br/protocolo-comunitario/
[107] http://www.gta.org.br/newspost/metodologia-de-criacao-de-protocolo-comunitario-no-amapa-e-divulgada-em-cartilha/
[108] See http://www.mma.gov.br/images/_noticias_fotos/2018/Guia_PG.pdf
[109] E.g. Handbook for SisGen users, available at https://sisgen.gov.br/download/Manual_SisGen.pdf
[110] Material transfer agreement model, available at http://www.mma.gov.br/images/arquivo/80043/resolucoes/res1-cgen.pdf
[111] Decree 8772, Article 25

	Moreover, it is important that the legislation provides the minimum standards, content and aspects that need to be considered within benefit-sharing agreements.[112] With respect to the access to associated traditional knowledge, the model clauses can only be established or developed by the providers, for example in community protocols. In relation to access to genetic heritage, the Ministry of Environment is currently working on the development of model contractual clauses that will be made available in the Ministry's website as soon as they are finalised.

9. Key challenges of implementation	
Identified challenge	Brief explanation
Uneven availability of scientific knowledge of existing species and the use of biodiversity in research and development in different sectors	Brazil's vast geography and biodiversity, with astonishing richness of biomes, ecosystems, species and people, poses a challenge for the implementation of biodiversity policies. In general, at the global level, there is a bias in knowledge among taxa and ecosystems, where most species remain unknown or unstudied, while only some attract more attention and funding. Additionally, differences in economic resources, development, language and geographical location play an important role in the resulting divergence of scientific knowledge within the country, among regions and states. It has been estimated that Brazil is home to 170-210 thousand known species (which corresponds, roughly to 10% of all known biota in the world). Projections calculate that there are 1.8 million species, meaning there are great gaps in Brazilian biodiversity knowledge.[113] Despite the efforts that Brazil has invested to increase biodiversity knowledge, some ecosystems and species have been studied more than others. Some of the barriers mentioned above play a role in this bias. In this regard, to cite an example, Joly et al reported in 2011 that in the directory of the Brazilian National Council for Scientific and Technological Development, only 3 of the 25 registered research groups are focused on marine ecosystems.[114] This situation of course also affects the implementation of ABS policies.
Extent of and diversity within the national territory	Beyond the large extension and outstanding biological diversity of the Brazilian territory, implementation of the ABS framework needs to also take due consideration of the existing

[112] Law 13.123, Article 26
[113] Lewinsohn, T. M. and Prado, P. I., 2005. "How Many Species Are There in Brazil?" Conservation Biology 19, pp. 619-24.
[114] Joly, C. A. et al., 2011. Diagnóstico da pesquisa em biodiversidade no Brasil. Rev. USP [online], n.89, pp. 114-133. Available at: http://rusp.scielo.br/scielo.php?script=sci_arttext&pid=S0103-99892011000200009&lng=pt&nrm=iso. ISSN 0103-9989.

	social, economic, and technological diversity. Therefore, all instruments created by the ABS framework must consider the large number of variables and problems encountered in the attempt to reach solutions that will allow for an effective implementation of the ABS system throughout the national territory. To illustrate, building capacity of providers of traditional knowledge associated with genetic heritage need to be carefully thought through given the wide range of languages and dialects found across the territory.

4.2 Colombia

Colombia has not yet ratified the Nagoya Protocol. However, as member of the Andean Community, its ABS framework has been shaped around the regional framework developed in the early days of the Convention on Biological Diversity to regulate the access to genetic resources, their by-products and associated intangible component. In this respect, Decision 391 (1996) related to the common regime on the access to genetic resources, and Decision 486 (2000) on the common regime for industrial property play a crucial role in this regard. At the domestic level, the following are also key measures for access and benefit-sharing:

- Resolution 620 of 1997 that specifies the process to be followed domestically with respect to the applications for access to genetic resources and their by-products.
- Decree 1375 of 2013 related to biological collection; and Decree1376 of 2013 that regulates permit process for requesting permits for collecting wild species for non-commercial scientific research. These are currently compiled within Decree 1076 of 2015.
- Resolution 1348 of 2014 that indicates the activities that constitute access to genetic resources and their by-products for the application of Decision 391 in Colombia, and Resolution 1352 of 2017 that modified some of the provisions in Resolution 1348 of 2014.

1. Definition of key terms	
a) Definition of access to genetic resources and associated traditional knowledge	Access: obtaining and use of genetic resources conserved in *ex situ* and *in situ* conditions, as well as of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things[115]
b) Definition of collection	Biological collection: Set of specimens of biological diversity preserved under standards of specialized curatorship for each of the groups deposited therein, which must be properly catalogued, maintained and organized taxonomically, in accordance with the provisions of the respective management protocol, which constitute the Nation's assets and which are under the administration of a natural or legal person, such as herbaria, natural history museums, germplasm banks, tissue and DNA banks, gene libraries and bacterial culture collections, and others as considered by the Ministry of Environment and Sustainable Development[116] (*definition applicable for the application of Decree 1375 of 2013 relating to biological collections*) Collection of specimens: Processes of capture, removal or temporary or permanent extraction of biological specimens from the natural environment for obtaining scientific information for non-commercial purposes, inventories integration, or to increase resources of scientific or

[115] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[116] Decree 1375 of 2013, Article 3

	museum collections[117] (*definition applicable for the application of Decree 1376 of 2013 relating to permit process for permits for collecting wild species for non-commercial scientific research*)
c) Definition of utilisation of genetic resources and associated traditional knowledge	The term "utilisation" is not defined in the ABS legal framework.
d) Definition of bioprospecting	Not defined in the ABS legislation. However, there is a definition of bioprospecting in the document CONPES 3697 of 2011 "Policy for the commercial development of biotechnology through the sustainable use of biodiversity"[118], which states that bioprospecting is the systematic and sustainable exploration of biodiversity in order to identify and obtain new chemical compounds, genes, proteins, microorganisms and other products that can be utilised for their commercial potential.
e) Others definitions of relevance? E.g. biological resources, in situ conservation; indigenous species; benefit-sharing, derivative; genetic resources; genetic material	**Biological resources:** individuals, organisms or parts of them, populations or any biotic component of value or of real or potential use that contains a genetic resource, or its by-products[119] **Genetic resources:** all biological material that contains genetic information of value or of real or potential use [120] **By-product:** a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings[121] **Country of origin of the genetic resource**: country that possesses genetic resources in *in situ* conditions, including those which, having been in *in situ* conditions, are now in *ex situ* conditions[122] ***Ex situ* conditions:** those in which the genetic resources are not found in *in situ* conditions[123] ***In situ* conditions:** those 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[124]

[117] Decree 1376 of 2013, Article 3
[118] Available at https://www.cbd.int/doc/measures/abs/post-protocol/msr-abs-co-es.pdf
[119] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[120] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[121] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[122] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[123] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[124] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1

	Intangible component: all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes[125] **Native, Afro-American or local community**: a human group whose social, cultural and economic conditions distinguish it from other sectors of the national community, that is governed totally or partially by its own customs or traditions or by special legislation and that, irrespective of its legal status, conserves its own social, economic, cultural and political institutions or a part of them[126] **Supplier of the biological resource**: a person empowered by this Decision and complementary national legislation to supply the biological resource that contains the genetic resource, or its by-products[127] **Supplier of the intangible component**: a person that, through an access contract and pursuant to this Decision and to complementary national legislation, is empowered to supply the intangible component associated with the genetic resource or its by-products[128] **Synthesized product**: a substance obtained through the artificial processing of genetic information or of information from other biological molecules. Includes semi-processed extracts and substances obtained by converting a by-product through an artificial process (hemisynthesis)[129] **Biotechnology**: any technological application that utilises biological systems or live organisms, parts of them or their by-products, to create or modify products or processes for specific uses[130]
2. General information	
a) To whom do genetic resources belong? Are these considered private goods, goods of common use by the	In accordance with CAN Decision 391 the Member Countries exercise sovereignty over their genetic resources and their by-products and consequently determine the conditions for access

[125] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[126] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[127] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[128] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[129] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[130] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1

population, public goods or do they belong to the State, etc.?	to them.[131] Furthermore, it indicates that genetic resources and their by-products which originated in the Member Countries are goods belonging to or the heritage of the Nation or of the State in each Member Country, as stipulated in their respective national legislation.[132] Genetic resources in Colombia belong to the State, hence inalienable, imprescriptible and guaranteed against seizure. Consequently, their use requires approval from the Colombian government through the Ministry of Environment.[133] Furthermore, the Constitution stipulates that the State will regulate the entry and exit of genetic resources from the country, as well as their utilisation in accordance with the national interest.[134] The National Code for Renewable Natural Resources and Protection of the Environment stipulates that renewable natural resources and other environmental aspects within the national territory, and regulated by the Code, belong to the Nation.[135] The environment is considered common heritage.[136] In accordance with the National Constitution, it is the State's and the people obligation to protect the natural and cultural assets of the country.[137] The State is in charge of regulating the management and use of natural resources.[138] Public goods and communal lands, among others, are inalienable, imprescriptible and guaranteed against seizure.[139]
b) Does the legislation provide any indication on when it is considered that species have developed their own characteristics, i.e. distinctive properties, to start being considered a genetic resource of that country?	In accordance with Regulation 1348 of 2014 only native species are subject to the regime relating to access to genetic resources and their by-products. As such, species that have been introduced are not subject to this regime as they are not considered native to Colombia.[140] Importantly, even species that have been domesticated for many years in Colombia, where they have developed unique properties due to the specific environmental conditions (e.g. coffee) fall outside the ABS regime.

[131] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 5
[132] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 6
[133] See http://www.minambiente.gov.co/index.php/component/content/article?id=782:plantilla-bosques-biodiversidad-y-servicios-ecosistematicos-57
[134] Political Constitution of Colombia, Article 81
[135] Legislative Decree 2811 of 1974, National Code of Renewable Natural Resources and Environmental Protection, Article 42
[136] Legislative Decree 2811 of 1974, National Code of Renewable Natural Resources and Environmental Protection, Article 1
[137] Political Constitution of Colombia, Article 8
[138] Political Constitution of Colombia, Article 80
[139] Political Constitution of Colombia, Article 63
[140] Resolution 1348 of 2014, Article 2

	There is no single inventory of native species in Colombia. However, the ABS authorities have access to a number of catalogues[141] and literature, relating to the origin and distribution of species, that they use when analysing the ABS applications.
c) Objective of the ABS legislation	The purpose of Decision 391 is to regulate access to the genetic resources of Member Countries of the Andean Community and their by-products, in order to: • Establish the conditions for fair and equitable participation in the benefits of the access • Lay the foundations for the recognition and valuation of genetic resources and their by-products and of their associated intangible components, especially when native, Afro-American or local communities are involved • Promote the conservation of biological diversity and the sustainable use of the biological resources that contain genetic resources • Promote the strengthening and development of scientific, technological and technical capacities at the local, national and sub-regional levels; and Strengthen the negotiating capacity of the Member Countries.[142]
d) Scope of the legislation – does it refer to all genetic resources or only to a subset (e.g. genetic resources for food and agriculture)? Are there any exemptions of genetic resources that fall outside of the scope (e.g. human genetic resources)?	Decision 391 applies to genetic resources- for which the Member Countries are the countries of origin- their by-products, their intangible components and genetic resources of migratory species that for natural reasons are found in the territories of those countries. In turn, the following are **excluded** from the scope of the Decision: • Human genetic resources and their by-products; and • The exchange of genetic resources, their by-products, the biological resources containing them, or their associated intangible components among native, Afro-American and local communities of the Member Countries for their own consumption, based on their customary practices. [143] In addition to the provisions included in Decision 391, Colombia adopted a resolution that further defines the **activities that constitute access** to genetic resources and their by-products. In particular, the following activities constitute access to genetic resources and their by-products in Colombia, when carried out with native species (wild, domesticated, cultivated or

[141] For example, see http://catalogo.biodiversidad.co/ and http://catalogoplantasdecolombia.unal.edu.co/en/
[142] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 2
[143] CAN, Decision 391 Common Regime on Access to Genetic Resources, Articles 3 and 4

	escaped from domestication), including viruses, viroid or similar that are within or outside the national territory: • Activities aimed at separating functional and non-functional units[144] of DNA and/or RNA, in any of the forms in which these are found in nature • Activities aimed at isolating one or various (micro or macromolecules) molecules produced by the metabolism of an organism.[145] The following activities do not constitute access to genetic resources and their by-products: • Activities identified in the points above that are carried out on genetic resources and products derived from introduced species (wild, domesticated, cultivated or escaped from domestication) and human genetic resources[146] • Basic scientific research for non-commercial purposes that uses biological collections and that involves activities of molecular systematics, molecular ecology, evolution and molecular biogeography[147] • Basic scientific research carried out within the framework of a permit for the collection of specimens of wild species of biological diversity for non-commercial purposes and involving activities of molecular systematics, molecular ecology, evolution and biogeography.[148]
e) Is ABS regulated at the national or subnational level? To what extent does the national government share competencies with subnational entities?	In Colombia, ABS is regulated at the national level, with the national government being responsible for the management, control and oversight of activities relating to access to Colombian genetic heritage and associated traditional knowledge either for research or technological development, or commercial exploitation. In particular, the Ministry of Environment has the following functions:

[144] In this context, the following definitions apply: (i) functional units of heredity: those that contain a gene code or that perform any molecular activity; and (ii) non-functional units of heredity: those for which a functionality has not been identified (Resolution 1348 of 2014, Article 2)
[145] Resolution 1348 of 2014, Article 2
[146] Resolution 1348 of 2014, Article 2, paragraph 2
[147] Decree 1375 of 2013
[148] Decree 1376 of 2013. This does not exempt the researcher from supplying information related to the Colombia's Biodiversity Information System (SIB) and sending it digitally to the Ministry of Environment and Sustainable Development

	• Coordinate, promote and provide guidance for research activities relating to the environment and renewable natural resources; establish the environmental information system and organise the inventory of national biodiversity and genetic resources[149] • Regulate the obtaining, use, management, research, import, export and distribution and trade of species and genetic stocks of wild flora and fauna • Regulate the import, export and trade of such genetic material; establish control and surveillance mechanisms and procedures, and make the necessary arrangements to claim for the payment or recognition of the rights and royalties generated due to the use of the Nation's genetic material[150] • Administer the National Environment Fund (Fondo Nacional Ambiental, FONAM)[151]-FONAM collects economic resources resulting from environmental activities- and administer these funds through various accounts. One of these accounts is where resources received due to access to genetic resources and their derivatives are deposited • Monitor to ensure that the examination, exploration and research carried out by nationals or foreigners on the country's renewable natural resources respects the national sovereignty and rights of the Nation over its genetic resources.[152]

3. Access to genetic resources and associated traditional knowledge	
a) According to the legislation, is access to genetic resources and/or associated traditional knowledge subject to prior informed consent (PIC)?	Yes. In Colombia, access to genetic resources, their derivatives and associated traditional knowledge requires concluding a contract of access, with PIC being part of that process.[153] PIC is a separate document from the contract. In particular, when access to genetic resources is expected to take place in areas where there are ethnic groups or when the project involves use of traditional knowledge, an additional requirement is considered when presenting the application for a contract of access (or ultimately before subscribing the contract). In accordance with Law 21 of 1991 through which the Convention concerning Indigenous and Tribal Peoples in Independent Countries of the

[149] Law 99 of 1993, Article 5(20)
[150] Law 99 of 1993, Article 5(21)
[151] Law 99 of 1993, Article 5(37)
[152] Law 99 of 1993, Article 5(38)
[153] Colombia National Implementation of Access & Benefit-Sharing for Non-Commercial Academic Research https://naturwissenschaften.ch/uuid/020159ab-66b3-53e8-8b3c-0555949d1883?r=20170706115333_1499300236_1996edb4-9d19-55ad-b4f0-0c3b84f5cdb4

	International Labour Organization (known as Convention 169) was approved in Colombia, the application for access needs to include a certificate regarding the presence of ethnic groups in the areas where research will be taking place, and evidence of prior consultation with ethnic groups (notarised document of the prior consultation with ethnic groups, to be formalised at the Ministry of the Interior). In case of not having it at the time of the request, this will not be cause for rejection but will be a prerequisite for signing the contract and must be provided in order for the application to be assessed.[154] Further, Decree 1320 of 1998 regulates prior consultation with indigenous and Afro-American communities for the exploitation of natural resources within their territory. It specifies the process to be followed for the prior consultation relating to permits for use and utilisation of renewable natural resources, though specific reference to genetic resources is not made.[155]
b) Does the legislation establish rules/procedures for requiring and establishing mutually agreed terms (MAT)?	Yes. As mentioned, access to genetic resources, their by-products and intangible component in Colombia is materialised through a contract of access that sets the conditions under which access is granted.[156] In accordance with Decision 391 an access contract is an agreement between the Competent National Authority in representation of the State and a person. It establishes the terms and conditions for access to genetic resources, their by-products and, if applicable, the associated intangible component.[157] In Colombia, the process for applying to a contract of access allows for both natural and legal persons to do so. When done by a legal person, additional supporting documents are required (e.g. evidence regarding existence and legal representation of the entity).[158] In Colombia, the Ministry of Environment and Sustainable Development is the entity responsible for entering this agreement with the applicant. There are two types of contracts: • Contract of access ("*Contrato individual de acesso a recursos genéticos y sus productos derivados")*, applicable for commercial, industrial or bioprospecting purposes

[154] Rojas, P. A. et al., 2016. Manual de solicitud del contrato de acceso a recursos genéticos y sus productos derivados en Colombia. Ministerio de Ambiente y Desarrollo Sostenible. Bogotá, Colombia. 122 pp.
[155] Decree 1320 of 1998
[156] Colombia National Implementation Of Access & Benefit-Sharing For Non-Commercial Academic Research https://naturwissenschaften.ch/uuid/020159ab-66b3-53e8-8b3c-0555949d1883?r=20170706115333_1499300236_1996edb4-9d19-55ad-b4f0-0c3b84f5cdb4
[157] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[158] Rojas, P. A., et al., 2016. Manual de solicitud del contrato de acceso a recursos genéticos y sus productos derivados en Colombia. Ministerio de Ambiente y Desarrollo Sostenible. Bogotá, Colombia. 122 pp.

	• Framework contract of access ("*Contrato Marco de acesso a recursos genéticos y sus productos derivados")*, applicable for basic research and bioprospecting.[159] In addition to the access contracts, there is a specific type of contract, accessory contracts to the access contract, applicable to the development of activities related to the access to genetic resources or their by-products. These accessory contracts are to be concluded between: • the owner, holder or administrator of the land where the biological resource containing the genetic resource is found • the *ex situ* conservation centre • the owner, holder or administrator of the biological resource containing the genetic resource • the provider of the intangible component associated with the genetic resource and the national institution of support with respect to the activities that it needs to undertake and which are not already included in the access contract. If the provider of the associated traditional knowledge is an indigenous people or community, the contract should be developed in accordance with national and international provisions for the protection of traditional knowledge of indigenous peoples and communities. Accessory contracts do not authorise access to genetic resources or their by-products, and their content is subject to the provisions in the access contract. If an access contract is revoked, then this will also apply to the related accessory contract.[160] Resolution 620 of 1997 describes the procedure for processing applications for access to genetic resources and their by-products products.[161] The period of validity of access contracts in Colombia usually considers the period proposed by the applicant. Contracts involving a commercial purpose will extend up to 20 years, as this is the term of protection of patents.
c) Does the legislation set out criteria for the approval and involvement of indigenous and local communities for access to genetic resources and associated traditional knowledge?	Decision 391 stipulates that Member Countries recognize and value the rights and the authority of the native, Afro-American and local communities to decide about their know-how, innovations and traditional practices associated with genetic resources and their by-products.[162] In this regard, 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 that contract, an annex

[159]CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 36
[160] CAN, Decision 391 Common Regime on Access to Genetic Resources, Articles 41 and 44
[161] Resolution 620 de 1997, Preamble
[162] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 7

	stipulating the fair and equitable distribution of the profits from use of that component. Failure to comply with the stipulations of the annex shall constitute grounds for the rescission and nullification of the access contract.[163] Further, in accordance with the Constitution of Colombia, for any decisions related to the exploitation of natural resources in indigenous lands, the Government shall promote the participation of the representatives from the relevant indigenous communities.[164] In this respect, as mentioned in item 3.a) above, when access to genetic resources is expected to take place in areas where there are ethnic groups or when the project involves use of traditional knowledge, the application for access needs to include a certificate regarding the presence of ethnic groups in the areas where research will be taking place, and evidence of the prior consultation with ethnic groups.[165] For situations in which the application for access entails access to associated traditional knowledge, or when prior consultation with ethnic communities is required, different dependencies of the Ministry of Environment will work towards safeguarding the rights of those communities.[166]
e) Does the legislation consider any simplified measures on access for non-commercial research purposes; or for cases of present or imminent emergencies that threaten or damage human, animal or plant health?	Yes. Under the Colombian framework, some cases are not regarded as access to genetic resources and their by-products. As a result, these activities do not require a contract of access. This specifically relates to basic research activities relating to molecular systematics, molecular ecology and/or biogeography.[167]
d) Does the legislation address any changes of intent in the utilisation of accessed genetic resources? (e.g. initially accessed for non-commercial research and then changing their utilisation to commercial)	Yes. Based on the procedures in place, modification of access contracts is not allowed when there is a change in the nature or objective of the specific project. As a result, when there is a change of intent in the utilisation of the accessed genetic resources or associated traditional knowledge, a new application needs to be presented to the Ministry of Environment.
f) Are there any specific provisions/piece of law related to genetic resources for food and agriculture?	The measures in place do not make reference to specific sectors.

[163] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 35
[164] Political Constitution of Colombia, Article 330
[165] Rojas, P. A. et al., 2016. Manual de solicitud del contrato de acceso a recursos genéticos y sus productos derivados en Colombia. Ministerio de Ambiente y Desarrollo Sostenible. Bogotá, Colombia. 122 pp.
[166] Rojas, P. A. et al., 2016. Manual de solicitud del contrato de acceso a recursos genéticos y sus productos derivados en Colombia. Ministerio de Ambiente y Desarrollo Sostenible. Bogotá, Colombia. 122 pp.
[167] Decree 1376 of 2013, paragraph 5

4. Benefit-sharing	
a) What triggers benefit-sharing? Does any utilisation of genetic resources create a benefit-sharing obligation, even if it does not add value to the product or market?	Decision 391 does not establish a detailed benefit-sharing mechanism. However, it indicates that when access is requested to genetic resources or their by-products or intangible component, the access contract needs to incorporate, as an integral part of that contract, an annex stipulating the fair and equitable distribution of the benefits derived from the utilisation of such component.[168] In Colombia, the one who carries out access activities is the one responsible for sharing benefits. In practice, when an access contract is subscribed for bioprospecting purposes, non-monetary benefits are agreed. If the contract is agreed for commercial or industrial purposes, both monetary and non-monetary benefits are considered. Currently, benefit-sharing is assessed following a series of steps/criteria such as sector, size of the company, species to be utilised, etc. The benefit-sharing mechanism could entail milestone payments, a percentage of sold products, or patents licensing that would be attributed to the Colombian government. Decree 3570 of 2011 mandates the Office of Green and Sustainable Businesses (Oficina de negocios verdes y sostenibles) to propose and support the adoption of mechanisms for the fair and equitable distribution of benefits derived from access to genetic resources, and participate in the formulation of strategic elements to ensure that intellectual property systems respect the rights over the country's biological and genetic resources.[169] The Office of Green and Sustainable Businesses is currently working on the development of legislation to regulate benefit-sharing.
b) Does the national legislation exempt benefit-sharing arising from any particular utilisation (research and development), even if the CBD support the sharing of the benefits arising from such activities?	No. The only activities that do not require benefit-sharing are those that do not constitute access and are therefore not subject to ABS measures. When the aim of the access is non-commercial research, basic research activities relating to molecular systematics, molecular ecology and/or biogeography are exempted of concluding an access contract for access to genetic resources and their by-products, therefore not being subject to benefit-sharing.

[168] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 35
[169] Decree 3570 of 2011, Article 9(13)

c) How does the national legislation define the amount to be paid as benefit-sharing? Does it establish a fixed percentage for benefit-sharing?	Such amount is not defined in the legislation. In practice, the Ministry makes a benefit-sharing proposal to the applicant. This is used as a basis for the contract negotiation. Once the applicant and the Ministry reach an agreement, they sign the contract. The Office of Green and Sustainable Businesses is currently working on the development of legislation to regulate benefit-sharing.
d) Who should pay for the benefits to be shared (the one who carries out access to/utilisation of genetic resources and the associated traditional knowledge, the one who undertakes the economic exploitation, or both)?	Anyone carrying out access activities with native species (wild, domesticated, cultivated or escaped from domestication), including viruses, viroid or similar that are within or outside the national territory for bioprospecting, commercial or industrial purposes should pay benefits. These activities are the ones under the scope of the ABS regime as indicates under item 2.d), namely: • Activities aimed at separating functional and non-functional units[170] of DNA and/or RNA, in any of the forms in which these are found in nature; • Activities aimed at isolating one or various (micro or macro) molecules produced by the metabolism of an organism.[171] Likewise, patent applications for inventions that result from genetic resources or their by-products also require that a copy of the access contract is presented to the patent office thus entailing the need for benefit-sharing provisions to also be considered.[172]
e) Where within the production chain rests the obligation to pay benefits? o supplier of raw material, o intermediary, o final product ready for commercialisation, or o all	Regarding who is responsible for paying benefits, it is decided on a case by case basis based on each access application. The responsibility relies on the first one carrying out access activities. For example, if a company produces a raw material and sells it to another company for its further processing, only the first one would pay benefits. When the same company is the one that follows the entire production chain, then it is the one responsible for paying.
f) Is there anyone else that needs to share benefits? For example, non-commercial research, commercial research,	• In Colombia, contracts for both commercial and non-commercial activities require benefit-sharing. The difference relies on the type of benefits being shared. While it is possible for

[170] In this context, the following definitions apply: (i) functional units of heredity: those that contain a gene code or that perform any molecular activity; and (ii) non-functional units of heredity: those for which a functionality has not been identified (Resolution 1348 of 2014, Article 2)
[171] Resolution 1348 of 2014, Article 2
[172] Resolution 1352 of 2017, Article 2

intellectual property rights licensing, the whole value chain of an industry or the one with the greater added value?	non-commercial activities not to include monetary benefits; commercial activities always require monetary benefit-sharing.
g) Does the legislation provide an indication of what can constitute (monetary and non-monetary) benefits to be shared?	Decision 391 does not provide a list of potential monetary and non-monetary benefits to be considered, and in the other measures in force in Colombia there is no such indication either. Legislation is being developed to address monetary and non-monetary benefit-sharing.
h) Are there any specific provisions on how benefit-sharing should be dealt with respect to traditional knowledge hold by indigenous peoples and local communities?	As indicated in item 3.c) above, according to Decision 391, 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 that contract, an annex stipulating the fair and equitable distribution of the profits from use of that component. Such annex needs to be signed by the supplier of the intangible component and the applicant for the access.[173]
i) Does the national legislation consider benefit-sharing arising from the utilisation of traditional knowledge for those cases in which it was accessed from secondary sources (publications, registries, databases, inventories, etc.), or when it is not possible to identify the peoples or communities that hold it?	When intending to use genetic and chemical information available in databases or through any other public or private means of dissemination, an access contract needs to be subscribed with the Ministry of Environment (if the mentioned information is as found in nature). With respect to traditional knowledge, if it is available in databases or publicly available through any other means, it is then not considered traditional knowledge. For knowledge to be considered traditional knowledge, it cannot be public knowledge or knowledge publicly available because otherwise it would be part of the public domain and can then be freely utilised. Regarding situations in which it is not possible to identify the traditional knowledge holders, no specific procedures have been set up. Even though the government guarantees the rights of ethnic groups over their traditional knowledge, there are no mechanisms established for the protection of such knowledge (particularly, no inventory or registry of traditional knowledge of ethnic groups in Colombia exists).

5. Monitoring and reporting	
a) What are the designated checkpoints? What are their functions and responsibilities? How do they work?	Given that Colombia has not yet ratified the Nagoya Protocol, it has not designated any checkpoints in that context. However, some of the national agencies act as checkpoints for the verification of compliance with the procedures established in accordance with the national legislation. The checkpoints at the national level are the following: • Ministry of Environment

[173] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 35

	• National intellectual property office: according to Decisions 391 and 486, the IP office must require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when the products or processes for which property rights are being claimed have been obtained or developed from genetic resources or their by-products on which one of the Member Countries is country of origin (in this case, Colombia).[174] In this respect, based on Resolution 1352 of 2017, when a patent application is submitted for products or procedures obtained or developed from genetic resources or their by-products, the applicant must present a copy of the access contract.[175] • Colciencias (Administrative Department of Science, Technology and Innovation, government agency responsible for leading science, technology and innovation policy in Colombia): in order to provide funding or support for research projects, one of the requirements entails presentation of relevant environmental permits, including contract of access.
b) What are the reporting requirements? Who is responsible for reporting?	According to the reference contract model developed in the context of the Andean Community, the applicant needs to submit the national competent authority reports and other publications developed as a result of the accessed genetic resources.
c) How can access to/utilisation of genetic resources and associated traditional knowledge be tracked? Has the country developed any particular method/mechanism to monitor the access and utilisation of genetic resources and/or associated traditional knowledge?	The Ministry of Environment and Sustainable Development monitors compliance with the terms and conditions of the contracts of access. For this purpose, a mechanism to monitor the signed access contracts for genetic resources and their by-products was established. In particular, the Ministry manages a database through which they can verify the progress of reports that are being submitted by applicants (status of the monitoring exercise is published on the website of the Ministry of Environment).[176]
d) Does the country have any monitoring systems for patent databases, registries of products resulting from access, and scientific publications so to identify activities that are not in compliance with the domestic legislation of	The monitoring system in place is the one mentioned in item 5.c) above.

[174] CAN, Decision 391 Common Regime on Access to Genetic Resources, Third Complementary provision
[175] Resolution 1352 of 2017
[176] See http://www.minambiente.gov.co/index.php/bosques-biodiversidad-y-servicios-ecosistematicos/recursos-geneticos E.g. http://www.minambiente.gov.co/images/BosquesBiodiversidadyServiciosEcosistemicos/pdf/Recursos_Gen%C3%A9ticos_/seguimiento_EXp_CARG_MAYO2018.pdf

the country where the access took place and with the Nagoya Protocol?	

6. Compliance	
a) What are the competent authorities in charge of enforcement of the ABS legislation? Is compliance implemented in a centralised way (a single responsible body) or is it decentralised (several bodies with different competences)? What measures have been adopted to integrate/coordinate the actions of the bodies responsible for enforcing ABS rules at the national level? How to promote the integration/coordination of the various bodies responsible for enforcing ABS rules?	In Colombia, compliance is implemented in a centralised way. The national competent authority is the Ministry of Environment and Sustainable Development.[177] In particular, compliance falls under the responsibility of the Group on Genetic Resources, which is composed by a multidisciplinary team and is responsible for overseeing and monitoring compliance of the terms of the access contracts, as well as of the provisions in Decision 391.[178]
b) What measures have already been adopted to promote the effective monitoring of legal compliance?	The Ministry of Environment and Sustainable Development monitors compliance with the terms and conditions of the contracts of access. For this purpose, a mechanism to monitor the signed access contracts for genetic resources and their by-products was established. In particular, the Ministry manages a database through which they can verify if the progress reports are being submitted in time (the status of the monitoring exercise is published on the website of the Ministry of Environment).[179] Furthermore, as appropriate, the Ministry can organise visits to the place where access to the genetic resource and traditional knowledge is being carried out, with the objective of getting in contact with the user and helping them complying with the terms of the contract.[180] In addition, Decision 391 stipulates a series of sanctions for situations in which users do not comply with the measures in place. Some of these include: suspension or cancellation of the authorised access; fines; inability for the user to present new applications for access.[181] Based

[177] Resolution 620 of 1997; and Decree 3570 of 2011
[178] Resolution 620 of 1997, Article 1, item 5
[179] See http://www.minambiente.gov.co/index.php/bosques-biodiversidad-y-servicios-ecosistematicos/recursos-geneticos E.g. http://www.minambiente.gov.co/images/BosquesBiodiversidadyServiciosEcosistemicos/pdf/Recursos_Gen%C3%A9ticos_/seguimiento_EXp_CARG_Feb_2018.pdf
[180] Rojas, P. A. et al., 2016. Manual de solicitud del contrato de acceso a recursos genéticos y sus productos derivados en Colombia. Ministerio de Ambiente y Desarrollo Sostenible. Bogotá, Colombia. 122 pp
[181] CAN, Decision 391 Common Regime on Access to Genetic Resources, Articles 46 and 47

	on Decision 391 it is not only punitive to the person that carries out access without the required authorisation, but also any person that carries out transactions relating to by-products or synthesized products of such genetic resources or the associated intangible component, when these activities are not covered by the relevant contract/s.[182]
c) Are there any measures foreseen in the national legislation to ensure benefit-sharing when access and utilisation of genetic resources and associated traditional knowledge occur outside the jurisdiction of the country where the access took place, especially when it is in a country that is not a Party to the Nagoya Protocol or when the user is based in a country that is not a Party?	Even when access activities are not carried out in Colombia, access to native genetic resources and their by-products require signing of a contract. Compliance provisions are agreed as part of that contract signed with the Ministry of Environment, and as such the user is obliged to comply with them even when access takes place outside Colombia.

7. Intellectual property rights (focusing on patents)	
a) How does the country deal with patentability of living organisms found in nature and of its components, such as DNA, molecules and metabolites?	Decision 486 stipulates that plants, animals and essentially biological processes for the production of plants or animals that are not non-biological or microbiological processes are not patentable.[183] Moreover, the following are not considered inventions and therefore cannot be patented: • Discoveries • The entirety or part of living beings as encountered in nature, natural biological processes, biological material existing in nature or which may be isolated, including the genome or germplasm of any natural living being • Methods of presenting information[184] Where the patent protects biological material that can be reproduced, the patent shall not extend to the biological material obtained by reproduction, multiplication or propagation of the material that has been brought on to the market in any country by the owner of the patent, or by another person who has obtained his consent or is economically associated with him, provided that:

[182] CAN, Decision 391 Common Regime on Access to Genetic Resources, Articles 46 and 47
[183] CAN, Decision 486 Common Regime for Industrial Property, Article 20
[184] CAN, Decision 486 Common Regime for Industrial Property, Article 15

	• The reproduction, multiplication or propagation was necessary so that the material might be used to achieve the purposes for which it was brought on to the market; and • that the material derived from such use is not used for multiplication or propagation purposes.[185]
b) Do patent applications include disclosure of origin among the requirements that need to be filled in by the applicant? Is it a mandatory or optional element? Is it only related to genetic resources or also to the associated traditional knowledge?	Yes. The disclosure of origin is a mandatory requirement in Colombia. Decision 391 indicates that the Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components that were obtained or developed through an access activity that does not comply with the provisions of the Decision. Furthermore, the competent National Intellectual Property Offices must require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries. The Decision further indicates that the Competent National Authority and the Competent National Offices on Intellectual Property shall set up systems for exchanging information about the authorized access contracts and intellectual property rights granted.[186] The ABS authority in Colombia has regular communication with the competent authority for intellectual property. As a result, they are not only aware of patent applications being presented that relate to native genetic resources but also they give their views on whether the access contract should be approved or not. Among others, patent applications shall contain: • where applicable, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom, of which any of the member countries is the country of origin • where applicable, a copy of the document accrediting the licensing or authorization of the use of traditional knowledge of indigenous, Afro-American and local communities of Member Countries where the products or procedures for which protection is sought have

[185] CAN, Decision 486 Common Regime for Industrial Property, Article 54
[186] CAN, Decision 391 Common Regime on Access to Genetic Resources, Complementary provisions, Second and Third

	been obtained or developed from such knowledge of which any of the Member Countries is the country of origin, in accordance with the provisions of Decision 391.[187] The competent national authority shall declare the absolute invalidity of a patent at any time where a copy of the access contract has not been filed where the products or processes to which the patent application relates have been produced or developed with genetic resources or derived products of which any of the member countries is the country of origin; or a copy of the document evidencing the licensing or authorization of the use of traditional knowledge of the indigenous Afro-American or local communities of the member countries has not been filed where the products or processes for which protection is sought have been produced or developed on the basis of such knowledge of which one of the Member Countries is the country of origin.[188] As a result, when a patent application is submitted in Colombia for products or procedures obtained or developed from genetic resources or their derived products, the applicant must present a copy of the contract of access to the genetic resources and their by-products.[189]

8. Supporting instruments for the implementation of ABS legislation	
a) Does the legislation consider the development of community protocols related to access to traditional knowledge associated with genetic resources? If so, has the country developed them so far?	Community protocols are not mentioned in the Colombian legislation.
b) Has the country developed any guidelines, codes of conduct, best practices or standards related to the implementation of their ABS legislation? If so, which ones?	The Ministry of Environment of Colombia has recently developed a handbook describing the process of applying for and developing access contracts as well as monitoring (*Manual de solicitud del contrato de acceso a recursos genéticos y sus productos derivados en Colombia*).[190]
c) Does the legislation include any model contractual clauses/standard agreement to be used for exchange of materials and establishment of MAT?	In the context of the Andean Community, the following two regulations were adopted: 1. Reference model of application to request for access to genetic resources (Regulation 414)

[187] CAN, Decision 486 Common Regime for Industrial Property, Article 26
[188] CAN, Decision 486 Common Regime for Industrial Property, Article 75
[189] Resolution 1352 of 2017, Article 2
[190] Rojas, P. A. et al., 2016. Manual de solicitud del contrato de acceso a recursos genéticos y sus productos derivados en Colombia. Ministerio de Ambiente y Desarrollo Sostenible. Bogotá, Colombia. 122 pp

	2. Reference model contract of access to genetic resources (Regulation 415) – includes the different elements that could be included but does not provide model contractual clauses[191]

9. Key challenges of implementation	
Identified challenge	Brief explanation
Amount of time needed for getting approval for access to genetic resources	The key actions on which the government is currently working on relate to: • Reducing the amount of time needed to obtain access to genetic resources and their by-products, as well as the steps involved in these procedures • Advancing the regulation of access to genetic resources and their by-products, for example to provide for more detailed benefit-sharing mechanisms
Limited knowledge on genetic diversity in the country	Colombia is a megadiverse country and, as such, collecting information to develop the inventory of genetic resources is challenging.

[191] Both Regulations are available from http://intranet.comunidadandina.org/documentos/Gacetas/gace217.pdf

4.3 Ecuador

Ecuador is a Party to the Nagoya Protocol, which was ratified through Executive Decree No. 157/2017. As a Member Country of the Andean Community (CAN), decisions adopted at the regional level have subsequently been internalized in national legislation, mainly through Executive Decree No. 905 (2011), Regulation to the common regime on access to genetic resources, which is under review. This mainly covers Andean Decision 391 Common Regime on Access to Genetic Resources and Andean Decision 486 Common Regime on Industrial Property, both from the CAN.

It should be noted that, at the national level, recent legislative reforms became in place through the adoption of:

- Organic Code of the Environment 2017, in force from 12 April 2018 (regulations are currently being developed)[192]
- Organic Code of the Social Economy of Knowledge, Creativity and Innovation (2016, known as the Ingenios Code), and its regulations (Executive Decree No. 1435 of 2017)

As both Codes have been approved recently, detailed procedures for implementing their provisions are being developed. These are being done through the development of new regulatory instruments or updating of existing standards. In this sense, due to the modifications made to the entities responsible for ABS, Ecuador is currently working on the articulation of processes that would allow for the effective implementation of the system.

In this regard, Ecuador's regulatory framework for access and benefit-sharing is mainly composed of the above mentioned instruments. It is worth also highlighting the Constitution of the Republic of Ecuador (2008), which recognizes environmental principles and rights, in addition to establishing in Article 313 biodiversity and genetic heritage as a strategic resource of the Ecuadorian State.

1. Definition of key terms	
a) Definition of access to genetic resources and associated traditional knowledge	**Access:** obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things[193] **Access to genetic resources:** obtaining and use of genetic conserved in *ex situ* and *in situ* conditions, their derived products or, where applicable, their associated intangible components for research, prospecting, conservation, industrial application or commercial use, among others, through the signing of a Contract for the Authorization of Access to Genetic Resources and its conditions, concluded with the Competent National Environmental Authority[194]
b) Definition of collection	Not defined in legislation

[192] See http://www.ambiente.gob.ec/ecuador-inicia-proceso-participativo-para-la-creacion-del-reglamento-del-codigo-organico-del-ambiente/

[193] Executive Decree No 905, Regulation to the Common Regime on Access to Genetic Resources, Article 6 (same definition as in Decision 391 Common Regime on Access to Genetic Resources CAN, Article 1)

[194] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 6

c) Definition of utilisation of genetic resources and associated traditional knowledge	Potential use: determined according to interest for the pharmaceutical, food and agricultural, horticultural, cosmetic and other industries, or only for scientific and academic research[195] As Ecuador is a Party to the Nagoya Protocol, its definitions apply. Utilisation of genetic resources means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention[196]
d) Definition of bioprospecting	Bioprospecting: systematic search, classification and research, for commercial purposes, of new sources of chemical compounds, genes, proteins, microorganisms and other products with current or potential economic value found in biodiversity [197]
e) Others definitions of relevance? E.g. biological resources, in situ conservation; indigenous species; benefit-sharing, derivative; genetic resources; genetic material	Biological resources: individuals, organisms or parts thereof, populations or any biotic component of actual or potential value or use contained in the genetic resource or its derived products. [198] Genetic resources: any material of biological nature containing genetic information of actual or potential value or use[199] Genetic material: any material of plant, animal, microbial or from other origin which contains functional units of heredity[200] Genetic heritage: genetic material of real value or the potential of living beings that are within the national territory[201] Derivative product: a molecule, combination or mixture of natural molecules, including raw extracts of living or dead organisms of biological origin, derived from the metabolism of living beings[202]

[195] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 6
[196] Nagoya Protocol, Article 2
[197] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 6
[198] Executive Decree No 905, Regulation to the Common Regime on Access to Genetic Resources, Article 6 (same definition as in CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1)
[199] Executive Decree No 905, Regulation to the Common Regime on Access to Genetic Resources, Article 6 (same definition as in CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1)
[200] Organic Code on the Environment, 2017, Glossary of terminology. It should be noted that the Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Title II, Article 6 also includes a definition of "genetic material" (all material of plant, animal, microbial or other origin containing units (DNA) or ribonucleic acid (RNA) with determinant information on heredity traits transferable to offspring).
[201] Organic Code on the Environment, 2017, Glossary of terminology.
[202] Executive Decree No 905, Regulation to the Common Regime on Access to Genetic Resources, Article 6 (same definition as in CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1

	As Ecuador is a Party to the Nagoya Protocol, its definitions apply. **Derivative** means a biochemical compound that is naturally produced by the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity[203] **Synthesized product**: a substance obtained through the artificial processing of genetic information or of information from other biological molecules. Includes semi-processed extracts and substances obtained by converting a by-product through an artificial process (hemisynthesis)[204] **Biotrade**: set of activities comprising the collection, production, processing and commercialization of goods and services derived from native biodiversity, under criteria of environmental, social and economic sustainability[205] **Biopiracy**: It constitutes illicit means of appropriation of genetic heritage and traditional knowledge; collective knowledge and ancestral knowledge of original peoples and communities.[206] **Biotechnology**: any technological application that utilises biological systems and living organisms, or their derivatives, for the creation or modification of products or processes for specific uses.[207] **Intangible component**: all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes[208] **Traditional knowledge**: all collective knowledge, such as practices, methods, experiences, capabilities, signs and symbols of peoples, nationalities and communities, that are part of their cultural heritage, and that have been developed, updated and transmitted from generation to generation. Traditional knowledge is, among others, ancestral and local knowledge, the intangible component associated with genetic resources and traditional cultural expressions.

[203] Nagoya Protocol, Article 2
[204] Executive Decree No 905, Regulation to the Common Regime on Access to Genetic Resources, Article 6 (same definition as in CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[205] Organic Code on the Environment, 2017, Glossary of terminology
[206] Organic Code on the Environment, 2017, Glossary of terminology
[207] Organic Code on the Environment, 2017, Glossary of terminology
[208] Executive Decree No 905, Regulation to the Common Regime on Access to Genetic Resources, Article 6 (same definition as in CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1)

	This traditional knowledge can refer to ecological, climatic, agricultural, medicinal, artistic, artisanal, fishing, hunting matters, among others, which have been developed from the close relationship of human beings with territory and nature[209] Native, Afro-American or local community: a human group whose social, cultural and economic conditions distinguish it from other sectors of the national community, that is governed totally or partially by its own customs or traditions or by special legislation and that, irrespective of its legal status, conserves its own social, economic, cultural and political institutions or a part of them[210] Local community: for the purposes of this Regulation, it refers to the Communities, Peoples and Nationalities legally recognized by the Ecuadorian State.[211] *In situ* conditions: those 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[212] Country of origin of the genetic resource: country that possesses genetic resources in *in situ* conditions, including those which, having been in *in situ* conditions, are now in *ex situ* conditions[213] Supplier of the intangible component: a person that, through an access contract and pursuant to this Regulation and to complementary national legislation, is empowered to supply the intangible component associated with the genetic resource or its by-products[214] Supplier of the biological resource: a person empowered by this Regulation and complementary national legislation to supply the biological resource that contains the genetic resource or its by-products[215]

[209] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 511.
[210] CAN, Decision 391 Common Regime on Access to Genetic Resources, 1996, Article 1.
[211] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 6
[212] Executive Decree No 905, Regulation to the Common Regime on Access to Genetic Resources, Article 6 (same definition as in CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1)
[213] Executive Decree No 905, Regulation to the Common Regime on Access to Genetic Resources, Article 6 (same definition as in CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1)
[214] Executive Decree No 905, Regulation to the Common Regime on Access to Genetic Resources, Article 6 (same definition as in CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1)
[215] Executive Decree No 905, Regulation to the Common Regime on Access to Genetic Resources, Article 6 (same definition as in CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1)

2. General information	
a) To whom do genetic resources belong? Are these considered private goods, goods of common use by the population, public goods or do they belong to the State, etc.?	Decision 391 of the CAN establishes that each of the Member States exercises sovereignty over their genetic resources and their derivatives. In addition, the Decision adds that genetic resources and their derivative, for which Members are their countries of origin, are assets or heritage of the Nation or the State of each Member Country, in accordance with their domestic laws.[216] The Constitution of Ecuador indicates that biodiversity and its genetic heritage are property of the State that is inalienable, imprescriptible and guaranteed against seizure, a concept that is reaffirmed by the Ingenios Code.[217] It should however be noted that the State can grant authorizations or their utilisation or access through contracts, licenses, or others for their utilisation, without this implying that they are giving up their ownership.[218] Likewise, the Constitution emphasises that, as such, they can only be exploited in strict compliance with the environmental principles established in the Constitution, and that the State participates in the benefits of the utilisation of these resources, in an amount not lower than that of the company exploiting them.[219] In this regard, the Code also states that they cannot be privatised, and their access, use and exploitation will be carried out strategically, seeking the generation of endogenous knowledge and national technological development.[220] The Constitution also indicates that the State reserves the right to administer, regulate, control and manage strategic sectors, among which are biodiversity and genetic heritage. The strategic sectors under the exclusive control and decision of the State are those that, due to their importance and magnitude, have decisive economic, social, political or environmental influence, and should be oriented to the full development of their rights and social interest.[221] The Constitution also declares the conservation of biodiversity and all its components, in particular the agricultural and wild biodiversity and the genetic heritage of the country as of public

[216] CAN, Decision 391 Common Regime on Access to Genetic Resources, 1996, Articles 5 and 6
[217] Organic code of the Social Economy of the Knowledge, Creativity and Innovation, 2016, Article 4
[218] Ministry of the Environment of Ecuador "National Biodiversity Strategy 2015-2030, first edition, November 2016, Quito-Ecuador
[219] Constitution of Ecuador, Article 408
[220] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 4
[221] Constitution of Ecuador, Article 313

	interest.[222] In this regard, it should be noted that the Organic Code of the Environment also addresses the consideration of the genetic heritage of the territory's biodiversity as a strategic sector, and stipulates that the State shall administer and control the access to genetic resources, derivatives, synthesized and components thereof.[223] Another aspect to be highlighted is that in Ecuador, the rights granted over biological resources grant neither any rights over genetic resources or their derivatives, nor over the collective knowledge associated therewith. Administrative authorizations to the research, management, marketing or other activities of specimens, constitutive elements and by-products of wildlife species do not authorize access to their genetic resources or their derivatives. [224] Moreover, the Regulation of the Andean Decision 391, in Ecuador, stipulates that genetic resources constitute national goods for public use. These resources are inalienable, imprescriptible and indefeasible, sovereignly managed with social and environmental responsibility, without prejudice to applicable regimes of use and property, the biological resources that contain them, the property in which they are located, or the associated intangible component.[225]
b) Does the legislation provide any indication on when it is considered that species have developed their own characteristics, i.e. distinctive properties, to start being considered a genetic resource of that country?	Under the Regulation of Andean Decision 391, the competent national authority will prepare a national inventory of genetic resources of which Ecuador is a country of origin. However, it is worth noting that Ecuador has not developed regulatory measures in this regard so far. They are currently developing a national biodiversity database.
c) Objective of the ABS legislation	Among others, the objective of Decision 391 is to regulate access to genetic resources of Member Countries and their derived products.[226] In this regard, the objectives of the Ecuadorian Regulation are to: • Promote the conservation and sustainable use of biological diversity and biological resources, guaranteeing the stability of ecosystems and the rights of nature for *Buen Vivir* (good living)

[222]Constitution of Ecuador, Article s 14 and 400
[223] Organic Code on the Environment, 2017, Article 73
[224] Organic Code on the Environment, 2017, Article 72
[225] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 3
[226] CAN, Decision 391 Common Regime on Access to Genetic Resources, 1996, Article 2

	• Establish the authorities in charge of the registration of applications, the public registry for these and the monitoring of the files relating to the Framework Contracts and Contracts of Access to Genetic Resources • Anticipate and ensure conditions for fair and equitable sharing of the benefits derived from the access to genetic resources • Ensure access to and transfer of appropriate technologies for the conservation and sustainable use of biological diversity or that utilise genetic resources and do not harm the environment • Promote the consolidation and development of scientific, technological and technical capacities at local and national levels, resulting from genetic resources that contribute to the fulfilment of *Buen Vivir* (good living), ensuring that basic needs are met, conservation of natural and cultural heritage and that fosters the productive diversification of the country • Guarantee the principle of prior informed consent of the State to grant authorization for access to genetic resources, and • Guarantee the principle of prior informed consent of local communities with respect to their traditional knowledge associated with genetic resources.[227]
d) Scope of the legislation – does it refer to all genetic resources or only to a subset (e.g. genetic resources for food and agriculture)? Are there any exemptions of genetic resources that fall outside of the scope (e.g. human genetic resources)?	According to the Regulation of Decision 391, the Ecuadorian ABS framework applies to genetic resources for which the Ecuadorian State is the country of origin, its derived products, its associated intangible components as well as the genetic resources of migratory species that due to natural causes are in its territory. The following are excluded from its scope: • Human genetic resources and their derivatives • The exchange of genetic resources, their derived products, the biological resources containing them, or of the intangible components associated therewith, carried out by indigenous, Afro-Ecuadorian and local communities among them, and for their own consumption, based on their customary practices. • The species and varieties listed in the Multilateral System of Annex 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture, and • The uses of genetic and biological material for scientific purposes such as: systematics, taxonomy, conservation, evolution, population biology, biogeography and phylogeography.

[227] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 1

	Research projects for such scientific purposes must be supported by a university, museum, herbarium or any other research centre duly recognized by the Competent National Environmental Authority, and the National Secretariat for Higher Education, Science, Technology and Innovation (SENESCYT), and a Framework Contract for these purposes must be signed.[228] Furthermore, the collection, capture, hunting, fishing, manipulation or movement of the biological resource, nationally and internationally, for research purposes, without the relevant permits is prohibited. However, this prohibition does not apply when movement of the resource is carried out as part of a traditional knowledge practice, by its legitimate holders.[229]
e) Is ABS regulated at the national or subnational level? To what extent does the national government share competencies with subnational entities?	In Ecuador, ABS is regulated at the national level. Under the Organic Code of the Environment, the State has the following objectives, among others: • To regulate the access, management, utilisation and sustainable use of biological resources • To protect genetic resources and their derivatives and prevent their misappropriation • To regulate and encourage the participation of people, communes, communities, peoples and nationalities in the conservation and sustainable use of biodiversity, as well as in the fair and equitable sharing of the benefits derived from the utilisation of genetic resources • Promote scientific research, the development and transfer of technologies, education and innovation, exchange of information and the strengthening of capacities related to biodiversity and its products, in order to promote the generation of bio-knowledge. • Protect and recover the traditional knowledge, collective and ancestral knowledge of the communes, communities, peoples and nationalities associated with biodiversity, and incorporate these experiences and knowledge in the management of public policies relating to biodiversity.[230] Also, the Code explains that the National Environmental Authority, i.e. the Ministry of Environment: (i) may limit the access to genetic resources, their components and derivatives[231]; (ii) it is responsible for regulating biotrade[232]; and, (iii) in coordination with the governing authority of the National System of Science, Technology, Innovation and Ancestral Knowledge,

[228] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 2
[229] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 68
[230] Organic Code on the Environment, 2017, Article 30
[231] Organic Code on the Environment, 2017, Article 74
[232] Organic Code on the Environment, 2017, Article 80

	it will promote the use and sustainable utilisation of native biodiversity and its components within the biotrade framework.[233] Furthermore, the governing body of the National System of Science, Technology, Innovation and Ancestral Knowledge is responsible for issuing the necessary regulations and public policy for the subscription of contracts for access, use and exploitation of genetic resources associated with biodiversity or traditional knowledge, in coordination with the National Environmental Authority.[234] In accordance with the Regulation of Decision 391, the Ministry of Environment of Ecuador is responsible, among others, for: • Defining, implementing and disseminating the public policy relating to the conservation and sustainable use of genetic resources and their associated intangible component existing in the Ecuadorian territory • Establishing specific requirements to authorise, negotiate, and sign contracts for access to genetic resources; • Convening and coordinating, on an ongoing basis, with the evaluating entities on issues related to compliance with the provisions of national, international and community regulations on access to genetic resources • Guaranteeing the recognition of the rights of local communities as providers of the intangible component associated with genetic resources, in coordination with the Secretariat of Peoples, Social Movements and Citizen Participation, and the organizations of these indigenous peoples and nationalities and their communities.[235] It should be noted that according to recent changes in the legal framework, the Regulation must be updated to contemplate the changes implemented.

3. Access to genetic resources and associated traditional knowledge	
a) According to the legislation, is access to genetic resources and/or associated traditional knowledge subject to prior informed consent (PIC)?	Yes. Access to genetic resources and their derivatives for commercial or research purposes requires prior authorization from the Ecuadorian State.

[233]Organic Code on the Environment, 2017, Article 81
[234] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 8
[235] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 8

	In the case of access for commercial purposes, individuals or legal entities, either national or foreign, who access the country's genetic resources or their derivative products for commercial purposes need to obtain prior authorization to access such resource.[236] With respect to development of scientific research relating to the biological and genetic resources and their derived products in Ecuadorian territory, natural and legal persons or other associative forms, both national and foreign, must obtain the corresponding authorization for access to biological, genetic resources and their derivatives for research purposes.[237] Furthermore, in accordance with their customary norms and legally constituted representation institutions, the legitimate traditional knowledge holders, through participatory mechanisms, have the exclusive right to authorise a third party in a free, explicit and informed way to access, use or utilise their traditional knowledge, upon prior, free and informed consent. The National Secretariat of Higher Education, Science, Technology and Innovation (SENESCYT) may provide, at the request of a party, advice on the negotiation processes between the communities and the interested parties.[238] The Code defines the legitimate traditional knowledge holders as the communities, peoples, indigenous nationalities, the Afro-Ecuadorian people, the Montubio people and the legally recognized communes that inhabit the Ecuadorian territory.[239] It also points out that in no case can a legal entity have rights over traditional knowledge, that is, it can never have the status of legitimate traditional knowledge holder. When access to a genetic resources is authorized or consent is granted for access to traditional knowledge in favour of a legal entity, this does not grant rights over the possession of the traditional knowledge or genetic resources, but only entails an authorization to use them under the terms specified in the authorization or contract, as appropriate.[240] In accordance with the Regulation, prior informed consent is the principle by which applicants for a genetic resource can gain access to it, once they have the authorization of the Ecuadorian State for situations in which Ecuador is the country of origin of the biological and genetic resources pursuant to the Convention on Biological Diversity. The prior informed consent is a

[236] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 69
[237] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 68
[238] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 530
[239] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 513
[240] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 514

	prerequisite to the negotiation or subscription of contracts for access to genetic resources, setting the foundations for a fair and equitable benefit sharing. The regulation also stipulates that when contracts for access to genetic resources include the intangible component associated with a genetic resource, prior informed consent over that component must also be granted by the local communities that are holders or owners of the relevant knowledge.[241] When access is requested for genetic resources that include an associated intangible component, the applicant must submit the corresponding plan to obtain the prior informed consent of the local community that would allow him to gain access to the intangible component.[242] See more details in item 3.c). It is worth noting that one of the provisions in the Regulation stipulates the development of a Protocol of Prior Informed Consent, led by the Ministry of Environment.[243] In this regard, the National Strategy on Biodiversity indicates the development of a proposal of a "Protocol for prior informed consent for access to traditional knowledge associated with genetic resources.[244] This has not yet been neither approved nor published.
b) Does the legislation establish rules/procedures to require the establishment of mutually agreed terms?	Yes. According to the regulatory framework of the Andean Community, access to genetic resources in Ecuador is subject to the execution of an access contract. This contract is an agreement between the Competent National Authority and a person, setting the terms and conditions for access to genetic resources, their derivative products and, if applicable, the associated intangible component.[245] The following are some of the mandatory clauses of access contracts: • Benefit sharing defining specific mechanisms for this purpose • Agreement on the intangible component, when applicable • Limitations to land use[246] • Sovereign rights over genetic resources • Intellectual property rights, and

[241] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 6
[242] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 20
[243] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, General Provisions, Fourth
[244] Ministry of the Environment of Ecuador "National Biodiversity Strategy 2015-2030, first edition, November 2016, Quito-Ecuador
[245] CAN, Decision 391 Common Regime on Access to Genetic Resources, 1996, Article 1
[246] For example, avoiding the land is used in ways which are contrary to what is allowed (e.g. a person cannot sell or give permission over something that does not belong to the them)

	• Surveillance and control.[247] In turn, the definition of the term "benefit" states that benefits must be mutually agreed between the State and the interested party, in accordance with the provisions of the respective access contract.[248] With respect to access to genetic resources and their derivatives for commercial purposes, the public institute for scientific research on biodiversity, through the unit in charge of technology transfer, shall be the competent body to carry forward the negotiating process for the relevant monetary and non-monetary benefits, as well as to authorise access to the genetic resource and its derived products. The Consultative Council established in Article 536 of the Ingenios Code, may be consulted in the access to genetic resources that contain biological diversity and agrobiodiversity located in the lands of communities, peoples and nationalities.[249] The procedures for the application of this article will be developed through a regulation, which is being developed. Regarding access to traditional knowledge, once the interested party obtained the prior, free and informed consent, a written contract must be signed in Spanish and, if applicable, simultaneously in the mother tongue of the legitimate holders. Terms and conditions for the use, access or utilisation of traditional knowledge must be established in the contract. Among these, the relevant motivation shall be necessarily included in relation to the scope and potential international effects that are expected to be obtained (potential derivative that can be obtained for which income from the resource is foreseen); the fair and equitable sharing of monetary and non-monetary benefits, including the plan for the sustainability of traditional knowledge; and, the possible authorizations or future assignments.[250]
c) Does the legislation set out criteria for the approval and involvement of indigenous and local communities for access to genetic resources and associated traditional knowledge?	Decision 391 indicates that Member Countries recognise and value the rights and power for indigenous, Afro-American and local communities to decide with respect to their knowledge, innovations and traditional practices associated with genetic resources and their by-products.[251] In this respect, when access to genetic resources or their derivative products with an intangible component is requested, the access contract shall incorporate an annex as an integral part

[247] Executive Decree No 905, Regulation to the Common Regime on Access to Genetic Resources, Article 30
[248] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 6
[249] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 69
[250] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 532
[251] CAN, Decision 391 Common Regime on Access to Genetic Resources, 1996, Article 7

	thereof, where the fair and equitable sharing of benefits arising from the use of component is set out. Failure to comply with the provisions in the annex provides grounds for termination and nullity of the access contract.[252] In addition to the provisions of the Ingenios Code mentioned in item (3.b) above, the Regulation stipulates that in cases where access to genetic resources that includes an associated intangible component has been requested, the applicant must present a plan to obtain the prior informed consent of the local community that would allow to gain access to the intangible component. The mentioned plan must be approved by the competent national authority together with the Secretary of the Peoples, Social Movements and Citizen Participation and the Ecuadorian Institute of Intellectual Property. Once the plan has been executed and prior informed consent obtained, the applicant must submit the supporting documents that serve as evidence of the planned activities and carried out to the National Environmental Authority.[253] These provisions are currently under revision in order to make them compatible with the most recent regulatory developments. With respect to the access contract, if the application for access to genetic resources or its by-products includes an associated intangible component an Annex to the contract shall be included, providing details on the conditions for its access. The determination of the mechanisms of fair and equitable benefit-sharing arising from the utilisation of the associated intangible component is one of the elements of the Annex, which is to be subscribed by the legal representative of the local community providing the associated intangible component and the applicant of the Access Contract.[254] Ecuador recognises the collective rights of legitimate holders over their traditional knowledge. These rights are not time-bound, are inalienable and non-sizeable and are part of the cultural identity of their legitimate holders.[255] The recognition and protection of collective rights over the intangible component and traditional cultural expressions are complementary to the rules on access to genetic resources.[256] The recognition of rights about traditional knowledge includes the expression of their culture or practice as well as the ability to designate traditional

[252] CAN, Decision 391 Common Regime on Access to Genetic Resources, 1996, Article 35
[253] Executive Decree No 905, Regulation of the Common Regime on Access to Genetic Resources, Article 20
[254] Executive Decree No 905, Regulation of the Common Regime on Access to Genetic Resources, Article 34
[255] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 512
[256] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 511

	knowledge, and for this denomination to be maintained in the derived products that may be generated from it, allowing its traceability. This ability to designate their knowledge also implies the ability for opposing to the registration by third parties of denominations that are from peoples and nationalities.[257] Third parties must obtain the prior, free and informed consent of their legitimate holders, which entails that fair and equitable sharing of monetary and non-monetary benefits is established.[258]
d) Does the legislation consider simplified access measures for non-commercial research purposes; or for cases of present or imminent emergencies that threaten or damage human, animal or plant health?	Yes. Uses of genetic and biological material for scientific purposes such as systematics, taxonomy, conservation, evolution, population biology, biogeography and phylogeography are excluded from the access regime. Research projects for such scientific purposes must be supported by a university, museum, herbarium or any other research centre duly recognised by the Competent National Environmental Authority, and SENESCYT, and sign a Framework Contract for these purposes.
e) Does the legislation address any change of intention in the use of the genetic resources accessed? (for example, access initially for non-commercial research that then changes to commercial use)	According to the Ingenios Code, any products and research that have not been originally contemplated in the negotiation must be the subject to a new process.[259] Likewise, the Regulation of Decision 391 establishes that the results of access for research purposes cannot be used for purposes other than those under the scope of the signed agreement[260]
f) Is there any specific provision / law related to genetic resources for food and agriculture?	Ecuador's ABS regime does not make distinctions with respect to different sectors. It should be noted that Ecuador ratified the International Treaty on Plant Genetic Resources for Food and Agriculture (Official Register No. 423 of September 17, 2004).

4. Benefit-sharing	
a) What triggers benefit-sharing? Does any utilisation of genetic resources create a benefit-sharing obligation, even if it does not add value to the product or market?	In accordance with the public policy issued by SENESCYT, the State will participate at least in the same proportion as any natural or legal person that has obtained monetary or non-monetary benefits derived from the research, use, transfer, development and commercialization of biological or genetic material, as well as the information, products or procedures derived from them. Allocation of the received benefits will be done in accordance with the public policy

[257] According to the Constitution, "Ecuadorian nationality is the legal and political link of persons with the State, without prejudice to them belonging to any of the indigenous nationalities that coexist in the plurinational Ecuador" (Article 6). See list in http://www.siise.gob.ec/siiseweb/PageWebs/glosario/ficglo_napuin.htm
[258] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 512
[259] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 69
[260] Executive Decree No 905, Regulation of the Common Regime on Access to Genetic Resources 4 and 6

	decided by the SENESCYT, which in all cases must provide a majority percentage for activities of science, technology, innovation, ancestral knowledge. Also, part of these benefits will be allocated to the conservation, restoration and repair of biodiversity, in coordination with the governing entity for the environment. When resources have been obtained from the territories of indigenous communities, peoples and nationalities, the Afro-Ecuadorian people, the Montubio people and their communities, the predominant proportion will be allocated to the previously detailed activities in those territories. In the case of access to genetic resources with associated intangible component, the participation in the benefits by the State will be given only with respect to genetic resources. The benefits derived from intangible components will correspond to their legitimate owners.[261] The Regulation indicates that the following elements must be considered as part of the process of negotiation of access contracts: • Establishment of benefit-sharing mechanisms that will result from the contract for access to genetic resources and their derivatives. • Access to and transfer of technology used and biotechnology derived from the utilisation of the genetic resource in accordance with mutually agreed terms. • Payment of (actual or potential) economic benefits derived from the international commercialisation of products developed utilising the requested genetic resource. If the genetic resource for which access is requested is contained in an endemic species or variety, the National Environmental Authority shall establish the payment of a higher amount compared to cases relating to species or varieties shared with other countries.[262]
b) Does the national legislation exempt benefit sharing derived from any particular use (research and development), even if the Convention on Biological Diversity (CBD) supports the sharing of the benefits derived from such activities?	No
c) How does the national legislation define the amount to be paid as benefit-sharing? Does it establish a fixed percentage for benefit-sharing?	To agree on the benefit-sharing in cases in which the State subrogates the rights of legitimate holders, the SENESCYT will develop a technical report based on the inputs submitted by the interested party during the consent phase. Consideration should be given to the commercial

[261] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 73
[262] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 26

d) Who should pay for the benefits to be shared (the one who carries out access to/utilisation of genetic resources and the associated traditional knowledge, the one who undertakes the economic exploitation, or both)?	applicability of the research, its budget and the various actors supporting it. The benefit-sharing amount will be determined based on those elements. The benefits will not necessarily be monetary and may be granted through transfer of technology and other parameters that the SENESCYT determines for this purpose. If the benefits from the research are monetary or other type, they will be used to strengthen traditional knowledge, according to the public policy developed by the SENESCYT.[263] Although draft regulations relating to the benefit-sharing mechanism were developed, they have not been published to date.
e) Where within the production chain rests the obligation to pay benefits? • supplier of raw material, • intermediary, • final product ready for commercialisation, or • all	
f) Is there anyone else who needs to share the benefits? For example, for non-commercial research, commercial research, licensing of intellectual property rights, the entire value chain of an industry, or the highest value-added?	
g) Does the legislation provide any indication as to what can constitute benefits (monetary and non-monetary) to be distributed?	The Regulation does not include an exhaustive list of monetary and non-monetary benefits. It however indicates that transfer of technology and royalties, among others, can be considered benefits. The benefits must be mutually agreed between the State and the interested party, in accordance with the provisions of the respective access contract.[264] In accordance with the Regulation, the above options are defined as follows: • *Royalties*: It is the benefit received by the State, consisting on a percentage of the monetary value resulting from the commercialization of a genetic resource subject to an access contract, which is negotiated in accordance with the Constitution, laws and international instruments. • *Technology transfer*: Systematic transfer of skills and knowledge of the owner or whoever holds the rights over the technology to the State, in accordance with the national interests and needs, including, among others: creation of legal capacity, facilitation of access to technologies, strengthening of the capacities of communities, peoples and nationalities,

[263] Executive Decree No. 1435 of 2017, Article 53
[264] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 6

	development of national research capabilities for the expansion of science and technology.[265] The benefits are not necessarily monetary and may be granted by transfer of technology and other criteria as established by the SENESCYT. If the benefit of research is monetary or other type, it shall be used for strengthening of traditional knowledge, in accordance with the public policy developed by SENESCYT. [266] Since Ecuador is a Party to the Nagoya Protocol, the list provided in its Annex also applies.
h) Are there specific provisions on how benefit-sharing should be dealt with in respect of traditional knowledge of indigenous peoples and local communities?	As mentioned in item 3.c), if the application for access to genetic resources or their derivative products includes an associated intangible component, an annex agreement shall be incorporated as an integral part of the access contract. The annex will detail the conditions for accessing the intangible component. The definition of the mechanisms for the fair and equitable sharing of benefits arising from the utilisation of the associated intangible component shall be part of the annex to the contract. The annex shall be signed by the legal representative of the local community providing the associated intangible component and the applicant for the contract of access to genetic resources.[267] Furthermore, the Ingenios Code stipulates that the State is not a right holder of traditional knowledge. However, when the legitimate holders do not voluntarily exercise their rights, the State, through SENESCYT, will subrogate its right grant consent and agree on the sharing of benefits in order to protect, manage and conserve traditional knowledge. The perceived benefits shall be used for the strengthening of traditional knowledge.[268] In Ecuador, the protection of traditional knowledge shared among communes, communities, peoples and nationalities located in the same geographic area is recognised for all legitimate holders. These should seek joint management of the knowledge. Those who wish to access knowledge in these situations must request the consent of the community or communities that they have identified as legitimate holders. The applicant should make its best efforts in the search and identification of the legitimate holders. Once the consent has been granted and the access contract has been registered, the appearance of new legitimate holders that were

[265] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 6
[266] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 53
[267] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 34
[268] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016, Article 515

	unknown when access took place, shall not affect the signed contract. Each legitimate owner may freely exercise their collective rights without prejudice to the exercise of these rights by other legitimate holders. As a result, in situations in which several groups are legitimate holders of the same knowledge, the granted consent and the benefits received by one of them does not prevent another group of legitimate holders from granting their consent in favour of a third person. Likewise, does not create the right for the legitimate holder's group that had not been initially consulted to claim benefits from the one who obtained consent and accessed the knowledge in the first place.[269]
i) Does the national legislation consider benefit-sharing arising from the utilisation of traditional knowledge for those cases in which it was accessed from secondary sources (publications, registries, databases, inventories, etc.), or when it is not possible to identify the peoples or communities that hold it?	As stipulated in the Ingenios Code, traditional knowledge is widespread when such knowledge and information are outside of the cultural context of communities, peoples and nationalities, and are included in widely disseminated publications or in *ex situ* collections in ethnobotanical centres, or have been disclosed orally and informally to become the state of the art, obtained with or without the free, prior and informed consent of the communes, communities, peoples and nationalities. The Ecuadorian State recognises the right of legitimate holders over such traditional knowledge, including the right to a fair and equitable sharing of benefits through mutually agreed terms established with the relevant custodians and their users, notwithstanding that they might be protected by traditional intellectual property regimes.[270] The State may subrogate the rights of legitimate holders when these cannot be determined due to the knowledge being widely disseminated. In all cases, the State should be advised by the Traditional Knowledge Consultative Council[271] throughout all stages of the subrogation. The State cannot however subrogate the rights of legitimate holders when the traditional knowledge for which access is desired has been voluntarily deposited; and, when the legitimate holders have denied or not participated in the prior, free and informed consent.[272] The SENESCYT will be the body to implement the subrogation on behalf of the State. The consent must be granted by

[269] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 516
[270] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 526
[271] Under the Organic Code of the Social Economy of Knowledge, Creativity and Innovation, the Traditional Knowledge Consultative Council was created as a space for the participation of the peoples and nationalities, which will be made up of a representative of the indigenous nationalities, a representative of the Afro-Ecuadorian peoples, a representative of the Montubio people and a representative of higher education institutions (Article 536). The functioning of the Advisory Council is regulated by Executive Decree No 1435, which stipulates that the Advisory Council will have an Executive Secretariat in charge of technical and operational matters. This function will be exercised by SENESCYT (Article 59).
[272] Executive Decree No. 1435 of 2017, Article 51

	the highest authority of this institution, with the Consultative Council of Traditional Knowledge shall acting as advisory body.[273]

5. Monitoring and reporting	
a) What are the designated checkpoints? What are their functions and responsibilities? How do they work??	Although no designated checkpoints are published the ABSCH, the entity that performs this role in Ecuador is the National Service of Intellectual Rights (SENADI) (previously known as the Ecuadorian Office of Intellectual Property). Being the competent authority on intellectual rights, prior to the registration of contracts the SENADI is responsible for verifying that prior, free and informed consent and fair and equitable benefits exist for the legitimate holders of traditional knowledge. It is also responsible for monitoring compliance with relevant national and international regulations. Contracts related to access, use and utilisation of traditional knowledge must be registered with the SENADI, who should approve them after receiving the favourable opinion of the SENESCYT and of the relevant competent authorities.[274] If the contract would not contain the elements mentioned above, or if it could cause prejudice to the legitimate holders, the SENESCYT will submit its observations and suggestions for these to be fully or partially accepted and the contract be modified or ratified accordingly.[275] In addition, being the SENADI the agency responsible for enforcing the procedures to grant and register patens, it should verify that patent applications related to access to genetic resources or associated traditional knowledge, include a copy of the relevant certificate of compliance.[276]
b) What are the reporting requirements? Who is responsible for reporting?	Further to the reports to be submitted regarding the utilisation of the accessed resources (based on what had been agreed as part of the access contract), the Ecuadorian regulations stipulate that the owner, holder or administrator of the property where the biological resource containing genetic resources is located; the *ex situ* conservation centre, the National Support Institution, should inform the national environmental authority of the activities that may involve access to the genetic resources of which they are aware.[277]

[273] Executive Decree No. 1435 of 2017, Article 52
[274] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 533
[275] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 533
[276] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 282
[277] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 38

c) How can access to/utilisation of genetic resources and associated traditional knowledge be tracked? Has the country developed any particular method/mechanism to monitor the access and utilisation of genetic resources and/or associated traditional knowledge?	SENESCYT in coordination with the national environmental authority and the national competent authority on intellectual rights should regularly evaluate the state of protection of biodiversity and traditional knowledge, as well as take action to prevent the exploitation, patenting and commercialisation of inventions consisting of endemic genetic resources or developed therefrom.[278] No details were found relating to the implementation of specific monitoring mechanisms to date. The regulation also stipulates that any activity of technological access, use, management and application of genetic resources is subject to monitoring. This will be in charge of the competent national environmental authority, in coordination with other entities based on the nature of the resource.[279] The regulation further indicates that the competent national environmental authority can carry out inspections as deemed necessary to verify the fulfilment of the obligations established in the Framework Contract and the regulations in force.[280]
d) Does the country have any monitoring systems for patent databases, registries of products resulting from access, and scientific publications so to identify activities that are not in compliance with the domestic legislation of the country where the access took place and with the Nagoya Protocol?	Although Ecuador's ABS regulations do not include details in this regard, it should be noted that in 2016 Ecuador presented the First Report on Biopiracy in Ecuador - Report on patents or patent applications that protect inventions developed from Ecuadorian endemic genetic resources.[281] This study was carried out using the international patent database Thomson Innovation, identifying the presence of 16 endemic species of the country in patent applications and granted patents.

6. Compliance	
a) Which are the competent authorities in charge of the application of the legislation of access and distribution of benefits? Is compliance implemented centrally (a single responsible body) or is decentralized (several agencies with different competencies)? What measures have been taken to integrate / coordinate the actions of the agencies responsible for enforcing access and benefit-sharing rules	The following are the competent authorities in Ecuador: • Ministry of Environment • Secretariat for Higher Education, Science, Technology and Innovation (SENESCYT) • National Institute of Biodiversity (INABIO), created in 2014 with the objective of planning, promoting, coordinating and executing research processes related to biodiversity, towards the conservation and sustainable use of this strategic resource, in accordance with the applicable environmental policies and legislation.[282]

[278] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 70
[279] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 5
[280] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 40
[281] Click on https://www.propiedadintelectual.gob.ec/wp-content/uploads/2013/09/Primer-Informe-29-de-junio-12-43.pdf
[282] Executive Decree No 245 of 2014.Click on http://www.biodiversidad.gob.ec/wp-content/uploads/downloads/2018/02/ANIB-compressed.pdf

at the national level? How to promote the integration / coordination of the various agencies responsible for enforcing access and benefit-sharing rules?	The *public institute of scientific biodiversity research* (that is, INABIO), through the unit responsible for technology transfer, is the competent body to carry out the negotiating process for monetary and non-monetary benefits, as well as authorizing access to the genetic resource and its derivatives.[283] INABIO will create the National Bank of Genetic Resources for the safeguard and custody of Ecuador's genetic resources.[284] The *Ministry of Environment* is the national environmental authority responsible for access to genetic resources. The National Environmental Authority is responsible for issuing the national environmental policy, as well as for establishing guidelines, instructions, regulations and control and monitoring mechanisms for the conservation, sustainable management and restoration of biodiversity and natural heritage[285]. In terms of ABS, the Ministry of the Environment is responsible for: • Issuing internal administrative, and technical and legal measures for compliance with applicable regulations regarding access to genetic resources • Authorizing, negotiating and signing access contracts, and for issuing the relevant resolutions, considering compliance with the applicable regulations and the technical opinion issued by the evaluating entities • Establishing the specific requirements for the subscription of framework contracts relating to research on genetic resources • Subscribing, modifying, suspending, resolving or terminating access contracts, and providing for their cancellation, as appropriate, in accordance with the terms of the contracts and the applicable national, international and community regulations after obtaining the opinion of evaluating entities • Applying administrative sanctions as established in the national and community regulations in place • Coordinating prevention, control and sanction actions against illegal and illegitimate access to genetic resources and associated traditional knowledge with the support of other national institutions

[283] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 69
[284] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 71
[285] Organic Code on the Environment, 2017, Article 24

	• Carrying out the qualification, enrolment and registration of natural and legal persons, whether national or foreign, dedicated to scientific research on biological and genetic resources, as well as individuals and entities that carry out *ex situ* conservation of genetic resources.[286] The Ministry is supported by evaluating entities in charge of preparing a technical report, which is the main instrument for decision-making of access applications.[287] Evaluating authorities perform the following functions: • Provide advice and technical support to the national environmental authority in the process related to access to genetic resources • Prepare a report of presented access requests • Inform the national environmental authority in cases of objections on the competence/suitability of a National Support Institution • Advise and be part of the process for the negotiation of access contracts, in particular with respect to benefit-sharing due to the contract of access subscribed by the national environmental authority with the applicant.[288] The evaluating entities have different competences according to the nature of their mandates. Their competences in relation to ABS as specified in the regulations are indicated below. It should however be noted that these competences might vary on the decisions by the Ministry of Environment and the SENESCYT. • Ministry of the Environment: competent body on genetic resources of wild terrestrial organisms: animals, plants and microorganisms. • Ministry of Agriculture, Livestock, Aquaculture and Fisheries: o through the National Fisheries Institute: competent body on genetic resources of marine and freshwater organisms except amphibians o through the National Institute of Agricultural Research: competent body on genetic resources of cultivated and domesticated organisms, as well as wild species and varieties related to crops.

[286] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 8
[287] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Title II, Article 9
[288] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Title II, article 10

	• SENESCYT: competent body regarding innovation and technology transfer, scientific research, intellectual support, knowledge and recovery networks, reinforcing and strengthening of ancestral knowledge. • Secretariat of People´s Social Movements and Citizen Participation: responsible for coordinating with local communities the relevant processes for obtaining prior informed consent for access to traditional knowledge associated with genetic resources. • Ecuadorian Institute of Intellectual Property: coordinates actions aimed at determining the existence of an intangible component associated with genetic resources. • Applications for access to genetic resources related to crops in areas of the National System of Protected Areas, Forests and Vegetation and other areas under the jurisdiction of the Ministry of the Environment will require a technical evaluation by such Ministry.[289] Authorizations for access to genetic resources and their derivatives for research or commercial purposes, as well as import permits for living organisms, specimens from scientific collections for the development of research processes shall be processed through a single window for biodiversity research. The SENESCYT, the public institute for scientific research on biodiversity, the national environmental authority, the customs authority, as well as the other pertinent bodies work jointly. The platform will be managed by SENESCYT and is part of the National Information System of Science, Technology, Innovation and Ancestral Knowledge, notwithstanding that its content is reproduced in other public information systems or it is linked to them.[290] It is expected the this platform is used for monitoring purposes in the future.
b) What measures have already been taken to promote effective monitoring of legal compliance?	There are no specific measures that trigger monitoring of compliance with the conditions established in the access contracts. However, among the measures aimed at promoting compliance with the provisions established in Ecuador's ABS regime there is an obligation for a compensation's warranty for cases of non-compliance by the applicant. The warranty is to be executed in cases of non-compliance, in favour of the national environmental authority. The amount of the warranty will be: • 10% of the budget in the Access Project, if the research is financed by a profit-seeking natural or legal person or if the applicant is a legal entity with such purposes subject to national legislation

[289] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Title II, Article 11
[290] Executive Decree No 1435 of 2017, Article 25

	• 5% of the budget in the Access Project, if the research is financed by a not-for-profit natural or legal person or if the applicant is a not-for-profit natural or legal person. Payment of the warranty does not prevent the national environmental authority from initiating legal actions against the applicant when the amount of the unfulfilled obligations exceeds the value paid by the insurer. Upon completion of the project, once the evaluation has been carried out, the warranty shall be reimbursed to the issuer.[291]
c) Are there measures in the legislation to ensure benefit-sharing when access and use of genetic resources and associated traditional knowledge occur outside the jurisdiction of the country where the access was made, especially when you are in a country that is not a Party to the Nagoya Protocol or when the user is in a country that is not a Party to the Protocol?	The Ecuadorian Institute of Intellectual Property (IEPI) at the National Service of Intellectual Rights (SENADI) is responsible for monitoring. This is sometimes done in coordination with the Ministry of Environment. However, with a recent change of authorities and competent entities, there are several processes to coordinate, which are no longer under the exclusive responsibility of the Ministry of Environment.

7. Intellectual Property Rights (focusing on patents)	
a) How do countries treat the patentability of living organisms found in nature and their components, such as DNA, molecules and metabolites?	Decision 486 stipulates that member countries shall grant patents for inventions, whether of goods or of processes, in all areas of technology, provided that they are new, involve an inventive step and are industrially applicable.[292] In this respect, living organisms or parts thereof as found in nature, natural biological processes, biological material existing in nature or that can be isolated, including genome or germplasm of any natural living organism is not considered an invention and cannot be patented.[293] Further, the Decision indicates that plants, animals and essentially biological processes for the production of plants or animals that are not non-biological or microbiological processes are not patentable.[294] Where the patent protects biological material, except plants, that can be reproduced, the patent shall not extend to the biological material obtained by reproduction, multiplication or propagation of the material that has been brought on to the market in any country by the patent

[291] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Resources, Article 31
[292] CAN, Decision 486 Common Regime for Industrial Property, Article 14
[293] CAN, Decision 486 Common Regime for Industrial Property, Article 15
[294] CAN, Decision 486 Common Regime for Industrial Property, Article 20

	holder, or by any other person who has obtained his consent or is economically associated with him, provided that: • The reproduction, multiplication or propagation was necessary so that the material might be used to achieve the purposes for which it was brought on to the market; and • that the material derived from such use is not used for multiplication or propagation purposes.[295] In Ecuador, the following are not considered inventions: discoveries, living organisms or parts thereof as found in nature, natural biological processes, biological material existing in nature or that can be isolated, including genes, proteins, genome or germplasm of any living organism; a new form of a substance, including salts, esters, ethers, complexes, combinations and other derivatives; polymorphs, metabolites, pure forms, particle size and isomers; and the genetic resources that contain biological diversity and agrobiodiversity.[296] The Code also indicates that, among others, the following are not patentable: • plants and animals, as well as essentially biological procedures for obtaining plants or animals that are not non-biological or microbiological processes • the product of polymorphs, metabolites, pure forms, particle size and isomers that have not been investigated in Ecuador • the product of genetic resources that contain biological diversity and agro-biodiversity that have not been investigated in Ecuador. [297] The following considerations are considered to determine the patentability of an invention: • An invention concerning the product of polymorphs, metabolites, particle size and isomers may take place in any country, without any discrimination; however, the investigative process or at least one of its phases must have been developed in Ecuador for its presentation • A product of polymorphs is interpreted as the process for obtaining polymorphs or a composition containing a polymorph. These will then be subject to analysis of compliance with the patentability criteria. A product of polymorphs will not be considered an invention if it does not describe the procedure for obtaining the polymorph or a composition containing

[295] CAN, Decision 486 Common Regime for Industrial Property, Article 54
[296] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 268
[297] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 273

	the polymorph in a sufficiently clear and complete manner. The same applies to those inventions identified only by the characterisation of physical chemical parameters. • A product of the metabolites is the metabolite's synthesis procedure or a composition containing the isolated metabolite. It will then be subject to analysis of compliance with the patentability requirements. If the procedures for synthesising a metabolite or a composition containing the isolated metabolite are not described in a sufficiently clear and complete manner, then the product will not be considered an invention. Likewise, products produced within the human or animal body but that have not been isolated therefrom, and those determined solely by functional features, are not considered inventions. • A product of the isomers is the method of isolating stereoisomers with the necessary data relating to its effectiveness, or a composition containing the isomer. These will then be subject to analysis of compliance with the patentability requirements. A product of the isomers will not be considered an invention if it does not describe the isolation process or a composition containing the isomer in a sufficiently clear and complete manner; nor, when the stereoisomers are only identified without determining the process for their separation.[298] Further, the Constitution of Ecuador prohibits granting of rights, including intellectual property rights, over derivatives or synthesized products obtained from collective knowledge associated with national biodiversity.[299] Also prohibited are all forms of appropriation of collective knowledge in the field of science, technology and ancestral knowledge as well as the appropriation on the genetic resources that contain the biological diversity and the agro-biodiversity.[300] In this regard, the Regulation for the application of Decision 391 in Ecuador also stipulates that the Ecuadorian State will not recognize any right, including intellectual property rights, over derivatives or synthesized products obtained from the collective knowledge associated with national biodiversity.[301]
b) Do patent applications include disclosure of origin among the requirements that the applicant must	Yes. Decision 486 of the CAN stipulates that Member Countries shall ensure that the protection provided over elements of industrial property shall be granted safeguarding and respecting their

[298] Executive Decree No.1435 of 2017, Article 32
[299] Constitution of Ecuador, Article 402
[300] Constitution of Ecuador, Article 322
[301] Executive Decree No 905, Regulations to the Common Regime on Access to Genetic Title I, Article 4

complete? Is it a mandatory or optional item? Is it related only to genetic resources or also to associated traditional knowledge?	biological and genetic heritage, as well as the traditional knowledge of their indigenous, Afro-American or local communities. As such, granting of patents regarding inventions developed from material obtained from this heritage or knowledge requires that this material has been acquired in accordance with international, community and national legal systems.[302] As a result, applications for obtaining a patent must contain the following: • as appropriate, the copy of the access contract, when the products or procedures for which the patent is requested have been obtained or developed from genetic resources or derivatives products of which any of the Member Countries is a country of origin • as appropriate, the copy of the document that certifies the license or authorization to use the traditional knowledge of the indigenous, Afro-American or local communities of the Member Countries, when the products or procedures whose protection is requested have been obtained or developed from such knowledge originated in any of the Member Countries is, in accordance with the provisions of Decision 391 and its modifications and current regulations.[303] Not presenting the copy of the access contract, or the copy of the document that certifies the license or authorization to use the traditional knowledge of the Afro-American or local indigenous communities of the Member Countries under the circumstances described above, provide grounds for the nullity of the patent.[304] When the invention relates to a product or a process relating to a biological material and the invention cannot be described in a way that it can be understood and executed by a person with the skills in the specific subject matter, the description should be supplemented with a deposit of this material. [305] In Ecuador, when the patent application relates to a subject that implies the utilisation of genetic resources and associated traditional knowledge, the applicant must inform: • The country where those resources or associated traditional knowledge were obtained and, • The source, including details of the entity as appropriate, from which those resources or associated traditional knowledge were obtained.

[302] CAN, Decision 486 Common Regime on Propiedad Industrial, Article 3
[303] CAN, Decision 486 Common Regime on Propiedad Industrial, Article 26
[304] CAN, Decision 486 Common Regime on Propiedad Industrial, Article 75
[305] CAN, Decision 486 Common Regime on Propiedad Industrial, Article 29

	It must also attach the copy of the internationally recognized certificate of compliance with the legislation on access to genetic resources or associated traditional knowledge. If an internationally recognized certificate of compliance is not applicable in the provider country, the applicant must provide relevant information regarding compliance with prior informed consent and access and fair and equitable benefit-sharing, in accordance with the legislation of the country providing the genetic resources and/or associated traditional knowledge, that is the country of origin of those resources or a country that has acquired them in accordance with the Convention on Biological Diversity and other international treaties to which Ecuador is a party.[306] The national authority responsible for intellectual rights will declare the absolute nullity of a patent, if: • when applicable, a copy of the access contract has not been submitted when the products or procedures for which a patent is requested have been obtained or developed from genetic resources or their derivatives of which Ecuador is a country of origin • when applicable, if a copy of the document proving the license or authorization to use the traditional knowledge of the indigenous, Afro-American or local communities of Ecuador or of any member country of the Andean Community has not been submitted, when the products or processes for which is protection is requested have been obtained or developed from such knowledge of which Ecuador or any of the member countries of the Andean Community is a country of origin.[307]

8. Support instruments for the implementation of access and benefit-sharing legislation	
a) Does the legislation consider the development of community protocols related to access to traditional knowledge associated with genetic resources? if so, have these protocols been developed in practice?	No information was identified/provided
b) Have any guidelines, codes of conduct, best practices or standards related to the implementation of your access	No information was identified/provided

[306] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 282
[307] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 303

and benefit-sharing legislation been developed in the country? If so, what?	
c) Does the legislation include model contractual clauses or a standard agreement for the exchange of materials and the establishment of mutually agreed terms?	In the context of the CAN, the following resolutions were adopted: 1. Reference model of application to request for access to genetic resources (Regulation 414) 2. Reference model contract of access to genetic resources (Regulation 415) – includes the different elements that could be included but does not provide model contractual clauses [308]

9. Key challenges of implementation	
Identified challenge	Brief explanation
Limited knowledge of biodiversity at the genetic level	The mega diversity of the country is also expressed in its genetic wealth. However, knowledge of national biodiversity at the genetic level continues to be limited and there is no appropriate information regarding its current status. The analysis of genetic diversity has been mostly directed to programs for the improvement of the species used in agriculture and livestock, with little research carried out on wild flora and fauna.[309]
Lack of adequate articulation amongst governmental agencies with responsibility on ABS	No adequate articulation of the competent bodies based on the recent changes in legislation in the country, that would allow for the processes for access to genetic resources be carried out adequately and smoothly.
Difficulties in monitoring of intellectual property rights granted abroad that relate to the utilisation of Ecuadorian genetic resources	The Ecuadorian State does not recognise intellectual property rights over biodiversity in the country. It cannot however prevent that patents or any other form of intellectual property are granted beyond national borders. [310]

[308] Both resolutions are available at http://intranet.comunidadandina.org/documentos/Gacetas/gace217.pdf
[309] Ministry of the Environment of Ecuador "National Biodiversity Strategy 2015-2030, first edition, November 2016, Quito-Ecuador.
[310] Ministry of the Environment of Ecuador "National Biodiversity Strategy 2015-2030, first edition, November 2016, Quito-Ecuador

4.4 European Union

- The European Union (EU), as a Party to the Nagoya Protocol, developed legislation to regulate access and benefit-sharing. The Regulation (EU) 511/2014, usually known as the EU ABS Regulation[311], is the overarching framework developed to respond to the obligations arising from the Nagoya Protocol. Furthermore, the EU ABS Regulation is complemented by the Implementing Regulation (EU) 2015/1866. In addition, a Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 was developed by the Commission in close cooperation with Member States to assist users in understanding of their obligations under the EU ABS Regulation.
- Both the EU ABS Regulation and the Implementing Regulation are directly applicable in all Member States of the EU, regardless of the status of the Nagoya Protocol's ratification in different Member States.[312] At the time an EU regulation comes into force, it is automatically binding for the EU Member States with no need for transposition into domestic law (as opposed to EU directives).
- A key feature of the Protocol is that it requires Parties to establish compliance measures for users of genetic resources and traditional knowledge associated with genetic resources. More specifically, the Protocol requires Parties to put in place measures (i.e. laws, administrative measures or other policy instruments) to ensure that users within their jurisdiction have accessed genetic resources in accordance with prior informed consent, and that mutually agreed terms have been established, as required by domestic access rules of provider countries. The compliance part of the Protocol is 'transposed' into the EU legal framework by means of the EU ABS Regulation. With regard to access measures in the EU, Member States are free to establish such measures, which are not regulated at EU level.[313]
- While the Regulation as a whole entered into force on 9 June 2014, and into application on 12 October 2014, Articles 4, 7 and 9 only became applicable one year later. Users are thus bound by the provisions of those Articles as of October 2015, but the obligations in principle still concern all genetic resources accessed after 12 October 2014.
- According to the Preamble of the EU Regulation, the due diligence obligation should apply to all users irrespective of their size (including micro, small and medium-sized enterprises). The Preamble further states that measures and tools are offered by the Regulation to enable micro, small and medium-sized enterprises to comply with their obligations at an affordable cost and with a high level of legal certainty.[314]

1. Definition of key terms	
a) Definition of access to genetic resources and the associated traditional knowledge	Access: acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol.[315] The EU ABS Regulation also defines "illegally

[311] It is worth highlighting that the Regulation entered into application on 12 October 2014; all of its provisions apply from 12 October 2015.
[312] 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
[313] 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
[314] Regulation (EU) No 511/2014, Preamble
[315] Regulation (EU) No 511/2014, Article 3

	accessed genetic resources", which are genetic resources and traditional knowledge associated with genetic resources, which were not accessed in accordance with the national access and benefit-sharing legislation or regulatory requirements of the provider country that is a Party to the Nagoya Protocol requiring prior informed consent.[316]
b) Definition of collection	**Collection**: a set of collected samples of genetic resources and related information that is accumulated and stored, whether held by public or private entities.[317] Importantly, the definition needs to be read in conjunction with its Preamble, which recognises that collections are major suppliers of genetic resources and traditional knowledge associated with genetic resources utilised in the EU, while indicating that the collection of genetic resources in the wild (i.e. in *in situ* conditions) is mostly undertaken for non-commercial purposes. In the vast majority of cases and in almost all sectors, newly-collected genetic resources are accessed through intermediaries, collections, or agents that acquire genetic resources in third countries. As suppliers they can play an important role in helping other users in the chain of custody to comply with their obligations. A system of registered collections within the EU, to be maintained by the European Commission, will be put in place to support users to comply with their obligations.
c) Definition of utilisation of genetic resources and the associated traditional knowledge	**Utilisation of genetic resources:** to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention[318] (defined as in the Nagoya Protocol, Article 2)
d) Definition of bioprospecting	Term not defined within the EU ABS framework
e) Others definitions of relevance? E.g. biological resources, in situ conservation; indigenous species; benefit-sharing, derivative; genetic resources; genetic material	**Genetic material**: any material of plant, animal, microbial or other origin containing functional units of heredity[319] (defined as in CBD, Article 2) **Genetic resources**: genetic material of actual or potential value[320] (defined as in CBD, Article 2) **Traditional knowledge associated with genetic resources**: traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is

[316] Regulation (EU) No 511/2014, Article 3
[317] Regulation (EU) No 511/2014, Article 3
[318] Regulation (EU) No 511/2014, Article 3
[319] Regulation (EU) No 511/2014, Article 3
[320] Regulation (EU) No 511/2014, Article 3

	as such described in the mutually agreed terms applying to the utilisation of genetic resources[321]

2. General information	
a) To whom do genetic resources belong? Are these considered private goods, goods of common use by the population, public goods or do they belong to the State, etc.?	The EU ABS Regulation does not regulate ownership of genetic resources. Ownership of genetic resources might be regulated at the national level if access measures are established.
b) Does the legislation provide any indication on when it is considered that species have developed their own characteristics, i.e. distinctive properties, to start being considered a genetic resource of that country?	Given the absence of any access measures at EU level, the EU ABS Regulation does not include references as to when species have developed their distinctive properties.
c) Objective of the ABS legislation	The **objective** of the EU ABS Regulation is to support the fair and equitable sharing of the benefits arising from the utilisation of genetic resources in accordance with the Nagoya Protocol.[322] In this respect, the ABS Regulation establishes rules governing compliance with access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources in accordance with the provisions of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation.[323]
d) Scope of the legislation – does it refer to all genetic resources or only to a subset (e.g. genetic resources for food and agriculture)? Are there any exemptions of genetic resources that fall outside of the scope (e.g. human genetic resources)?	The EU ABS Regulation applies to **genetic resources** over which States exercise sovereign rights and to **traditional knowledge associated with genetic resources** that are accessed after the entry into force of the Nagoya Protocol for the Union, i.e. 12 October 2014, as well as to the **benefits arising from the utilisation** of such genetic resources and traditional knowledge associated with genetic resources. Moreover, the Regulation clarifies that it applies to genetic resources and traditional knowledge associated with genetic resources accessed from a Party

[321] Regulation (EU) No 511/2014, Article 3 // (20) There is currently no internationally-agreed definition of 'traditional knowledge associated with genetic resources'. Without prejudice to the competence and responsibility of the Member States for matters relating to traditional knowledge associated with genetic resources and the implementation of measures to safeguard indigenous and local communities' interests, in order to ensure flexibility and legal certainty for providers and users, this Regulation should make reference to traditional knowledge associated with genetic resources as described in benefit-sharing agreements. (Preamble, Regulation (EU) No 511/2014)
[322] Regulation (EU) No 511/2014, Preamble
[323] Regulation (EU) No 511/2014, Article 1

	to the Nagoya Protocol for which access and benefit-sharing legislation or regulatory requirements exist.[324] In brief, the EU ABS Regulation applies to genetic resources and associated traditional knowledge that were accessed after 12 October 2014 from a Party to the Nagoya Protocol that has access and benefit-sharing regulatory requirements in place. The guidance document developed by the European Commission indicates that "provider countries must have ratified the Protocol and established access measures on genetic resources for them to be in the scope of the Regulation".[325] Since the Regulation is applicable to genetic resources (and associated traditional knowledge), to which access and benefit-sharing legislation or regulatory requirements apply, *if* certain types of activities are excluded from a given country's access legislation, then such activities would not trigger obligations under the EU ABS Regulation.[326] The due diligence obligations resulting from the Regulation apply to all genetic resources independent of the users' size or of the intent of the use (i.e. commercial and non-commercial). Even though not explicitly mentioned in the Regulation, in accordance with the guidance, research and development on derivatives (whether or not containing functional units of heredity) fall within scope when they are derived from genetic resources that were accessed under the Protocol, covered by the required prior informed consent related to genetic resources from which they were derived, and addressed in mutually agreed terms.[327] The guidance also indicates that the use of digital data obtained from gene sequencing, frequently stored in publicly available databases, *could be* considered to be out of scope of the ABS Regulation (emphasis added).[328]

[324] Regulation (EU) No 511/2014, Article 2
[325] 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
[326] 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
[327] 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, Section 2.3.3
[328] 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, Section 2.3.3

	For traditional knowledge associated with genetic resources to be within the scope of the EU ABS Regulation, it needs to be related to the *utilisation of those resources* and it must be covered by the relevant contractual agreements.[329] Regarding **exemptions**, the Regulation does not apply to: • human genetic resources[330] • genetic resources for which access and benefit-sharing is governed by specialised international instruments,[331] such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[332] and the World Health Organization's Pandemic Influenza Preparedness (PIP) Framework[333] • genetic resources obtained in areas beyond national jurisdiction (for example, from the high seas), or from areas covered by the Antarctic Treaty System[334] (in line with scope of Article 15 of the Convention on Biological Diversity)
e) Is ABS regulated at the national or subnational level? To what extent does the national government share competencies with subnational entities?	The EU ABS Regulation recognises that its objective cannot be sufficiently achieved only by Member States at the domestic level, and therefore measures were established at the Union level.[335] However, is it worth noting that the Regulation only relates to measures regarding **user compliance**, while access to genetic resources is subject to domestic legislation of the Member States, if they deem it appropriate.[336] Only the EU framework is covered in this study.

[329] 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
[330] Regulation (EU) No 511/2014, Preamble (19); and 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
[331] Regulation (EU) No 511/2014, Article 2. Importantly, the Regulation applies to resources covered by such specialised instruments when these are utilised for purposes other than those of the specialised instrument in question.
[332] Regulation (EU) No 511/2014, Preamble (12), Article 2(2)
[333] Regulation (EU) No 511/2014, Preamble (16), Article 2(2)
[334] Regulation (EU) No 511/2014, Preamble (8); and 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
[335] Regulation (EU) No 511/2014, Preamble (35)
[336] Regulation (EU) No 511/2014, Article 2

3. Access to genetic resources and associated traditional knowledge	
a) According to the legislation, is access to genetic resources and/or associated traditional knowledge subject to prior informed consent (PIC)?	The EU ABS framework does not regulate access to genetic resources or associated traditional knowledge, which might be subject to national legislation of Member States, if they deem appropriate. No requirements are therefore established at the EU level regarding prior informed consent, establishment of mutually agreed terms, involvement of indigenous peoples and local communities, and consideration of simplified measures for access. As previously mentioned, the EU ABS Regulation was developed to ensure user compliance, and specifically stipulates that mutually agreed terms would only be required as part of the compliance measures if they are required by the applicable legislation or regulatory requirements in the country where the access takes place.
b) Does the legislation establish rules/procedures for requiring and establishing mutually agreed terms (MAT)?	
c) Does the legislation set out criteria for the approval and involvement of indigenous and local communities for access to genetic resources and associated traditional knowledge?	
d) Does the legislation consider any simplified measures on access for non-commercial research purposes; or for cases of present or imminent emergencies that threaten or damage human, animal or plant health?	
e) Does the legislation address any changes of intent in the utilisation of accessed genetic resources? (e.g. initially accessed for non-commercial research and then changing their utilisation to commercial)	The EU ABS Regulation does not regulate access, but user compliance. The guidance document refers to situations of change of intent. In particular, the guidance document indicates that even though genetic resources traded as commodities fall outside of the scope of the EU ABS Regulation, there are some situations where research and development is carried out on genetic resources which originally entered the EU as commodities. Given that the intended use has changed, the new use falls within the scope of the Regulation and consequently, the user is expected to contact the provider country and clarify whether requirements to obtain prior informed consent and establishment of mutually agreed terms apply to utilisation of such genetic resources. In case these requirements exist, then the user needs to obtain the necessary approval.[337]

4. Benefit-sharing	
a) What triggers benefit-sharing? Does any utilisation of genetic resources create a benefit-sharing obligation, even if it does not add value to the product or market?	The EU ABS Regulation does not include benefit-sharing measures (related to access legislation). Nonetheless, it specifically acknowledges the importance of supporting the effective implementation of benefit-sharing commitments set out in mutually agreed terms

[337] 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, Section 2.3.1

	between providers and users.[338] It indicates the intention of preventing misappropriation of genetic resources and associated traditional knowledge, while supporting the effective implementation of benefit-sharing commitments set out in mutually agreed terms between providers and users.[339] Member States may however establish access and benefit-sharing measures if they deem it appropriate.
b) Does the legislation provide an indication of what can constitute (monetary and non-monetary) benefits to be shared?	Not covered by the EU ABS measures (see item 4.a) above).
c) Does the national legislation exempt benefit-sharing arising from any particular utilisation (research and development), even if the CBD support the sharing of the benefits arising from such activities?	
d) Are there any specific provisions on how benefit-sharing should be dealt with respect to traditional knowledge hold by indigenous peoples and local communities?	
e) Does the national legislation consider benefit-sharing arising from the utilisation of traditional knowledge for those cases in which it was accessed from secondary sources (publications, registries, databases, inventories, etc.), or when it is not possible to identify the peoples or communities that hold it?	
f) How does the national legislation define the amount to be paid as benefit-sharing? Does it establish a fixed percentage for benefit-sharing?	
g) Who should pay for the benefits to be shared (the one who carries out access to/utilisation of genetic resources and the associated traditional knowledge, the one who undertakes the economic exploitation, or both)?	

[338] Regulation (EU) No 511/2014, Preamble
[339] Regulation (EU) No 511/2014, Preamble

h) Where within the production chain rests the obligation to pay benefits? ○ supplier of raw material, ○ intermediary, ○ final product ready for commercialisation, or ○ all	
i) Is there anyone else that needs to share benefits? For example, non-commercial research, commercial research, intellectual property rights licensing, the whole value chain of an industry or the one with the greater added value?	

5. Monitoring and reporting	
a) What are the designated checkpoints? What are their functions and responsibilities? How do they work?	There are two checkpoints designated at the EU level and implemented at the Member States' level: 1. At the stage of research funding (when such research involves utilisation of genetic resources or traditional knowledge associated with genetic resources), the Member States and the Commission are to request all recipients of research funding to declare that they exercise due diligence. The declaration of due diligence needs to be submitted to the competent authority of the Member State where the user is established, although in case of more than one recipient of funding for the same research project, it is possible that the co-ordinator of the project files a due diligence declaration to the authorities where he/she is established.[340] Templates for submitting due diligence declarations by the researchers are contained in Annex II of the Commission Implementing Regulation. 2. At the final stage of development of a product developed through utilisation of genetic resources or associated traditional knowledge, a user needs to declare to the competent national authority where the user is established that he/she has complied with the user obligations. The user needs to submit information about the Internationally Recognised Certificate of Compliance (IRCC), and for situations where

[340] Commission Implementing Regulation (EU) 2015/1866, Article 5(3)

	no IRCC is available, the Regulation requires to provide alternative set of information related to date and place of access, access permits, the source from which the genetic resources or associated traditional knowledge were directly obtained, and subsequent users of those resources, amongst others.[341] Templates for submitting due diligence declarations by users are contained in Annex III to the Commission Implementing Regulation. The competent national authorities designated in Member States for the implementation of the EU ABS Regulation under Article 6 of the Regulation (usually ministries of environment or their equivalent) serve as checkpoints collecting the information required by the Regulation. They are also responsible for transferring this information to the ABS Clearing House. In addition to the two checkpoints described above which are applicable in all Member States, Member States can introduce additional checkpoints, for example research organizations.
b) What are the reporting requirements? Who is responsible for reporting? c) How can access to/utilisation of genetic resources and associated traditional knowledge be tracked? Has the country developed any particular method/mechanism to monitor the access and utilisation of genetic resources and/or associated traditional knowledge?	In accordance with the EU ABS Regulation, "users shall seek, keep and transfer to subsequent users" relevant information and documentation. In particular, this refers to the internationally-recognised certificate of compliance and information on the content of the mutually agreed terms to subsequent users. For cases where such an internationally-recognised certificate of compliance is not available, the following information needs to be made available as an alternative: • Date and place of access to genetic resources and associated traditional knowledge • Description of the utilised genetic resources and associated traditional knowledge • Source from where those were obtained, and subsequent users • Information on presence or absence of rights and obligations relating to access and benefit-sharing, including rights and obligations regarding subsequent applications and commercialisation • And, where applicable: access permits; and mutually agreed terms, including benefit-sharing arrangements.[342] The legislation also indicates that when the information held by users is insufficient or there are uncertainties regarding the legality of the access to genetic resources and associated

[341] Regulation (EU) No 511/2014, Article 3.3
[342] Regulation (EU) No 511/2014, Article 4

	traditional knowledge, users need to obtain an access permit (or equivalent) and establish mutually agreed terms, or otherwise discontinue utilisation.
d) Does the country have any monitoring systems for patent databases, registries of products resulting from access, and scientific publications so to identify activities that are not in compliance with the domestic legislation of the country where the access took place and with the Nagoya Protocol?	The EU does not have monitoring systems for patent databases, registries of products, and scientific publications. As mentioned under item 5.a) above, monitoring of user compliance takes place at two different stages: (i) research funding; and (ii) final stage of development of a product developed through the utilisation of genetic resources or associated traditional knowledge. In both cases, the user is responsible for submitting the necessary information to the relevant national competent authority of the relevant Member State. The Commission Implementing Regulation (EU) 2015/1866 defines when the stage of final development of a product takes place. In this respect, it indicates that the due diligence declaration needs to be placed when the first of the following events takes place: a) when seeking market approval or authorisation of the product; or b) when making a notification required before placing the product for the first time on the EU market[343]; or c) when placing the product for the first time on the EU market; or d) when selling the result of the utilisation[344] or transferring it in any other way within the EU, for someone else to undertake a), b) or c) from above; or e) when the utilisation has ended and its outcome is sold or transferred outside the EU. In addition to collecting information as described above, the competent authorities of the Member States carry out checks to verify whether users comply with their obligations under Articles 4 and 7 of the EU ABS Regulation.[345] This is done based on periodically reviewed plan, and also when a competent authority is in possession of relevant information (including on the basis of substantiated concerns provided by third parties) regarding a user's non-compliance

[343] "Placing on the Union market" is defined as *the first making available of a product developed through the utilisation of genetic resources and associated traditional knowledge on the EU's market*. In turn, "making available" means the supply by any means, for distribution, consumption or use on the EU market in the course of a commercial activity, whether in return for payment or free of charge. Placing on the market does not include pre-commercial trials, including clinical, field or pest resistance trials, nor the making available of unauthorised medicinal products in order to provide treatment options for individual patients or groups of patients (Commission Implementing Regulation (EU) 2015/1866, Article 6).

[344] The "result of the utilisation" is defined as *products, precursors or predecessors to a product, as well as parts of products to be incorporated into a final product, blueprints or designs, based on which manufacturing and production could be carried out without further utilisation of the genetic resource and traditional knowledge associated with genetic resources* (Commission Implementing Regulation (EU) 2015/1866, Article 6).

[345] Regulation (EU) No 511/2014, Article 9

	with this Regulation. The Regulation requires that special considerations are given to such concerns raised by the provider countries. The checks may include an examination of the measures taken by a user to exercise due diligence; of documentation and records that demonstrate the exercise of due diligence in relation to specific use activities; instances where a user was obliged to make declarations under Article 7 etc. In addition, on-the-spot checks may also be carried out, as appropriate. [346] In summary, the two checkpoints as referred above and checks carried out under Article 9 form a monitoring system in the EU. The system is aimed at ensuring that users exercise due diligence to ascertain that the genetic resources they utilise have been accessed in accordance with applicable access and benefit-sharing legislation, and that benefits are fairly and equitably shared upon mutually agreed terms in accordance with any applicable legislation.

6. Compliance	
a) What are the competent authorities in charge of enforcement of the ABS legislation? Is compliance implemented in a centralised way (a single responsible body) or is it decentralised (several bodies with different competences)? What measures have been adopted to integrate/coordinate the actions of the bodies responsible for enforcing ABS rules at the national level? How to promote the integration/coordination of the various bodies responsible for enforcing ABS rules?	The EU ABS Regulation focuses on compliance measures, which are regulated at EU level. In accordance with the Regulation, Member States were to designate the competent authorities that are responsible for its application. Member States' competent authorities vary per case; both in terms of the specific agency in charge, and the amount of designated competent authorities. In some cases, there is only one, usually the ministry of environment or its equivalent. In others, a number of institutions have been designated, for example depending on the purpose or intended utilisation of the genetic resources.[347] In addition, the European Commission designated a focal point to liaise with the secretariat of the Convention on Biological Diversity.[348]
b) What measures have already been adopted to promote the effective monitoring of legal compliance?	The EU ABS framework as a whole is aimed at promoting user compliance. In addition, the EU ABS framework provides for the establishment of specific mechanisms to monitor compliance regarding the due diligence obligations applicable to users. Importantly, in addition to spelling out the obligations that users have regarding due diligence, the Regulation also acknowledges that there are a number of tools and approaches aimed at promoting or facilitating users'

[346] Regulation (EU) No 511/2014, Article 9
[347] The full list of designated competent authorities under the Regulation EU (No) 511/2014 is available from http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm
[348] Regulation (EU) No 511/2014, Article 6

	compliance. Some of these include best practices, sectoral codes of conduct, model contractual clauses and guidelines and a register of collections.[349] • Best practices: In accordance with the EU ABS Regulation best practices developed by users should play an important role in identifying due diligence measures that can support compliance with ABS measures at an affordable cost while providing legal certainty.[350] Competent authorities of the Member States should consider that the implementation of a recognised best practice by a user, reduces the user's risk of non-compliance and justifies a reduction in compliance checks. The same should apply to best practices adopted by the Parties to the Nagoya Protocol. [351] The Commission is in charge of the process of recognition of best practices, establishing and keeping up-to-date an internet-based register of recognised best practices. The process for application for recognition of a best practice is set out in Commission Implementing Regulation (EU) 2015/1866, Article 8.[352] • Guidance: The Regulation indicates that users should build on existing access and benefit-sharing codes of conduct developed for the academic, university and non-commercial research sectors and different industries.[353] Sector-specific guidance for a range of sectors (cosmetics, animal breeding, plant breeding, biocontrol, pharmaceuticals, food and feed, biotechnologies and upstream actors) is under development.[354] • Register of collections: The European Commission will establish and maintain a register of collections, once the need to do so is identified. The competent authorities of Member States are responsible for verifying that a collection under their jurisdiction meets the requirements for recognition as a collection for inclusion in the register. In turn, users that obtain a genetic resource from a collection included in the register should be considered in compliance with due diligence measures, with respect to seeking all necessary information.[355] The Regulations specifies the characteristics that the collection needs to perform in order to be included in the registry, as follows:

[349] Regulation (EU) No 511/2014, Preamble
[350] Regulation (EU) No 511/2014, Preamble
[351] Regulation (EU) No 511/2014, Preamble
[352] Commission Implementing Regulation (EU) 2015/1866, Article 8
[353] Regulation (EU) No 511/2014, Preamble
[354] See http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm
[355] Regulation (EU) No 511/2014, Preamble

	○ The relevant collection needs to be accompanied by the relevant document providing evidence of the legal access and, if required based on the legislation in the country providing the genetic resources. Evidence relating to the establishment of mutually agreed terms should also be submitted. ○ Apply standardised procedures for exchanging samples of genetic resources and related information. ○ Keep records of all samples of genetic resources and related information supplied for their utilisation. ○ Use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections.
c) Are there any measures foreseen in the national legislation to ensure benefit-sharing when access and utilisation of genetic resources and associated traditional knowledge occur outside the jurisdiction of the country where the access took place, especially when it is in a country that is not a Party to the Nagoya Protocol or when the user is based in a country that is not a Party?	The EU ABS Regulation was established to support the fair and equitable sharing of the benefits arising from the utilisation of genetic resources in accordance with the Nagoya Protocol. It acknowledges the importance of supporting the effective implementation of benefit-sharing commitments set out in mutually agreed terms between providers and users.[356] The Regulation applies to genetic resources that are accessed in the Nagoya Protocol countries and utilised in the EU. Thus, the Regulation does not apply to utilisation of the genetic resources outside of the EU.

7. Supporting instruments for the implementation of ABS legislation	
a) Does the legislation consider the development of community protocols related to access to traditional knowledge associated with genetic resources? If so, has the country developed them so far?	Not covered in the EU ABS framework.
b) Does the legislation include any model contractual clauses/standard agreement to be used for exchange of materials and establishment of MAT? Please specify	Given that establishment of mutually agreed terms is not covered at the EU level, model contractual clauses are not included in the legislation.

[356] Regulation (EU) No 511/2014, Preamble

8. Other areas of relevance to access and benefit-sharing	
a) Are there any specific provisions/piece of law related to genetic resources for food and agriculture?	In accordance with the EU ABS Regulation, "users acquiring plant genetic resources for food and agriculture in a country that is a Party to the Nagoya Protocol which has determined that these genetic resources under its management and control and in the public domain, not contained in Annex I to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), will also be subject to the terms and conditions of the standard material transfer agreement for the purposes set out under the ITPGRFA, shall be considered to have exercised due diligence."[357]
b) Intellectual property rights (focusing on patents): How do countries deal with patentability of living organisms found in nature and of its components, such as DNA, molecules and metabolites?	There is no reference to intellectual property rights in the EU ABS Regulation. In particular patent offices have not been established as checkpoints at the EU level. Patentability of living organisms is regulated by the general EU patent legislation, which predates the EU ABS legislation. Inventions can be protected in Europe either by national patents granted by the competent national intellectual property authorities in EU Member States or by European patents granted centrally by the European Patent Office. Only EU legislation is covered in this study. In accordance with EU legislation, the following can be patented: • Plants and animals.[358] Inventions which concern plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety[359] • A plant grouping which is characterised by a particular gene (and not its whole genome). Given that this is not covered by plant variety protection, it is therefore eligible for a patent even if it comprises new varieties of plants[360] • Biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature[361] • A microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety

[357] Regulation (EU) No 511/2014, Article 4.4
[358] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Preamble
[359] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Article 4.2
[360] WIPO Secretariat. (2009). *SCP/13/3 - Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights*. Geneva. Retrieved from http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=153917
[361] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Article 3

	• An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.[362] Regarding the scope of the protection of biotechnological inventions, the Directive 98/44/EC stipulates that the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material in which the product in incorporated and *in which the genetic information is contained and performs its function*.[363] Excluded from patentability are: • Plant and animal varieties[364] • Essentially biological processes for the production of plants or animals are excluded from patentability (however, microbiological processes or the products resulting from these can be patented)[365] • Processes for cloning human beings • Processes for modifying the germ line genetic identity of human beings • Uses of human embryos for industrial or commercial purposes • Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes [366] • Discoveries[367] • A mere DNA sequence without indication of a function[368] • The human body at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene.[369]
c) Do patent applications include disclosure of origin among the requirements that need to be filled in by the	No, this element is not included in the European patent application.[370] However, according to Directive 98/44/EC, if an invention is based on biological material of plant or animal origin or if it

[362] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Article 5
[363] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Article 9
[364] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Article 4.1
[365] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Article 4.1
[366] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Article 6
[367] See https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_2.htm
[368] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Preamble (23)
[369] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Article 5
[370] See http://documents.epo.org/projects/babylon/eponet.nsf/0/5C683C367A8DFBC7C12577F400449FD8/$File/1001_11_15_editable.pdf

applicant? Is it a mandatory or optional element? Is it only related to genetic resources or also to the associated traditional knowledge?	uses such material Member States could require the disclosure of the geographical origin of such material in the patent applications.[371]
d) International Treaty on Plant Genetic Resources for Food and Agriculture	The EU ABS framework recognises the ITPGRFA as a specialised international access and benefit-sharing instrument which should not be affected by the rules implementing the Nagoya Protocol.[372]
e) Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (PIP Framework) – World Health Organization	The EU ABS Regulation recognizes PIP Framework as a specialised ABS instrument that is consistent with the Nagoya Protocol.[373]

9. Key challenges of implementation	
Identified challenge	Brief explanation
Need for enhanced awareness raising about the EU ABS legal framework	Even though a lot has been done in order to raise awareness regarding the scope and application of the EU ABS framework, it is recognised that more needs to be done in this regard.
Perceived lack of clarity of the definitions provided by the Nagoya Protocol, and copied by the EU ABS Regulation	One of the widely recognised difficulties for implementing the Nagoya Protocol is the lack of clarity of its definitions. Since the EU ABS Regulation copied them into the regional framework, the same challenges currently exist at the EU level.

[371] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Preamble (27)
[372] Regulation (EU) No 511/2014, Preamble (12)
[373] Regulation (EU) No 511/2014, Preamble (16)

4.5 India

- Pursuant to the Convention on Biological Diversity, India enacted the Biological Diversity Act in 2002 and notified the Rules (Biological Diversity Rules) in 2004 to give effect to the provisions of the Convention. The Biological Diversity Act was enacted to comply with provisions of the Convention on Biological Diversity and, as such, it covers its three objectives, including fair and equitable sharing of benefits. The Nagoya Protocol is also being implemented at the national level through the Biological Diversity Act, 2002 and Biological Diversity Rules, 2004.
- In addition to the Biological Diversity Act, 2002, and the Biological Diversity Rules, 2004, the Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 (ABS Guidelines) complete the set of legally binding measures of the Indian ABS framework.
- Definitions in the Biological Diversity Act are based on those in the CBD, but they are not exactly the same. They were adapted to respond to the circumstances of the country.
- The ABS framework in India considers different requirements for non-Indians than for Indian citizens or organisations that are users of biological resources and associated knowledge.

1. Definition of key terms	
a) Definition of access to genetic resources and the associated traditional knowledge	While there is no definition of access in the legislation in place, the Biological Diversity Act, 2002 stipulates the scope and conditions for the utilisation of biological resources, including genetic resources occurring in India.
b) Definition of collection	The term "**collection**" is not defined. It is however mentioned in the definition of bio-survey or bio-utilisation (see definition below); Section 41(3) of the Biological Diversity Act; and Form I of the Biological Diversity Rules 2004 (application form for access to biological resources and associated traditional knowledge). **Bio-survey or bio-utilisation:** *survey or collection of species, subspecies, genes, components and extracts of biological resource for any purpose and includes characterisation, inventorisation and bioassay*[374]. In accordance with explanatory note developed by the National Biodiversity Authority (NBA), bio-survey and bio-utilisation refer to the survey or collection of species, subspecies, genes, components of biological resources and extracts of biological resources, as well as characterisation, inventorisation and bio-assay of biological resources and their components.[375]

[374] Biological Diversity Act, 2002, Chapter I
[375] http://nbaindia.org/content/565/56/1/explanatorynote.html

c) Definition of utilisation of genetic resources and the associated traditional knowledge	**Commercial utilisation:** *end uses of biological resources for commercial utilisation such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping*.[376] In accordance with the explanatory note developed by the National Biodiversity Authority (NBA), the utilisation of biological resources for conventional breeding; traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry, or bee keeping are exempted from being categorised as commercial utilisation under the provisions of the Biological Diversity Act.[377] **Research:** *study or systematic investigation of any biological resource or technological application that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use*.[378]
d) Definition of bioprospecting	Under the Biological Diversity Act, 2002, it is referred to as **bio-survey and bio-utilisation** which is defined as "*survey or collection of species, subspecies, genes, , components and extracts of biological resource for any purpose and includes characterisation, inventorisation and bioassay*"
e) Others definitions of relevance? E.g. biological resources, in situ conservation; indigenous species; benefit-sharing, derivative; genetic resources; genetic material	**Biological resources**: plants, animals and microorganisms or parts thereof, their genetic material and by-products with actual or potential value or use.[379] The definition explicitly excludes human genetic material and value added products (which are defined as products that may contain portions or extracts of plants and animals in unrecognisable and physically inseparable form).[380] Based on this definition, genetic resources are included within the meaning of the term biological resources, and therefore the provisions, which apply to biological resources also apply to genetic resources.[381] **Fair and equitable benefit-sharing:** sharing of benefits as determined by the National Biodiversity Authority under Section 21 of the Act.

[376] Biological Diversity Act, 2002, Chapter I
[377] http://nbaindia.org/content/565/56/1/explanatorynote.html
[378] Biological Diversity Act, 2002, Chapter I
[379] Biological Diversity Act, 2002, Chapter I
[380] Biological Diversity Act, 2002, Chapter I
[381] Research and Information Centre for Developing Countries (RIS), 2014, "National Study on ABS Implementation in India." Available at http://www.abs-initiative.info/fileadmin/media/Knowledge_Center/Pulications/ABS_Dialogue_042014/National_study_on_ABS_implementation_in_India_20140716.pdf

	Benefit claimers: the conservers of biological resources, their by-products, creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application.[382]

2. General information	
a) To whom do genetic resources belong? Are these considered private goods, goods of common use by the population, public goods or do they belong to the State, etc.?	The Biological Diversity Act does not regulate ownership of genetic resources but only the utilisation of biological resources and associated knowledge occurring in India for certain activities. Also, no direct reference to ownership or legal status of genetic resources exist in the constitution or any other law.[383] The Biodiversity Act however stipulates that prior approval of the competent national authority, the National Biodiversity Authority (NBA), or the State must be obtained before applying for intellectual property rights for an invention based on a biological resource obtained from India. Nonetheless, the Act includes no reference to the rights of ownership over the biological resources or land which may contain the genetic resources.
b) Does the legislation provide any indication on when it is considered that species have developed their own characteristics, i.e. distinctive properties, to start being considered a genetic resource of that country?	The ABS framework governs utilisation of biological resources occurring in or obtained from India, therefore including endemic resources as well as those that have been introduced.
c) Objective of the ABS legislation	The objective of the Biological Diversity Act is "to provide for conservation, sustainable use and fair and equitable sharing of the benefits arising out of the utilisation of biological resources, knowledge and for matters connected therewith or incidental thereto".[384]
d) Scope of the legislation – does it refer to all genetic resources or only to a subset (e.g. genetic resources for food and agriculture)? Are there any exemptions of genetic resources that fall outside of the scope (e.g. human genetic resources)?	Based on the definition of biological resources (see 1.e) above), the ABS framework applies to biological resources occurring in or obtained from India, that includes any plant genetic material that originated in Indian territory or has been introduced and/or adapted to Indian agro-ecologies where they have developed distinctive properties.[385] The Act also regulates activities that involve utilisation of knowledge associated with the biological resources.

[382] Biological Diversity Act, 2002, Chapter I
[383] Convention on Biological Diversity, UNEP/CBD/WG-ABS/5/5, Report on the legal status of genetic resources in national law, including property law, where applicable, in a selection of countries
[384] Biological Diversity Act, 2002, Preamble
[385] See http://nbaindia.org/content/19/16/1/faq.html

	Human genetic material and value added products based on biological resources are excluded from the definition of biological resources and are thus not covered by the ABS framework. In particular, the utilisation of biological resources for specific purposes is exempted from the categorisation of commercial utilisation, namely: • traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping[386] • biological resources *normally traded as commodities* are also exempted from the provisions in the Act.[387] In this respect, with the support of an expert committee established for the purpose, a list of biological resources normally traded as commodities was developed and notified in the Official Gazette in 2016.[388] However, an explanatory note developed by the NBA indicates that when the same item is used as a resource in a process or for the development of a product, such item is not exempt and shall be treated as a biological resource[389] • use by local people and communities of the area, including growers and cultivators of biodiversity, and vaids and hakims[390], who have been practicing indigenous medicine.[391] Furthermore, the government has issued a Notification[392] under Section 40 of the Biological Diversity Act 2002 to exempt crops listed in Annex 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) from the provisions of the Biological Diversity Act. This exemption only applies if they are used for the purpose of utilisation and conservation for research, breeding and training for food and agriculture, and not chemical, pharmaceutical and/or other non-food or feed industrial uses.
e) Is ABS regulated at the national or subnational level? To what extent does the national government share competencies with subnational entities?	Being India is a federal country, and as such ABS is regulated at the national level with some competencies shared with the States and local authorities. The ABS framework therefore

[386] http://nbaindia.org/content/565/56/1/explanatorynote.html
[387] Biological Diversity Act, 2002, Chapter IX, Section 40
[388] The Gazette of India, Notification No. S.O. 1352(E), 2016. Available at http://nbaindia.org/uploaded/pdf/Notification_of_Normally_Tradeded_Commidities_dt_7_April_2016.pdf
[389] http://nbaindia.org/content/565/56/1/explanatorynote.html
[390] Vaids and hakims are practitioners of two different medicine systems in India. Vaids practice Ayurveda and Hakims are physicians practising traditional remedies like Unani. For more information, see http://shodhganga.inflibnet.ac.in/bitstream/10603/13539/10/10_chapter%204.pdf
[391] Biological Diversity Act 2002, Chapter II, Section 7
[392] Gazette Notification S.O. 3232 (E), 2014

	envisages different aspects to be dealt with at national, provincial (State) and local levels, as follows: • National level: The NBA regulates the access to biological resources and fair and equitable benefit-sharing, and is responsible for granting access to biological resources or associated knowledge by foreign nationals or institutions, or non-resident Indians or entities registered in India, which have any non-Indian participation in its share of capital or management. The NBA also grants approvals to any person who applies for intellectual property rights in and outside India, for any invention based on any research or information on a biological resource obtained from India. • States: If an Indian citizen or organisation registered in India with no non-Indian participation in its share capital or management wants to obtain a biological resource for commercial utilisation or bio-survey and bio-utilisation for commercial utilisation, they need to prior approval the relevant State Biodiversity Board (SBB).[393] • Local level (villages): The Biodiversity Management Committees are in charge of preparing, maintaining and validating the People's Biodiversity Registers which contain comprehensive information on availability and knowledge of local biological resources, their medicinal or any other use or any other traditional knowledge associated with them.[394] In turn, the NBA and the State Biodiversity Boards have to consult the Biodiversity Management Committees while taking any decision relating to the use of biological resources and knowledge associated with such resources occurring within the territorial jurisdiction of the Biodiversity Management Committee (BMC).[395] The BMC may levy charges by way of collection fees from any person for accessing or collecting any biological resource for commercial purposes from areas falling within its territorial jurisdiction.[396]

[393] Biological Diversity Act, 2002, Chapter VI
[394] NBA, Revised PBR Guidelines, 2013. Available at http://nbaindia.org/uploaded/pdf/PBR%20Format%202013.pdf
[395] Biological Diversity Act 2002, Chapter X
[396] Biological Diversity Act 2002, Chapter X, Section 41(3)

3. Access to genetic resources and associated traditional knowledge	
a) According to the legislation, is access to genetic resources and/or associated traditional knowledge subject to prior informed consent (PIC)?	Prior informed consent is not explicitly mentioned in the Indian ABS framework. However, the first interim national report to the Nagoya Protocol affirms that access to the biological resources in India operates on the principle of prior informed consent (PIC), as provided in the Biological Diversity Act, 2002.[397] The approval of NBA, is a pre-requisite for carrying out research/commercial utilisation/bio-survey and bio-utilisation/obtaining intellectual property rights/transfer of results of research over biological resources and third party transfer of the already accessed biological resources. In particular, it is considered that PIC is accorded with the involvement of local people and communities following a process of *consultation* with them through the established institutional mechanism of SBBs, which in turn *consult* the BMCs at the local (village) level.[398] The NBA and SBBs are required to consult the concerned local level BMCs on matters relating to the use of biological resources and associated traditional knowledge within their jurisdiction.[399] This mandatory consultation of the concerned BMCs formalises the prior informed consent by communities for access and benefit-sharing.[400] It is worth noting that in accordance with the Fifth National Report on the implementation of the Convention on Biological Diversity, one of the actions India is working on refers to development of an appropriate system and modalities for operationalizing provisions for prior informed consent and benefit-sharing under the Biological Diversity Act, working towards greater congruence between these provisions and trade related aspects of intellectual property rights.[401] The process stipulated in the Biological Diversity Rules 2004 refers to the approval required for access to genetic resources. The NBA needs to grant permission to: • Any person who is not a citizen of India, or who is a non-resident Indian or a body corporate, association or organisation not incorporated or registered in India or registered/incorporated in India which having on-Indian participation in its share capital or management interested in accessing biological resources and/or associated knowledge occurring in India for research, or for commercial utilisation, or for bio-survey and bio-utilisation (Form I)

[397] India, 2017, Interim National Report on the Implementation of the Nagoya Protocol, available at https://s3.amazonaws.com/absch.documents.abs/records/absch-nr-in-238716-2-en.pdf
[398] India, 2017, Interim National Report on the Implementation of the Nagoya Protocol, available at https://s3.amazonaws.com/absch.documents.abs/records/absch-nr-in-238716-2-en.pdf
[399] Biological Diversity Act 2002, Chapter X, Section 41(3)
[400] India, 2005, Third National Report on the implementation of the Convention on Biological Diversity
[401] This action was initially identified in the National Biodiversity Action Plan (NBAP) 2008, then also included in the Addendum 2014 to NBAP 2008

	• Transfer[402] of results of research relating to biological resources obtained from India for monetary consideration to foreign nationals, companies and Non-Resident Indians (Form II) • Apply for any intellectual property right (patents or any other) in India or abroad, for any invention based on any research or information on a biological resource occurring in or obtained from India (Form III) • Apply for third party transfer of the already accessed biological resources and associated traditional knowledge (Form IV) In turn, as mentioned above, the State Biodiversity Boards are in charge of granting permission to Indian nationals or a body corporate, association or organization which is registered in India to obtain any biological resource for commercial utilisation, or bio-survey and bio-utilisation for commercial utilisation. The following activities or persons are exempted from requesting approval of the NBA or State Biodiversity Board: • Indian citizens or entities accessing biological resources and/or associated knowledge, occurring in or obtained from India, for research or bio-survey and bio-utilisation for research in India • Collaborative research projects, involving the transfer or exchange of biological resources or related information, if the projects have been approved by the relevant governmental body (exempted from the regulatory scope of Sections 3 and 4 of the Act)[403] • Local people and communities of the area, including growers and cultivators of biological resources, and vaids and hakims, practising indigenous medicine (exempted from activities mentioned under Section 7 of the Act) • accessing value added products, which are products containing portions or extracts of plants and animals in unrecognisable and physically inseparable form[404]; and • biological resources, normally traded as commodities notified by the Central Government under Section 40 of the Biological Diversity Act. When a normally traded commodity is used for a purpose other than commodity trade, there is a need to get prior approval from the

[402] The Biological Diversity Act, 2002, clarifies that "transfer" does not include publication of research papers or dissemination of knowledge.
[403] Biological Diversity Act, 2002, Section 5. Also see Guidelines for International Collaboration of Research Projects involving Transfer or exchange of Biological Resources or information relating thereto between institutions including Government sponsored Institutions and such institutions in other countries, 2006
[404] In an explanatory note in the NBA website, it is explained that even though the biological resources by definition do not include value added products, an explicit exemption has been mentioned to allay the fears of Indian industry so that export of value added products is not hampered. Available at http://nbaindia.org/content/19/16/1/faq.html

	NBA.[405] When they are utilised for research and development by certain individuals under Section in 3 of the Biological Diversity Act (i.e. foreign individuals and organisations) and for alternate/commercial uses they need to get prior approval from NBA, as the exemption is only for purposes of commodity trade. • Persons making an application for any right under the Protection of Plant Varieties and Farmers' Rights Act, 2001 are exempted from the scope of Section 6 of the Act. The Authority can revoke approval of any application due to various reasons, e.g. when the person that has been granted approval has failed to comply with the terms of the agreement.[406] Information on how to apply for permission to access biological resources and/or associated traditional knowledge occurring in India is provided in the Biological Diversity Rules, 2004 and the ABS Regulations, 2014. The NBA, in its role as the Competent National Authority for the country, has provided information such as: user guidelines, interactive videos, online ABS application format and process, and FAQs to facilitate the application process.[407]
b) Does the legislation establish rules/procedures for requiring and establishing mutually agreed terms (MAT)?	Yes. In accordance with the Biological Diversity Rules 2004, the approval of access to biological resources and associated traditional knowledge needs to be communicated through a written agreement between the NBA and the applicant.[408] Furthermore, the Biological Diversity Act 2002 stipulates that the NBA shall ensure that the terms and conditions subject to which approval is granted secures equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge in accordance with the mutually agreed terms and conditions between the person applying for such approval, relevant local bodies and benefit claimers.[409] Minimum requirements for MAT are provided in the agreements signed by the NBA with the applicant for access to bio-resources/traditional knowledge as provided in Rule 14(6) of the Biological Diversity Rules, 2004, including: • description of the biological resources and traditional knowledge including accompanying information

[405] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Regulation 17
[406] Biological Diversity Rules, 2004, Rule 15
[407] India, 2017, Interim National Report on the Implementation of the Nagoya Protocol, available at https://s3.amazonaws.com/absch.documents.abs/records/absch-nr-in-238716-2-en.pdf Also see www.nbaindia.org
[408] Biological Diversity Rules 2004, Rule 14(5)
[409] Biological Diversity Act, 2002, Chapter V, Section 21

	• intended uses of the biological resources (research, breeding, commercial utilisation etc.) • conditions under which the applicant may seek intellectual property rights • quantum of monetary and other incidental benefits • submitting to the Authority a regular status report of research and other developments.[410]
c) Does the legislation set out criteria for the approval and involvement of indigenous and local communities for access to genetic resources and associated traditional knowledge?	India has put in place measures with the aim of ensuring the prior informed consent or approval and involvement of local communities as provided in Article 6.2 of the Nagoya Protocol. For that purpose, India has also set out criteria and/or process for obtaining prior informed consent or approval and involvement of local communities for access to genetic resources. The Biological Diversity Act, 2002 provides for the involvement of local communities through Biodiversity Management Committees in the decision making process relating to access to biological resources and associated traditional knowledge through consultation by the NBA. India has taken measures to ensure that traditional knowledge associated with biological resources that is held by local communities within the country is accessed with the PIC or approval and involvement of these local communities, and that MAT have been established as provided in Article 7 of the Nagoya Protocol. The Biological Diversity Act, 2002 provides mandatory consultation with the BMCs by NBA and SBBs before granting access to biological resources. Hence, the decisions taken at the national and provincial levels relating to access and utilisation of biological resources are taken with the involvement of the local people/communities through consultations. Regarding the composition of the BMCs, they consist of a Chairperson and no more than six persons nominated by local bodies, of whom not less than one third should be women and not less than 18% should belong to the Scheduled Castes/Scheduled Tribes. [411, 412] The BMC will be constituted by the local body with members of the participatory forest/natural resources management committees members, including from members of horticulture/vaids/foot botanists/tribal heads, etc., based on the local conditions. The requests for access to biological resources and/or associated knowledge received by the NBA are examined in consultation with the BMCs, wherein communities are required to provide their inputs on the requests made. Upon receipt of the consultation form from NBA/SBB, the BMC will interact with the concerned communities, individual or group who holds the rights on

[410] Biological Diversity Rules 2004, Rule 14(6)
[411] Scheduled Castes and Scheduled Tribes are among the most disadvantaged socio-economic groups in India.
[412] Biological Diversity Rules 2004, Rule 22

	the biological resources and associated traditional knowledge and obtain their consent or otherwise on the access requests made for and communicate the same to the NBA/SBB. If the knowledge holders or communities could not be identified, the BMC will provide the consent or otherwise on its own initiative based on the facts/information available to them. Thus, by way of involving the local level functionaries in the process of consultation, the NBA facilitates the communities to exercise their collective rights in the process to prevent abuse, misuse, misappropriation and/or infringement of the rights held by them. Wherever, the BMCs are not formed yet, the consultation process is being done by the SBB in consultation with the communities concerned. Also, the People's Biodiversity Register (containing information on availability and knowledge of local biological resources, their medicinal or any other use, or any other traditional knowledge associated with them) is prepared by the Biodiversity Management Committee in consultation with the local people.[413] India endeavours to not to restrict the customary use and exchange of genetic resources and associated traditional knowledge within and among local communities as provided on Article 12.4 of the Nagoya Protocol. Consequently, the Biological Diversity Act, 2002 provides for certain exemptions so as not to restrict the customary use and exchange of biological resources and associated traditional knowledge within and among local people and communities. For example, the definition of "commercial utilisation" in Section 2(f) does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping. Further, Section 7 of the Biological Diversity Act 2002, which requires prior intimation to be given to the SBB for obtaining biological resources, excludes local people and communities of the area, including growers and cultivators of biodiversity, and vaids and hakims, who have been practicing indigenous medicine.[414]
e) Does the legislation address any changes of intent in the utilisation of accessed genetic resources? (e.g. initially accessed for non-commercial research and then changing their utilisation to commercial)	Yes. There is no requirement under the legislation for seeking permission for carrying out research, when it is carried out in India by Indians. Regulation 13 of the ABS Guidelines 2014 through Form B facilitates carrying/sending of biological resources outside India to undertake basic research by Indian researchers/governmental institutions in India to carry out urgent studies to avert emergencies like epidemics etc., through an expeditious and simplified process.

[413] NBA, Revised PBR Guidelines 2013. Available at http://nbaindia.org/uploaded/pdf/PBR%20Format%202013.pdf
[414] India, 2017, Interim National Report on the Implementation of the Nagoya Protocol

	The applications filed under this provision are considered and disposed expeditiously within a specified timeframe through simplified measures; no fee is charged for such applications.[415]
d) Does the legislation address any changes of intent in the utilisation of accessed genetic resources? (e.g. initially accessed for non-commercial research and then changing their utilisation to commercial)	If an applicant obtains approval for access and utilisation of biological resources for basic research but at a later stage decides to utilise them for commercial purposes, a new access permit needs to be obtained, with an agreement signed between the NBA and the applicant to decide the terms and conditions to ensure the equitable sharing of benefits. [416] In this respect, the NBA may either on the basis of any complaint or on its own initiative withdraw the approval granted for access and revoke the written agreement when the applicant has failed to comply with any of the conditions of access granted, including when there is a change in the use of biological resources for purposes other than that for which the approval was originally granted.[417]
f) Are there any specific provisions/piece of law related to genetic resources for food and agriculture?	The Indian ABS framework provides a differential treatment for agricultural activities. In particular, the Government of India has issued a notification under Section 40 of the Biological Diversity Act 2002 exempting crops listed in Annex 1 of the ITPGRFA from the provisions of the Act. This exemption only applies if they are utilised for the purpose of research, breeding and training for food and agriculture, and not for chemical, pharmaceutical and/or other non-food or feed industrial uses.[418] The Protection of Plant Varieties and Farmers' Rights Act, 2001 was enacted for protection of plant varieties, the rights of farmers and plant breeders and to encourage the development of new varieties of plants. In addition, the Biological Diversity Act, 2002 provides the opportunity for the NBA to constitute a committee to deal with agro-biodiversity, which is defined as biodiversity of agriculture-related species and their wild relatives. As a result, the Expert Committee on Agro-biodiversity was established in 2005 to focus on issues relating to agro-biodiversity vis-à-vis the objectives of the Act.

[415] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Regulation 13
[416] Research and Information Centre for Developing Countries (RIS), 2014. "National Study on ABS Implementation in India."
[417] Biological Diversity Rules 2004, Rule 15
[418] Gazette Notification on exemption of crops listed in the Annex I of the ITPGRFA, 2014

4. Benefit-sharing	
a) What triggers benefit-sharing? Does any utilisation of genetic resources create a benefit-sharing obligation, even if it does not add value to the product or market?	When it comes to benefit-sharing, the legislation considers the crucial role of the benefit-claimers who conserve biological resources and its by-products, creators and holders of associated knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application.[419] The National Biodiversity Authority shall, while granting approvals for the above purposes, ensure that the terms and conditions - subject to approval granted - secures equitable sharing of benefits arising from the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.[420] If the biological resources occurring in India or knowledge associated thereto are intended to be used for research, commercial utilisation, bio-survey and bio-utilisation, transfer of results of any research, apply for a patent or any other form of intellectual property protection in India or outside India, or transfer any biological resource or knowledge associated thereto for which approval has already been granted by the NBA, the benefit-sharing obligation is invoked.
b) Does the legislation provide an indication of what can constitute (monetary and non-monetary) benefits to be shared?	The ABS Guidelines 2014 provide a list of options for monetary and non-monetary benefits (see below). These options are indicative in nature and other options, as approved by the NBA in consultation with the Central Government, may also be adopted (Annexure I). Benefit-sharing will be agreed on a case-by-case basis in accordance with mutually agreed terms between the applicant and the NBA. • Monetary benefits options: Up-front payment; one-time payment; milestone payments; Share of the royalties and benefits accrued; share of the licensee fees; contribution to National, State or Local Biodiversity Funds[421]; funding for research and development in India; joint ventures with Indian institutions and companies; joint ownership of relevant intellectual property rights • Non-monetary benefits options: providing institutional capacity building, including training on sustainable use practices, creating infrastructure and undertaking development of work

[419] Biological Diversity Act, 2002, Chapter I
[420] Biological Diversity Act, 2002, Section 21
[421] These funds are currently operational.

	related to conservation and sustainable use of biological resources; transfer of technology or sharing of research and development results with Indian institutions/individuals/entities; strengthening of capacities for developing technologies and transfer of technology to India and/or collaborative research and development programmes with Indian institutions/ individuals/ entities; contribution/ collaboration related to education and training in India on conservation and sustainable use of biological resources; location of production, research, and development units and measures for conservation and protection of species in the area from where biological resource has been accessed, contributions to the local economy and income generation for the local communities; sharing of scientific information relevant to conservation and sustainable use of biological diversity including biological inventories and taxonomic studies; conducting research directed towards priority needs in India including food, health and livelihood security focusing on biological resources; providing scholarships, bursaries and financial aid to Indian institutions/ individuals preferably to regions, tribes/ sects contributing to the delivery of biological resources and subsequent profitability if any; setting up of venture capital fund for aiding the cause of benefit claimers; payment of monetary compensation and other non-monetary benefits to the benefit claimers as the NBA may deem fit.[422]
c) Does the national legislation exempt benefit-sharing arising from any particular utilisation (research and development), even if the CBD support the sharing of the benefits arising from such activities?	Not all activities that are regulated under the Act incur benefit-sharing obligation. For instance, non-commercial research or research for emergency purposes outside India by Indian researchers/government institutions fall outside the purview of benefit-sharing mechanism. In addition, the notification issued under Section 40 of the Biological Diversity Act 2002 exempted crops listed in Annex 1 of the ITPGRFA from the provisions of the Act.
d) Are there any specific provisions on how benefit-sharing should be dealt with respect to traditional knowledge hold by indigenous peoples and local communities?	Access to traditional knowledge is regulated under Sections 3, 6 and 20 of the Act (see items 3.a, b and c) above relating to access) and the respective benefit-sharing obligation is elaborated under the ABS Guidelines (see items 4.e, and f below).
e) Does the national legislation consider benefit-sharing arising from the utilisation of traditional knowledge for those cases in which it was accessed from secondary sources (publications, registries, databases, inventories,	The Act considers benefit-sharing arising from access to or utilisation of traditional knowledge occurring in and obtained from India from any source. With respect to situations in which the peoples or communities that hold it cannot be identified, the legislation stipulates that the benefits need to be deposited in the National Biodiversity

[422] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Form B, Annexure 1

etc.), or when it is not possible to identify the peoples or communities that hold it?`	Fund.[423] The benefits accrued are to be used for conservation of biological resources, and to promote livelihoods of the local people from the area where such resources are accessed.[424]
f) How does the national legislation define the amount to be paid as benefit-sharing? Does it establish a fixed percentage for benefit-sharing?	The Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations 2014 stipulate a series of options relating to the amount of the benefit-sharing obligations. This amount is presented in the form of percentage of the purchase price of the biological resources[425], and the amount of benefits is to be mutually agreed upon between the applicant and the NBA in consultation with the local bodies and benefit claimers. The NBA is responsible for determining, on a case by case basis, the applicable benefit-sharing, taking into consideration the following aspects: commercial utilisation of the biological resource, stages of research and development, potential market for the outcome of research, amount of investment already made for research and development, nature of technology applied, time-lines and milestones from initiation of research to development of the product and risks involved in commercialisation of the product.[426] The amount of benefit-sharing remains the same whether the end product contains one or more biological resources. Where the biological resources of a product are sourced from the jurisdiction of two or more State Biodiversity Boards, the total amount of the accrued benefits is to be shared among them in proportion as decided by the NBA/relevant State Biodiversity Boards, depending on the case.[427] The following percentages apply to the different types of activities: *Benefit-sharing for access to biological resources, for commercial utilisation or for bio-survey and bio-utilisation for commercial utilisation*: • Where the applicant/trader/manufacturer has not entered into any prior benefit-sharing negotiation with persons such as the Joint Forest Management Committee (JFMC)/Forest dweller/Tribal cultivator/Gram Sabha[428], and purchases any biological resources directly

[423] Biological Diversity Rules, 2004, Rule 20(8)
[424] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Regulation 15; and India's Interim National Report on the Implementation of the Nagoya Protocol, 2017, available at https://s3.amazonaws.com/absch.documents.abs/records/absch-nr-in-238716-2-en.pdf
[425] Biological resources are raw materials whose purchase price is being considered for determining the benefit-sharing obligation.
[426] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Regulation 14(2). Special consideration might be given to cases where technologies/products are developed for controlling epidemics/diseases and for mitigating environmental pollution affecting human/animal/plant health.
[427] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Regulation 14(3) and (4)
[428] Gram Sabha means a village assembly, comprising all adult members of the village. See Model Rules for the Panchayats (Extension of The Scheduled Areas) Act, 1996, available at http://www.panchayatgyan.gov.in/documents/30336/0/7.+MoPR%27s+Model+Rules+on+PESA.pdf/903a7933-dd33-404a-93b2-561bba89fd44

	from these persons, the *benefit-sharing obligations on the trader* ranges between 1 to 3% of the purchase price of the biological resources and the *benefit-sharing obligations on the manufacturer* ranges between 3 to 5% of the purchase price of the biological resources. • Where the trader sells the biological resource purchased by him to another trader or manufacturer, the *benefit-sharing obligation on the buyer* ranges: (i) between 1 to 3% of the purchase price, if it is a trader, and (ii) between 3 to 5%, if he is a manufacturer. Where a buyer submits proof of benefit-sharing by the immediate seller in the supply chain, the benefit-sharing obligation on the buyer shall be applicable only on that portion of the purchase price for which the benefit has not been shared in the supply chain. • Where the applicant/trader/manufacturer has entered into any prior benefit-sharing negotiation with persons such as the Joint Forest Management Committee (JFMC)/Forest dweller/Tribal cultivator/Gram Sabha, and purchases any biological resources directly from these persons, the benefit-sharing obligations on the applicant shall be not less than 3% of the purchase price of the biological resources in case the buyer is a trader and not less than 5% in case the buyer is a manufacturer. • In cases of biological resources having high economic value[429] such as sandalwood, red sanders, etc. and their derivatives, the benefit-sharing may include an upfront payment of not less than 5%, on the proceeds of the auction or sale amount, as decided by the NBA or SBB, as the case may be, and the successful bidder or the purchaser shall pay the amount to the designated fund, before accessing the biological resource. [430] The NBA has issued Guidelines for Upfront Payment. These indicate the amount of upfront payment for access to biological resources and associated traditional knowledge for research or bio-survey and bio-utilisation leading to commercial utilisation applicable to different sectors. The amounts of the upfront payments vary not only depending on the sector but also on the source from which the biological resources are being accessed (e.g. natural habitat; cultivated source, etc.)[431]

[429] The criteria to define biological resources of high economic value as been decided on a case by case basis, by an Expert Committee.
[430] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Section 3
[431] The Guidelines on upfront payment are available at http://nbaindia.org/uploaded/pdf/Guidelines_for_Upfront_Payment.pdf

	Option of benefit-sharing on sale price of the biological resources accessed for commercial utilisation:[432] When the biological resources are accessed for commercial utilisation or when the bio-survey and bio-utilisation leads to commercial utilisation, the applicant has the option to pay benefit-sharing ranging from 0.1 to 0.5 % of the annual gross ex-factory sale of the product which shall be calculated based on the annual gross ex-factory sale minus government taxes. The Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014 provide thresholds depending on the value of the annual gross ex-factory sale of product, with benefit-sharing components of 0.1%, 0.2% or 0.5% respectively.[433] *Benefit-sharing for transfer of results of research*: The applicant shall, in case of transfer of results of research, pay to the NBA such monetary and/or non-monetary benefit, as agreed between the applicant and the NBA. Provided that in case of monetary benefit received by him, if any, on such transfer, the applicant needs to pay to the NBA between 3 and 5% of the monetary consideration.[434] *Benefit-sharing in intellectual property rights*: The applicant shall, in case of commercializing the obtained intellectual property right, pay to the NBA such monetary and/or non-monetary benefit, as agreed between the applicant and the NBA. • Where the applicant himself commercialises the process/product/innovation, the monetary sharing shall be in the range of 0.2 to 1% based on sectoral approach, which shall be worked out on the annual gross ex-factory sale minus government taxes. • Where the applicant assigns/licenses the process/product/innovation to a third party for commercialisation, the applicant shall pay to NBA 3 to 5% of the fee received (in any form including the license/assignee fee) and 2 to 5% of the royalty amount received annually from the assignee/licensee, based on sectoral approach[435].[436]

[432] The option of choosing sale price of biological resources accessed for commercial utilisation to determining benefit-sharing is done through the mutually agreed terms between the applicant and the NBA. If opting for sale price, benefit-sharing based on purchase price of the biological resources does not apply.
[433] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Section 4
[434] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Section 7
[435] Applications are considered and decided on a case-to-case basis by the Expert Committee for Access and Benefit-sharing. The Committee takes into account the nature of the applicant (academic or industry) and the sector of innovation that applies to them (agricultural or nutraceutical, pharmaceutical, chemical and diagnostic, cosmetic and luxury products, environmental bio-remediation or waste conversion/recycling).
[436] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Section 9

	Benefit-sharing for transfer of accessed biological resource and/or associated knowledge to third party for research/commercial utilisation: The applicant shall pay to the NBA such monetary and/ or non-monetary benefit, as agreed between the applicant and the NBA. • Applicant (transferor) shall pay to the NBA 2% to 5% (following a sectoral approach) of any amount and/or royalty received from the transferee, as benefit-sharing, throughout the term of the agreement. • In case the biological resource has high economic value, the applicant shall also pay the NBA an upfront payment, as mutually agreed between the applicant and the NBA.[437] Where any amount of money is ordered by way of benefit-sharing, the National Biodiversity Authority may direct the amount to be deposited in the National Biodiversity Fund. In cases where biological resource or knowledge was a result of access from a specific individual or group of individuals or organisations, the National Biodiversity Authority may direct that the amount shall be paid directly to such individual or group of individuals or organisations in accordance with the terms of any agreement and in such manner as it deems fit.[438] Where approval has been granted by the NBA for research or for commercial utilisation or for transfer of results of research or for intellectual property rights or for third party transfer, the received benefits need to be shared as follows: • 5% of the accrued benefits directed towards the NBA. Half of this amount is retained by the NBA and the other half may be passed on to the concerned State Biodiversity Board for administrative charges • 95% of the accrued benefits directed towards the relevant Biodiversity Management Committees and/or benefit claimers. For situations in which the biological resource or associated knowledge was a result of access from a specific individual or group of individuals or organisations, the NBA is responsible for ensuring that the agreed amount is paid directly to such individual or group of individuals or organisations through the district administration. If these individuals or group of individuals or organisations cannot be identified, the monetary benefits are deposited in the National Biodiversity Fund.[439]

[437] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Section 12
[438] Biological Diversity Act, 2002, Section 21(3)
[439] Biological Diversity Act, 2002, Chapter V; Biological Diversity Rules, 2004, Rule 20; and Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Section 15

	Where approval has been granted by a State Biodiversity Board, this may retain a share, not exceeding 5% of the benefits accrued towards their administrative charges and the remaining share shall be passed on to the relevant Biodiversity Management Committee or to benefit claimers, where identified. [440] The NBA, SBB and BMC are responsible for monitoring the flow of benefits in a manner determined by them.[441] For this purpose, the users of the biological resources and associated knowledge are required to submit the annual status report on the use of such biological resources and associated knowledge.
g) Who should pay for the benefits to be shared (the one who carries out access to/utilisation of genetic resources and the associated traditional knowledge, the one who undertakes the economic exploitation, or both)?	The benefits are to be shared by both, the one who carries out access to/utilisation of genetic resources and the associated traditional knowledge and the one who undertakes the economic exploitation.
h) Where within the production chain rests the obligation to pay benefits? ○ supplier of raw material, ○ intermediary, ○ final product ready for commercialisation, or ○ all	In the production chain, the obligation to pay benefits lies with all of them, namely the supplier of raw materials, intermediary, final product ready for commercialisation. The ABS Guidelines, 2014 indicate the person responsible for complying with the benefit-sharing obligations as well as the amount for each of those based on the type of activity of the specific individual (see 4.f) above).
i) Is there anyone else that needs to share benefits? For example, non-commercial research, commercial research, intellectual property rights licensing, the whole value chain of an industry or the one with the greater added value?	As specified in 4.f) above, not only final products but also research for commercial utilisation, intellectual property licensing for commercial utilisation, transfer the results of research for monetary consideration, third party transfer of accessed biological resources and/ or associated knowledge, have benefit-sharing obligations.

5. Monitoring and reporting	
a) What are the designated checkpoints? What are their functions and responsibilities? How do they work?	India is yet to designate checkpoints. In accordance with its Interim National Report, the government is currently in the process of consultation with the various governmental agencies with functions relevant to the utilisation of biological resources or collection of relevant information at different stages of research, development, innovation, pre-commercialisation, or commercialisation. Although checkpoints are yet to be designated, the Indian Patent Office is

[440] Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, Section 15.
[441] Biological Diversity Rules, 2004

	performing a similar function as patents for inventions based on biological resources and associated knowledge obtained from India can be granted only upon submission of the necessary approvals under the Biological Diversity Act, 2002.[442]
b) What are the reporting requirements? Who is responsible for reporting?	Reporting requirements relating to the utilisation of biological resources and/or associated knowledge are included in the mutually agreed terms which is incorporated in the agreement executed between the user and the NBA.[443]
c) How can access to/utilisation of genetic resources and associated traditional knowledge be tracked? Has the country developed any particular method/mechanism to monitor the access and utilisation of genetic resources and/or associated traditional knowledge?	NBA gives approvals in the form of ABS Agreements. The ABS Agreement contains a clause for submitting annual status reports on the usage of biological resources. This report is used as tool for monitoring the accrual of benefits. Furthermore, there is a dedicated system to monitor patents filed abroad without seeking approval from the NBA. Non-compliance with Section 6 is a punishable offence under the Act.
d) Does the country have any monitoring systems for patent databases, registries of products resulting from access, and scientific publications so to identify activities that are not in compliance with the domestic legislation of the country where the access took place and with the Nagoya Protocol?	There is a system to monitor and identify patent applications that are filed abroad without complying with the provisions of the Act and to react accordingly to such non-compliant patent application by taking steps to oppose it. Under Section 18(4) of the Act, the NBA is provided statutory power to take any measures necessary to oppose the grant of intellectual property rights in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource which is derived from India.

6. Compliance	
a) What are the competent authorities in charge of enforcement of the ABS legislation? Is compliance implemented in a centralised way (a single responsible body) or is it decentralised (several bodies with different competences)? What measures have been adopted to integrate/coordinate the actions of the bodies responsible for enforcing ABS rules at the national level? How to promote the integration/coordination of the various bodies responsible for enforcing ABS rules?	The National Biodiversity Authority (NBA) has been designated as the Competent National Authority as provided in Article 13 of the Protocol. However, in order to carry out the functions of the Biological Diversity Act, a three-tiered structure has been established consisting of national, state and local level institutions as follows: • National Biodiversity Authority (NBA) – national level • State Biodiversity Boards (SBBs) – state level. • Biodiversity Management Committees (BMCs) – local level They are the competent authorities responsible for implementing the Biological Diversity Act and the Rules.[444]

[442] India's Interim National Report on the Implementation of the Nagoya Protocol, 2017, available at https://s3.amazonaws.com/absch.documents.abs/records/absch-nr-in-238716-2-en.pdf
[443] India's Interim National Report on the Implementation of the Nagoya Protocol, 2017, available at https://s3.amazonaws.com/absch.documents.abs/records/absch-nr-in-238716-2-en.pdf
[444] Research and Information Centre for Developing Countries (RIS), 2014, "National Study on ABS Implementation in India."

	While taking decisions on the application seeking approval, the decision would be intimated to the concerned SBBs for monitoring. The Act, Rules and guidelines prescribe exclusive powers and mandates to each of these bodies to ensure coordination/integration of the actions taken at each level.
b) What measures have already been adopted to promote the effective monitoring of legal compliance?	The following measures have been adopted to monitor legal compliance: • Section 39 of the Act provides that the applicant shall deposit the voucher specimen of biological material/specimens in the institutions notified as designated repositories by the Central Government. This obligation is one of the conditions mentioned in the mutually agreed terms entered with the applicant. • The ABS Agreement contains a clause for submitting annual status reports on the usage of biological resources. This serves as an effective way to monitor legal compliance by the applicant. • The IRCC procedure provides an authentic platform to track/monitor access and utilisation of biological resources and associated knowledge.
c) Are there any measures foreseen in the national legislation to ensure benefit-sharing when access and utilisation of genetic resources and associated traditional knowledge occur outside the jurisdiction of the country where the access took place, especially when it is in a country that is not a Party to the Nagoya Protocol or when the user is based in a country that is not a Party?	In accordance with the Indian ABS legislation even when some activities take place outside India, there is a benefit-sharing obligation attached to them. In particular: • When any person intends to obtain any intellectual property right in or outside India, for any invention based on any research or information on any biological resources and associated knowledge obtained from India (as it needs to, in accordance with the Biological Diversity Rules 2004, make an application to the NBA).[445] • When any non-Indians intend to access the microorganisms deposited by an Indian scientist in the foreign repository under the Budapest Treaty, they will need to seek prior approval of NBA.

7. Intellectual property rights (focusing on patents)	
a) How does the country deal with patentability of living organisms found in nature and of its components, such as DNA, molecules and metabolites?	In India, the following are not considered patentable inventions and are therefore *excluded* from patentability:

[445] Biological Diversity Act, 2002, Section 6; and Biological Diversity Rules, 2004, Rule 18 and Form III

	• plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals • an invention which in effect, is traditional knowledge[446] or which is an aggregation or duplication of known properties of traditionally known component or components • the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature • the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process (For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance are considered to be the same substance, unless they differ significantly in properties with regard to efficacy) • a method of agriculture or horticulture[447] As a result, naturally existing products such as nucleic acid sequences, proteins, enzymes, compounds, etc., which are directly isolated from nature are not patentable subject matter.[448] Genetically modified organisms and microorganisms, other than those that are naturally occurring in nature, may be patentable.[449] Claims relating to basic biological processes of growing plants, germination of seeds, of development stages of plants and animals are not patentable. [450] Irrespective of the nature of the biological resources, any person who intends to obtain IPA based on any biological resources as defined in the Biological Diversity Act, 2002 needs prior approval of NBA.

[446] The Examiner conducts an investigation by using the Traditional Knowledge Digital Library (TKDL) and other resources to decide as to whether the claimed subject matter falls within the purview of this provision (Manual of Patent Office Practice and Procedure, 2011)
[447] The Patents Act, 1970, Chapter II, Section 3
[448] Laskar, Mansoor Elahi, 2013, "Patentability of Life Forms (USA, Europe and Asia) - IPR and Biotechnology." Available at http://ssrn.com/abstract=2408510
[449] Manual of Patent Office Practice and Procedure, 2011
[450] Laskar, Mansoor Elahi, 2013, "Patentability of Life Forms (USA, Europe and Asia) - IPR and Biotechnology." Available at http://ssrn.com/abstract=2408510

b) Do patent applications include disclosure of origin among the requirements that need to be filled in by the applicant? Is it a mandatory or optional element? Is it only related to genetic resources or also to the associated traditional knowledge?	Yes. Disclosure of origin is a mandatory requirement in India.[451] Where an application for a patent has been published but a patent has not been granted, any person may, in writing, present an opposition against the grant of patent if the specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention. Moreover, a granted patent may be revoked based on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court, if the specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention.[452] Traditional knowledge is also grounds for revocation of patent, whereby the invention so far as specified in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.[453] Furthermore, based on the ABS legislation, any person who intends to obtain any intellectual property right, in or outside India, for any invention based on any research or information on any biological resources and associated knowledge obtained from India needs to make an application to the NBA. If the applicant is a foreign individual or organisation, it has to provide evidence of approval of NBA for access to the biological resources and/or associated knowledge used in the research leading to the invention.[454] Applications for the protection of plant varieties are exempted from these rules.[455]

8. Supporting instruments for the implementation of ABS legislation	
a) Does the legislation consider the development of community protocols related to access to traditional knowledge associated with genetic resources? If so, has the country developed them so far?	In implementing the Nagoya Protocol, and in accordance with its domestic law, India takes into consideration local communities' customary laws, community protocols and procedures with respect to traditional knowledge associated with genetic resources. Regarding community protocols, the Biological Diversity Act, 2002 mandates the preparation of People's Biodiversity Registers (PBR) by BMCs through chronicling knowledge related to local biodiversity. The PBR contains comprehensive information on available knowledge of local

[451] The Patents Act, 1970, Section 10(4)(d)(ii)
[452] Patents Act, 1970, Chapter VI
[453] Patents Act, 1970, Section 64
[454] Biological Diversity Act, 2002, Chapter II, Section 6
[455] Biological Diversity Act, 2002, Chapter II

	biological resources, their medicinal or any other use or any other traditional knowledge associated with them. India endeavours to not to restrict the customary use and exchange of genetic resources and associated traditional knowledge within and among local communities as provided on Article 12.4 of the Nagoya Protocol. Consequently, the Biological Diversity Act, 2002 provides for certain exemptions so as not to restrict the customary use and exchange of biological resources and associated traditional knowledge within and among local people and communities. For example, the definition of "commercial utilisation" (see 1.c) above) does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping. Further, Section 7 of the Biological Diversity Act 2002, which requires prior intimation to be given to the SBB for obtaining biological resources, excludes local people and communities of the area, including growers and cultivators of biodiversity, and vaids and hakims, who have been practicing indigenous medicine.[456]
b) Has the country developed any guidelines, codes of conduct, best practices or standards related to the implementation of their ABS legislation? If so, which ones?	• Guidelines for International Collaboration Research Projects involving Transfer or exchange of Biological Resources or information relating thereto between institutions including Government sponsored Institutions and such institutions in other countries • Guidelines for Upfront Payment • Biological Resources/items notified as normally traded commodities under Section 40 of BD Act, 2002 Dated: 7 April 2016 • Revised People's Biodiversity Register Guidelines, 2013 • Guidelines for Operationalization of Biodiversity Management Committees (BMCs)
c) Does the legislation include any model contractual clauses/standard agreement to be used for exchange of materials and establishment of MAT?	The NBA has developed model contractual clauses containing minimum requirements for the mutually agreed terms of the agreement to be signed with the users. Four different types of model contractual agreements have been developed in consultation with the concerned stakeholders to cater to the requirements of different activities covered under the Biological Diversity Act, 2002. These relate to: a) Research or commercial utilisation or bio-survey and bio-utilisation b) Transfer the results of research c) Seeking intellectual property right d) Third party transfer

[456] India's Interim National Report on the Implementation of the Nagoya Protocol, 2017, available at https://s3.amazonaws.com/absch.documents.abs/records/absch-nr-in-238716-2-en.pdf

	Although the model contractual clauses in these agreements are not sector specific, there are common terms and conditions that exist in these four agreements, which are simple and easy to understand. Some of them are: 1. Written notice in case of non-compliance 2. Administrative sanctions in case of breach of contractual clauses 3. Termination and revocation 4. Liabilities of the user 5. Confidentiality 6. Scope for making amendment There are other clauses which are case specific and depends on the purpose for which access is sought for. These include: 1. Period of collection 2. Obligations of the applicant during the existence of the agreement 3. Annual status reports 4. Benefit-sharing component 5. Details of biological resources These clauses enable the applicant to understand the roles and responsibilities that arise out of accessing the biological resources and/or associated traditional knowledge for various purposes as well as the rights and duties of the competent authority responsible for providing access.[457]

9. Key challenges of implementation	
Identified challenge	Brief explanation
Lack of coordination and capacity building among implementing agencies and relevant stakeholders	Biodiversity is a multidisciplinary subject, and involves a range of diverse stakeholders at different vertical and horizontal levels. Enhancing awareness among these stakeholders, as well as coordination among different implementing agencies are continuing challenges.[458] Raising of awareness among the public at large is also a challenge. The Ministry of Environment, Forests and Climate Change, NBA and State Biodiversity Boards engage regularly with research

[457] India's Interim National Report on the Implementation of the Nagoya Protocol, 2017, available at https://s3.amazonaws.com/absch.documents.abs/records/absch-nr-in-238716-2-en.pdf
[458] India's Interim National Report on the Implementation of the Nagoya Protocol, 2017, available at https://s3.amazonaws.com/absch.documents.abs/records/absch-nr-in-238716-2-en.pdf

	institutions, academia, training institutes, industries, civil society organisations and others for addressing these challenges[459]
Difficulties resulting from the large extension of the country	India is a large country, and awareness on the sharing of benefits accruing from utilisation of biological resources and associated knowledge among the several stakeholders remains a challenge. India has taken several measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources and related access and benefit-sharing issues through different agencies. These awareness generation programmes such as seminars, trainings, programmes, workshops etc. are organised for various stakeholders such as government officials, scientists and researchers, industries, media, local communities etc.
Need to create a formal consultative mechanism among the NBA and SBBs and BMCs to help in overcoming the deficiencies in the implementation of the Biological Diversity Act	Facilitating access to genetic resources requires capacity building and co-ordination among multiple implementing agencies. Some believe that consultation between the three agencies is generally inadequate, which has hampered the implementation of the Biological Diversity Act. In most states, the number of BMCs remains vastly inadequate, because of which this important agency is not effectively involved while the Act is being implemented.[460] It is worth noting that in the absence of BMCs, the Biological Diversity Rules, 2004 makes provision for consultation with the local bodies of the respective area.

[459] India's Interim National Report on the Implementation of the Nagoya Protocol, 2017, available at https://s3.amazonaws.com/absch.documents.abs/records/absch-nr-in-238716-2-en.pdf
[460] Research and Information Centre for Developing Countries (RIS), 2014, "National Study on ABS Implementation in India."

4.6 Japan

- Japan's domestic ABS measures are contained in the Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation (ABS Guidelines). Although these were released in May 2017, they became effective on 20 August 2017, the day that Japan became a Party to the Nagoya Protocol. The ABS Guidelines were developed as a joint effort of different governmental agencies of Japan, namely 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 and Ministry of the Environment.
- ABS in Japan is regulated through the ABS Guidelines, which are administrative measures adopted by administrative authorities to regulate the activities if the government agencies specified in each case, and not a legislative body.

1. Definition of key terms	
a) Definition of access to genetic resources and the associated traditional knowledge	Not mentioned
b) Definition of collection	Not mentioned
c) Definition of utilisation of genetic resources and the associated traditional knowledge	To conduct research and development on the genetic and/or biochemical composition of genetic resources[461]
d) Definition of bioprospecting	Not mentioned
e) Others definitions of relevance? E.g. biological resources, in situ conservation; indigenous species; benefit-sharing, derivative; genetic resources; genetic material	Genetic resources: genetic material of actual or potential value, where genetic material is material of plant, animal, microbial or other origin containing functional units of heredity.[462] Provider country: Party to the Protocol other than Japan providing genetic resources or traditional knowledge associated with genetic resources.[463] Acquirer: a person who has obtained access to genetic resources, to which legislation in the provider country applies (excluding genetic resources, etc. to which the Protocol does not apply) and imported them into Japan.[464] Importer: a person who has received from another person genetic resources to which the legislation in the provider country applies and imported them into Japan (excluding acquirers).[465]

[461] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 1.2. Available at https://absch.cbd.int/api/v2013/documents/E9EF6761-B9F4-4C7E-5580-C08594B789E4/attachments/ABS%20Guidelines_EN.pdf
[462] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 1.2.
[463] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 1.2.
[464] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 2.1.1 Available from http://www.env.go.jp/press/files/jp/105772.pdf
[465] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 2.1.3.

	Traditional knowledge associated with genetic resources: knowledge related to the utilisation of genetic resources among unique knowledge that has been long used according to traditions, customs, cultures, etc. in indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. [466]

2. General information	
a) To whom do genetic resources belong? Are these considered private goods, goods of common use by the population, public goods or do they belong to the State, etc.?	Ownership of genetic resources is not stipulated in the Japanese legislation and varies on a case-by-case basis. Furthermore, collecting and/or importing plants, animals, microorganisms or other biological materials may be subject to other existing regulations (e.g. regulations regarding protected areas, endangered species, quarantine etc.) and agreements with land/specimen owners.[467]
b) Does the legislation provide any indication on when it is considered that species have developed their own characteristics, i.e. distinctive properties, to start being considered a genetic resource of that country?	Not mentioned in the ABS Guidelines
c) Objective of the ABS legislation	To ensure the appropriate and smooth implementation of the Nagoya Protocol to the Convention on Biological Diversity, through taking measures concerning access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation, and thereby contributing to the conservation and sustainable use of biological diversity.[468]
d) Scope of the legislation – does it refer to all genetic resources or only to a subset (e.g. genetic resources for food and agriculture)? Are there any exemptions of genetic resources that fall outside of the scope (e.g. human genetic resources)?	The ABS Guidelines only applies to genetic resources that fall under the scope of the Nagoya Protocol and which were accessed after 20 August 2017. In turn, they **do not apply to** some areas that fall outside of the scope of the Protocol, namely: • Information concerning genetic resources, such as nucleic acid base sequences (excluding those that qualify as traditional knowledge associated with genetic resources) • Synthetic nucleic acids (limited to those not containing fragments derived from organisms) • Biochemical compounds that do not contain functional units of heredity • Human genetic resources

[466] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 1.2.
[467] See http://www.env.go.jp/nature/biodic-abs/english.htm
[468] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 1.1.

	• Genetic resources or traditional knowledge associated with genetic resources that were accessed from a provider country prior to 20 August 2017, the date on which the Protocol entered into force in Japan • Genetic resources that are generally sold for purposes other than the utilisation of genetic resources, which have been purchased not for the purpose of utilisation of genetic resources[469] Furthermore, the ABS Guidelines do not apply to the utilisation of genetic resources to which the International Treaty on Plant Genetic Resources for Food and Agriculture applies, nor to the utilisation of other genetic resources to which the Protocol does not apply (such as utilisation of genetic resources to which the Pandemic Influenza Preparedness Framework applies).[470] The following plant genetic resources for food and agriculture are also excluded from the scope of the ABS Guidelines: • Plant genetic resources for food and agriculture held by international agricultural research centres of the Consultative Group on International Agricultural Research and other international institutions that were obtained based on a standard material transfer agreement • Plant genetic resources for food and agriculture that were obtained from a country wherein the law, etc. requires the said plant genetic resources to be transferred based on a standard material transfer agreement
e) Is ABS regulated at the national or subnational level? To what extent does the national government share competencies with subnational entities?	National level

3. Access to genetic resources and associated traditional knowledge	
a) According to the legislation, is access to genetic resources and/or associated traditional knowledge subject to prior informed consent (PIC)?	Japan does not request prior informed consent for the provision of genetic resources that exist in Japan.[471] Nonetheless, this is subject to re-consideration once the implementation of the ABS Guidelines advances. In particular, the guidelines indicate that the need to develop laws and regulations concerning the provision of access to genetic resources existing in Japan is to be

[469] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 1.3.1.
[470] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 1.3.2.
[471] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 4.

	further considered within five years from the date on which the Guidelines come into effect (based on changes in social circumstances in Japan in relation to access to genetic resources and fair and equitable benefit-sharing).[472] In addition to the development of specific regulatory instruments as mentioned before, the Guidelines could also be revised.[473] It is however worth noting that collection and/or import of plants, animals, microorganisms or other biological materials may be subject to other regulations (e.g. regulations regarding protected areas, endangered species, quarantine) and agreements with land/specimen owners.[474] While Japan has no access measures, one of its agencies can upon request of an interested party issue a "notification of acquisition of the genetic resources in Japan", as stipulated in Chapter 5 of the ABS Guidelines. In particular, the National Institute of Technology and Evaluation (NITE) is authorised by the Ministry of Economy, Trade and Industry to issue such a notification. For that purpose, the following criteria must be met: 1. Japan is the country of origin of the genetic resource (CBD definitions are used) 2. Japan is the country providing the genetic resource (CBD definitions are used) 3. The genetic resource is utilised for business under the jurisdiction of the Minister of Economy, Trade and Industry of Japan 4. The genetic resource is not utilised under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) 5. The genetic resource is not utilised under the Pandemic Influenza Preparedness Framework (PIPF).[475]
b) Does the legislation establish rules/procedures for requiring and establishing mutually agreed terms (MAT)?	In accordance with Article 6.1 of the Nagoya Protocol, which stipulates the competence for regulating access to genetic resources at the national level, Japanese government made a decision not to introduce access measures in the ABS Guidelines (Chapter 4). Therefore, Japan does not establish any access rules/procedures.
c) Does the legislation set out criteria for the approval and involvement of indigenous and local communities for	No

[472] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Supplementary provisions
[473] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Supplementary provisions
[474] http://www.env.go.jp/nature/biodic-abs/english.html
[475] See http://www.nite.go.jp/en/nbrc/global/abs-chap5/index.html

access to genetic resources and associated traditional knowledge?	
d) Does the legislation address any changes of intent in the utilisation of accessed genetic resources? (e.g. initially accessed for non-commercial research and then changing their utilisation to commercial)	Not mentioned in the ABS Guidelines. In accordance with the forms included in the ABS Guidelines, users do not need to state the intended utilisation of the genetic resources and associated traditional knowledge.
e) Does the legislation consider any simplified measures on access for non-commercial research purposes; or for cases of present or imminent emergencies that threaten or damage human, animal or plant health?	In accordance with the ABS Guidelines, specific conditions apply for human health emergencies.[476]

4. Benefit-sharing	
a) What triggers benefit-sharing? Does any utilisation of genetic resources create a benefit-sharing obligation, even if it does not add value to the product or market?	Importantly, the 2017 ABS Guidelines do not specify mandatory measures related to benefit-sharing resulting from the utilisation of genetic resources or associated traditional knowledge. Instead, the Guidelines foster a voluntary approach by encouraging that mutually agreed terms (contract) are established to ensure fair and equitable benefit-sharing is concluded: • If a person is to provide genetic resources existing in Japan for their utilisation • If a person is to utilise genetic resources existing in Japan and is requested to share benefits arising from their utilisation • If a person utilises genetic resources or associated traditional knowledge from a country that has access and benefit-sharing legislation in place.[477] The Guidelines also encourage that the agreed contract includes provisions to report on the implementation of terms and conditions as established in the mutually agreed terms.[478]
b) Does the legislation provide an indication of what can constitute (monetary and non-monetary) benefits to be shared?	The ABS Guidelines provide no indication regarding what is considered as “benefits”. However, given that the Guidelines were developed to cover the scope of the Nagoya Protocol, the provisions of the Nagoya Protocol related to monetary and non-monetary benefits, including the list in the annex, are applicable.

[476] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 2, Section 1.2.
[477] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 3, Section 1.
[478] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 3, Section 3.

c) Does the national legislation exempt benefit-sharing arising from any particular utilisation (research and development), even if the CBD support the sharing of the benefits arising from such activities?	Not considered in the ABS Guidelines
d) Are there any specific provisions on how benefit-sharing should be dealt with respect to traditional knowledge hold by indigenous peoples and local communities?	Not covered by the ABS Guidelines
e) Does the national legislation consider benefit-sharing arising from the utilisation of traditional knowledge for those cases in which it was accessed from secondary sources (publications, registries, databases, inventories, etc.), or when it is not possible to identify the peoples or communities that hold it?	Not covered by the ABS Guidelines
f) How does the national legislation define the amount to be paid as benefit-sharing? Does it establish a fixed percentage for benefit-sharing?	Not covered by the ABS Guidelines
g) Who should pay for the benefits to be shared (the one who carries out access to/utilisation of genetic resources and the associated traditional knowledge, the one who undertakes the economic exploitation, or both)?	Depends on the conditions stipulated under the mutually agreed terms
h) Where within the production chain rests the obligation to pay benefits? ○ supplier of raw material, ○ intermediary, ○ final product ready for commercialisation, or ○ all	Not mentioned in the ABS Guidelines
i) Is there anyone else that needs to share benefits? For example, non-commercial research, commercial research, intellectual property rights licensing, the whole value chain of an industry or the one with the greater added value?	Not mentioned in the ABS Guidelines

j) Does the legislation require that benefits arising out of the utilisation of genetic resources are directed towards conservation and sustainable use?	The ABS Guidelines encourage that benefits arising from the utilisation of genetic resources are allocated to the conservation and sustainable use of biodiversity.[479]

5. Monitoring and reporting	
a) What are the designated checkpoints? What are their functions and responsibilities? How do they work?	The Ministry of the Environment is Japan's designated checkpoint. In particular, the Minister is responsible for requesting users of genetic resources to provide the relevant information related to the utilisation of genetic resources. The website of the Ministry has a section specifically focused on ABS, where the reports that are received under the ABS Guidelines are to be posted.[480]
b) What are the reporting requirements? Who is responsible for reporting?	In accordance with the ABS Guidelines, there are a number of forms that users may need to fill and submit depending on the specific situations under which access and utilisation takes place: • Form 1: Report concerning access to genetic resources (when the user has the unique identifier of the internationally recognised certificate of compliance) • Form 2: Report based on permit or its equivalent concerning access to genetic resources (when users do not have the previously mentioned unique identifier) • Form 3: Report concerning information related to utilisation of genetic resources Reporting procedures vary depending on the person that accesses genetic resources, as follows: 1. Report concerning the lawful access to genetic resources • Reports from those that acquired genetic resources: a person that has obtained access to genetic resources for which the Nagoya Protocol applies, and imported them into Japan, needs to submit to the Minister of the Environment a report based on Form No. 1 (included in the guidelines) stating the unique identifier of the internationally recognised certificate of compliance to prove that the relevant genetic resources were lawfully accessed, attaching a copy of the internationally recognised certificate of compliance that has been posted in the ABSCH. The intended utilisation of the genetic resources in question is not included as a reporting requirement in Form 1, as a specific form exists for this purpose (Form 3). Submission of this report needs to be completed

[479] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 3, Section 2.
[480] http://www.env.go.jp/nature/biodic-abs/english.html

	within 6 months from the date in which the international certificate of compliance was posted in the ABSCH. The following exemptions apply: o When the person accessing genetic resources submits the report before the internationally recognised certificate of compliance is posted in the ABSCH, they should use form 2 which requires attaching a copy of the permit or equivalent. In this respect, they should inform about: (i) Provider country; (ii) Institution that issued the permit or its equivalent; (iii) Date of issuance of the permit or its equivalent; (iv) Expiration date of the permit or its equivalent; (v) Provider; (vi) Genetic resources; (vii) Whether mutually agreed terms were established with the provider; (viii) Whether the purpose is commercial use or non-commercial use o If the permit or its equivalent has not been posted after a year of being issued.[481] • Reports from importers of genetic resources: This refers to a person who has received genetic resources from another person in a place where legislation in the provider country applies, and imported them into Japan (excluding acquirers) or to a person who has received genetic resources in Japan (excluding acquirers and importers). In any of these cases, the person who receives the genetic resources may submit either Form 1 stating the unique identifier of the internationally recognised certificate of compliance along with a copy of such internationally recognised certificate of compliance; or Form 2 if reporting is made before the internationally recognised certificate of compliance is posted on the ABSCH.[482] Again neither Form 1 nor Form 2 requires the inclusion of information relating to the intended utilisation of the genetic resources in question as a specific form (Form 3 applies). 2. Report concerning the lawful access to traditional knowledge associated with genetic resources Those that have obtained access to and imported traditional knowledge associated with genetic resources, with the intention of utilising this knowledge in combination with genetic resources

[481] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 2, Section 1.1.
[482] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 2, Section 1.3.

	that are subject to reporting obligation, need to report with respect to the associated traditional knowledge to indicate that it was lawfully accessed. Forms 1 and 2 include a specific section for associated traditional knowledge. As in the case of genetic resources, reporting is exempted when the internationally recognised certificate of compliance of the permit or its equivalent has not been posted in the ABSCH after a year since it was issued.[483] Although not specified in the section dealing with reporting, the ABS Guidelines also encourage reporting with respect to the utilisation of genetic resources. To this effect, Form 3 applies, which includes an indicative list of areas of utilisation, namely: cosmetics, pharmaceuticals, food and beverage, plant breeding, development of other products and varieties, research for a non-commercial purpose, and others. The Guidelines specifically mention that information that is likely to undermine the rights, competitive position, or other legitimate interests of the individual or corporation that may be identified as confidential information, which means that the said information is not posted on the ABSCH and the website of the Ministry of the Environment. This is to be determined by the person reporting and set forth in the said report (there is no need to indicate the reasons).
c) How can access to/utilisation of genetic resources and associated traditional knowledge be tracked? Has the country developed any particular method/mechanism to monitor the access and utilisation of genetic resources and/or associated traditional knowledge?	Under the ABS Guidelines, the Ministry of the Environment is to receive reports from all those who accessed genetic resources within the framework of the Nagoya Protocol. In addition, the Ministry regularly checks information of internationally-recognised certificates of compliance in the ABSCH for missing reports. This allows the Ministry to have complete information on genetic resources which were accessed through the framework of the Nagoya Protocol and coming into Japan. In terms of monitoring of utilisation, the Ministry of the Environment is to request persons who have reported through forms No.1 or 2 and that will be the ones utilising the genetic resources, to provide relevant information related to the utilisation of genetic resources after approximately five years from the submission of the report.
d) Does the country have any monitoring systems for patent databases, registries of products resulting from access, and scientific publications so to identify activities that are not in compliance with the domestic legislation of	Japan does not have monitoring systems for patent databases, registries of products resulting from access, and scientific publications

[483] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 2, Section 2.

the country where the access took place and with the Nagoya Protocol?	

6. Compliance	
a) What are the competent authorities in charge of enforcement of the ABS legislation? Is compliance implemented in a centralised way (a single responsible body) or is it decentralised (several bodies with different competences)? What measures have been adopted to integrate/coordinate the actions of the bodies responsible for enforcing ABS rules at the national level? How to promote the integration/coordination of the various bodies responsible for enforcing ABS rules?	Compliance is implemented in a centralised way, though in cooperation with competent ministries. The Ministry of the Environment is the main agency responsible for ensuring compliance with ABS measures in Japan, and in this regard, it is responsible for coordinating with other competent ministries. In addition to the Ministry of the Environment, the following ministries are also involved in the process: Ministry of Finance; Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour and Welfare; Ministry of Agriculture, Forestry and Fisheries; and Ministry of Economy, Trade and Industry.[484] With respect to the coordination between the competent authorities for the implementation of the Nagoya Protocol, meetings among them are held, as appropriate. Coordination was one of the key challenges that the government of Japan had encountered in the course of developing the ABS guidelines.
b) What measures have already been adopted to promote the effective monitoring of legal compliance?	The ABS Guidelines stipulates a number of measures for promoting compliance with the legislation in the provider countries. In particular, these measures include: • Acquirers and importers encouraged to submit reports relating to the lawful access to genetic resources • Acquirers and importers encouraged to submit reports relating to the lawful access to traditional knowledge associated with genetic resource • The Minister of the Environment to encourage reporting from those that have not sent the relevant reports • Specific measures are considered for situations in which a provider country which is a Party to the Nagoya Protocol alleges a violation of its domestic legislation. In particular, the Minister of the Environment is to urge acquirers, importers, users of the genetic resources or associated traditional knowledge, and others who handle the genetic resources or traditional knowledge associated with genetic resources concerning the case for which the allegation is made, to provide information on the violation related to access to, or import or

[484] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 6.

	utilisation of, and other handling of the said resources. This falls within the scope of the Nagoya Protocol's obligation of cooperation as stipulated in its Articles 15.3 and 16.3. Importantly, the Minister of the Environment is to provide the received information to the Party to the Nagoya Protocol that made the allegation. This is to be done through the relevant national focal point. • The Minister of the Environment is to request for the provision of information related to the utilisation of genetic resources. The Minister of the Environment is to provide information related to utilisation of genetic resources to the ABSCH. The type of information to be submitted depends on what the person reporting completed in the relevant forms, as confidential information is not to be uploaded into the ABSCH. The frequency for the Ministry to provide information to the ABSCH is not stipulated in the ABS Guidelines. With respect to reporting on the utilisation of genetic resources, after 5 years of the submission of Form 1, the Minister of Environment has to request information regarding utilisation of the respective genetic resources. If after the request being made the information is not submitted, the Minister of the Environment has to repeat the request.[485] If an acquirer of genetic resources and associated traditional knowledge does not submit the information to the Minister of the Environment, then the Minister will urge the relevant person for the submission of such report. Minister of the Environment has to provide necessary guidance and advice concerning the reporting process, in addition to other competent ministers (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).[486] Although no penal provisions are stipulated in the ABS Guidelines, they do include several measures for addressing cases of non-compliance of the reporting obligation. In addition to the Minister of the Environment repeating the request, it will disclose the unique number of the internationally-recognised certificates of compliance which are not reported.

[485] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 2, Section 5.1.
[486] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 2, Section 3.

c) Are there any measures foreseen in the national legislation to ensure benefit-sharing when access to/utilisation of genetic resources and the associated traditional knowledge and economic exploitation occur outside national jurisdiction, especially in a country that is not a Party to the Nagoya Protocol or a non-Party country enterprise?	No

7. Intellectual property rights (focusing on patents)	
a) How does the country deal with patentability of living organisms found in nature and of its components, such as DNA, molecules and metabolites?	Japan grants patents to plants, animals and microorganisms.[487] In Japan, a biological invention is patentable as long as it is a creation and not just a discovery. Therefore, if organisms in nature such as microorganisms have been isolated artificially from their surroundings, those are patentable inventions. However, the Japan Patent Office maintains that "methods of surgery, therapy or diagnosis of humans" fall outside the scope of patentable inventions, because they fall under industrially inapplicable inventions.[488] In Japan, microorganisms include yeast, moulds, mushrooms, bacteria, actinomycetes, unicellular algae, viruses, protozoa, as well as undifferentiated animal or plant cells, and animal or plant tissue cultures. The Japan Patent Office requires invention to be creations, not just discoveries of naturally existing organisms, so generally substantive human intervention such as isolation or purification is necessary. Also the Japan Patent Office requires that the claimed invention exclude methods of surgery, therapy or diagnosis of humans. Biological inventions are patentable subject matter. Such inventions would include processes using micro-organisms, recombinant DNA (rDNA) molecules, subcellular units such as plasmids, and methods for making these inventions as long as they are isolated artificially from their surroundings.[489] A process using them is also patentable subject matter.
b) Do patent applications include disclosure of origin among the requirements that need to be filled in by the applicant? Is it a mandatory or optional element? Is it only	Not in Japan

[487] https://www.jpo.go.jp/torikumi_e/kokusai_e/training/textbook/pdf/Bio_Patent.pdf (pp.29-30)
[488] Examination Guidelines for Patent and Utility Model in Japan part III, Chapter 1 http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/files_guidelines_e/03_0100_e.pdf
[489] http://www.eubios.info/EJ66/EJ66M.htm

related to genetic resources or also to the associated traditional knowledge?	

8. Supporting instruments for the implementation of ABS legislation	
a) Does the legislation consider the development of community protocols related to access to traditional knowledge associated with genetic resources? If so, has the country developed them so far?	No
b) Has the country developed any guidelines, codes of conduct, best practices or standards related to the implementation of their ABS legislation? If so, which ones?	The ABS Guidelines encourage that organisations, including industry, develop and update voluntary codes of conduct, guidelines and best practices or standards concerning access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation, while promoting their use.[490]
c) Does the legislation include any model contractual clauses/standard agreement to be used for exchange of materials and establishment of MAT?	The ABS Guidelines do not include model contractual clauses but encourage that organisations, including industry, develop and update sectoral and cross-sectoral model contractual clauses for contracts concerning the access to genetic resources for utilisation, while promoting the use of those model clauses.[491]

9. Key challenges of implementation	
Identified challenge	Brief explanation
Coordination of relevant ministries and stakeholders	Coordinating among the competent ministries and relevant stakeholders for the development of the Guidelines, was one of the most important challenges that had been encountered. Having established the structure for coordination during the development of the domestic measures, close communication among the agencies and working in a cooperative manner will be one of the key aspects for a successful implementation.

[490] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 3, Section 5.
[491] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 3, Section 4.

4.7 Peru

In 2014, Peru ratified the Nagoya Protocol (through Supreme Decree N° 029-2014-RE). However, well before then, the country had a framework regulating access to genetic resources and associated knowledge.

Peru is member of the Andean Community and, as such, its ABS framework has been shaped around the regional framework developed for access to genetic resources. In this respect, Decision 391 of 1996 related to the common regime on the access to genetic resources plays a crucial role in this regard, together with Decision 486 on the common regime for industrial property. At the domestic level, the following are also key measures for access and benefit-sharing:

- Supreme Decree N° 003-2009-MINAM (2009) Regulation for access to genetic resources through which Decision 391 is adjusted to the national circumstances while further specifying some of the provisions in such Decision
- Law 26839 of 1997 on the conservation and sustainable use of biological diversity and its regulation (Supreme Decree N° 068-2001 PCM)
- Law 27811 of 2002 establishing the regime for the protection of collective knowledge of indigenous peoples associated with biological resources
- Law 28216 of 2004 relating to the protection for the access to Peruvian biological resources and collective knowledge of indigenous peoples
- Law 29763 of 2011 relating to forest resources and wildlife, and its implementing regulations (Supreme Decree Nº 018-2015-MINAGRI Regulation for Forest Management, which includes access regulation of wild flora; and Supreme Decree Nº 019-2015-MINAGRI Regulation for Wildlife Management, which includes access regulation of wildlife)

The implementation of the ABS regime in Peru is shared among different entities. While the Ministry of Environment is the lead agency in regulating access to genetic resources, it works in collaboration with other governmental agencies such as Servicio Nacional Forestal y de Fauna Silvestre (SERFOR) and Instituto Nacional de Innovación Agraria (INIA) which are competent authorities relating to genetic resources or their by-products under the scope of their competencies.492 It is worth noting that SERFOR, the Ministry of Production (PRODUCE) and INIA are competent authorities to grant access permits and therefore to subscribe contracts. In this sense, for example SERFOR and INIA have issued guidance relating to genetic resources under the scope of their competencies. This study focuses on the overarching ABS measures applicable in the country, and some examples are provided in terms of the measures approved by the other agencies.

1. Definition of key terms	
a) Definition of access to genetic resources and the associated traditional knowledge	Access: obtaining and use of genetic resources conserved *in situ* and *ex situ*, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things[493]
b) Definition of collection	Term not defined within Peru's ABS framework.

[492] Cabrera Medaglia, Jorge, 2017. "Diagnóstico de Los Marcos Regulatorios de Acceso a Recursos Genéticos y Distribución de Beneficios y Experiencias Contractuales en los Países Miembros de ALADI." doi:10.13140/RG.2.2.30719.51361

[493] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1

c) Definition of utilisation of genetic resources and the associated traditional knowledge	Utilisation of genetic resources: to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention[494] (being Peru Party to the Nagoya Protocol, its definitions also apply)
d) Definition of bioprospecting	Term not defined within Peru's ABS framework
e) Others definitions of relevance? E.g. biological resources, in situ conservation; indigenous species; benefit-sharing, derivative; genetic resources; genetic material	By-Product: a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings[495]. Being Peru Party to the Nagoya Protocol, its definitions also apply – derivative: naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity[496] Biological Resources: individuals, organisms or parts thereof, populations or any biotic component of real or potential value or use that contains a genetic resource or its by-products[497] Genetic Resources: all biological material that contains genetic information of value or of real or potential use[498] Country of origin of the genetic resource: country that possesses genetic resources in *in situ* conditions, including those which, having been in *in situ* conditions, are now in *ex situ* conditions[499] *Ex situ* conditions: those in which the genetic resources are not found in *in situ* conditions[500] *In situ* conditions: those 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[501]

[494] Supreme Decree N° 029-2014-RE, Ratification of the Nagoya Protocol
[495] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[496] Supreme Decree N° 029-2014-RE, Ratification of the Nagoya Protocol
[497] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[498] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[499] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[500] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[501] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1

	Intangible component: all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes[502] Collective knowledge: accumulated and transgenerational knowledge developed by indigenous peoples and communities in relation to the properties, uses and characteristics of biological diversity. The intangible component covered in Decision 391 includes this type of collective knowledge[503] Native, Afro-American or local community: a human group whose social, cultural and economic conditions distinguish it from other sectors of the national community, that is governed totally or partially by its own customs or traditions or by special legislation and that, irrespective of its legal status, conserves its own social, economic, cultural and political institutions or a part of them[504] Indigenous peoples: original peoples that had rights prior to the establishment of the Peruvian State, have their own culture, territories and self-identify as such. Peoples that are in voluntary isolation or out of contact, as well as peasant and native communities are included. The term "indigenous" include and can be interpreted as a synonym of: "original", "traditional", "ethnic", "ancestral", "native" or other terms[505] Supplier of the biological resource: a person empowered by Decision 391 and complementary national legislation to supply the biological resource that contains the genetic resource or its by-products[506] Supplier of the intangible component: a person that, through an access contract and pursuant to Decision 391 and to complementary national legislation, is empowered to supply the intangible component associated with the genetic resource or its by-products[507] Synthesized product: a substance obtained through the artificial processing of genetic information or of information from other biological molecules. Includes semi-processed extracts

[502] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[503] Law 27811 of 2002, Ley que establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos, Article 2
[504] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[505] Law 27811 of 2002, Ley que establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos, Article 2
[506] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[507] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1

	and substances obtained by converting a by-product through an artificial process (hemisynthesis)[508] Biopiracy: Unauthorised and uncompensated access and use of biological resources or traditional knowledge of indigenous peoples by third parties, without the relevant authorisation and contravening the principles established in the Convention on Biological Diversity and the relevant rules in place. This appropriation can be done through physical control, through property rights over products that incorporate these illegally obtained elements, or in some cases through claiming the rights[509]

2. General information	
a) To whom do genetic resources belong? Are these considered private goods, goods of common use by the population, public goods or do they belong to the State, etc.?	In accordance with CAN Decision 391 the Member Countries exercise sovereignty over their genetic resources and their by-products and consequently determine the conditions for access to them.[510] Furthermore, the Decision indicates that genetic resources and their by-products which originated in the Member Countries are goods belonging to or consist on the heritage of the Nation or of the State in each Member Country, as stipulated in their respective national legislation.[511] Those resources are inalienable, not subject to prescription and not subject to seizure or similar measures. This is without detriment to the property regimes applicable to the biological resources that contain those genetic resources, the land on which they are located or the associated intangible component.[512] In accordance with Peru's Constitution, renewable and non-renewable natural resources are part of the Nation's heritage, with the State having sovereignty for their use.[513] In this respect, the State has sovereignty to adopt measures for the conservation and sustainable use of biological diversity and, as such, it is in charge of regulating on matters related to the sustainable use of biological diversity.[514]

[508] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 1
[509] Law 28216 of 2004, Ley de Protección al Acceso a la Diversidad Biológica Peruana y a los Conocimientos Colectivos de los Pueblos Indígenas, Complementary and Final provisions, Third
[510] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 5
[511] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 6
[512] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 6
[513] Political Constitution of Peru, 1993, Article 66
[514] Law 26839 of 1997, Ley sobre la conservación y aprovechamiento sostenible de la diversidad biológica, Article 4

	Furthermore, the Law relating to the conservation and sustainable use of biological diversity indicates that rights granted over biological resources do not entail that rights are granted over the genetic resources contained within those biological resources. Taking the regulation on forest and wildlife heritage as an example, authorisation certificates do not grant any rights over the genetic resources which are regulated under the ABS regime.[515] Moreover, the State is part of, and participates in the procedures for access to genetic resources, which is established though specific measures covering genetic resources and their by-products. [516] It is also worth noting that the forest and (wild) fauna heritage of the country is composed, among others, by the forest and fauna biodiversity, including associated genetic resources.[517] The Law stipulates that the State has domain over Peru's forest and fauna heritage, and also over their products when those have been unlawfully obtained.[518]
b) Does the legislation provide any indication on when it is considered that species have developed their own characteristics, i.e. distinctive properties, to start being considered a genetic resource of that country?	Supreme Decree N°003-2009-MINAM establishes that genetic characterisation of plants, wild animals and microorganisms from Peru is to be determined by natural and legal persons registered by the administrative and executing authorities[519],[520]. It further stipulates that the authorities would establish, together with the Ministry of Environment, an information mechanism for the characterisation of the relevant access activities.[521] The criteria being currently used includes: • Access to genetic resources involving native species from Peru (this is defined at the domestic level. Aspects to be considered include that the species have been obtained from the national territory or that the *ex situ* centre has collected the resources from Peruvian territory) • Genetic resources related to naturalised species, i.e. species that despite being exotic have adapted and evolved in the national territory therefore developing distinctive properties and

[515] Law 29763, Article 60
[516] Law 26839 of 1991, Ley sobre la conservación y aprovechamiento sostenible de la diversidad biológica, Articles 27-29
[517] Law 29763 of 2011, Article 4
[518] Law 29763 of 2011, Article 1
[519] Administrative and Executing Authorities is the term used for National Competent Authorities in Supreme Decree. N° 003-2009-MINAM.
[520] When natural and legal persons are indicated, it refers to researchers and institutions such as universities, research institutes, public institutions for research, as well as private companies that carry out research and innovation.

	genetic diversification (e.g. broad beans, eucalyptus, Peruvian Paso horse, some coffee varieties, and corn, among others). There are experts who are responsible for identifying and listing these species.[522]
c) Objective of the ABS legislation	The purpose of the Regulation for Access to Genetic Resources is to further specify and develop the provisions from Decision 391, and according with its Title II it aims to: • Foresee the conditions for fair and equitable participation in the benefits of the access • Lay the foundations for the recognition and valuation of genetic resources and their by-products and of their associated intangible components, especially when native or local communities are involved • Promote the conservation of biological diversity and the sustainable use of the biological resources that contain genetic resources • Promote the strengthening and development of scientific, technological and technical capacities at the local, regional and national level; and • Strengthen the negotiating capacity of the country.[523]
d) Scope of the legislation – does it refer to all genetic resources or only to a subset (e.g. genetic resources for food and agriculture)? Are there any exemptions of genetic resources that fall outside of the scope (e.g. human genetic resources)?	Decision 391 applies to genetic resources for which is the Member Countries are the countries of origin, to their by-products, to their intangible components and to the genetic resources of the migratory species that for natural reasons are found in the territories of the Member Countries. [524] In turn, the following are **excluded** from the scope of this Decision: • Human genetic resources and their by-products; and • The exchange of genetic resources, their by-products, the biological resources containing them, or their associated intangible components among native, Afro-American and local communities of the Member Countries for their own consumption, based on their customary practices.[525] In addition, for the adequate implementation of Decision 391, Peru adopted the regulation for access to genetic resources (Supreme Decree 003-2009-MINAM). This regulation applies to genetic resources for which Peru is country of origin, their by-products, intangible components

[522] Not yet developed.
[523] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 2
[524] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 3
[525] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 4

	and genetic resources of migratory species that for natural reasons are found in Peruvian territory.[526] In addition to the exclusions indicated in Decision 391, the following resources or activities are also excluded from the scope of the Peruvian regulation: • Food crops and forages listed in Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture • Use of genetic resources as crops within the Peruvian territory ("crop" is defined as development and growth of plant species in field as well as in *in vitro* conditions, hydroponics, among others) • Activities entailing use of non-timber products, for the production of natural products (nutraceuticals and functional foods)[527] – this exclusion is currently being interpreted in the sense that non-timber products would be restricted to wild plant species (thus not being applicable to wild animals and to cultivated, domesticated or hydrobiological species) • With the aim of fostering knowledge generation relating to wildlife biodiversity, SERFOR has developed exemptions for non-commercial scientific research relating to molecular studies with the following purposes: taxonomy, systematics, phylogeography, biogeography, evolution and conservation genetics.[528] As a result, no contract of access, simply a research authorisation, is required for these cases. SERFOR however includes clauses to ensure mutually agreed terms are part of the research authorization.
e) Is ABS regulated at the national or subnational level? To what extent does the national government share competencies with subnational entities?	ABS in Peru is regulated at the national level. The Ministry of Environment is the regulatory body for access to genetic resources and as such it provides guidance and oversight on this matter.[529] Among others, the Ministry performs the following functions: • Approve the national policy on conservation and sustainable use of genetic resources • Dictate the rules and guidelines for the management of genetic resources • Coordinate joint actions with administrative and executing authorities and with the entities for which their competencies relate to genetic resources • Coordinate the national inventory of the country's genetic resources with the administrative and executing authorities.[530]

[526] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 4
[527] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 5
[528] Supreme Decree 018-2015-MINAGRI (Article 154); and Supreme Decree 019-2015-MINAGRI (Article 134.5)
[529] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 13
[530] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 13

	• Further, the National Commission on Biological Diversity was established to serve as the multisectoral consultative mechanism for policies related to conservation and sustainable utilisation of biological resources that contain genetic resources.[531]

3. Access to genetic resources and associated traditional knowledge	
a) According to the legislation, is access to genetic resources and/or associated traditional knowledge subject to prior informed consent (PIC)?	Yes. According to the Bonn Guidelines and the Regulation for access to genetic resources, any contract for access needs to include provisions relating to prior informed consent, among others.[532] Moreover, one of the purposes of the national mechanism for monitoring and surveillance is to ensure that access to genetic resources takes place following the prior informed consent of the government.[533] Furthermore, the law on the protection of indigenous peoples' collective knowledge associated with biological resources is aimed, among others, at ensuring that use of collective knowledge is subject to the prior informed consent of the indigenous peoples.[534] It therefore stipulates that those interested in accessing collective knowledge for scientific, commercial and industrial purposes need to request the prior informed consent of those organisations representing the indigenous peoples that hold such collective knowledge.[535] It is worth noting that Peru has a series of legislative measures aimed at ensuring compliance with PIC (e.g. Law 26839; Law 27811, and other regulations such as Supreme Decree 021-2015-MINAGRI).
b) Does the legislation establish rules/procedures for requiring and establishing mutually agreed terms (MAT)?	Yes. According to Decision 391 and the Regulation for Access to Genetic Resources, all access procedures require the presentation, admission, publication and approval of an application, the signing of a contract, the issuing and publication of the corresponding Resolution and the registration of the acts connected with that access.[536] The conclusion of a contract of access is therefore mandatory in Peru. Furthermore, the Regulation stipulates that any contract for

[531] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 17
[532] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 20
[533] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 38
[534] Law 27811, Article 5
[535] Law 27811 of 2002, Ley que establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos, Article 6
[536] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 16

	access needs to include provisions relating to the mutually agreed terms, among others, in accordance with the Bonn Guidelines.[537] The contracts are concluded between the sectoral administrative and executing authority and the applicant.[538] Different types of contracts exist: • Access contracts: subscribed between the relevant administrative and executing authority and the applicant (the latter being a natural or legal person), for either commercial or non-commercial purposes • Framework access contracts: they can only be subscribed with universities, research centres and researchers when access is needed for the implementation of two or more projects, and only for non-commercial purposes. If commercial activities are carried out as a result of the accessed material, the relevant access contract needs to be negotiated. If a potential commercial use of the genetic resource is identified as a result of the undertaken research, a contract needs to be negotiated. If such a contract is not concluded, the legislation stipulates that the access is illegal and subject to administrative sanctions[539] • Mutual Transfer Agreement, which approves the transfer of genetic material from an *ex situ* centre located in Peru to a user[540], only for research (non-commercial) purposes. Due to some confusion that had been identified between the first two types, SERFOR and the legal department at MINAM have agreed for the contracts to be known as "contracts of access to genetic resources". On a case-by-case basis, the objective should clarify the purpose of the utilisation of the resources for each case. In addition to the access contracts, in accordance with Decision 391 and the Regulation, there is another type of contract; accessory contracts to the access contract, which applies to the development of activities related to the access to genetic resources or their by-products. These accessory contracts can be concluded with: • the owner, holder or administrator of the land where the biological resource containing the genetic resource is found • the *ex situ* conservation centre

[537] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 20
[538] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 20
[539] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 26
[540] It is worth noting that due to the Regulation not specifying whether the user can be national or foreigner, it applies to both.

	• the owner, holder or administrator of the biological resource containing the genetic resource • the provider of the intangible component associated with the genetic resource. If the provider of the associated traditional knowledge is an indigenous people or community, the contract should be developed in accordance with national and international provisions for the protection of traditional knowledge of indigenous peoples and communities[541] ; and • the national institution of support with respect to the activities that it needs to undertake and which are not already included in the access contract. Accessory contracts require that an access contract is concluded for access to be granted. Genetic resources that are transferred from *ex situ* conservation centres located in Peru for research purposes require a material transfer agreement that specifies the obligations and conditions to which the utilisation of such material is subject to, including recognition of its origin. If the transfer of genetic resources from these centres is for commercial purposes, then a contract of access is required.[542] Below are some of the minimum conditions that need to be considered in the contracts of access celebrated in Peru: • Prohibition to claim property over the material or its by-products • Mandatory requirement of requesting authorisation from the component authority to transfer genetic material to third parties • Recognise the origin of the genetic resource to which the contract relates • Participation of national staff in the collection, research and gathering of genetic resources data (their by-products and associated intangible component) • Need to acknowledge the Peruvian origin of the accessed genetic resources and their by-products in any publications, research and results • Economic compensation to the State for the benefits derived from the access and utilisation of genetic resources • Specific clauses relating to potential intellectual property rights on the processes or products resulting from the utilisation of genetic resources or their by-products and the intangible component.[543]

[541] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 21
[542] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 29
[543] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 23

c) Does the legislation set out criteria for the approval and involvement of indigenous and local communities for access to genetic resources and associated traditional knowledge?	Yes. Decision 391 stipulates that Member Countries recognise and value the rights and authority of the native, Afro-American and local communities to decide about their know-how, innovations and traditional practices associated with genetic resources and their by-products.[544] In this regard, 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 that contract, an annex stipulating the fair and equitable distribution of the profits derived from the use of that component. Such annex must be signed by the supplier of the intangible component and the applicant for the access. Not complying with the provisions in this annex provides grounds to nullify the access contract.[545] Peru recognises that knowledge, innovations and practices associated with biodiversity of peasant, native and local communities constitute their cultural heritage and, as such, they have rights over them and the authority to decide about their utilisation.[546] In this respect, through Law 27811 relating to the protection of collective knowledge, the Peruvian State recognises the right and authority of indigenous peoples and communities to decide over their collective knowledge.[547] Law 27811 therefore establishes the obligation that access to collective knowledge is subject to the prior informed consent of the indigenous people through their representative organizations, and there is a need to subscribe a license agreement contract for commercial and industrial purposes. The organization representing the indigenous peoples to which prior informed consent was requested, needs to inform about the start of the negotiations to the largest possible number of indigenous peoples that are holders of such knowledge, in order to take their interests and concerns into account during this process (in particular those related to spiritual and religious matters).[548]
d) Does the legislation consider any simplified measures on access for non-commercial research purposes; or for cases of present or imminent emergencies that threaten or damage human, animal or plant health?	The only mechanism of facilitation is the possibility to conclude framework access contracts (only for non-commercial purposes). In accordance with Article 24 of the Regulation of access, the administrative and executing agencies can conclude this type of contract with universities,

[544] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 7
[545] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 35
[546] Law 26839 Ley sobre la conservación y aprovechamiento sostenible de la diversidad biológica, Article 24
[547] Law 27811, Article 1
[548] Law 27811, Article 6

	research centres or researchers to cover the implementation of several projects.[549] No other simplified measures exist within the Peruvian ABS system. In turn, SERFOR also implements measures aimed at strengthening the applicable procedures for research activities involving access to wildlife genetic resources and their by-products (for example, the exemption to subscribe access contracts for basic non-commercial research, as indicated under item 2.d).[550]
e) Does the legislation consider any simplified measures on access for non-commercial research purposes; or for cases of present or imminent emergencies that threaten or damage human, animal or plant health?	Yes. As previously mentioned under item 3.b), framework access contracts are for non-commercial purposes only. As a result, if commercial activities are carried out as a result of the accessed material, a contract of access needs to be concluded. The Regulation also specifies that when a potential commercial use is identified resulting from the conducted research, the contract needs to be renegotiated or otherwise, the access will be considered as illegal.[551]
f) Are there any specific provisions/piece of law related to genetic resources for food and agriculture?	As indicated in item 2.d) above, food crops and forages listed in Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture, and use of genetic resources as crops[552] within the Peruvian territory, are excluded from the ABS system.[553]

4. Benefit-sharing	
a) What triggers benefit-sharing? Does any utilisation of genetic resources create a benefit-sharing obligation, even if it does not add value to the product or market?	One of the governing guidelines of the General Law on the Environment refers to the inclusion of mechanisms for effective benefit-sharing for the use of genetic and biological resources in all plans, programmes, actions or projects related to access to, commercial utilisation of, or research on natural resources or biological diversity.[554] This is reflected in the ABS framework although no detailed provisions describing the triggering event for benefit-sharing exist.
b) Does the national legislation exempt benefit-sharing arising from any particular utilisation (research and development), even if the CBD support the sharing of the benefits arising from such activities?	No.

[549] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 24
[550] For more information see https://www.serfor.gob.pe/bosques-productivos/servicios-de-investigacion
[551] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 26
[552] The regulation states that crops are interpreted as development and growth of plant species in the field, as well as in in vitra conditions, hydroponics, etc.
[553] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 5
[554] Law 28611 Ley general del ambiente, Article 97(g)

c) How does the national legislation define the amount to be paid as benefit-sharing? Does it establish a fixed percentage for benefit-sharing?	The Peruvian ABS regime does not include details in terms of how to calculate the amount to be paid as benefit-sharing resulting from the utilisation of genetic resources or their by-products. Such information is however indicated with respect to the utilisation of collective knowledge. In accordance with the law for the protection of collective knowledge, when access to this knowledge is for commercial and industrial applications, a license agreement with the conditions for benefit-sharing needs to be subscribed.[555]
	At least 10% of the gross sales (before taxes) resulting from the commercialization of the products developed as a result of this collective knowledge must be paid to the Fund for the Development of Indigenous Peoples (Fondo para el Desarrollo de los Pueblos Indígenas). The parties in the agreement can agree on a higher percentage depending on the level of utilisation or direct application of the knowledge in the final product, the contribution that the knowledge might have had in reducing the costs of research and development of by-products, etc.[556]
	Furthermore, license agreements for the use of collective knowledge need to contain at least the following, among others:
	• Establishment of the compensation to be received by the indigenous peoples, which should include:
	  o Initial payment (can be monetary or equivalent)
	  o At least 5% of the gross sales (before taxes) resulting from the commercialization of the products directly or indirectly developed as a result of the collective knowledge
	• Obligation of the licensee to inform regularly with respect to the research, industrialisation and commercialisation of the products developed as a result of the respective collective knowledge.[557]

d) Who should pay for the benefits to be shared (the one who carries out access to/utilisation of genetic resources	In Peru, this is decided on a case-by-case basis. For some activities, the obligation is shared throughout the entire production chain while for others it is restricted to a specific stage.[558]

[555] Law 27811, Article 7
[556] Law 27811, Article 8
[557] Law 27811, Article 27
[558] To illustrate, a local community provides a medicinal plant to a national company (user 1) that prepares extracts of that plant, which contains a mixture of molecules. Then this national company provides this extract to a foreign company (user 2), which produces a pharmaceutical product isolating the active principles contained in the extract, which then patents and commercialise. In this case, user 1 needs to share benefits with the first provider, i.e. the local community; and user 2 needs to share benefits with the second provider, i.e. the national company.

and the associated traditional knowledge, the one who undertakes the economic exploitation, or both)?	Likewise, in some cases the user is an individual whilst in others there are several users involved throughout the value chain. To cover this variety of situations, the government identifies the relevant parties on a case-by-case basis. As indicated above, the beneficiaries are specified in the accessory contracts subscribed with the providers of genetic resources, their by-products and the intangible component. When the government and applicant subscribe the access contract, the terms agreed in those accessory contracts need to be duly considered.
e) Where within the production chain rests the obligation to pay benefits? ○ supplier of raw material, ○ intermediary, ○ final product ready for commercialisation, or ○ all	
f) Is there anyone else that needs to share benefits? For example, non-commercial research, commercial research, intellectual property rights licensing, the whole value chain of an industry or the one with the greater added value?	
g) Does the legislation provide an indication of what can constitute (monetary and non-monetary) benefits to be shared?	Decision 391 does not provide a list of potential monetary and non-monetary benefits to be considered. However, being Peru Party to the Nagoya Protocol, the indicative lists included in its Annex are applicable. It is also worth noting that the Regulation includes a number of minimum conditions that need to be considered in the access contracts. Among these, the following benefits are listed: • Participation of national professionals in the collection, research and data gathering of genetic resources, their by-products and associated intangible component • Institutional capacity development and strengthening of the national support institution or the provider of genetic resources, among others, through capacity-building, provision of equipment and infrastructure • The commitment of transferring to those national professionals, scientific knowledge and technologies resulting from access-related activities • Establishment of conditions for research within the country to contribute to biodiversity conservation and sustainable use • Strengthening of mechanisms for technology and knowledge transfer, including biotechnology, that are culturally, socially and environmentally sustainable and efficient • Strengthening and development of capacities of indigenous peoples and communities in relation to the intangible component associated with genetic resources

	• Economic compensation to the government for the benefits generated by the access and utilisation of the genetic resources • Provisions relating to potential intellectual property rights in accordance with Law 27811 on the protection of collective knowledge.[559] The first interim national report on the implementation of the Nagoya Protocol in turn refers to the benefits more frequently established in the contracts, these being: paying the provider for the biological collection; participation of national professionals; and supporting conditions for research within the country to contribute to biodiversity conservation and sustainable use.[560]
h) Are there any specific provisions on how benefit-sharing should be dealt with respect to traditional knowledge hold by indigenous peoples and local communities?	As indicated in item 3.c) above, according to Decision 391, 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 that contract, an annex stipulating the fair and equitable distribution of the profits from use of that component. Such annex needs to be signed by the supplier of the intangible component and the applicant for the access.[561] Furthermore, in accordance with the provisions in the law for the protection of collective knowledge in Peru, when access to this type of knowledge is intended for commercial or industrial use, a license agreement specifying the terms and conditions for the use of such knowledge needs to be concluded, including for an adequate compensation for the access and ensuring equitable sharing of benefits derived from its use. Such agreement can also be an annex to the main contract of access.[562] The benefits are to be paid to the Fondo para el Desarrollo de los Pueblos Indígenas (Fund for the Development of Indigenous Peoples). The Fund was established to contribute to the development of indigenous peoples, by financing projects and other activities.[563] It is also worth noting that, for example, the guidelines for approval of research authorisations by SERFOR include a template for PIC which includes a series of questions for the communal organisation to assess (e.g. What type of benefit could be obtained with the findings from the research (also state the benefits to be obtained by the community)?; What are the monetary and

[559] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 23
[560] Peru, 2017, Interim National Report on the implementation of the Nagoya Protocol. Available at https://absch.cbd.int/pdf/documents/absNationalReport/ABSCH-NR-PE-238684/2
[561] CAN, Decision 391 Common Regime on Access to Genetic Resources, Article 35
[562] See definition of "license agreement for the use of collective knowledge" in Law 27811, Article 2
[563] Law 27811, Article 37

	non-monetary benefits that will be obtained by the community as a result of the information that will be given to the researchers? and; What are the future benefits from this?).
i) Does the national legislation consider benefit-sharing arising from the utilisation of traditional knowledge for those cases in which it was accessed from secondary sources (publications, registries, databases, inventories, etc.), or when it is not possible to identify the peoples or communities that hold it?	The legislation dealing with the protection of collective knowledge refers to collective knowledge that is in the public domain (that is, when this knowledge is accessible to people outside of the indigenous peoples, either through media such as publications, or when the uses or characteristics of a biological resource are widely known outside the indigenous peoples and communities). When knowledge has become part of the public domain in the 20 years after the entry into force of the law, i.e. since 1982, a specific percentage (see question f) below) of the gross sales (before taxes) resulting from the commercialization of the products developed as a result of this collective knowledge is to be paid to the Fondo para el Desarrollo de los Pueblos Indígenas (Fund for the Development of Indigenous Peoples).[564] Importantly, Law 27811 protects all collective knowledge, even if not registered. It is for cases when this knowledge has not been registered, that mechanisms such as the Fund for the Development of Indigenous Peoples and licenses have been established.

5. Monitoring and reporting	
a) What are the designated checkpoints? What are their functions and responsibilities? How do they work?	Peru designated the following two checkpoints: • National Commission for the protection for the access to Peruvian biological diversity and collective knowledge of the indigenous peoples (usually known as Nacional Commission against Biopiracy) • Directorate of Inventions and New Technologies of the National Institute for the Defence of Competition and the Protection of Intellectual Property (INDECOPI) The designated checkpoints need to comply with the functions as established in Article 17 of the Nagoya Protocol. These are only some of the functions covered within their respective regulations which include a broader range of responsibilities. In this respect, it is worth noting that the functions mentioned below include the broader spectrum of competencies and not only those in light of Article 17 of the Nagoya Protocol. The National Commission against Biopiracy, established in 2004, is presided by INDECOPI and is comprised of representatives from the following institutions:

[564] Law 27811, Article 13

	1. National Institute for the Defence of Competition and the Protection of Intellectual Property (INDECOPI) 2. Ministry of Foreign Affairs 3. Ministry of International Trade and Tourism (MINCETUR) 4. National Council for the Environment (CONAM) 5. Commission for the Promotion of Exports (PROMPEX) 6. National Institute of Natural Resources (INRENA) 7. National Institute of Agricultural Innovation (INIA) 8. International Potato Centre 9. National Institute of Intercultural Health (CENSI) 10. National Commission of Andean, Amazonian and Afro-Peruvian peoples 11. Peruvian Society of Environmental Law (SPDA), on behalf of NGOs 12. Peruvian Institute of Natural Producers (IPPN), on behalf of business associations.[565] Given that the National Commission was designated as a checkpoint, its role is performed by the Commission itself and not by the previously mentioned institutions on an individual basis. Its functions include: • Create and maintain a registry of biological resources of Peruvian origin and collective knowledge of Peruvian indigenous peoples • Protect from acts of biopiracy • Identify and monitor patent applications or patents granted abroad that relate to Peruvian biological resources or collective knowledge of Peruvian indigenous peoples • Technically assess the previously mentioned patent applications and granted patents, submitting reports of the analysed cases and making recommendations to be followed by the government as appropriate • File opposition actions or actions for the revocation of patents applied for or granted abroad when these relate to Peruvian biological or genetic material or collective knowledge of its indigenous or native peoples

[565] Law 28216 Ley de protección al acceso a la diversidad biológica peruana y los conocimientos colectivos de los pueblos indígenas, Article 3 (updated with information available from the Commission's website http://www.biopirateria.gob.pe)

	• Establish regular communication channels and dialogue with intellectual property office in third countries.[566] Other functions of the National Commission include creating and maintaining a registry of biological resources of Peruvian origin and collective knowledge of Peruvian indigenous peoples. The database is not publicly available and currently contains around 20.000 registries. In turn, the Directorate of Inventions and New Technologies has the following functions which relate to being a checkpoint: • Request a copy of the contract of access when the claimed patents refer to products or processes that are the result of Peruvian genetic resources or their by-products[567] • Request a copy of the license for the use of traditional knowledge when the products or processes for which protection is claimed are the result of Peruvian traditional knowledge[568] • Evaluate the validity of the license agreements.[569] Other functions of the Directorate include maintaining the register of collective knowledge of indigenous peoples, and the register on the license agreements for the use of collective knowledge.[570]
b) What are the reporting requirements? Who is responsible for reporting?	In accordance with the minimum requirements that need to be covered in the access contracts, the applicant commits to inform the relevant administrative and executing authority about the progress, results and publications generated as a result of the carried out research.[571]
c) How can access to/utilisation of genetic resources and associated traditional knowledge be tracked? Has the country developed any particular method/mechanism to monitor the access and utilisation of genetic resources and/or associated traditional knowledge?	Peru established an integrated national mechanism for monitoring and surveillance of genetic resources, which is led by the Ministry of Environment. The objective of this mechanism is to track the utilisation of genetic resources accessed in the country while ensuring that access to genetic resources was subject to prior informed consent. For this purpose, compliance with the terms and conditions of access contracts is verified.[572] The national mechanism has the following functions:

[566] Law 28216 Ley de protección al acceso a la diversidad biológica peruana y los conocimientos colectivos de los pueblos indígenas, Article 4
[567] CAN, Decision 486 Common Regime for Industrial Property, Article 26(h)
[568] CAN, Decision 486 Common Regime for Industrial Property, Article 26(i)
[569] Law 27811, Article 64
[570] Law 27811, Article 64
[571] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 23
[572] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 38. Also see http://genesperu.minam.gob.pe/recursosgeneticos/supervision-y-seguimiento/

	• Establish coordination mechanisms with the institutions in charge of monitoring and surveillance to verify compliance with the terms agreed in the access contracts in relation to the utilisation of genetic resources • Oversee that the utilisation of genetic resources is done in accordance with the scope of the project and access contract – this is done based on the reporting requirements in accordance with the contracts • Identify and evaluate cases of unauthorised utilisation of genetic resources and associated traditional knowledge, including that related to intellectual property rights • Lead and maintain the public register of access contracts and related registers[573] – it is being established. It should be noted that the mechanism is not yet working in an integrated manner but, instead, through actions by the different institutions: • Administrative and executing authorities request for report to users • INDECOPI requests access contract to patent applicants • National Commission against Biopiracy conducts searches of patent applications and granted patents.
d) Does the country where utilisation of genetic resources takes place have any monitoring systems for patent databases, registries of products resulting from access, and scientific publications so to identify activities that are not in compliance with the domestic legislation of the country where the access took place and with the Nagoya Protocol?	As previously indicated, the National Commission against Biopiracy is responsible for: • Identifying and monitoring patent applications or patents granted abroad that relate to Peruvian biological resources or collective knowledge of Peruvian indigenous peoples • Technically assessing patent applications and granted patents, submitting reports of the analysed cases and making recommendations to be followed by the government as appropriate.[574] SERFOR also has some measures in place. For example export permits for CITES and non-CITES species, that ensure traceability of the use of the genetic resources and their derivatives abroad.

6. Compliance	
a) What are the competent authorities in charge of enforcement of the ABS legislation? Is compliance	Peru has designated a number of competent national authorities. In accordance with its Regulation (Supreme Decree 003-2009-MINAM), these are:

[573] See http://genesperu.minam.gob.pe/recursosgeneticos/supervision-y-seguimiento/

[574] Law 28216 Ley de protección al acceso a la diversidad biológica peruana y los conocimientos colectivos de los pueblos indígenas, Article 4

implemented in a centralised way (a single responsible body) or is it decentralised (several bodies with different competences)? What measures have been adopted to integrate/coordinate the actions of the bodies responsible for enforcing ABS rules at the national level? How to promote the integration/coordination of the various bodies responsible for enforcing ABS rules?	• Lead agency: Ministry of Environment (General Directorate of Biological Diversity): Normative, guiding and overseeing authority in terms of access to genetic resources. Also, responsible for the administration and management of the integrated National Mechanism for Monitoring and Surveillance (see item 6.b) below); oversees compliance with the provisions of the regulation, and coordinates actions to prevent and tackle biopiracy with the National Commission for the protection of access to Peruvian biological diversity and the collective knowledge of indigenous peoples[575]
	• Administrative and executing authorities – responsible for subscribing contracts and enforcing their provisions:
	  o Ministry of Agriculture, National Forest and Wildlife Service (SERFOR): Responsible for genetic resources, molecules, combination or mixture of natural molecules, including extracts and other by-products contained in wild inland species. Such content can be found in all or part of the plant or animal, including amphibians and microorganisms. The Ministry of Agriculture evaluates applications for access to genetic resources of wild relatives of cultivated species
	  o National Institute of Agricultural Innovation: Responsible for genetic resources, molecules, combination or mixture of natural molecules, including extracts and other by-products contained in cultivated or domesticated inland species
	  o Vice-Ministry of Fisheries and Aquaculture under the Ministry of Production,: Responsible for genetic resources, molecules, combination or mixture of natural molecules, including extracts and other by-products contained in hydrobiological marine species and those of inland waters[576]
	The administrative and executing authorities for access to genetic resources are responsible for:
	• Establishing sectoral policies on access to genetic resources to ensure compliance under Decision 391 and the Peruvian regulation
	• Receiving, evaluating, accepting and rejecting applications for access to genetic resources
	• Subscribing and authorising access contracts

[575] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 13
[576] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 15

	• Protecting the rights of suppliers of biological resources that contain genetic resources, and of the suppliers of the intangible component • Applying administrative sanctions as well as civil and/or criminal proceedings as appropriate • Overseeing and monitoring compliance of the terms in the concluded contracts, based on the mechanisms for monitoring and evaluation established by the Ministry of Environment • Coordinating with the regional governments relevant measures for surveillance of genetic resources in their areas.[577] Furthermore, in accordance with Law 27811, the following was also designated as national competent authority: • Directorate of Inventions and New Technologies of the National Institute for the Defence of Competition and the Protection of Intellectual Property (INDECOPI): It is the national competent authority to solve, in the first instance, aspects concerned with the protection of collective knowledge of indigenous peoples. It is responsible for maintaining the Register of Collective Knowledge of Indigenous Peoples, and the Register of Licences for the Use of Collective Knowledge.[578] Regarding the measures adopted to integrate/coordinate the actions of the bodies responsible for enforcing ABS rules at the national level, the following can be mentioned: • The lead agency is developing a proposal of standardised guidelines, in coordination with the administrative and executing agencies. This objective of this proposal is to homogenise the procedures that relate to authorisations, negotiation, and monitoring and surveillance of ABS obligations, with the ultimate goal of establishing a one-stop-shop for these matters • Convening of intersectoral meetings, coordinated by the lead agency, to analyse cases relating to access • Convening of meetings with the designated checkpoints for analysing the scope of the patent applications and granted patents, as well as with respect to the report to the monitoring and surveillance mechanism.
b) What measures have already been adopted to promote the effective monitoring of legal compliance?	In Peru, an integrated national mechanism for monitoring and compliance on genetic resources was established under the Ministry of Environment to promote the effective monitoring of legal

[577] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 14
[578] Law 27811, Articles 63-64

	compliance.[579] The aim of this mechanism is to ensure that prior informed consent was obtained and mutually agreed terms established for the access to genetic resources. The mechanism allows for monitoring to track the utilisation of genetic resources of Peruvian origin that were accessed in the country with a view to verifying compliance with the terms and conditions in the contract of access.[580] For that purpose, the mechanism performed carries out the following functions: • Request, from the users that obtained permission to access genetic resources, information relating to the utilisation of genetic resources and the results of their research • Establish coordination mechanisms with the administrative and executing authorities to provide guidance with respect to the procedures applicable to the subscription of access contracts • Liaise with INDECOPI regularly, and establish exchange of information systems relating to authorisations and granted intellectual property rights on products and processes related to genetic resources and their by-products within the scope of Decision 391, and inform about cases that entail illegal access to genetic resources or unauthorised access to traditional knowledge of indigenous peoples • Establish coordination mechanisms with regional and local governments for surveillance measures of genetic resources within their areas[581] – this has not yet been implemented Additionally, the legislation stipulates a series of sanctions for situations in which users do not comply with the measures in place. Some of these include: suspension or cancellation of the authorised access, fines, inability for the user to present new applications for access.[582] Furthermore, the National Commission against Biopiracy informs the Ministry of Environment every six months with respect to the actions undertaken for the research and identification of cases in which illegal access to genetic resources took place.[583]
c) Are there any measures foreseen in the national legislation to ensure benefit-sharing when access and utilisation of genetic resources and associated traditional	With the aim of identifying potential cases of biopiracy, the National Commission against Biopiracy is in charge of identifying and monitoring patent applications and patents granted in

[579] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 37
[580] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 38
[581] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 39
[582] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Articles 34 and 35
[583] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Complementary provisions, First

knowledge occur outside the jurisdiction of the country where the access took place, especially when it is in a country that is not a Party to the Nagoya Protocol or when the user is based in a country that is not a Party?	third countries, which relate to Peruvian biological resources and/or collective knowledge of indigenous peoples in Peru.[584] Among others, the National Commission for the protection of access to Peruvian biological diversity and the collective knowledge of indigenous peoples related to that diversity can bring proceedings for the opposition of patent applications or revocation of patents granted in third countries when the claimed patents relate to Peruvian biological or genetic material, or to collective knowledge of indigenous and native peoples for which access requirements in place have not been followed.[585] In relation to bringing actions abroad, the National Commission against Biopiracy is responsible for determining the situations where biopiracy takes place and for which actions should be pursued.[586] In accordance with the definition of biopiracy indicated in item 1.e) above, cases for which a third party accesses and/or uses a Peruvian biological resources and/or collective knowledge of Peruvian indigenous peoples without the consent of their holders and/or without adequately sharing benefits resulting from their use, fall within the scope of the actions previously mentioned. Actions from the National Commission against Biopiracy can be pursued even when the third party is not the one that accessed the resources and/or intend to obtain intellectual property rights for its benefit.[587]
7. Intellectual property rights (focusing on patents)	
a) How does the country deal with patentability of living organisms found in nature and of its components, such as DNA, molecules and metabolites?	Decision 486 stipulates that plants, animals and essentially biological processes for the production of plants or animals that are not non-biological or microbiological processes are not patentable.[588] Moreover, the following are not considered inventions and therefore cannot be patented: • Discoveries • The entirety or part of living beings as encountered in nature, natural biological processes, biological material existing in nature or which may be isolated, including the genome or germplasm of any natural living being

[584] Supreme Decree 022-2006-PCM Reglamento de la Ley de Protección al Acceso a la Diversidad Biológica y los Conocimientos Colectivos de los Pueblos Indígenas
[585] Law 28216, Article 4
[586] Supreme Decree 022-2006-PCM Reglamento de la Ley de Protección al Acceso a la Diversidad Biológica y los Conocimientos Colectivos de los Pueblos Indígenas, Article 7
[587] Supreme Decree 022-2006-PCM Reglamento de la Ley de Protección al Acceso a la Diversidad Biológica y los Conocimientos Colectivos de los Pueblos Indígenas, Article 11
[588] CAN, Decision 486 Common Regime for Industrial Property, Article 20

	• Methods of presenting information[589] Where the patent protects biological material that can be reproduced, the patent shall not extend to the biological material obtained by reproduction, multiplication or propagation of the material that has been brought on to the market in any country by the owner of the patent, or by another person who has obtained his consent or is economically associated with him, provided that: • The reproduction, multiplication or propagation was necessary so that the material might be used to achieve the purposes for which it was brought on to the market; and • that the material derived from such use is not used for multiplication or propagation purposes.[590]
b) Do patent applications include disclosure of origin among the requirements that need to be filled in by the applicant? Is it a mandatory or optional element? Is it only related to genetic resources or also to the associated traditional knowledge?	Yes. The disclosure of origin is a mandatory requirement in Colombia. Decision 391 indicates that the Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components that were obtained or developed through an access activity that does not comply with the provisions of the Decision. Furthermore, the competent National Intellectual Property Offices must require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries. The Decision further indicates that the Competent National Authority and the Competent National Offices on Intellectual Property shall set up systems for exchanging information about the authorized access contracts and intellectual property rights granted.[591] The ABS authority in Colombia has regular communication with the competent authority for intellectual property. As a result, they are not only aware of patent applications being presented that relate to native genetic resources but also they give their views on whether the access contract should be approved or not. Among others, patent applications shall contain:

[589] CAN, Decision 486 Common Regime for Industrial Property, Article 15
[590] CAN, Decision 486 Common Regime for Industrial Property, Article 54
[591] CAN, Decision 391 Common Regime on Access to Genetic Resources, Complementary provisions, Second and Third

	• where applicable, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom, of which any of the member countries is the country of origin • where applicable, a copy of the document accrediting the licensing or authorization of the use of traditional knowledge of indigenous, Afro-American and local communities of Member Countries where the products or procedures for which protection is sought have been obtained or developed from such knowledge of which any of the Member Countries is the country of origin, in accordance with the provisions of Decision 391.[592] The competent national authority shall declare the absolute invalidity of a patent at any time where a copy of the access contract has not been filed where the products or processes to which the patent application relates have been produced or developed with genetic resources or derived products of which any of the member countries is the country of origin; or a copy of the document evidencing the licensing or authorization of the use of traditional knowledge of the indigenous Afro-American or local communities of the member countries has not been filed where the products or processes for which protection is sought have been produced or developed on the basis of such knowledge of which one of the Member Countries is the country of origin.[593] As a result, when a patent application is submitted in Colombia for products or procedures obtained or developed from genetic resources or their derived products, the applicant must present a copy of the contract of access to the genetic resources and their by-products.[594]

8. Supporting instruments for the implementation of ABS legislation	
a) Does the legislation consider the development of community protocols related to access to traditional knowledge associated with genetic resources? If so, has the country developed them so far?	The Peruvian ABS regime goes beyond the specific reference to community protocols. Law 27811 is a *sui generis* regime for the protection of collective knowledge which brings together elements from intellectual property and from customary law, such as: • PIC has to be obtained in accordance with the norms recognised by the indigenous peoples • Dispute settlement between indigenous peoples

[592] CAN, Decision 486 Common Regime for Industrial Property, Article 26
[593] CAN, Decision 486 Common Regime for Industrial Property, Article 75
[594] Resolution 1352 de 2017, Article 2

	• To the extent possible, the Steering Committee of the Fund for the Development of Indigenous Peoples needs to make use of benefit-sharing mechanisms that have been collectively established and traditionally used by the indigenous peoples.[595]
b) Has the country developed any guidelines, codes of conduct, best practices or standards related to the implementation of their ABS legislation? If so, which ones?	No information provided
c) Does the legislation include any model contractual clauses/standard agreement to be used for exchange of materials and establishment of MAT?	In the context of the CAN, the following two regulations were adopted: 1. Reference model of application to request for access to genetic resources (Regulation 414) 2. Reference model contract of access to genetic resources (Regulation 415) – includes the different elements that could be included but does not provide model contractual clauses[596] Furthermore, in accordance with the Peruvian ABS framework, the national competent authorities are developing standard material transfer agreements.[597] Moreover, they are developing material to support the process for contracts' negotiation and a model contract of access. This still needs to go through a validation process. SERFOR has developed forms for applications for access to genetic resources under their competence that require subscription of an access contract.

9. Challenges of implementation	
Identified challenge	Brief explanation
Need for a multidisciplinary team to improve the management of authorisations, negotiations, benefit-sharing, and monitoring and surveillance	Implementation of the ABS system in Peru is at an initial stage, with a gap being observed between access that takes place within the system and the one taking place outside of it. In particular, there is a need to develop legal and technical capacities regarding the negotiation of access contracts. Within the context of the current legislation the need for these to adequately reflect the mutually agreed terms is identified (e.g. benefit-sharing, change of intent).
Lack of technical and legal specialists for the management of genetic resources, and for the implementation of ABS measures in general	Composition and number of staff dedicated to the ABS system is determined on a sectoral basis in accordance with the relevant regulations of each organisation and thus not based on what is necessary for the holistic implementation of the ABS regime. The demand of specialists has increased with the entry into force of the Nagoya Protocol. There is a need to strengthen

[595] Peru, 2017, Interim National Report on the implementation of the Nagoya Protocol. Available at https://absch.cbd.int/pdf/documents/absNationalReport/ABSCH-NR-PE-238684/2
[596] Both Regulations are available from http://intranet.comunidadandina.org/documentos/Gacetas/gace217.pdf
[597] Supreme Decree 003-2009-MINAM

	the capacities of the lead agency (MINAM) to effectively lead and articulate the ABS system. Also, a full time administrative technical unit within each of the institutions that subscribe access contracts is needed (SERFOR, INIA, PRODUCE) to support management of access to genetic resources and research, in the context of the Nagoya Protocol and related legislation.
Insufficient articulation among the competent authorities in relation to traditional knowledge	Regarding traditional knowledge, there is not enough coordination between INDECOPI and the administrative and executing authorities designated through DS 003-2009-MINAM. The need for further articulation and coordination between the sectoral, regional and local authorities with competences for the protection of traditional knowledge associated to genetic resources has therefore been identified.
Need for legislation that strengthens scientific research, innovation and development at the national level	Building solid, consensual regulations that promote and strengthen scientific research, innovation and development at the national level.
Lack of staff dedicated to the management of the ABSCH	There is a need for staff fully dedicated to the management of the CIIAPB/ABSCH
Insufficient number of checkpoints thus not allowing for utilisation to be adequately monitored at all stages of the production chain	To date, the designated checkpoints have competencies in terms of granting patents at the national level, and monitoring patents granted in third countries. However, no checkpoints to monitor the process through research, development, and commercialisation exist. The first interim national report identifies a number of institutions that could perform this role, namely: • Consejo Nacional de Ciencia, Tecnología e Innovación Tecnológica (CONCYTEC): responsible for funding projects relating to scientific and technological research • Direccion General de Salud Ambiental e Inocuidad Alimentaria (DIGESA): responsible for sanitary measures • Dirección General de Medicamentos, Insumos y Drogas (DIGEMID): responsible for pharmaceutical products • Superintendencia Nacional de Administración Tributaria (SUNAT).

4.8 South Africa

- South Africa is a Party to the Nagoya Protocol since its entry into force in 2014. However, its ABS system precedes the existence of the Protocol.
- Access and benefit-sharing in South Africa is regulated through a series of instruments, the main two being the National Environmental Management Biodiversity Act (NEMBA) 2004 (and its subsequent amendments), and Regulations on Bio-Prospecting, Access and Benefit-Sharing (BABS) 2015. Even though these two instruments are at the cornerstone of the South African ABS framework, there is a series of related crosscutting legislative and policy measures that complement them. These include, among others, amendments to South Africa's Patents Act No. 57 of 1978, such as:
    - Amendments Act 2005 that make the disclosure of origin of South African genetic resources and associated traditional knowledge compulsory
    - Intellectual Property Laws Amendment Act 2013 relating to the protection of indigenous knowledge
- It is worth noting that the NEMBA and the BABS regulations are currently being amended to be fully consistent with the Nagoya Protocol.
- Furthermore, South Africa is currently establishing a *sui generis* system for the protection, promotion, development and management of indigenous knowledge systems. The draft bill passed from the National Assembly in November 2017 to the National Council of Provinces.[598] Once adopted, this Bill will also form an essential part of the ABS framework in place.

1. Definition of key terms	
a) Definition of access to genetic resources and the associated traditional knowledge	Not defined in the South African ABS framework
b) Definition of collection	Not defined in the South African ABS framework
c) Definition of utilisation of genetic resources and the associated traditional knowledge	Not defined in the South African ABS framework
d) Definition of bioprospecting	Bioprospecting, in relation to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes: a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application; b) the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities; c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation; or

[598] As of 12 August 2018. See https://pmg.org.za/bill/635/

	d) the trading in and exporting of indigenous biological resources in order to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and essential oils[599]
e) Others definitions of relevance? E.g. biological resources, in situ conservation; indigenous species; benefit-sharing, derivative; genetic resources; genetic material	Genetic material: any material of animal, plant, microbial or other biological origin containing functional units of heredity[600] (same definition as the one in the Convention on Biological Diversity) Genetic resource: includes: (a) any genetic material; or (b) the genetic potential, characteristics or information of any species[601] Derivative: in relation to an animal, plant or other organism, means any part, tissue or extract of an animal, plant or other organism, whether fresh, preserved or processed, and includes any genetic material or chemical compound derived from such part, tissue or extract[602] Indigenous species: a species that occurs, or has historically occurred, naturally in a free state in nature within the borders of the Republic, but excludes a species that has been introduced in the Republic as a result of human activity[603] Indigenous biological resource: • when used in relation to bioprospecting, means any indigenous biological resource as defined in Section 80(2) of the NEMBA[604]; or • when used in relation to any other matter, means any resource consisting of: (i) any living or dead animal, plant or other organism of an indigenous species; (ii) any derivative of such animal, plant or other organism; or (iii) any genetic material of such animal, plant or other organism.

[599] National Environmental Management: Biodiversity Act, 2004, and amendments, Chapter 1
[600] National Environmental Management: Biodiversity Act, 2004, Chapter 1, paragraph 1
[601] National Environmental Management: Biodiversity Act, 2004, and amendments
[602] National Environmental Management: Biodiversity Act, 2004, and amendments
[603] National Environmental Management: Biodiversity Act, 2004, Chapter 1, paragraph 1
[604] Section 80(2) of the NEMBA indicates that "indigenous biological resources":
a) includes: (i) any indigenous biological resources as defined in paragraph (b) of the definition of "indigenous biological resource" in Section 1, whether gathered from the wild or accessed from any other source, including any animals, plants or other organisms of an indigenous species cultivated, 35 bred or kept in captivity or cultivated or altered in any way by means of biotechnology; (ii) any cultivar, variety, strain, derivative, hybrid or fertile version of any indigenous species or of any animals, plants or other organisms referred to in subparagraph (i); and (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 referred to in subparagraph (i) or (ii); but
(b) excludes: (i) genetic material of human origin; (ii) any exotic animals, plants or other organisms, other than exotic animals, plants or other organisms referred to in paragraph (a)(iii); and (iii) indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture.

	Commercialisation: in relation to indigenous biological resources, includes the following activities: • the filing of any complete intellectual property application, whether in South Africa or elsewhere • obtaining or transferring any intellectual property rights or other rights • commencing product development, including the conducting of market research and seeking pre-market approval for the sale of resulting products • the multiplication of indigenous biological resources through cultivation, propagation, cloning or other means to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and essential oils • trading in and exporting of indigenous biological resources to develop and produce products, such as drugs, industry enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts and essential oils; and • commercial exploitation [605] **Commercial exploitation:** the engaging in any bioprospecting activity with the intention of making a profit[606] **Commercialisation phase of bioprospecting:** any research on, or development or application of, indigenous biological resources where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is sufficiently established to begin the process of commercialisation[607] **Discovery phase of bioprospecting:** any research on, or development or application of, indigenous biological resources where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is not sufficiently clear or known to begin the process of commercialisation[608] **Traditional use or knowledge:** customary utilisation or knowledge of indigenous genetic and biological resources by an indigenous community or specific individual, in accordance with

[605] National Environmental Management: Biodiversity Act, 2004, and amendments
[606] National Environmental Management: Biodiversity Act, 2004, and amendments
[607] National Environmental Management: Biodiversity Act, 2004, and amendments
[608] National Environmental Management: Biodiversity Act, 2004, and amendments

	written or unwritten rules, usages, customs or practices traditionally observed, accepted and recognised by them, and include discoveries about the relevant indigenous genetic and biological resources by that community or individual[609] **Biotrade:** buying and selling of milled, powdered, dried, sliced or extract of indigenous genetic and biological resources for further commercial exploitation[610]

2. General information	
a) To whom do genetic resources belong? Are these considered private goods, goods of common use by the population, public goods or do they belong to the State, etc.?	In South Africa, the State is the trustee of biological diversity. In this respect, the Biodiversity Act stipulates that "In fulfilling the rights contained in Section 24 of the Constitution, the state through its organs that implement legislation applicable to biodiversity, must: a) manage, conserve and sustain South Africa's biodiversity and its components and genetic resources; and b) implement this Act to achieve the progressive realisation of those rights."[611] Nevertheless, legislation does not vest ownership of genetic resources in the State, with the only exception of those in State's land.[612] In accordance with South African law: • A landowner owns both the biological and the genetic resources on or under his/her property – thus private ownership being applicable • Indigenous knowledge holders and indigenous knowledge practitioners are the custodians of the indigenous knowledge associated with the use of indigenous genetic and biological resources in accordance with customary laws and practices of their particular community. Indigenous communities have rights over their traditional knowledge when there is a common understanding that a specific community discovered or developed the knowledge. However, knowledge that is widely known or shared among a number of communities is considered in the public domain.[613] Information about traditional knowledge that is already in the public domain does not mean that the community which developed or discovered this

[609] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 1
[610] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 1
[611] National Environmental Management: Biodiversity Act, 2004, and amendments
[612] ABS Initiative, 2014. National Study on ABS Implementation in South Africa, available at http://www.abs-initiative.info/fileadmin/media/Knowledge_Center/Pulications/ABS_Dialogue_042014/National_study_on_ABS_implementation_in_South_Africa_20140716.pdf
[613] ABS Initiative, 2014. Table 1: Overview of key elements of national ABS frameworks in Brazil, India and South Africa

	knowledge no longer has any rights over it. Consent is still needed from knowledge holders.[614]
b) Does the legislation provide any indication on when it is considered that species have developed their own characteristics, i.e. distinctive properties, to start being considered a genetic resource of that country?	The South African ABS framework applies to indigenous biological resources, being these understood as South African biological resources. In addition to the definition of indigenous biological resources that was presented above, the legislation further defines the term **"indigenous species"** as "a species that occurs, or has historically occurred, naturally in a free state in nature within the borders of the Republic, but excludes a species that has been introduced in the Republic as a result of human activity".[615] However, yet no detailed criteria have been developed to know when a genetic resource should start being considered a South African genetic resource. This is an area to be possibly addressed through the amendments to the NEMBA.
c) Objective of the ABS legislation	NEMBA contains overarching legislative measures for the regulation of biodiversity management. As such, its objectives go beyond access and benefit-sharing. However, given the scope of this study the focus is on the one aiming for the *fair and equitable sharing among stakeholders of benefits arising from bioprospecting involving indigenous biological resources*.[616] In this respect, the purpose of the chapter dealing with bioprospecting, access and benefit-sharing is to: • regulate bioprospecting involving indigenous genetic and biological resources • regulate the export from South Africa of indigenous genetic and biological resources for the purpose of bioprospecting or any other kind of research • provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous genetic and biological resources; and • ensure that the nation's indigenous genetic and biological resources are developed and utilised in an ecologically sustainable manner while promoting social and economic development, in particular in the areas where the indigenous genetic or biological resources and associated traditional knowledge are accessed.[617]

[614] South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators, 2012, available at https://www.environment.gov.za/sites/default/files/legislations/bioprospecting_regulatory_framework_guideline.pdf
[615] National Environmental Management: Biodiversity Act, 2004, Chapter 1, paragraph 1
[616] National Environmental Management: Biodiversity Act, 2004, Chapter 1, Section 2
[617] National Environmental Management: Biodiversity Act, 2004, Chapter 6, and amendments

	Furthermore, the Regulations on Bio-Prospecting, Access and Benefit-Sharing 2015 (BABS Regulations) prescribe the notification process for the discovery phase of bioprospecting involving any indigenous genetic and biological resources; and the permit system applicable to bioprospecting involving any indigenous genetic and biological resources or export from South Africa of any indigenous genetic and biological resources for bioprospecting or any other kind of research. Moreover, they set out the form and content of and requirements for benefit-sharing and material transfer agreements; and the administration process of the Bioprospecting Trust Fund.[618,619]
d) Scope of the legislation – does it refer to all genetic resources or only to a subset (e.g. genetic resources for food and agriculture)? Are there any exemptions of genetic resources that fall outside of the scope (e.g. human genetic resources)?	In accordance with the NEMBA, "indigenous biological resources" include: i) any indigenous biological resources as in the definition mentioned above, whether gathered from the wild (*in situ*) or accessed from any other source, including any animals, plants or other organisms of an indigenous species cultivated bred or kept in captivity or cultivated or altered in any way by means of biotechnology ii) any cultivar, variety, strain, derivative, hybrid or fertile version of any indigenous species or of any animals, plants or other organisms referred to in item i) above, and 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 in any indigenous species or any animals, plants or other organisms referred to items i) and ii) above.[620] The following activities are covered by the South African ABS framework: • commercial or industrial sectors that utilise any indigenous genetic and biological resources for biotrade or for research, application or development of drugs, complementary medicines, nutraceuticals, industry enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts, and essential oils

[618] The Bioprospecting Trust Fund was established through the National Environmental Management: Biodiversity Act 2004 to receive all payments arising from benefit-sharing agreements and material transfer agreements, due to stakeholders; and to make all payments to stakeholders (Chapter 6, Section 85(1)). The Director-General of the Department of Environmental Affairs is responsible for management and administration of the Fund (Regulations on Bio-Prospecting, Access and Benefit-Sharing 2015, Section 40(1)). Each benefit-sharing agreement is considered as the trust instrument that details the specific purpose for which money received by the Bioprospecting Trust Fund may be used (Regulations on Bio-Prospecting, Access and Benefit-Sharing 2015, Section 40(2)). The transfer of money to the relevant stakeholders is done annually unless otherwise stipulated in the benefit-sharing agreement or agreed between the Director-General and the parties to a benefit-sharing agreement (Regulations on Bio-Prospecting, Access and Benefit-Sharing 2015, Section 40(4)).
[619] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 1
[620] National Environmental Management: Biodiversity Act, 2004, Chapter 6

	• commercial or industrial sectors that utilise traditional knowledge associated with any indigenous genetic and biological resources for biotrade or for research, application or development of drugs, complementary medicines, nutraceuticals, industry enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts, and essential oils
	• non-commercial sectors that export any indigenous genetic and biological resources for a research to generate scientific data.[621]
	The following resources and activities are excluded from the scope of the ABS legislation:
	• Human genetic resources
	• Exotic animals, plants or other organisms
	• Indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture
	• Research other than bioprospecting if the research is conducted in South Africa and is not for commercial purposes
	• Export of ex-situ indigenous biological resources[622] if the export is for research other than bioprospecting, provided that the exporter has concluded an export agreement and notified the issuing authority accordingly
	• Trade of commercial products purchased from a retailer
	• Artificial propagation and cultivation of flora species for the cut flower and ornamental plant markets
	• Aquaculture and mariculture activities for consumption purposes[623]
	• The keeping, breeding, cultivation, moving, trading and use of wildlife not directed at the development and production of:
	  ○ products such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours and extracts
	  ○ new plant varieties and products
	  ○ the collection, use, propagation cultivation or trade of indigenous biological resources for domestic use or subsistence purposes.[624]

[621] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 1
[622] In accordance with Exemption notice No. R. 149, 2008, National Environmental Management: Biodiversity Act 2004, "ex situ indigenous biological resources" means indigenous biological resources that occur in collections outside their natural habitat.
[623] Exemption notice No. R. 149, 2008, National Environmental Management: Biodiversity Act 2004; and National Environmental Management: Biodiversity Act, 2004, and amendments, Chapter 6
[624] Exemption notice No. R. 149, 2008, National Environmental Management: Biodiversity Act 2004.

e) Is ABS regulated at the national or subnational level? To what extent does the national government share competencies with subnational entities?	In accordance with the Constitution of South Africa, "nature conservation, excluding national parks, national botanical gardens and marine resources" is one of the areas of concurrent national and provincial legislative competence.[625] Therefore, ABS is regulated at various levels with the Department of Environmental Affairs being in charge of the development and implementation of legislative, administrative and policy measures on ABS.[626] In particular, the NEMBA stipulates that the "issuing authorities" of a permit or registration relating to bioprospecting involving indigenous biological resources; or the export of indigenous biological resources for bioprospecting or any other type of research are: • The Minister of Environment • The Member of the Executive Council • An organ of state in the national, provincial or local sphere of government delegated in terms of Section 42 of the National Environmental Management Act, 1998 or assigned in terms of Section 41 of the National Environmental Management Act, 1998 as an issuing authority for a permit or registration of the kind in question[627]

3. Access to genetic resources and associated traditional knowledge	
a) According to the legislation, is access to genetic resources and/or associated traditional knowledge subject to prior informed consent (PIC)?	Yes. In South Africa, PIC from the owners of indigenous biological resources and/or associated traditional knowledge is required prior to accessing those resources for bioprospecting, for research other than bioprospecting, and for biotrade activities conducted in or outside the country with South African genetic and biological resources. The competent authority responsible for issuing permits has to ensure that the interests of: (a) those that provide access to the indigenous biological resources to which the application relates, and (b) any indigenous community: (i) whose traditional uses of the indigenous biological resources to which the application relates have initiated or will contribute to or form part of the proposed bioprospecting; or (ii) whose knowledge of or discoveries about the indigenous biological resources to which the application relates are to be used for the proposed bioprospecting; are safeguarded. As such, when the authority is requested to consider an application for access to indigenous genetic and biological resources, it needs to ensure that

[625] Constitution of the Republic of South Africa, 1996, Chapter 14, Schedule 4: Functional Areas of Concurrent National and Provincial Legislative Competence, Part A
[626] ABS initiative, National Study on ABS Implementation in South Africa, 2014
[627] National Environmental Management: Biodiversity Act, 2004, Chapter 1

	there is evidence that the applicant has obtained the prior consent of any person, including any organ of state or community providing or giving access to the indigenous genetic and biological resources to which the application relates, or from any affected indigenous communities or individuals. With respect to indigenous communities, evidence consists of a community resolution authorizing a representative to give prior consent to the applicant, giving access to indigenous genetic and biological resources and traditional knowledge associated with the use of indigenous genetic and biological resource and to further enter into benefit-sharing and material transfer agreements on behalf of the indigenous community.[628] Importantly, the South African ABS framework makes a distinction between the discovery phase of a bioprospecting project (when the intention is to find out if an indigenous biological resource has any potential to be further developed into a commercial product), and the commercialisation phase (when commercial potential has already been identified). Regardless of the types of permit being applied for under each of these phases, there is a need to present evidence of prior consent from the relevant stakeholder/s. A permit application may only be submitted by: • a natural person registered in terms of South African law • a natural person, who is a South African citizen or permanent resident of South Africa; or • a legal person that is not registered in terms of South African law or a natural person who is not a South African citizen or permanent resident of South Africa, if that legal person or foreign national applies jointly with legal or natural person referred to in the two previous points.[629] The following types of permits are applicable for the different activities: 1. Types of permits applicable for the *discovery phase of bioprospecting*: • Notification: Those doing discovery phase research need to notify the Minister about what they are doing, but do not require a bioprospecting permit. Notification can only be done if the discovery research is taking in the Republic. A bioprospecting permit is needed only for the commercialisation phase[630]

[628] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 2
[629] South Africa, 2017, Interim National Report on the implementation of the Nagoya Protocol. Available at https://absch.cbd.int/database/NR/ABSCH-NR-ZA-238752
[630] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 3, Part 3, regulation 13

	• Discovery phase export permit: Applicable when someone wishes to export from South Africa any indigenous genetic and biological resources for the purpose of bioprospecting for commercial research[631] 2. Types of permits applicable for the *commercialisation phase of bioprospecting*: • Bioprospecting permit: Needed for bioprospecting projects involving any indigenous genetic and biological resources within South Africa, as well as for export from South Africa for bioprospecting purposes of any indigenous genetic and biological resources covered in the permit application[632] • Biotrade permit: Necessary when a person wishes to engage in biotrade within South Africa; and for export from South Africa of indigenous genetic and biological resources covered in the permit application[633] • Integrated biotrade and bioprospecting permit: Needed when the intention is to engage in both biotrade and bioprospecting involving indigenous genetic and biological resources within South Africa, or for export from South Africa of any indigenous genetic and biological resources covered in the permit application for these purposes[634] 3. Type of permit for *research other than bioprospecting*: • Export permit for research other than bioprospecting: Necessary when the intention is to export from South Africa any indigenous genetic and biological resources for research other than bioprospecting[635] In addition to the provisions included in the current ABS framework, the Protection, Promotion, Development and Management of Indigenous Knowledge Systems Bill that is under development addresses the access to and use of indigenous knowledge (that is defined as "knowledge which has been developed within an indigenous community and has been assimilated into the cultural and social identity of that community, and includes (…) knowledge of natural resources…" (the definition provided for natural resources explicitly includes genetic resources).[636] Any person who intends to use indigenous knowledge for commercial purposes

[631] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 3, Part 3, regulation 14
[632] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 3, Part 3, regulation 17
[633] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 3, Part 3, regulation 16
[634] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 3, Part 3, regulation 18
[635] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 3, Part 4, regulation 19
[636] Draft Bill on the Protection, Promotion, Development and Management of Indigenous Knowledge Systems, Chapter 7, Section 26. Available at https://pmg.org.za/bill/635/

	must apply for a licence authorising the use of that indigenous knowledge; and enter into a licence agreement with the trustee of the relevant indigenous community for the use of that indigenous knowledge. No prior informed consent for the use of indigenous knowledge is required for criticism or academic review; or non-commercial research purposes, amongst others.[637] For more details on the South African policy framework for indigenous knowledge systems, please see item 8.d) below.
b) Does the legislation establish rules/procedures for requiring and establishing mutually agreed terms (MAT)?	Yes. In addition to PIC, there is a need for the permit applicant and the access provider to negotiate and sign: • a material transfer agreement that regulates the provision of or access to indigenous biological resources and associated traditional knowledge; and • a benefit-sharing agreement that provides for sharing by the stakeholder in any future benefits that may derive from the relevant activity related to the relevant permit application.[638] Among others, the following aspects need to be included in benefit-sharing agreements: • area or source from which the indigenous biological resources are to be collected or obtained; • quantity of indigenous biological resources that is to be collected or obtained; • any traditional uses of the indigenous biological resources by an indigenous community; and • present potential uses of the indigenous biological resources.[639] In turn, a material transfer agreement needs to specify, among others: • provider, exporter or recipient of the indigenous biological resources; • type of indigenous biological resources to be provided or to be given access to; • area or source from which the indigenous biological resources are to be collected, obtained or provided; • quantity of indigenous biological resources that is to be provided, collected, obtained or exported; • purpose for which such indigenous biological resources are to be exported;

[637] Draft Bill on the Protection, Promotion, Development and Management of Indigenous Knowledge Systems, available at https://pmg.org.za/bill/635/
[638] National Environmental Management: Biodiversity Act, 2004, Chapter 6, Section 82(2)
[639] National Environmental Management: Biodiversity Act, 2004, Chapter 6, Section 83

	• potential uses of the indigenous biological resources; and • conditions under which the recipient may provide any such indigenous biological resources.[640] Importantly, any benefit-sharing agreement, material transfer agreement or amendment to such agreements must be submitted to the Minister for approval; and do not take effect until the Minister approves them.[641] The legislation also indicates that a benefit-sharing agreement must achieve one or more of the following benefits: • conservation of the indigenous genetic and biological resources • support for further research on indigenous genetic and biological resources and traditional knowledge • enhancement of the scientific knowledge and technical capacity to conserve, use and develop indigenous genetic and biological resources • any other activity that promotes the conservation, sustainable use and development of indigenous biological resources for the benefit of South Africa; or • improve livelihoods of the communities and enhancement of technical capacity of the communities or individuals involved.[642]
c) Does the legislation set out criteria for the approval and involvement of indigenous and local communities for access to genetic resources and associated traditional knowledge?	Yes. As specified in item 3.a), the competent authority responsible for issuing access permits has to ensure that the interests of: (a) those that provide access to the indigenous biological resources to which the application relates, and (b) any indigenous community: (i) whose traditional uses of the indigenous biological resources to which the application relates have initiated or will contribute to or form part of the proposed bioprospecting; or (ii) whose knowledge of or discoveries about the indigenous biological resources to which the application relates are to be used for the proposed bioprospecting; are safeguarded. When the authority is requested to consider an application for access to indigenous genetic and biological resources, it needs to ensure that there is evidence that the applicant has obtained the prior consent of anyone providing or giving access to the indigenous genetic and biological resources to which the application relates, or from any affected indigenous communities or individuals.

[640] National Environmental Management: Biodiversity Act, 2004, Chapter 6, Section 84
[641] National Environmental Management: Biodiversity Act, 2004, Chapter 6, Sections 83 and 84
[642] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 4, Part 1

	With respect to indigenous communities, evidence consists of a community resolution authorizing a representative to give prior consent to the applicant, giving access to indigenous genetic and biological resources and traditional knowledge associated with the use of indigenous genetic and biological resource and to further enter into benefit-sharing and material transfer agreements on behalf of the indigenous community. This is because the representatives of local and indigenous communities cannot act on behalf of them and instead they need to get approval from its entire community. When engaging with indigenous and local communities, the entry point will be through the Traditional Councils comprised by the elders and Chief of the community. Governmental agencies such as the Department of Environmental Affairs also encourage the communities that do not have formal structures to organise themselves. Other Departments like Science and Technology and Cooperative Governance and Traditional Affairs are also involved in terms of ensuring that community protocols and customary laws are taken into consideration.[643]
d) Does the legislation address any changes of intent in the utilisation of accessed genetic resources? (e.g. initially accessed for non-commercial research and then changing their utilisation to commercial)	Based on the information included in the BABS regulations, when there is a change in the intended utilisation of the indigenous genetic and biological resources, the permit applicant needs to request for new PIC and enter into a new benefit-sharing agreement relating to the proposed changes in such utilisation.[644]
e) Does the legislation consider any simplified measures on access for non-commercial research purposes; or for cases of present or imminent emergencies that threaten or damage human, animal or plant health?	Yes. With the goal of promoting scientific academic research and collaboration, there are simplified procedures in place for non-commercial research purposes in South Africa. As a result, this type of research is excluded from the ABS framework and consequently does not require issuance of a bioprospecting permit (see item 2.d) above).
f) Are there any specific provisions/piece of law related to genetic resources for food and agriculture?	No specific references to sectors are included in the South African ABS framework, with the only exemption of crops listed in Annex I of the ITPGRFA being excluded from this framework.

4. Benefit-sharing	
a) What triggers benefit-sharing? Does any utilisation of genetic resources create a benefit-sharing obligation, even if it does not add value to the product or market?	As specified in South Africa's first interim national report to the Nagoya Protocol, everyone in the value chain involved in bioprospecting activities has to obtain a bioprospecting permit.[645]

[643] South Africa, 2017, Interim National Report on the implementation of the Nagoya Protocol. Available at https://absch.cbd.int/database/NR/ABSCH-NR-ZA-238752
[644] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Annexure 11
[645] South Africa, 2017, Interim National Report on the implementation of the Nagoya Protocol. Available at https://absch.cbd.int/database/NR/ABSCH-NR-ZA-238752

	Benefit "in relation to bioprospecting involving indigenous biological resources, means any benefit, whether commercial or not, arising from bioprospecting involving such resources, and includes both monetary and non-monetary returns".[646] In particular, based on the ABS legislation, applying for a bioprospecting or biotrade permit require that the applicant has previously concluded a benefit-sharing agreement with those providing access to indigenous genetic and biological resources and/or with traditional knowledge holders, as appropriate (and the issuing authority needs to specifically safeguard the interests of these stakeholders). Furthermore, given that the existing distinction between the discovery phase, and the commercialisation phase of a bioprospecting project, if a bioprospecting project is initiated through the discovery phase but later on moves into the commercialisation phase, there is a need to apply for a new permit. The main reason is that while a benefit-sharing agreement is not needed for the former, there is a need to conclude a benefit-sharing agreement in the commercialisation phase (triggering element for benefit-sharing).[647]

b) Does the national legislation exempt benefit-sharing arising from any particular utilisation (research and development), even if the CBD support the sharing of the benefits arising from such activities?	Yes, for the following cases:
	• Research other than bioprospecting if the research is conducted in South Africa and is not for commercial purposes
	• Export of ex-situ indigenous biological resources[648] if the export is for research other than bioprospecting, provided that the exporter has concluded an export agreement and notified the issuing authority accordingly
	• Artificial propagation and cultivation of flora species for the cut flower and ornamental plant markets
	• Aquaculture and mariculture activities for consumption purposes
	• The keeping, breeding, cultivation, moving, trading and use of wildlife not directed at the development and production of
	  o products such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours and extracts; or
	  o new plant varieties and products;

[646] National Environmental Management: Biodiversity Act, 2004, Chapter 1, paragraph 1
[647] ABS initiative, National Study on ABS Implementation in South Africa, 2014
[648] In accordance with Exemption notice No. R. 149, 2008, National Environmental Management: Biodiversity Act 2004, "ex situ indigenous biological resources" means indigenous biological resources that occur in collections outside their natural habitat.

	○ the collection, use, propagation cultivation or trade of indigenous biological resources for domestic use or subsistence purposes.[649]
c) How does the national legislation define the amount to be paid as benefit-sharing? Does it establish a fixed percentage for benefit-sharing?	The legislation does not include details relating to how to calculate the amount to be paid as benefit-sharing, as this is negotiated on a case-by-case basis.
d) Who should pay for the benefits to be shared (the one who carries out access to/utilisation of genetic resources and the associated traditional knowledge, the one who undertakes the economic exploitation, or both)?	Both (see 4.e) below).
e) Where within the production chain rests the obligation to pay benefits? ○ supplier of raw material, ○ intermediary, ○ final product ready for commercialisation, or ○ all	Intermediary and final product development ready for commercialisation in the production chain are obliged to pay benefits. The definitions of bioprospecting and commercialisation covers all areas in the value chain. As previously mentioned, while a benefit-sharing agreement is not needed for the discovery phase of bioprospecting, there is a need to conclude a benefit-sharing agreement in the commercialisation phase (triggering element for benefit-sharing).[650]
f) Is there anyone else that needs to share benefits? For example, non-commercial research, commercial research, intellectual property rights licensing, the whole value chain of an industry or the one with the greater added value?	The whole value chain of industry is required to share benefits with the providers of the resources and/or the knowledge holders associated with the resource.
g) Does the legislation provide an indication of what can constitute (monetary and non-monetary) benefits to be shared?	Yes. The benefit-sharing agreements' templates included in Annexure 12 of the BABS Regulations contain a non-exhaustive list of monetary and non-monetary benefits to be considered. The elements listed in the template relating to indigenous genetic and biological resources differ from those in the list included the template for traditional knowledge associated with indigenous genetic and biological resources. If there is more than one stakeholder a separate agreement must be entered into with each stakeholder. Even though no details are provided regarding when each type of benefits are applicable, Annexure 12 specifies that benefits will vary considerably from case to case, particularly depending on the nature of the project. As such, the list of monetary and non-monetary benefits included is only indicative. Monetary benefits mentioned include fees, royalties, upfront

[649] Exemption notice No. R. 149, 2008, National Environmental Management: Biodiversity Act 2004; and National Environmental Management: Biodiversity Act, 2004, and amendments, Chapter 6
[650] ABS initiative, National Study on ABS Implementation in South Africa, 2014

	payments, milestone payments, etc. Any monetary benefits arising out of a benefit-sharing agreement must be paid to the Bioprospecting Trust Fund.[651] Non-monetary benefits include, among others, community development projects[652], research results and copies of papers, acknowledgement of parties giving access to resources, access to international collections by South Africans, and joint research.[653]
h) Are there any specific provisions on how benefit-sharing should be dealt with respect to traditional knowledge hold by indigenous peoples and local communities?	Yes. Before a permit is issued, the issuing authority must protect any interests of an indigenous community or a specific individual: • whose traditional uses of the indigenous biological resources to which the application relates have initiated or will contribute to or form part of the proposed bioprospecting; or • whose knowledge of or discoveries about the indigenous biological resources to which the application relates are to be used for the proposed bioprospecting. This includes ensuring that the applicant and the relevant indigenous community or a specific individual have concluded a benefit-sharing agreement that provides for sharing any future benefits that may be derived from the relevant bioprospecting. This applies both to access to the indigenous biological resources utilised for bioprospecting; and to access to traditional knowledge whose uses on the indigenous biological resources have initiated or contributed to or form part of the proposed bioprospecting.[654] It is worth noting that all monetary benefits need to be paid to the Biodiversity Trust Fund (see item 4.g) above). In accordance with the draft bill on the protection, promotion, development and management of indigenous knowledge systems, it is the intention that where there are multiple claims to indigenous knowledge, any remuneration payable under a benefit-sharing agreement must be apportioned equally among the trustees. In this respect, where an existing benefit-sharing agreement does not include all the trustees of the relevant indigenous communities, the agreement must be amended accordingly.[655]
i) Does the national legislation consider benefit-sharing arising from the utilisation of traditional knowledge for those cases in which it was accessed from secondary	The legislation stipulates that if for whatever reason the stakeholders cannot be identified for the provision of or access to the indigenous genetic and biological resources to which the

[651] National Environmental Management: Biodiversity Act, 2004, Chapter 6, paragraph 85
[652] South Africa, 2017, Interim National Report on the implementation of the Nagoya Protocol. Available at https://absch.cbd.int/database/NR/ABSCH-NR-ZA-238752
[653] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Annexure 12
[654] South Africa, 2017, Interim National Report on the implementation of the Nagoya Protocol. Available at https://absch.cbd.int/database/NR/ABSCH-NR-ZA-238752
[655] Draft Bill on the Protection, Promotion, Development and Management of Indigenous Knowledge Systems, Chapter 9, Section 30. Available at https://pmg.org.za/bill/635/

sources (publications, registries, databases, inventories, etc.), or when it is not possible to identify the peoples or communities that hold it?	application for any of the permits relates, the Director-General must enter into a benefit-sharing agreement with the applicant.[656] Furthermore, it is worth noting that the draft bill on protection, promotion, development and management of indigenous knowledge systems that is under development addresses the situation where indigenous communities cannot be identified. Based on the current draft, the National Indigenous Knowledge Systems Office (NIKSO) would be responsible for liaising with the Department for Science and Technology to facilitate the entering into of license agreements with users of indigenous knowledge on behalf of an indigenous community where the relevant indigenous community cannot be identified. In the event that, and for as long as, the indigenous community of the relevant indigenous knowledge cannot be identified and designated, NIKSO must act as custodian of that indigenous knowledge, with the rights and obligations of a trustee in respect of that indigenous knowledge.[657]

5. Monitoring and reporting	
a) What are the designated checkpoints? What are their functions and responsibilities? How do they work?	While only the National Department of Environmental Affairs is designated as checkpoint in the ABS Clearing House, the following also serve as checkpoints at the national level although not yet formalised in the ABS Clearing House: • Patent office, • Ports of Entry and Exit, and • Provincial permit issuing authorities.[658] The Patents Amendment Act of 2005 was amended to include a verification point before patents relating to inventions that might be based on or derived from indigenous biological resource, genetic resource, or traditional knowledge or use are granted. In this respect, the Patent Office and the national competent authority work together in order to ensure that patents or other intellectual property rights connected or referring to the indigenous genetic and biological resources can only be claimed if there is compliance with the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) and the Bioprospecting, Access and

[656] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, regulation 39(2)
[657] Draft Bill on the Protection, Promotion, Development and Management of Indigenous Knowledge Systems, Chapter 4. Available at https://pmg.org.za/bill/635/
[658] South Africa, 2017, Interim National Report on the implementation of the Nagoya Protocol

	Benefit-Sharing Amendments Regulations of 2015 and if there is prior expression and written permission from the issuing authority to apply for such patent. At the Ports of Entry and Exit, the Compliance and Enforcement Officers check and verify if ABS products developed utilising indigenous genetic and biological resources exported complied with NEMBA and BABS Regulations. Provincial permit issuing authorities are responsible to issue permits for collection of indigenous biological resources in the province where they collected or gathered. They also issue export permit for research other than bioprospecting.
b) What are the reporting requirements? Who is responsible for reporting?	Given the conditions under which notifications are done and permits issued, the applicant or permit holder have to comply with certain reporting requirements, as specified below: 1. For *notifications*, the applicant must submit an annual status report on the discovery phase of the bioprospecting 2. For a *discovery phase export permit*, the permit holder must submit an annual status report on the discovery phase of the bioprospecting to the issuing authority 3. For a *biotrade permit*, a *bioprospecting permit or an integrated biotrade and bioprospecting permit*, the permit holders must: • notify the Department of Environmental Affairs when money due to stakeholders as specified in the benefit-sharing agreement will be transferred or paid into the Bioprospecting Trust Fund • notify the stakeholder or stakeholders entitled to a monetary benefit in terms of the benefit-sharing agreement that money was transferred or paid into the Bioprospecting Trust Fund • submit an annual status report to the issuing authority 4. For an *export permit for research other than bioprospecting*, the permit holder must submit an annual status report to the issuing authority in a format determined by the issuing authority. For all cases, the format of the report is to be determined by the issuing authority. Moreover, while annually would be the default frequency for the submission of the status reports, an alternative timeframe could be determined by the issuing authority.
c) How can access to/ utilisation of genetic resources and the associated traditional knowledge be tracked? Has the country developed any particular method/mechanism to	Importantly, in accordance with information provided in the first interim national report to the Nagoya Protocol, the ABS legislation is currently being revised, among others, to respond to the

monitor the access and utilisation of genetic resources and/or associated traditional knowledge?	provisions relating to monitoring the utilisation of genetic resources included in Article 17 of the Nagoya Protocol.[659]
d) Does the country have any monitoring systems for patent databases, registries of products resulting from access, and scientific publications so to identify activities that are not in compliance with the domestic legislation of the country where the access took place and with the Nagoya Protocol?	South Africa has no monitoring system in place. The legislation is currently being revised to also address such issues. The Patent Office does not conduct search and examination but is merely a depository system. Only when there is a dispute the relevant patent application is assessed.

6. Compliance	
a) What are the competent authorities in charge of enforcement of the ABS legislation? Is compliance implemented in a centralised way (a single responsible body) or is it decentralised (several bodies with different competences)? What measures have been adopted to integrate/coordinate the actions of the bodies responsible for enforcing ABS rules at the national level? How to promote the integration/coordination of the various bodies responsible for enforcing ABS rules?	The Department of Environmental Affairs is the only national competent authority designated for the Nagoya Protocol. However, due to the governance structure in South Africa, some of the responsibilities are shared with the provinces. The Minister of Environment is responsible for enforcing compliance with the conditions of issued permits, and it is the issuing authority for discovery phase export permits; biotrade permits; bioprospecting permits; or integrated biotrade and bioprospecting permits. Moreover, the Member of the Executive Council is the issuing authority for export permit for research other than bioprospecting. [660] In particular, the BABS Regulations also stipulate that the export permit for research other than bioprospecting must be submitted to the relevant provincial department responsible for environmental affairs, if the indigenous genetic and biological resources to be exported are collected or gathered in that province. [661] The two authorities work together in terms of conducting all NEMBA enforcement issues including ABS.
b) What measures have already been adopted to promote the effective monitoring of legal compliance?	The NEMBA stipulates the penalties that are applicable to a person not complying with the ABS requirements. In particular, a person that contravened the existing requirements, could be liable to a fine or to imprisonment, or to both. Furthermore, if a person is convicted for having commenced the commercialisation phase of bioprospecting without a permit issued, a fine would be applicable (one of the ways to estimate the amount of such a fine, would be for this to

[659] South Africa, 2017, Interim National Report on the implementation of the Nagoya Protocol
[660] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 2
[661] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Chapter 2

	be equal to three times the commercial value of the specimen or activity in respect of which the offence was committed, whichever is the greater).[662] In accordance with the information described in the first interim national report, when an applicant applies for a permit to utilise within South Africa genetic resources that were accessed from a third country, the issuing authority requests for the necessary documentation to confirm compliance with the ABS requirements of the provider country. In addition, the South African focal point notifies its peer of the provider country, and in case the applicant does not provide proof of compliance with the regulatory requirements of the provider country, the National Focal point alerts the National Focal Point of the provider country about the resources that are being imported into South Africa for them to take the necessary action. Likewise, when indigenous genetic and biological resources are exported to other countries, the user needs to present the permit as evidence of compliance both before leaving the country (port of exit), and in the country where the utilisation will take place (port of entry).[663]
c) Are there any measures foreseen in the national legislation to ensure benefit-sharing when access and utilisation of genetic resources and associated traditional knowledge occur outside the jurisdiction of the country where the access took place, especially when it is in a country that is not a Party to the Nagoya Protocol or when the user is based in a country that is not a Party?	No references on this matter are included in the ABS framework. The amendments will consider these issues.

7. Intellectual property rights (focusing on patents)[664]	
a) How does the country deal with patentability of living organisms found in nature and of its components, such as DNA, molecules and metabolites?	Patents are regulated by the Patents Act, 1978 (Act 57 of 1978) and its subsequent amendments. South Africa does not grant patents to plants and animals which have not been genetically modified; essentially biological process for the production of an animal or a plant, unless it is a

[662] National Environmental Management: Biodiversity Act, 2004, Chapter 9, Section 102

[663] South Africa, 2017, Interim National Report on the Implementation of the Nagoya Protocol

[664] Given that this study focuses on patents, no references are included in relation to other categories of intellectual property. However, the South African legislation regulates these other areas, such as copyrights in traditional works (see Act No. 28 of 2013: Intellectual Property Laws Amendment Act, 2013, that aims *to provide for the recognition and protection of certain manifestations of indigenous knowledge as a species of intellectual property; to this end to amend certain laws so as to provide for the protection of relevant manifestations of indigenous knowledge as a species of intellectual property*).

	microbiological process or the product of such a process; the metabolism of organisms or discoveries, i.e. natural phenomena that had to have existed previously in order to be discovered. Protection for plant varieties is however possible through the grant of plant breeders' rights. In the field of biotechnology, the following is patentable subject matter: • Non-living entities: DNA, recombinant DNA genes, promoters, plasmids, vectors, polypeptides, antibodies that are present in organisms • Living entities: Genetically modified organisms and plant and animal cultures. For this purpose, the researcher or applicant needs to be in possession of the isolated/purified entity prior to seeking patent protection.[665]
b) Do patent applications include disclosure of origin among the requirements that need to be filled in by the applicant? Is it a mandatory or optional element? Is it only related to genetic resources or also to the associated traditional knowledge?	Yes. Such legal requirement was introduced in the South African patents system through the 2005 amendments that entered into force in 2007. In accordance with the Patents Amendment Act No. 20 of 2005, every patent applicant must indicate whether or not the invention for which protection is claimed is *based on or derived from* an indigenous biological resource, genetic resource, or traditional knowledge or use[666] (emphasis added). This has to be done through Form P.26 that requests the applicant to specify whether the claimed invention is or is not: • based on or derived from an indigenous biological resource or a genetic resource • based on or derived from traditional knowledge or use • co-owned with the local community or individual.[667] Form P.26 does not have to be completed for provisional applications. Furthermore, in accordance with the template material transfer agreement provided in Annexure 11 of the BABS Regulations, a permit applicant "shall only claim patents or other intellectual property rights connected or referring to the indigenous genetic and biological resources [for new methods of utilising the indigenous genetic and biological resources, or new process for preparing, producing or manufacturing the indigenous genetic and biological resources], if there is compliance with the National Environmental Management: Biodiversity Act, 2004 (Act No. 10

[665] http://ship.mrc.ac.za/sectioncpatents.htm
[666] Amendment of Section 30 of Act 57 of 1978, Section 30(A)
[667] http://www.cipc.gov.za/files/8313/9443/4866/p26.pdf

	of 2004) and the Bioprospecting, Access and Benefit-Sharing Amendments Regulations of 2015", and if there permission was previously requested to the issuing authority.[668]
c) New developments in South African intellectual property system – links to ABS	South Africa has developed a *sui generis* system for the protection of indigenous knowledge. In December 2013, the Intellectual Property Laws Amendment Act was adopted with the objective of protecting indigenous knowledge and to enable traditional communities to exploit it commercially for their own gain. To this end, the Act creates rights of property in indigenous knowledge, as a species of intellectual property. More recently, the Draft Intellectual Property Policy of the Republic of South Africa – Phase I developed in the context of the Inter-Ministerial Committee on Intellectual Property was open for public consultation in August 2017. Among others, its goals include: to consider the development dynamics of South Africa and improve how intellectual property supports small institutions and vulnerable individuals in society, including in the domain of public health; and to solidify South Africa's various international obligations, such as the Convention on Biological Diversity and the Nagoya Protocol on ABS, in the service of South African genetic resources and traditional knowledge associated with genetic resources. For that purpose, some of the key proposed reforms include: • *A coordinated approach to creating awareness about intellectual property among South Africans, so as to protect nationally-owned intellectual property that is related to indigenous resources, traditional innovation and traditional knowledge* • *The creation of a system for protection for traditional knowledge which will safeguard misappropriation and exploitation, as well as promote further research and development into products and services based on traditional knowledge*. Phase I of these reforms will focus on intellectual property and public health, and on international IP cooperation at the multilateral, regional and bilateral levels, including in relation to the Nagoya Protocol. In turn, it is expected that Phase II will focus, among others, on intellectual property in agriculture; intellectual property and biotechnology, genetic resources, and genomic sovereignty, in particular in relation to: • How to reconcile provisions mandated by TRIPS and the CBD, especially as it pertains to "access and benefit-sharing" clauses that seek to give control of a region's natural heritage to residents of that region;

[668] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Annexure 11

	• Supporting efforts at developing indigenous and international biotechnology, without endangering access to agricultural products and/or limiting plant variety diversity; • Ensuring farmers' rights, as well as implementing constitutional obligations to protect genomic sovereignty within the state.[669]

8. Supporting instruments for the implementation of ABS legislation	
a) Does the legislation consider the development of community protocols related to access to traditional knowledge associated with genetic resources? If so, has the country developed them so far?	Community protocols are not mentioned in the ABS legislation.
b) Has the country developed any guidelines, codes of conduct, best practices or standards related to the implementation of their ABS legislation? If so, which ones?	As informed through the first interim national report, the revision of legislation that is underway would include encouraging the development and use of sector specific best practices.[670] Moreover, the Department of Science and Technology has developed research ethic guidelines for parties accessing associated traditional knowledge.
c) Does the legislation include any model contractual clauses/standard agreement to be used for exchange of materials and establishment of MAT? Please specify	Yes. The BABS Regulations include templates for the development of benefit-sharing agreements[671] and material transfer agreements[672]. These minimum guidelines are mandatory however parties can develop a more comprehensive agreement. In addition, if the stakeholder that is party to the material transfer agreement is a community, a community resolution authorizing a representative to enter into a material transfer agreement needs to be signed. The BABS Regulations also provide a prescribed format for this type of document.[673] As informed through the first interim national report, the revision of legislation that is underway would include updating the model contractual clauses for the establishment of mutually agreed terms.[674]
d) Recent developments relating to indigenous knowledge protection in South Africa	In addition to the provisions relating to indigenous knowledge associated to genetic and biological resources in the ABS legislation, South Africa has developed a policy framework

[669] Draft Intellectual Property Policy of the Republic of South Africa – Phase I, 2017
[670] South Africa, 2017, Interim National Report on the implementation of the Nagoya Protocol
[671] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Annexure 12
[672] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Annexure 11
[673] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, Annexure 13
[674] South Africa, 2017, Interim National Report on the implementation of the Nagoya Protocol

	dealing with indigenous knowledge more broadly. A brief summary relating to the key measures relating to ABS is presented in this section. In 2004, the Indigenous knowledge systems policy was adopted with the ultimate aim of further developing legal, policy and administrative measures that would protect the rights of indigenous knowledge holders by avoiding the misappropriation of such knowledge. One of the tools mentioned for this purpose was the establishment of a national system to record the knowledge assets of knowledge holders (developed in 2010). Later on, a more detailed policy framework dealing with the protection of indigenous knowledge through the intellectual property system was adopted in 2008. In accordance with this instrument, *if an invention took place because of using knowledge of local peoples, then the following must occur: disclosure of the origin of indigenous genetic/biological resources; disclosure of traditional knowledge; prior informed consent of the indigenous peoples; benefit-sharing agreements; and, where applicable, co-ownership of the patents*.[675] All these elements are currently part of the ABS and patent systems. Additionally, South Africa is currently establishing a *sui generis* system for the protection, promotion, development and management of indigenous knowledge systems. The draft bill passed from the National Assembly in November 2017 to the National Council of Provinces.[676] Subsequently, the last step prior for its approval would be submitting it for Presidential signature. Based on its current draft, among others, the key aims of the bill in relation to ABS would be to: • protect the indigenous knowledge of indigenous communities from unauthorised use, misappropriation and misuse • develop and enhance the potential of indigenous communities to protect their indigenous knowledge • regulate the equitable distribution of benefits • promote the commercial use of indigenous knowledge in the development of new products, services and processes • provide for registration, cataloguing, documentation and recording of indigenous knowledge held by indigenous communities • recognise indigenous knowledge as prior art under intellectual property laws.

[675] The Protection of Indigenous Knowledge through the Intellectual Property System – A policy framework
[676] As of 12 August 2018. See https://pmg.org.za/bill/635/

	The draft bill includes its own set of definitions, some of which are: • "access" includes the acquisition of indigenous knowledge by natural and legal persons as facilitated by NIKSO in terms of this Act • "benefit-sharing" means the fair and equitable sharing of monetary and non-monetary benefits in terms of a benefit-sharing agreement between the trustee of the indigenous community and the licence holder • "commercial use" means the use of indigenous knowledge for financial gain • "indigenous community" means any recognisable community of people: (a) developing from, or historically settled in a geographic area or areas located within the borders of the Republic; (b) characterised by social, cultural and economic conditions, which distinguish them from other sections of the national community; and (c) who identify themselves as a distinct collective • "indigenous knowledge" means knowledge which has been developed within an indigenous community and has been assimilated into the cultural and social identity of that community, and includes: (a) knowledge of a functional nature; (b) knowledge of natural resources[677]; and (c) indigenous cultural expressions. The National Indigenous Knowledge Systems Office would be established, with the following (non-exhaustive) key functions: • protecting and recognising indigenous knowledge as property owned by indigenous communities • facilitating the redress of rights and benefits to indigenous communities which have previously been deprived of such rights and benefits • empowering indigenous communities through education and awareness campaigns to enable them to recognise and utilise indigenous knowledge for cultural and economic benefit • determining the criteria for issuing licenses for the use of indigenous knowledge • certifying licence agreements for the use of indigenous knowledge • assisting indigenous communities in the negotiation of benefit-sharing agreements for the use of indigenous knowledge

[677] "Natural resources" means any materials and components that can be found within the environment and may exist as a separate entity, such as genetic resources, fresh water, air, and mineral deposits with actual or potential use or value.

	• facilitating the negotiation of licenses between trustees and users for the use of indigenous knowledge for commercial purposes • liaising with the Department for Science and Technology to facilitate the entering into of license agreements with users of indigenous knowledge on behalf of an indigenous community where the relevant indigenous community cannot be identified.[678]

9. Key challenges of implementation	
Identified challenge	Brief explanation
Insufficient human resource capacity	Although the Department of Environmental Affairs works in collaboration with provincial authorities in terms of implementation of the provisions of Access and Benefit-Sharing, there is currently insufficient human capacity to implement the ABS provision.
The different industries are interested in complying with the law but there are those users in the industries that still have resistance in terms of concluding benefit-sharing agreements with traditional knowledge holders.	The Department of Environmental Affairs has gazetted an Amnesty for public comment for industry not complying with BABS regulations.
Some of the challenges that south Africa faces in terms of traditional knowledge include: recording and documenting holder's knowledge before the Act comes in force; and how to deal with traditional knowledge associated with a non-indigenous resource	
Lack of mechanisms to monitor utilisation once the indigenous biological resources have been exported for bioprospecting and biotrade	Despite South Africa having several checkpoints, there are insufficient human resources capacity to monitor utilisation abroad.
Difficulties in identifying the indigenous communities or individuals holders of the accessed traditional knowledge	It is not unusual that more than one indigenous community holds traditional knowledge about an indigenous biological resource. These communities can be situated in different regions of the country, therefore making it difficult to seek consent from all of them.[679]
Some difficulties negotiating benefit-sharing agreements, particularly when done by indigenous communities	The Department of Environmental Affairs provides support to strengthen the negotiating skills from indigenous communities but more capacity development is required.

[678] Draft Bill on the Protection, Promotion, Development and Management of Indigenous Knowledge Systems, available at https://pmg.org.za/bill/635/
[679] Adapted from https://www.environment.gov.za/sites/default/files/legislations/bioprospecting_regulatory_framework_guideline.pdf

5 The access and benefit-sharing frameworks in a nutshell: Key features and challenges in implementation

Building upon the information presented in section 4, this final section of the report provides an overview of some key elements identified in the case studies, including a simple comparative analysis. The last part of the section includes a brief summary of key next steps and prospects for the future based on the work underway in the different case studies.

Importantly, this section is not intended to be an exhaustive analysis but instead it only aims to show the variety of approaches and mechanisms being developed and implemented at the national or regional levels in the field of access to genetic resources and benefit-sharing.

5.1 General features of the access and benefit-sharing regimes

Some of the access and benefit-sharing frameworks illustrated in this report have been developed as a result of the adoption and entry into force of the Nagoya Protocol (e.g. EU and Japan). However, most of them have been developed well in advance of the existence of the Protocol, but often adapted following its entry into force. It is worth mentioning that, with the exception of the EU and Japan, all the other countries studied in this report are megadiverse countries.

The entry into force of the Nagoya Protocol triggered the development or adjustment of national access and benefit-sharing frameworks across the globe. The majority of case study countries are Parties to the Nagoya Protocol. Others, despite not being Parties (yet), have comprehensive regimes in place. The table below presents a summary of the membership status to the Nagoya Protocol of the case study countries.

	Party to the Nagoya Protocol?	Party since?
Brazil	No	N/A
Colombia	No	N/A
Ecuador	✓	2017
European Union	✓	2014
India	✓	2014
Japan	✓	2017
Peru	✓	2014
South Africa	✓	2014

The Convention on Biological Diversity and the Nagoya Protocol request Parties to take legislative, administrative or policy measures with the aim of sharing benefits in a fair and equitable way. The analysed cases show a variety of **instruments and approaches to regulate access and benefit-sharing**. Some of the regimes mostly rely on legal measures (e.g.

Brazil, Ecuador, the European Union) while others present a series of intertwined legal and policy measures that should be read in conjunction (e.g. South Africa). At the same time, others to date depend on purely administrative measures to respond to the key obligations resulting from the Nagoya Protocol (e.g. Japan). The European Union has also developed legislation to regulate access and benefit-sharing. The EU ABS Regulation (Regulation (EU) 511/2014), is the overarching framework developed to respond to the obligations arising from the Nagoya Protocol and is complemented by an Implementing Regulation. Both are directly applicable in all Member States of the EU, regardless of the status of the Nagoya Protocol's ratification in different Member States.[680]

In addition to the types of instruments used, there are multiple aspects that can be analysed to better understand the configuration of access and benefit-sharing frameworks. Only some of these have been covered in this study. As outlined in section 2, the focus is on provisions that relate to access, benefit-sharing, monitoring and compliance. Further, there is also some emphasis on general aspects, such as terms and definitions used; legal status of genetic resources at the national level; and levels at which ABS is regulated as this helps understand the broader context in which the instruments are developed and implemented. Key findings include:

- The terminology and definitions used vary, thus entailing difference on the scope of the measures in place. For example, some of the regulatory instruments refer to genetic resources, others refer to biological resources (or indigenous biological resources) and others to genetic heritage. Likewise, while in general associated traditional knowledge is the expression used when referring to the traditional knowledge related to those resources, South Africa's legislation refers to indigenous knowledge. As members of the Andean Community, Colombia, Ecuador and Peru refer to *intangible component* associated to genetic resources, as this term is the one used in the regional framework.
- Even for those terms that are used across regimes, the definitions are in general different, with those from the Nagoya Protocol being explicitly included in domestic regimes only in some cases. In general, each of the analysed cases adopt the definitions that are more suitable for the specific context in which they operate. It is worth noting that in some cases the list of concepts being defined is quite extensive (e.g. Brazil) while in others only a few key terms are defined (e.g. EU). Furthermore, even though in some cases not the same terms are defined, related terms have been identified (for instance, Brazil does not define the term utilisation but instead, research and technological development).
- When looking at the level of governance at which ABS is regulated, this obviously again differs as this directly depends on the governance structure of each country/region. In most cases, regulation on access and benefit-sharing takes place at the national level. In these cases, national governments are responsible for the management and control of activities relating to access to genetic resources and associated traditional knowledge (e.g. Brazil, Colombia, Ecuador, India, Japan, Peru). In some cases, however, competencies are shared with subnational bodies:
    - For instance, in India as a federal country, access and benefit-sharing is regulated at the national level but with some competencies

[680] 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

shared with the provincial (States) and local authorities.
    - In the case of the EU, measures were established at the Union level, since it was found that the objective of the legislation cannot be sufficiently achieved only by Member States at the domestic level.[681]
- The legal status of genetic resources also relates to the governance structures in each country. As a result, the approach towards **ownership of genetic resources** also differs among the studied cases. In some cases, the legislation does not include references to ownership of genetic or biological resources. In others, the legislation is very detailed, providing for example a substantial description of the aspects covered, how ownership is held and the identification of a trustee. The table below provides an overview of the legal approaches in the cases study countries.

	To whom do genetic resources belong?
Brazil	Genetic heritage is considered a collective good, of use by the Brazilian people
Colombia	Genetic resources belong to the State
Ecuador	Biodiversity and genetic heritage belong to the State
European Union	Not regulated at EU level
India	Not stipulated in legislation
Japan	Not stipulated in legislation
Peru	Renewable and non-renewable natural resources are part of the Nation's heritage. Rights granted over biological resources do not entail that rights are granted over the genetic resources contained within those.
South Africa	The State is the trustee (guardian) of biodiversity. However, legislation does not vest ownership in the State

5.2 Access to genetic resources and associated traditional knowledge

When gathering information in terms of how access to genetic resources and/or associated traditional knowledge is addressed in the different regimes, a series of key elements have been considered. In particular:

- Consideration of prior informed consent and establishment of mutually agreed terms
- If and how indigenous peoples and local communities are involved in the process of granting access to genetic resources and associated traditional knowledge
- How simplified measures for access and changes of intent in utilisation are considered.

There is a variety of ways in which the different regimes address these issues.

The main difference is that while most of the reviewed frameworks have access measures in place, others have been developed around user compliance measures (EU and Japan). In this context it should be noted that even though there are currently no access measures in Japan, this is subject to re-consideration once the implementation of the access and benefit-sharing guidelines advances and there is sufficient experience.

Another distinctive feature is that some of the frameworks estipulate different procedures for nationals than those applicable to foreign users (e.g. India).

Below are some of the key features identified through the review, together with selected examples.

Prior informed consent is a requirement before accessing genetic resources in some of the reviewed cases. In others, access measures rely on the government authorising such access but with no need of presenting evidence of prior informed consent. Also worth noting is,

[681] Regulation (EU) No 511/2014, Preamble (35)

that in some countries access procedures are different depending on whether access is requested for genetic heritage or for associated traditional knowledge:

- In Brazil, for example, the legislation does not provide for procedures relating to obtaining prior informed consent for access to genetic heritage. Instead, access to genetic heritage is subject to registration in the national system for the management of genetic heritage and associated traditional knowledge (SisGen). However, access to traditional knowledge associated with genetic heritage is subject to prior informed consent, but only when it refers to traditional knowledge of *identifiable origin*.
- In South Africa, the prior informed consent from the owners of indigenous biological resources and/or associated traditional knowledge is required prior to accessing those resources for bioprospecting, for research other than bioprospecting, and for biotrade activities conducted in or outside the country with South African genetic and biological resources.
- In India, legislation does not refer explicitly to the term prior informed consent but, in accordance with their first interim national report to the Nagoya Protocol, access to biological resources in India *operates on* the principle of prior informed consent.[682]
- Colombia, Ecuador and Peru also require prior informed consent for access to genetic resources and/or associated traditional knowledge.

The establishment of mutually agreed terms is required in all of the case study countries which have access measures in place. There are however slight differences in terms of the terminology and mechanisms used. To illustrate, in Brazil and South Africa, benefit-sharing agreements are the equivalent of mutually agreed terms.[683] In Colombia, Ecuador and Peru, the terms are expressed in access contracts, which is the category that comes from the regime of the Andean Community.

The scope of the simplified measures on access vary widely among the reviewed regimes. Some of the countries have more generic provisions relating to simplified measures being applicable for non-commercial research (e.g. South Africa), while others describe specific fields in which simplified measures for basic research apply. For example:

- In Brazil, simplified measures are applicable in relation to health. Japan also has specific conditions for human health emergencies.
- In Colombia and Ecuador some activities are not regarded as access to genetic resources and their derivatives and, as a result, contract of access is not required. This exemption applies to basic research activities relating to molecular systematics, molecular ecology and/or biogeography.
- In Peru, the only possible mechanism for simplified access are framework access contracts for non-commercial purposes. In turn, SERFOR (body responsible for forestry and wildlife) also implements measures aimed at strengthening the applicable procedures for research activities involving access to wildlife genetic resources and their by-products, thus in areas of its competence (in particular, through exempting access contracts for basic non-commercial research).[684]
- Lastly, in India there is no requirement for seeking permission for carrying out research, if it is carried out in India by Indian nationals.

[682] India, 2017, Interim National Report on the Implementation of the Nagoya Protocol, available at https://s3.amazonaws.com/absch.documents.abs/records/absch-nr-in-238716-2-en.pdf

[683] Biological Diversity Rules 2004, Rule 14(5)

[684] For more information see https://www.serfor.gob.pe/bosques-productivos/servicios-de-investigacion

5.3 Benefit-sharing mechanisms

The present study looked into some detail to help gain a better understanding of how governments deal with benefit-sharing provisions in their regulatory frameworks. The goal of benefit-sharing is that users of genetic resources effectively share benefits derived from access and utilisation of those resources with the country providing those resources. Regarding traditional knowledge associated to genetic resources, benefits are to be shared with the communities that are knowledge holders.[685] The approaches and mechanisms aimed at ensuring benefit-sharing materialises vary widely. Given the scope of this report, the review aimed to:

- Better understand the triggers of benefit-sharing, e.g. whether any utilisation of genetic resources creates a benefit-sharing obligation
- Gain understanding on how the amount for benefit-sharing is calculated, including on identifying if fixed percentages are stipulated in the legislation; and regarding who should pay for the benefits to be shared
- Identify the types of utilisation that are exempt from benefit-sharing, if any
- Assess how benefit-sharing arising from the utilisation of traditional knowledge is dealt with when accessed from secondary sources (publications, registries, databases, inventories, etc.), or when it is not possible to identify the communities that hold it

Below, there is a summary of the key characteristics identified in the studied access and benefit-sharing regimes.

As mentioned, both the Japanese and the EU frameworks are aimed at encouraging users' compliance. Accordingly, neither of them include specific provisions to regulate benefit-sharing. However, both support the effective implementation of benefit-sharing commitments set out in mutually agreed terms between providers and users. The other studied regimes have established mechanisms to implement the benefit-sharing obligation for benefits derived from the utilisation of genetic resources and/or associated traditional knowledge.

Some key differences can be identified when comparing how these frameworks address the implementation of benefit-sharing. While some of the legislation provides a thorough description of the applicable benefit-sharing mechanism (e.g. Brazil, India), this is not spelled out in detail in others and the analysis is made by the national authorities on a case-by-case basis (e.g. Colombia, Peru). In the following, the **triggering event of the benefit-sharing obligation** is outlined for Brazil, India and South Africa:

- In Brazil, the triggering event for the benefit-sharing obligation is the economic exploitation of a finished product. For agricultural activities, the benefit-sharing obligation lies at the final point in the production chain of reproductive materials. In particular, benefits that result from the economic exploitation of finished products or reproductive material derived from access to genetic heritage of species found in *in situ* conditions or associated traditional knowledge, are to be shared. Importantly, this is also the case when products are produced outside of Brazil. The condition for triggering benefit-sharing obligations for a finished product is that the genetic heritage or associated traditional knowledge must be one of the key elements of adding value to the product.
- In India, the benefit-sharing obligation is invoked if biological resources occurring in India or associated knowledge are intended to be used for research; commercial utilisation; bio-survey and bio-utilisation; transfer of results of any research; apply for a patent or any other form of intellectual

[685] South Centre. (2015). The Nagoya Protocol: Main Characteristics, Challenges and Opportunities, (18). Retrieved from https://www.southcentre.int/wp-content/uploads/2015/06/PB18_Nagoya-Protocol-Main-Characteristics-Challenges-and-Opportunities_EN.pdf

property protection either in or outside India; or transfer any biological resource or associated knowledge for which approval has already been granted by the national authority.

- In South Africa, the triggering element for benefit-sharing is the commercialisation phase. If a bioprospecting project is initiated in South Africa through the discovery phase but later on moves into the commercialisation phase, there is a need to apply for a new permit. The main reason is that while a benefit-sharing agreement is not needed for the former, there is a need to conclude a benefit-sharing agreement in the commercialisation phase.[686]

Another aspect looked into refers to the measures in place for situations in which an amount is to be paid as benefit-sharing. From the reviewed frameworks, Brazil has the more detailed provisions relating to this aspect. Others provide no details with the definition being left to the discretion of the national authority, and negotiated with the applicants on a case-by-case basis. More detailed benefit-sharing mechanisms are currently being developed in some of the countries (e.g. Colombia, Ecuador).

As mentioned, the Brazilian ABS legislation is quite detailed in terms of how to calculate the amount to be shared as part of the benefit-sharing obligations, including on the different situations in which benefit-sharing is involved. When a finished product or reproductive material is the result of different accessions, these will not be considered cumulatively for the calculation of benefit-sharing.[687] The sharing of benefits resulting from finished products or reproductive material arising from access to associated traditional knowledge exempts the user from sharing benefits related to genetic heritage.[688] Concerning the calculation of the benefit-sharing amount for situations where the finished product or reproductive material have been produced outside Brazil, the Ministry of Environment can request supportive information from the manufacturer of the finished product or producer of the reproductive material or from other representative of the foreign producer situated in the Brazilian territory (such as importer, subsidiary companies, commercial representatives).[689]

In South Africa, the legislation does not include details relating to how to calculate the amount to be paid as benefit-sharing, as this is negotiated on a case-by-case basis. Likewise, in Colombia, Ecuador and Peru no details are provided in terms of the amount particularly when referring to the utilisation of generic resources or their derivatives. However, some of these systems are more detailed in relation to associated traditional knowledge. In Peru, for example, at least 10% of the gross sales (before taxes) resulting from the commercialization of the products developed as a result of this collective knowledge must be paid to the Fund for the Development of Indigenous Peoples (Fondo para el Desarrollo de los Pueblos Indígenas). In Ecuador, determination of the benefit-sharing amount requires that the competent authority develops a technical report with the information presented by the applicant for consideration of the authority. Some of the aspects considered in defining the specific amount include commercial potential of the research, budget and stakeholders supporting it.

There are also different approaches in terms of who is responsible for paying the agreed benefit-sharing amount, as summarized in the following table.

[686] ABS initiative, National Study on ABS Implementation in South Africa, 2014

[687] Law 13.123, Article 17, paragraph 3

[688] Law 13.123, Article 25, paragraph 3

[689] Decree 8772, Article 46

	Who is responsible for paying the agreed amount? At what stage of the value chain?
Brazil	The manufacturer of the finished product or the producer of the reproductive material are exclusively subject to benefit-sharing regardless of who would have previously accessed the resources
Colombia	Anyone carrying out access activities with native species (wild, domesticated, cultivated or escaped from domestication), including viruses, viroid or similar that can be found within or outside the national territory for bioprospecting, commercial or industrial purposes should pay benefits. Regarding who is responsible for paying benefits, it is decided on a case-by-case basis based on each access application. The responsibility relies on the first person carrying out access activities
Ecuador	No specific details are provided in the legislation in relation to benefit-sharing. However, some general aspects of how benefit-sharing has to be applied in relation to traditional knowledge associated with genetic resources are mentioned
European Union	Not covered by the EU measures
India	In the production chain, the obligation to pay benefits lies with the supplier of raw materials, intermediary, as well as final product ready for commercialisation
Japan	Not covered by the Japanese measures
Peru	In Peru, this is decided on a case-by-case basis. For some activities, the obligation is shared throughout the entire production chain while for others it is restricted for a specific stage
South Africa	Intermediary and final product development ready for commercialisation in the production chain are the stages at which there is an obligation to pay benefits

In addition to the amount, in some of the frameworks there are also provisions relating to when a certain **modality of benefit-sharing**, i.e. monetary or non-monetary, would be applicable. Sometimes the amounts to be considered vary depending on the chosen modality (e.g. Brazil). In general, in situations in which traditional knowledge holders cannot be identified, the benefits to be shared can only take the form of monetary benefits to be paid into a fund (e.g. Brazil, India). The received funds will then be used for projects aimed at promoting the conservation of biological diversity and/or traditional knowledge.

The issue of benefit-sharing arising from the **utilisation of traditional knowledge when accessed from secondary sources** (publications, registries, databases, inventories, etc.) is not extensively covered by the reviewed regimes. However, Brazil[690], Ecuador[691] and Peru[692] have provisions covering this aspect. For example, in Peru, the relevant amount derived from the commercialization of the products developed as a result of the utilisation of collective knowledge that is in the public domain is to be paid to the Fund for the Development of Indigenous Peoples.

Also, some of the reviewed regimes regulate benefit-sharing for **situations when it is not possible to identify the peoples or communities that hold the utilised traditional knowledge**. In Ecuador, the State can delegate the rights of the unidentified holders under certain circumstances (see sub section 4.4). Thereby, the government needs to be advised by the consultative committee of traditional knowledge.[693]

The South African framework stipulates that if for whatever reason the stakeholders cannot be identified, the Director-General of the Department of Environmental Affairs must enter into a benefit-sharing agreement with the

[690] Law 13.123, Article 2, point IX

[691] Organic Code of the Social Economy of Knowledge, Creativity and Innovation, Article 526

[692] Law 27811, Article 13

[693] Executive Decree No. 1435 de 2017, Article 52

applicant.[694] Furthermore, it is worth noting that the draft bill on protection, promotion, development and management of indigenous knowledge systems that is currently under development will address the situation where indigenous communities cannot be identified.[695]

Peru and South Africa have developed comprehensive systems for the protection of traditional knowledge, which specifically deal with access and benefit-sharing measures. In the case of South Africa, the development of some of the instruments is advanced but still underway.

Most of the reviewed frameworks include specific **situations that are exempted from the benefit-sharing obligation**, with the exception of Ecuador and Peru. At the same time, it is important to note that most of the regimes consider situations which do not fall under the scope of access measures, and these are of course also not subject to benefit-sharing. However, this subsection focuses on exemptions only in the area of benefit-sharing.

One of the most common exemptions refers to non-commercial research. In India, for example, non-commercial research or research for emergency purposes outside India by Indian researchers or Indian government institutions fall outside of their benefit-sharing mechanism. In South Africa, research other than bioprospecting, if the research is conducted in South Africa and is not for commercial purposes, is also exempt. Likewise, export of ex-situ indigenous biological resources[696] is also exempt if the export is for research other than bioprospecting.

The Brazilian ABS framework includes a number of situations or actors that are exempted from the benefit-sharing obligation. Some of these include:

- Manufacturers of intermediate products and developers of processes from access to genetic heritage and associated traditional knowledge along the production chain[697]
- Economic exploitation of finished products or reproductive material arising from access to genetic heritage of species introduced to the national territory by human action, even if domesticated. This exemption does not apply to those species that developed spontaneous populations with distinctive properties acquired in the country; and to local traditional variety or landrace, or locally adapted breed or creole breed.[698] It is worth noting that the latter differs from the approach used by Colombia.

In Brazil, there is another important exemption, as sharing benefits that result from access to associated traditional knowledge exempts the user from sharing benefits related to genetic heritage.[699]

South Africa in addition considers some specific situations such as artificial propagation and cultivation of flora species for the cut flower and ornamental plant markets; aquaculture and mariculture activities for consumption purposes and the keeping, breeding, cultivation, moving, trading and use of wildlife not directed at the development and production of products such as drugs, industrial enzymes, food flavours. fragrance, cosmetics, emulsifiers, oleoresins, colours and extracts, new plant varieties and products and the collection, use, propagation cultivation or trade of indigenous biological resources for domestic use or subsistence purposes.[700]

[694] Regulations on Bio-Prospecting, Access and Benefit-Sharing, 2015, regulation 39(2)

[695] Draft Bill on the Protection, Promotion, Development and Management of Indigenous Knowledge Systems, Chapter 4. Available at https://pmg.org.za/bill/635/

[696] In accordance with Exemption notice No. R. 149, 2008, National Environmental Management: Biodiversity Act 2004, "ex situ indigenous biological resources" means indigenous biological resources that occur in collections outside their natural habitat.

[697] Law 13.123, Article 17, paragraph 2

[698] Law 13.123, Article 18, paragraph 3

[699] Law 13.123, Article 25, paragraph 3

[700] Exemption notice No. R. 149, 2008, National Environmental Management: Biodiversity Act 2004; and National Environmental Management: Biodiversity Act, 2004, and amendments, Chapter 6

5.4 Monitoring of utilisation and compliance with access and benefit-sharing requirements

The Nagoya Protocol includes a series of provisions aimed at: (i) monitoring the utilisation of genetic resources, and (ii) supporting compliance with the domestic access and benefit-sharing legislation or regulatory requirements in place. Considering compliance and transparency as some of the key pillars on which the Protocol has been developed, this subsection presents some of the approaches and mechanisms being implemented in the case study countries.

With respect to monitoring, Parties to the Nagoya Protocol need to take measures to monitor and to enhance transparency about the utilisation of genetic resources, in particular through:

- designation of one or more checkpoints, which should be relevant to the utilisation of genetic resources, or to the collection of relevant information at any stage of research, development, innovation, pre commercialization or commercialization
- checkpoints collecting or receiving relevant information related to prior informed consent, source of the genetic resource, establishment of mutually agreed terms, and/or utilisation of genetic resources
- users of genetic resources having to provide specified information at a designated checkpoint
- encouraging the use of cost-effective communication tools and systems.[701]

Regarding compliance with domestic legislation or regulatory requirements on access and benefit-sharing, Parties need to take legislative, administrative or policy measures to provide that genetic resources and associated traditional knowledge utilised within their jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party or of the Party where such indigenous and local communities are located.[702]

In relation to the above elements, the following key areas have been looked into in the present study:

- Functions and responsibilities of checkpoints
- Mechanisms or methods to monitor utilisation of genetic resources and the associated traditional knowledge, including on whether there are monitoring systems for patent databases, registries of products resulting from access, and scientific publications
- Compliance mechanisms, including measures aimed at coordinating the actions of bodies responsible for enforcing ABS rules at the national level
- Measures aimed at ensuring benefit-sharing when utilisation of genetic resources and associated traditional knowledge occurs outside the jurisdiction of the country where the access took place

5.4.1 Monitoring of utilisation and checkpoints

Not all countries have so far established systems for monitoring the utilisation of genetic resources and/or associated traditional knowledge. Further, in some cases, mechanisms are in place but with additional developments needed to make them fully operational.

Japan and the European Union do not have monitoring systems for patent databases, registries of products resulting from access, and scientific publications. South Africa also has no monitoring system in place, but according to the first interim national report to the Nagoya Protocol the legislation is currently being revised to respond to the provisions

[701] Nagoya Protocol, Article 17

[702] Nagoya Protocol, Articles 15-16

relating to monitoring the utilisation of genetic resources.[703]

From those that have monitoring mechanisms, some differences in terms of methods and scope can be observed. To illustrate, the following are some of the key identified features:

- India's monitoring system covers different aspects. First, in accordance with the signed ABS agreements, the user needs to submit annual status reports on the usage of biological resources to the designated authority. This report is used as a tool for monitoring the accrual of benefits. Furthermore, there is a dedicated system to monitor patents filed abroad that have been made without seeking approval from the National Biodiversity Authority.
- In Brazil, the Genetic Heritage Governing Council is responsible for maintaining a system that tracks activities related to access to genetic heritage or associated traditional knowledge, including activities related to economic exploitation.[704] The Brazilian tracking system builds on linkages to a number of databases. Given that these databases are administered by different governmental agencies, the legislation in place allows for the establishment of the necessary arrangements to access the relevant information from each of them.[705] Furthermore, the national system of genetic heritage and associated traditional knowledge system (SisGen), created through Decree 8772/2016 and released on 6 November 2017[706], will be the system through which to gather information relating to: access to genetic heritage and associated traditional knowledge; shipment abroad of samples; authorizations granted for access and shipment; institutions in which *ex situ* collections are maintained; and finished products or reproductive material.[707]
- Peru established an integrated national mechanism for monitoring and surveillance of genetic resources, which is led by the Ministry of Environment. The objective of this mechanism is to track the utilisation of genetic resources accessed in the country while ensuring that access to genetic resources was subject to prior informed consent. For this purpose, compliance with the terms and conditions of access contracts is verified.[708] Among others, the mechanism will: (i) oversee that the utilisation of genetic resources is done in accordance with the scope of the project and access contract; (ii) identify and evaluate cases of unauthorised utilisation of genetic resources and associated traditional knowledge, including that related to intellectual property rights; and (iii) lead and maintain the public register of access contracts and related registers.[709] To date the integrated mechanism is not yet fully operational. In the meantime, the functions are carried out through actions by different institutions (administrative and executing authorities, INDECOPI and National Commission against Biopiracy).
  The National Commission against Biopiracy is responsible for identifying and monitoring patent applications or patents granted abroad that relate to Peruvian biological resources or collective knowledge of Peruvian indigenous peoples, and for technically assessing patent applications and granted patents.[710] SERFOR also has some measures in place. For example, export permits for CITES and

[703] South Africa, 2017, Interim National Report on the implementation of the Nagoya Protocol
[704] Decree 8772, Article 5
[705] Decree 8772, Article 5, paragraph 2
[706] Genetic Heritage Governing Council Executive Secretariat, Ordinance 1, October 2017
[707] Decree 8772, Article 20
[708] Supreme Decree 003-2009-MINAM, Regulation for access to genetic resources, Article 38. Also see http://genesperu.minam.gob.pe/recursosgeneticos/supervision-y-seguimiento/
[709] See http://genesperu.minam.gob.pe/recursosgeneticos/supervision-y-seguimiento/
[710] Law 28216 Ley de protección al acceso a la diversidad biológica peruana y los conocimientos colectivos de los pueblos indígenas, Article 4

non-CITES species that ensure traceability of the utilisation of the genetic resources and their derivatives abroad.

Not all of the studied cases have designated checkpoints through the Access and Benefit-Sharing Clearing House. However, for those that do not have a designated checkpoint under the Nagoya Protocol, institutions that perform such a role have been identified and considered in this report.

There is a variety of agencies that act as checkpoints in the different cases. In some, the role is performed by the Ministries of Environment or their equivalent (e.g. Japan, South Africa, Colombia). In others, such as Brazil, a specific body created under the Ministry of Environment (Genetic Heritage Management Council – CGen) serves as checkpoint in collaboration with other agencies. It is worth noting that despite Ministries of Environment or their equivalent are the only agencies designated to the Nagoya Protocol as checkpoints in some countries, others also perform this role in reality. Patent offices, for example, are increasingly acting as checkpoints (e.g. Brazil, Colombia, Ecuador, India, South Africa).

In some cases, institutions dealing with research also serve as checkpoints prior to research funding being allocated (e.g. Colombia, EU). Others performing this role at the national level include compliance and enforcement officers at the ports of entry and exit (e.g. South Africa), and provincial permit issuing authorities (e.g. South Africa).

Regarding the EU, the competent national authorities designated in Member States for the implementation of the EU ABS Regulation (usually ministries of environment or their equivalent) serve as checkpoints collecting the information required by the Regulation. In addition to the two checkpoints established through the Regulation, Member States can introduce additional checkpoints (e.g. research organizations).

5.4.2 Compliance with access and benefit-sharing requirements

Mechanisms for monitoring compliance focus on verifying compliance with domestic legislation or regulatory requirements on access and benefit-sharing.

User obligations under certain regimes are only triggered when genetic resources or associated traditional knowledge have been accessed from a Party to the Nagoya Protocol, and only if such a country has access and benefit-sharing requirements in place (e.g. EU, Japan). The EU ABS framework is aimed at promoting user compliance. For this purpose, it provides for the establishment of specific mechanisms to monitor compliance regarding due diligence obligations applicable to users of genetic resources. Importantly, in addition to spelling out the obligations that users have regarding due diligence, the Regulation also acknowledges that there are a number of tools and approaches aimed at promoting or facilitating users' compliance (e.g. best practices, sectoral codes of conduct, model contractual clauses and guidelines and a register of collections).

Regarding the measures to promote the effective monitoring of legal compliance, a number of approaches exist. The Ministry of Environment and Sustainable Development of Colombia, for example, manages a database through which they can verify the progress reports that are being submitted by applicants (status of the monitoring exercise is published on the website of the Ministry of Environment).[711] Even though Ecuador has no measures for monitoring compliance with the conditions stipulated in the contracts, their access and benefit-sharing framework requires that applicants make a deposit for situations of non-compliance. Details on how to calculate

[711] See http://www.minambiente.gov.co/index.php/bosques-biodiversidad-y-servicios-ecosistematicos/recursos-geneticos E.g. http://www.minambiente.gov.co/images/BosquesBiodiversidadyServiciosEcosistemicos/pdf/Recursos_Gen%C3%A9ticos_/seguimiento_EXp_CARG_MAYO2018.pdf

the amount are stipulated in the legislation (see sub section 4.4).

Another aspect studied in terms of compliance refers to better understanding the **governance approaches established to monitor and enforce compliance**. There is a variety of these. Some regimes have centralised structures (i.e. led by a single body such as Colombia, Japan and South Africa) while others stipulate decentralised mechanisms (i.e. several agencies responsible, such as Brazil, India and Peru).

In Japan, for example, the Ministry of Environment is the main agency responsible for ensuring compliance with ABS measures in the country. This is however done in cooperation with other competent ministries.[712] In South Africa, the Minister of Environment is also responsible for ensuring compliance. However, due to the governance structure of the country, some responsibilities are shared with the provinces.

Ecuador is currently establishing a "one-stop-shop" for biodiversity research, though which a range of agencies will work together (SENESCYT, public institute of scientific biodiversity research, national environmental authority, customs authority, and others). This platform, to be administered by SENESCYT and will be a component of the national information system for science, technology, innovation and ancestral knowledge. Once in place, it would be used for monitoring purposes.

The case of Brazil illustrates a decentralised mechanism to enforce compliance. In accordance with the Brazilian legislation, CGen's responsibility of monitoring activities of access and shipment of samples containing genetic heritage, and access to associated traditional knowledge can be done in collaboration with federal bodies, or by agreement with other institutions.[713] Other agencies with responsibility over monitoring of compliance of ABS provisions include the National Security Council and the Navy Command (regarding shipment abroad)[714], the Ministry of Agriculture, Livestock and Supply or the INPI (regarding plant varieties or other intellectual property rights respectively)[715], the Brazilian Institute for the Environment and Natural Resources (IBAMA).

In Peru, even though the Ministry of Environment is the lead agency, the administrative and executing authorities are also responsible for subscribing contracts and enforcing their provisions. These agencies have been designated as national competent authorities together with INDECOPI which is in charge of enforcing compliance with the legislation relating to traditional knowledge.

The EU ABS Regulation focuses on compliance measures, which are regulated at EU level. In accordance with the Regulation, Member States were to designate the competent authorities that are responsible for its application. Member States' competent authorities vary, both in terms of the specific agency in charge, as well as regarding the amount of designated competent authorities.

Finally, the review also considered whether any measures are foreseen to ensure benefit-sharing when **access to or utilisation** of genetic resources and the associated traditional knowledge **and economic exploitation occur outside of the jurisdiction of the country of origin**. While not being an aspect widely stipulated, some of the analysed regimes include it:

- In Brazil, if the finished product or the reproductive material has not been produced in the country, the importer, subsidiary, affiliate, or commercial representative of the foreign producer in the national territory or in the territory of countries with which Brazil has an agreement to this end, responds jointly with the manufacturer of the finished

[712] The Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation, 2017, Chapter 6.

[713] Law 13.123, Article 6

[714] Decree 8772, Articles 27-29

[715] Decree 8772, Article 29

product or the reproductive material for the sharing of benefits.[716]

- In India, even when some activities take place outside India, there is a benefit-sharing obligation attached to them. In particular: (i) when any person intends to obtain any intellectual property right in or outside India, for any invention based on any research or information on any biological resources and associated knowledge obtained from India (as it needs to make an application to the National Biodiversity Authority); and (ii) when any non-Indians intend to access the microorganisms deposited by an Indian scientist in the foreign repository under the Budapest Treaty on the international recognition of the deposit of microorganisms for the purposes of patent procedure[717], they will need to seek prior approval of the National Biodiversity Authority.
- Even when access takes place outside of Colombia, access to native genetic resources and their by-products require signing of a contract. Compliance provisions are agreed as part of that contract signed with the Ministry of Environment, and as such the user is obliged to comply with them.

5.5 The role of intellectual property rights in access and benefit-sharing

As indicated in the subsection relating to checkpoints, patent offices in some countries are performing the role of checkpoints. Further, it is important to gain a better understanding on whether intellectual property rights, in particular patents, are in any way considered with respect to the access and benefit-sharing regimes. For this purpose, the present review of legislation briefly covered the following:

- patentability of living organisms found in nature and of its components, such as DNA, molecules and metabolites
- disclosure of origin of genetic resources and/or associated traditional knowledge in patent applications.

Firstly, it should be noted that some of the access and benefit-sharing regimes make no reference to intellectual property (e.g. EU). Others consider specific procedures when applying for any intellectual property rights for inventions based in the utilisation of genetic resources or associated traditional knowledge (e.g. India).

The scope of what constitutes patentable inventions varies per country. Concerning **patentability of living organisms**, some of the regimes allow for living organisms or parts thereof to be patented (e.g. biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature[718] in the EU; or plants, animals and microorganisms in Japan[719]). In others these cannot be patented (e.g. Brazil, India, South Africa). Colombia, Ecuador and Peru as members from the Andean Community do not allow for the patentability of living organisms either.

With respect to the **disclosure of origin of genetic resources in patent applications**, a variety of approaches exist, as summarised in the table below.

[716] Law 13.123, Article 17

[717] See http://www.wipo.int/treaties/en/registration/budapest/

[718] Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Article 3

[719] https://www.jpo.go.jp/torikumi_e/kokusai_e/training/textbook/pdf/Bio_Patent.pdf (pp.29-30)

	Is disclosure of origin a mandatory requirement?	What is the scope of the measure?
Brazil	Yes	Patent applicants need to present evidence of the granted authorisation for access to genetic heritage for the application to be further processed
Colombia	Yes	The applicant must present a copy of the contract of access to the genetic resources and their by-products or of the document accrediting the licensing or authorisation of the use of traditional knowledge
Ecuador	Yes	The applicant needs to inform the source and country of origin of the genetic resources material or traditional knowledge used for the invention
European Union	No	
India	Yes	A granted patent may be revoked if the specification does not disclose or wrongly mentions the source or geographical origin of biological material or traditional knowledge used for the invention
Japan	No	
Peru	Yes	The applicant must present a copy of the contract of access to the genetic resources and their by-products or of the document accrediting the licensing or authorisation of the use of traditional knowledge. Certification of the legal provenance of the genetic resources is required to prevent misappropriation and patenting of genetic resources
South Africa	Yes	Patent applicants must indicate whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use

5.6 Key challenges in implementation and work underway: Potential areas for collaboration

The objective of the present study is to provide an up-to-date overview of selected national, and as appropriate regional, access and benefit-sharing policy and legal frameworks, while contributing to the promotion of South-South cooperation on these issues. It is therefore the intention that this study helps increase the understanding on some of the frameworks of access to genetic resources and benefit-sharing in place. For this purpose, the final part of this section aims to identify and present an overview of specific areas where work is underway as well as the key challenges faced by each country or regional organization in the implementation of their access and benefit-sharing frameworks.

A summary of the current developments taking place in the different cases, including associated challenges in subsection 5.6.1, and a summary of the key identified challenges is included in the last subsection.

5.6.1 Current areas of work

The table below identifies key areas of ongoing work in the case study countries. These areas provide potential for strengthening cooperation and mutual learning due to new approaches and mechanisms being developed and tested. As a result, they provide an opportunity for new experiences be identified and lessons exchanged. Full details relating to the areas identified below are covered in section 4 of this report.

	Key areas of work underway
Brazil	○ The Genetic Heritage Management Council (CGen) has recently established a Sectoral Committee of indigenous populations, traditional communities and traditional farmers that are holders of traditional knowledge associated to genetic heritage, which is, aimed at discussing issues relating to access and benefit -sharing for that sector ○ In the context of the CGen, a thematic group to deal with criteria relating to when it could be considered that species developed their own characteristics has been established in August 2017 ○ Specific administrative procedures will be established to consider additional agencies with a role in relation to tracking access to and utilisation of genetic heritage and associated traditional knowledge that can potentially be considered as checkpoints ○ Databases used in the Brazilian tracking system are administered by different governmental agencies, thus the legislation allows for the establishment of the necessary arrangements to access the relevant information from them ○ Further, the national system of genetic heritage and associated traditional knowledge system (SisGen), created through Decree 8772/2016 and recently released on 6 November 2017, will be the system through which to gather information relating to access to genetic heritage and associated traditional knowledge; shipment abroad of samples; authorizations granted for access and shipment; institutions in which *ex situ* collections are maintained; and finished products or reproductive material ○ Both national system of genetic heritage and associated traditional knowledge system (SisGen) and the tracking system are being designed as integrated systems, able to communicate also in communication with the rest of the databases (see details in section 4.1 above) ○ The legislation is quite recent and therefore the institutional arrangements and means to facilitate its implementation are being established gradually. Additional handbooks and guidelines are being developed, for example relating to the negotiation of benefit-sharing agreements, and the implementation of community protocols ○ In relation to access to genetic heritage, the Ministry of Environment is currently working in on the development of model contractual clauses that will be made available in the Ministry's website as soon as they are finalised
Colombia	○ Currently, benefit-sharing is assessed following a series of steps/criteria but details are not stipulated in the legislation. Decree 3570 of 2011 mandates the Office of Green and Sustainable Businesses to propose and support the adoption of mechanisms for the fair and equitable distribution of benefits derived from access to genetic resources, and participate in the formulation of strategic elements to ensure that intellectual property systems respect the rights over the country's biological and genetic resources. The Office of Green and Sustainable Businesses is currently working in the development of legislation to regulate benefit-sharing, including monetary and non-monetary modalities, calculation of the amount, etc.

	Key areas of work underway
Ecuador	○ Given the recently adopted legislation (Organic Code of the Environment and Organic Code of the Social Economy of Knowledge, Creativity and Innovation), Ecuador is currently developing and adjusting regulations and procedures for their implementation including, among others, on benefit-sharing; competencies for the regulation of access and benefit-sharing ○ A national inventory of biodiversity is being developed ○ Establishment of one-stop-shop for biodiversity research, with a range of agencies working together (SENESCYT, public institute of scientific biodiversity research, national environmental authority, customs authority, and others). This platform would be used for monitoring purposes in the future
European Union	○ Sector-specific guidance for a range of sectors (cosmetics, animal breeding, plant breeding, biocontrol, pharmaceuticals, food and feed, biotechnologies and upstream actors) is under development ○ The European Commission will establish and maintain a register of collections, once the need to do so is identified
India	○ An Expert Committee on Agro-biodiversity was established in 2005 to focus on issues relating to agro-biodiversity vis-à-vis the objectives of the Biological Diversity Act ○ The government is currently in the process of consultation with the various governmental agencies with functions relevant to the utilisation of biological resources or collection of relevant information at different stages of research, development, innovation, pre-commercialisation, or commercialisation for the designation of checkpoints
Japan	○ The guidelines indicate that the need to develop laws and regulations concerning the provision of access to genetic resources existing in Japan is to be further considered within five years from the date on which the Guidelines come into effect (based on changes in social circumstances in Japan in relation to access to genetic resources and fair and equitable benefit-sharing). In addition to the development of specific regulatory instruments as mentioned before, the guidelines could also be revised ○ In addition, the guidelines encourage that organisations, including industry, develop and update: (i) voluntary codes of conduct, guidelines and best practices or standards; and (ii) sectoral and cross-sectoral model contractual clauses
Peru	○ Peru established *a sui generis* regime for the protection of collective knowledge which brings together elements from intellectual property and customary law ○ A public register of access contracts and related registers[720] is being established ○ Regarding the measures adopted to integrate/coordinate the actions of the bodies responsible for enforcing ABS rules at the national level, the Ministry of Environment (lead agency) is developing a proposal of standardised guidelines, in coordination with the administrative and executing agencies, with the aim of homogenising the procedures that relate to authorisations, negotiation, and monitoring and surveillance of ABS obligations, with the ultimate goal of establishing a one-stop-shop for these matters ○ Regarding the functions of the integrated national mechanism for monitoring and compliance on genetic resources, coordination mechanisms with regional and local governments for surveillance measures of genetic resources within their areas are to be implemented

[720] See http://genesperu.minam.gob.pe/recursosgeneticos/supervision-y-seguimiento/

	Key areas of work underway
	○ The national competent authorities are developing standard material transfer agreements as well as material to support the process for contracts' negotiation and model contract of access
South Africa	○ South Africa is establishing a *sui generis* system for the protection, promotion, development and management of indigenous knowledge systems. The draft bill passed from the National Assembly in November 2017 to the National Council of Provinces.[721] Once adopted, this Bill will also take part of the ABS framework in place ○ The access and benefit-sharing legislation is currently being revised and will consider, among others: a. Article 17 of the Nagoya Protocol (monitoring of utilisation) b. Measures aimed at ensuring benefit-sharing when access and utilisation of genetic resources and associated traditional knowledge occur outside the jurisdiction of the country where the access took place c. Encouraging the development and use of sector-specific best practices d. Updating the model contractual clauses for the establishment of mutually agreed terms

[721] As of 12 August 2018. See https://pmg.org.za/bill/635/

5.6.2 Key challenges for implementation

During the development of the case study countries profiles, key challenges being encountered in implementation have been identified. These result not only from the cited sources but also from exchanges with the reviewers. In this final section, a summary of those key challenges is presented, with a view to identifying the main areas of convergence among the cases illustrated in this report. Some of the challenges include:

- Limited or uneven knowledge on genetic diversity (Colombia, Ecuador, Brazil)
- Difficulties resulting from the large area (and varied biodiversity) of some of the countries (Brazil, India)
- Limited or uneven knowledge relating to the utilisation of biodiversity in research and development in different sectors (Brazil)
- Need for enhanced awareness raising about the ABS frameworks (European Union)
- Perceived lack of clarity of the definitions provided by the Nagoya Protocol (European Union)
- Insufficient coordination and articulation among the competent authorities responsible for implementation of ABS frameworks (Ecuador, Japan, India, Peru)
- Insufficient human resource capacity among implementing agencies and relevant stakeholders for the management of genetic resources and the implementation of ABS measures in general (India, Peru, South Africa) and to perform as checkpoints (Peru)
- Need for multidisciplinary teams to improve the management of authorisations, negotiations, benefit-sharing and monitoring and surveillance (Peru)
- Need for legislation that strengthens scientific research, innovation and development at the domestic level (Peru)
- Lack of mechanisms to monitor utilisation of genetic resources, particularly when genetic resources or associated traditional knowledge are utilised outside of the national jurisdiction of the country of origin (Ecuador, South Africa)
- Some difficulties negotiating benefit-sharing agreements, particularly when done by indigenous communities (South Africa)
- Difficulties in identifying the indigenous communities or individual holders of the accessed traditional knowledge (South Africa)
- Recording and documenting holder's knowledge before the Act comes into force; and how to deal with traditional knowledge associated with a non-indigenous resource (South Africa)

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