

IMPLEMENTATION OF THE NAGOYA PROTOCOL IN BRAZIL



Brazilian National Confederation of Industry
THE FUTURE OF INDUSTRY

IMPLEMENTATION OF THE NAGOYA PROTOCOL IN BRAZIL

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INTRODUCTION

The Brazilian industry is aware of the importance of sustainable use and conservation of biodiversity, as biodiversity loss is one of the major global environmental challenges and a risk factor for the manufacturing sector.

International agreements are important mechanisms to achieve better global coordination on key sustainability challenges. Among the treaties that Brazil has recently ratified is the Nagoya Protocol, which supplements the Convention on Biological Diversity.

The Nagoya Protocol provides guidelines to achieve the third major goal of the Convention by regulating access and the fair and equitable sharing of benefits arising from the use of genetic resources of biodiversity. The agreement provides legal certainty and better business prospects for Brazilian and international companies that use these resources.

As a signatory, Brazil is required to fulfill the obligations set forth in the protocol. Currently, the country has only regulated access and sharing of benefits related to national biodiversity, but other commitments remain to be met.

Considering that the Brazilian industry uses resources from biodiversity, the Brazilian National Confederation of Industry (CNI) presents in this study recommendations for Brazil to comply with the obligations of the Nagoya Protocol that have not yet been met.

This publication identifies possible ways to guarantee greater legal certainty for biodiversity users and confirms the industry's commitment to the country's sustainable development.

Enjoy your reading.

Robson Braga de Andrade

President of CNI



1 EXECUTIVE SUMMARY

The Nagoya Protocol (the “Protocol” or NP) was ratified by Brazil in 2021¹. With that, the country was granted the rights and obligations stipulated in this international treated, whose purpose is to promote one of the key goals of the Convention on Biological Diversity (CBD): the fair and equitable sharing of benefits arising from the utilisation of genetic resources and the traditional knowledge associated with them.

In order to effectively implement this agreement in Brazil, the country must adopt important administrative and legal measures subject to strategic choices. These definitions shall consider not only the specific aspects of Brazil, but also the prior experience from countries who signed this contracted before. This study was made by the Brazilian Confederation of Industry as a tool to support this process.

Firstly, the study introduces the key obligations of the Protocol, using prior informed consent (PIC) and mutually agreed terms (MAT) as basis to benefit-sharing and training needs to be provided for the players involved. It must be pointed out that the protocol is of a singular nature, as it supposes that laws from a foreign country shall be complied with in a different country. This means Brazilian companies that opt to use genetic resources native from other countries or the traditional knowledge associated with them shall comply with the national legislation determining access and benefit-sharing.

At an international level, some challenges were already identified and have been the subject of in-depth discussions at CBD conferences as part of the Parties’ Meeting on the Nagoya Protocol. These challenges will also certainly be found in Brazil and were detailed throughout this study. Among them are the difficulty of tracking the source of genetic resources to obtain digital sequence information (DSI), the complexity in identifying the countries that provide transboundary species and the challenges in obtaining authorization for multiple accesses to genetic resources for the purposes of R&D. This study determined the discussion stage regarding these subjects.

While still at an international level, this study analyzes how deeply the Nagoya Protocol has been implemented in megadiverse countries and countries with the highest number of DSI users (theoretically those with the most developed biotechnology field). The purpose was to assess the subject both from the perspective of predominantly

¹ The ratification of the Nagoya Protocol in Brazil was made official on March 4th, 2021. The agreement was then made effective 90 days later, on June 3rd. This agreement shall be enacted through a decree, which will be edited by the President of Brazil.

providing countries and from those who more commonly use genetic resources. Among megadiverse countries, Bolivia, China, Indonesia, the Philippines, and Malaysia stand out for the low level of Protocol's implementation. South Africa and Peru are already among the countries with higher degrees of implementation. Compared to them, Brazil is at an intermediary position along with India. Regarding users, France and Spain already show high degrees of implementation, as in addition to EU regulations, these countries have their own laws and designated a verification point to comply with the access rules and distribution of benefits from other countries who signed the Protocol.

Finally, looking at the subject from Brazil's perspective, this study attempted to identify the legal and administrative instruments that need to be adopted by the country to ensure the Protocol and its contents are put into operation. In this sense, the study found that the key points to be addressed by internal regulations include: (a) definition of checkpoints; (b) definition of access monitoring processes for genetic resources and associated traditional knowledge from abroad; (c) definition of data that companies must archive and the maximum length of time permitted for the government to request such data; and (d) definition of applicable sanctions in case of breaches. Details regarding these points are extremely important to ensure legal security and operationalization of the Protocol. In order to contribute towards the development of a national model, the study suggests possible alternatives for the Brazilian government to regulate each of these aspects, while also considering international experience.

The Protocol's entry into effect is imminent, and the industry must pay attention and stay up to date regarding points that could impact businesses. Therefore, this study also focuses on the importance of due diligence, training, and maintenance of minimum information to ensure genetic resources can be tracked and to prevent unexpected occurrences in future inspections. The goal is to ensure knowledge about international laws is accessible so that implementation can occur without setbacks.



2 THE NAGOYA PROTOCOL AND ITS RATIFICATION IN BRAZIL

The Convention on Biological Diversity (CBD), a UN treaty from 1992, acknowledged biodiversity as a common concern for humanity and formalized the commitment of signatory countries to work together considering the three main objectives of the convention: biodiversity conservation, sustainable use of its components and fair and equitable sharing of benefits arising from the utilisation of genetic resources. The convention also outlines the need to finance and transfer technologies to achieve these objectives, as well as the need to ensure proper access to genetic resources and their related rights.

Since CBD is the primary international forum on biodiversity, the commitments undertaken by the parties (currently comprising 195 countries and the European Union) must be internalized at a national level through policies, programs, and projects. The maximum decision-making body of the CBD is the Conference of Parties (COP), a general meeting in which all parties are represented with equal importance.

Over twenty years after the CBD was adopted, it became clear that its efforts have not been enough to promote the implementation of an access and benefit-sharing (ABS) mechanism. For this reason, during the 10th COP in 2010, the Parties decided to sign a complementary international agreement: the Nagoya Protocol. This agreement reaffirms the countries' sovereign rights over their genetic resources and the benefits arising from the use of biodiverse resources found in their territories.

The Nagoya Protocol was put into effect at an international level in 2014. In order to be effective nationally and allow the Party to attend the agreement's meetings, the State must deposit a ratification, acceptance, approval or accession instrument in the UN. Brazil ratified the agreement in March 2021 and became a member of the Protocol on June 2nd of the same year².

² According to article 33, 2, of the Nagoya Protocol, the treaty goes into effect in a state 90 days after it is ratified. In the case of Brazil, since the ratification instrument was deposited on March 4th, 2021 Protocol was made effective on June 2nd, 2021.

As one of the 17 megadiverse nations, along with India, Australia, China, among others, Brazil stood to defend the Protocol to help implement the rules outlined by the CBD regarding access and benefit-sharing. Brazil even centralized ABS rules regarding Brazilian biodiversity through the Federal Law 13,123 from 2015.

However, new national measures must be adopted to fulfill the necessary obligations. This will require legal amendments, infralegal changes and administrative actions, as has already been happening in other countries that have signed the agreement. This is the case, for instance, of the European Union, who set forth rules to be followed by its states when implementing the NP (EU Regulation No. 511/2014).

Thus, the purpose of this study is to identify what obligations Brazil must fulfill to implement the Protocol and what paths can be taken to do so, considering the experience and context of such a megadiverse country who also uses and provides genetic resources. This study aims to help decision-makers understand the subject and how to develop the best environment to promote the Protocol's objectives, while driving innovation and supporting economic progress.

This study is a continuation of a prior study conducted in 2020 by the Brazilian National Confederation of Industry, which attempted to analyze how the Nagoya Protocol's ratification impacted the Brazilian industry at a regulatory level³.

3 CONFEDERAÇÃO NACIONAL DA INDÚSTRIA. Análise dos impactos regulatórios da ratificação do Protocolo de Nagoia para a indústria nacional. Brasília: CNI, 2020. Available at: <http://www.portaldaindustria.com.br/publicacoes/2020/5/importancia-da-ratificacao-do-protocolo-de-nagoia-para-industria-brasileira/>. Accessed on: Sept. 9th, 2021.



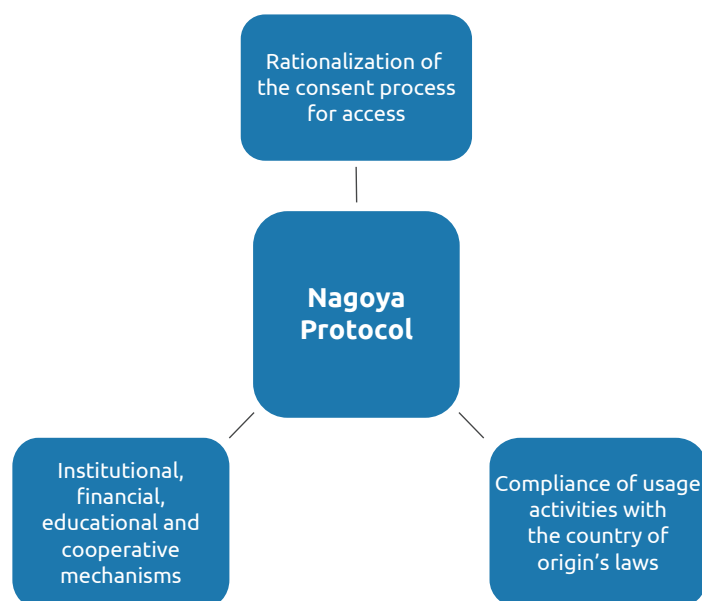
3 OBLIGATIONS DEFINED IN THE PROTOCOL

The Nagoya Protocol established a series of obligations that must be fulfilled by States member at a national and international level to fulfill its objectives.

In order to provide a judicial outlook to implement the CBD's third objective regarding benefit-sharing, the Protocol's predictions are centered around two essential pillars: (1) rationalization of the consent process to ensure access to genetic resources and associated traditional knowledge (ATK); and (2) compliance regarding activities to use⁴ the genetic resources and ATK through the country of origin's laws.

In addition to the obligations upheld by the parties directly related to these two pillars, the Protocol has a third pillar made up of institutional, financial, and educational mechanisms to support its implementation, as per Figure 1.

FIGURE 1 – Pillars of the Nagoya Protocol



Source: Author

⁴ According to the Nagoya Protocol, "use of genetic resources" means carrying out R&D activities on the genetic and/or biochemical composition of genetic resources, including through biotechnology, as determined by Article 2 of the convention.

3.1 GENERAL OBLIGATIONS RELATED TO THE RATIONALIZATION OF THE CONSENT PROCESS FOR ACCESS TO GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

In response to the users' demands for genetic resources and traditional knowledge, the Protocol defines specific obligations to be upheld by member states focused on rationalizing the process to obtain prior informed consent (PIC).

Understanding PIC

Prior informed consent is the authorization given by the party who provides genetic resources or associated traditional knowledge. For example, consent can be provided by a country or an indigenous community. The need for PIC stems from individual countries' sovereignty over the biological resources found in their territory. This means users require authorization to access them.

Consent may be given, for example, by a government agency or indigenous community according to local laws. The need for PIC stems from individual countries' sovereignty over their biological resources. The Protocol sets forth a few obligations regarding how PIC is obtained to ensure proper access to genetic resources, especially through articles 6, 7 and 8.

These articles refer specifically to the need to define a process to securely and predictably obtain PIC through the necessary players. Moreover, the articles refer to how these rules must consider the special traits of certain resources, as is the case with food and agriculture resources.

TABLE 1 – Process to obtain PIC according to articles 6 and 8 of the Nagoya Protocol

Forms of regulation determined by the Nagoya Protocol	Regulation's goals
Countries must approve the necessary legal, administrative or political measures.	<ul style="list-style-type: none"> • Provide legal security and clear rules; • Create fair standards and procedures; • Provide information; • Ensure the written decisions granted by national authorities are clear and transparent; • Determine, at the time of access, the issuance of licenses or equivalent documentation as proof of the decision to grant PIC; and • On a case-by-case basis and as per national laws, establish criteria and/or procedures to obtain PIC or approval and participation by indigenous and local communities to access genetic resources.
For specific cases: (1) genetic resources for food and agriculture; (2) resources for human, animal and vegetable health; and (3) studies that contribute towards the conservation of natural resources.	<ul style="list-style-type: none"> • Ensure genetic resources for food and agriculture are handled in a way that matches their importance for food safety; • Ensure seamless access for public health emergencies; and • Ensure seamless access for studies that promote the conservation of biological diversity.

TABLE 2 – Regulation on PIC and access to associated traditional knowledge according to articles 3 and 7 of the Nagoya Protocol

Forms of regulation determined by the Nagoya Protocol	Regulation's goals
National legislation	<ul style="list-style-type: none"> • Ensure that traditional knowledge associated with genetic resources held by indigenous and local communities is accessed upon prior informed consent or approval and participation of these indigenous and local communities, while also ensuring that mutually agreed terms are established.

In Brazil, Law No 13,123/2015 and Decree No 8,772/2016 can be perceived as national legislation implementing this part of the Protocol, even if these laws were still made before ratification. For this reason, Legislative Decree No. 136 of 2020, which authorized the Protocol's ratification, determined that Law No. 13,123/2015 must be considered domestic law for the purpose of implementing the Protocol.

Aligned with the objective of rationalizing the process, the Protocol defines obligations related to designating institutes that: (a) will provide information on the rules of access and benefit-sharing; and (b) will effectively consent to this access.

The first figure was designated the focal point and was in charge of bridging the member state and the CBD Secretariat. The focal point must provide information about the procedure involved in obtaining prior consent and mutually agreed terms, as well as about competent national authorities, communities, and stakeholders. The second figure is the competent national authority who will effectively grant consent to access and provide guidance to stakeholders.

TABLE 3 – The role of the focal point and the national authority according to article 13 of the Nagoya Protocol

Designation of agency in charge	The agency's role
Administrative measure (national focal point - Article 13.1)	<ul style="list-style-type: none"> • Provide information on the procedure to obtain PIC and the mutually agreed terms; and • Provide information on competent national authorities, communities and stakeholders.
Legal, administrative and political measures (national competent authority - Article 13.2)	<ul style="list-style-type: none"> • Grant access or, as the case may be, written proof that the access requirements were fulfilled; and • Provide guidance on procedures and applicable requirements to obtain PIC and negotiate mutually agreed terms.

Indeed, regarding these last obligations, Brazil has been diligent on the steps required to implement the Protocol. In April 2021, the Ministry of Foreign Relations was designated as the focal point for communications between the CBD's Executive Department and Brazil⁵. Moreover, the Ministry of Environment's Department of Genetic Heritage was already designated as the national authority to handle matters related to access and benefit-sharing.

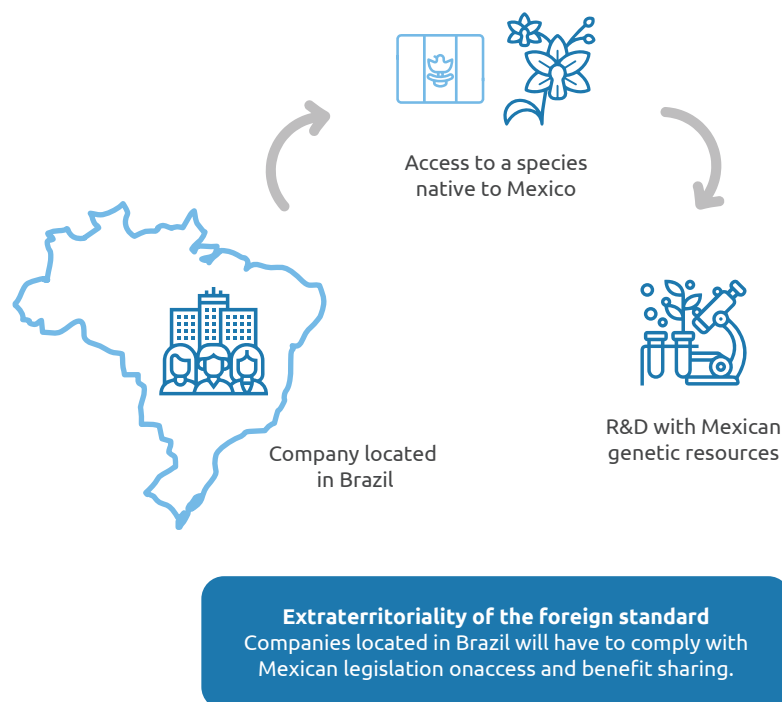
⁵ ACCESS AND BENEFIT-SHARING CLEARING-HOUSE. *Website*. Available at: <https://absch.cbd.int/countries/BR/NFP>. Accessed on: Oct. 1st, 2021.

3.2 GENERAL OBLIGATIONS RELATED TO THE COMPLIANCE FOR THE USE OF GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE PROVIDED BY THE COUNTRY OF ORIGIN'S LAWS

Access to Brazilian genetic resources is already regulated by domestic laws, as discussed above. However, the objectives of the Protocol are more ambitious, and look to ensure Brazil complies with domestic laws regarding the subject and create mechanisms to ensure foreign laws are fulfilled in case of access and benefit-sharing related to non-Brazilian genetic resources.

As an example, if a Brazilian company decides to conduct studies on the Mexico-native *Antigonon leptopus*⁶, the company must comply with Mexican laws regarding access and benefit-sharing. In order to ensure compliance with Mexican laws, Brazil and other countries who signed the Protocol must create a compliance system.

FIGURE 2 – Nagoya Protocol and the application of foreign laws in national territory



Source: Author

6 ROYAL BOTANIC GARDENS KEW. Plants of the World Online. *Antigonon leptopus* Hook. & Arn. Available at: <https://powo.science.kew.org/taxon/urn:lsid:ipni.org:names:15860-2>. Accessed on: Sept. 12th, 2021.

The Nagoya Protocol establishes that countries must adopt internal measures to ensure benefits arising from the use of genetic resources, while associated traditional knowledge, as well as applications and subsequent commercialization, will be shared fairly and equally. Sharing will be permitted according to mutually agreed terms (MAT).

Understanding MAT

Mutually agreed terms indicate how the parties (i.e., the user and the provider) agree on how the benefits of the use of genetic resources or associated traditional knowledge are shared fairly.

On the other hand, as with consent to access, the Protocol determines that the provider countries must consider the specific characteristics of the resources used for certain purposes, especially regarding how the benefits to be shared are determined. This is the case of food, agriculture and public health emergency resources and those focused on conservation and sustainable use, as discussed earlier.

These duties are outlined in article 5, as per the table below.

TABLE 4 – Compliance with benefits sharing according to article 5 of the Nagoya Protocol

Regulations on benefits sharing as defined by the Protocol	Regulation's goals
Legal, administrative or political measures on a case-by-case basis (Articles 5.1 and 5.3)	<ul style="list-style-type: none"> • Ensure the benefits stemming from the use of genetic resources, as well as subsequent application and commercialization, are shared fairly and equally.
Legal, administrative or political measures on a case-by-case basis (Article 5.2)	<ul style="list-style-type: none"> • Ensure the benefits stemming from the use of genetic resources found in indigenous or local communities, as well as subsequent application and commercialization, are shared fairly and equally with these communities.
Legal, administrative or political measures on a case-by-case basis (Article 5.5)	<ul style="list-style-type: none"> • Ensure the benefits stemming from the use of traditional knowledge associated with genetic resources are shared fairly and equally with indigenous and local communities who possess such knowledge.

In addition to these specific obligations related to how benefits are shared, the Protocol broadly requires that all member countries comply with domestic standards from other countries of origin, in case exotic genetic resources (i.e., resources from other countries) are used in their own territory. In order to comply with this obligation, the states must adopt preventive, repressive and monitoring measures as per the table below.

TABLE 5 – Internal compliance mechanisms according to articles 15, 16 and 17 of the Nagoya Protocol

Implementation at national level	Regulation's goals	Monitoring mechanisms
Legal, administrative or political measures	<ul style="list-style-type: none"> • Prevention: ensure that the genetic resources (or the associated traditional knowledge) used in one's jurisdiction were accessed upon prior informed consent and that mutually agreed terms were established; and • Repression: appropriate, effective and proportionate measures to handle situations in which the associated measures are not complied with, including cooperative measures in case of alleged violation. 	<ul style="list-style-type: none"> • Control points: designation of control points which will require information about the resources and knowledge that were accessed; • Mutually agreed terms: encourages providers and users to share information about their implementation; and • Communications: use of efficient tools and systems.

Regarding monitoring efforts, article 17 of the Protocol establishes that parties must designate one or more checkpoints. This means that, in order to ensure the treaty is effectively implemented, one or more internal agencies must be established to check the requirements to access and share the benefits. This agency will continuously share information with the ABS Clearing-House of the Protocol, and, according to the definitions established in Brazil, may issue a license that will constitute an international certificate as proof of compliance with the access rules.

About the ABS Clearing-House

The ABS Clearing-House is a tool created by the Protocol and found in its website, allowing member states to disclose information about their national standards, competent authorities, legal compliance control points and other mechanisms used to implement the Protocol's requirements. Since the signatory countries must comply with the laws of the genetic resources' countries of origin, even when such resources are found in their own territories, the ABS Clearing-House is a key tool to ensure the applicable laws are seamless and available.

In case the laws of the country of origin are not complied with, the Protocol establishes that appropriate, effective, proportionate responses to handle these situations must be adopted. However, these measures are not directly specified, and it is up to member states to define them. It is worth noting that Brazil has yet to adopt any measures related to the obligations outlined in this topic.

3.3 GENERAL OBLIGATIONS ON COOPERATION, EDUCATION AND STIMULUS TO PROMOTE THE OBJECTIVES OF THE PROTOCOL, AS WELL AS THE FINANCIAL AND INSTITUTIONAL MECHANISMS

The Protocol outlines general obligations related to cooperation, education and stimulus to promote its objectives, as well as financial and institutional mechanisms to aid its implementation, which involve more or less involvement by member states to effectively apply them.

Article 11 outlines a general cooperation requirement for the parties, related to the Protocol's implementation when it comes to transboundary resources, but it does not specify how this cooperation should happen. One example of this is resources shared by countries in which the Amazon rainforest is part of their individual territories. In this case, the parties must act according to bilateral and/or multilateral agreements to specify how this obligation must be fulfilled.

The awareness and qualification obligations are outlined in articles 21 and 22, respectively. The former refers equally to all member-countries, who shall adopt measures to raise awareness on the importance of genetic resources and associated traditional knowledge, as well as other matters related access and benefit-sharing. The Protocol provides a few examples of how awareness can be raised:

- promoting the Protocol, including its purpose;
- organizing meetings with local and indigenous communities and stakeholders;
- establishing and maintaining a help desk for indigenous and local communities and stakeholders;
- sharing information through a national clearing-house;
- promoting volunteer codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and stakeholders;
- promoting, as appropriate, experience exchange at domestic, regional, and international level;
- educating and training users and providers of genetic resources and associated traditional knowledge on their obligations related to access and benefit-sharing;
- involvement of indigenous and local communities and stakeholders in the implementation of this Protocol; and
- awareness regarding protocols and procedures of indigenous and local communities.

Regarding capacity-building, the focus is on ensuring that actions and resources are allocated to developing countries to create and develop skills while strengthening human resources and institutional capabilities, in order to effectively implement this Protocol. Since Brazil is considered a developing country, its specific needs must be identified to obtain support for internal qualification.

It is worth highlighting that the ABS Clearing-House, as previously mentioned, is an information exchange mechanism created by Article 14 of the NP. The idea is that this digital space allows parties to communicate effectively, including to provide information on initiatives related to qualification.

Moreover, the Protocol created obligations that parties must follow to encourage relevant implementation actions, including the creation of contract clause templates, definition of volunteer codes of conduct and encouragement to use benefits sharing resources for the purposes of sustainable biodiversity, as per the table below.

TABLE 6 – Actions outlined to ensure the better implementation of the Nagoya Protocol according to articles 9, 17, 20, and 20

Mutually agreed terms	Codes of conduct and best practices	Purpose of the resources
<p>The Protocol outlines:</p> <ul style="list-style-type: none"> • Inclusion of dispute solution mechanisms; • Resources for the judicial system and in case of disputes; • Access to legal means and use of mechanisms related to mutual acknowledgment and execution of foreign sentences and arbitrations; and • Update and use template contract clauses (in individual sectors and across many sector) for mutually agreed terms. 	<ul style="list-style-type: none"> • Develop, update and use volunteer codes of conduct, guidelines and good practices. 	<ul style="list-style-type: none"> • The Protocol encourages users and providers to direct benefits stemming from the use of genetic resources towards conservation of biological diversity and sustainable usage of its components.



4. CHALLENGES IN APPLYING THE PROTOCOL - MULTIPLE ACCESSES, TRANSBOUNDARY SPECIES AND DIGITAL SEQUENCE INFORMATION

Certain matters related to the implementation of the Protocol have been requiring additional studies due to their complexity and advances in biotechnology. This includes transboundary species, digital sequence information on genetic resources and multiple accesses. There is no consensus on how these issues should be addressed, as no definitive deliberations were made regarding the Parties' Meetings on the Protocol, which has the most decision-making powers regarding its implementation. Therefore, the main debates and current opinions on these matters can be found below to assist in the implementation of this treaty in Brazil.

4.1 SHARED AND TRANSBOUNDARY SPECIES

Transboundary species are those that exist naturally in more than one country; thus, they do not respect borders defined by society. One example is *açaí*, found in Brazil, but also in other countries like Venezuela and Guyana⁷.

Article 10 of the Protocol establishes that parties must consider a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations.. This is an extremely relevant subject for Brazil, as most of its genetic resources and associated traditional knowledge can be found in the Amazon rainforest, shared between Brazil and other countries in South America⁸. Therefore, more than one country can claim benefit-sharing for new research and development products based on Brazilian genetic resources and in any of the countries where the Amazonia is located⁹.

7 MINISTRY OF AGRICULTURE, LIVESTOCK AND SUPPLIES. List of best practices to handle organic sustainable extraction. *Açaí-de-touceira: Euterpe oleracea* MART. Department of Agricultural and Farming Development and Cooperativism – Brasília: MAPA/ACS, 2012.

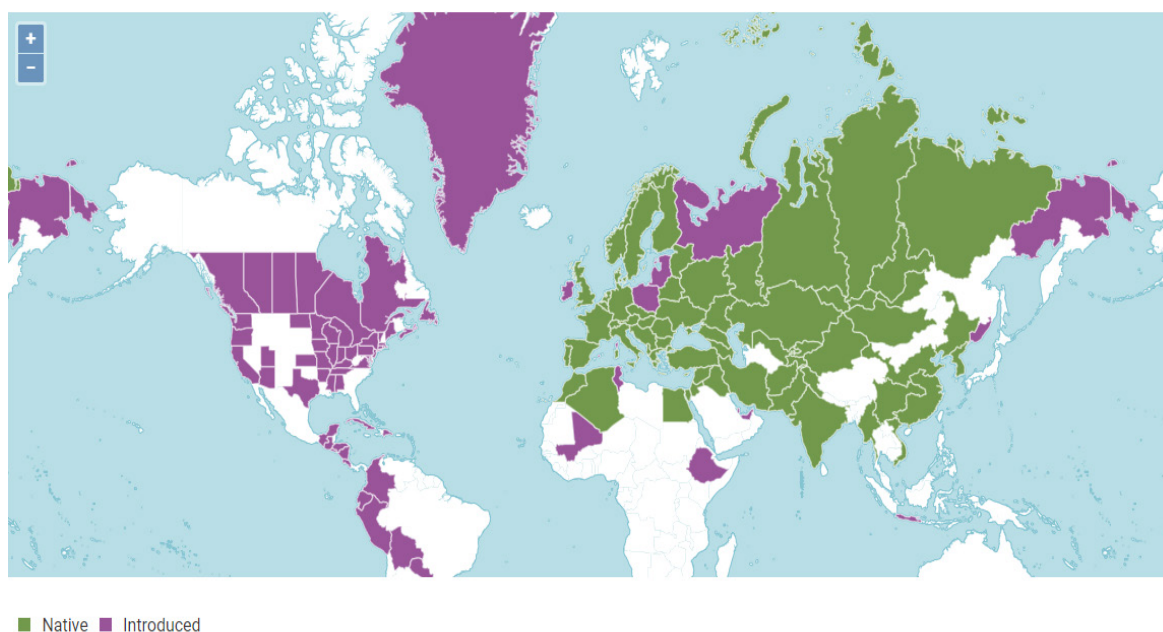
8 DIAS, Bráulio; SILVA, Manuela; MARINELLO, Luiz Ricardo. Comentários e recomendações para regulamentar o Protocolo de Nagoia no Brasil. *Revista da ABPI*, n° 171 mar/abr 2021 (28-49).

9 Ibidem.

In addition to species found in neighboring countries that share the same biome and borders, there are species found in distant countries that do not share borders. This is the case of Rosy periwinkle (*Catharanthus roseus*), which, although native from Madagascar, is grown and naturalized in India as well¹⁰. Another particularly complex situation happens with migrating species that, during their specific life cycles, migrate to and from different countries, as the case of the Monarch butterfly (*Danaus plexippus*)¹¹.

Another situation identified in a study sponsored by the CBD's and the Protocol's Executive Secretariat involves species found in so many different locations that it is difficult to determine what country would have enough legitimacy to authorize access and require shared benefits. One example is chamomile (*Matricaria chamomilla*), native to both Europe and Asia¹². In these cases, the authors recommend abandoning the bilateral system and using the multilateral benefit-sharing model, as per article 10 of the Protocol¹³.

FIGURE 3 – Distribution of *Matricaria chamomilla*



Source: Plants of the World Online. Royal Botanic Gardens Kew.

10 BAGLEY, Margo; PERRON-WELCH. **Study to Identify Specific Cases of Genetic Resources and Traditional Knowledge Associated with Genetic Resources that Occur in Transboundary Situations or for Which it is not Possible to Grant or Obtain Prior Informed Consent. As requested in decision NP-3/13 (paragraph 5(a)) by the Third Meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Nagoya Protocol.** March 2020 Available at: <https://www.cbd.int/abs/art10/2019-2020/study.shtml>. Accessed on: Aug. 2nd, 2021.

11 Ibidem.

12 ROYAL BOTANIC GARDENS KEW. Plants of the World Online. **Matricaria chamomilla L.** Available at: <http://www.plantsoftheworldonline.org/taxon/urn:lsid:ipni.org:names:154715-2>. Accessed on: Aug, 2nd, 2021.

13 Ibidem.

The bilateral benefit-sharing model is effective for certain situations, especially when the situation involves a single species. However, at present, access to multiple species for research purposes is becoming increasingly common. The need for many bilateral contracts, although not impossible, can make the process complex, costly, and inefficient.

Consequently, for these cases, the ABS global multilateral system would be more advantageous, as it would encourage scientific research and biodiversity conservation projects¹⁴. One system that could be used as reference for the Protocol is the International Treaty on Plant Genetic Resources for Food and Agriculture (TIRFAA) signed in 2001. The need for a simpler and more agile system to access resources made it so TIRFAA would not adopt the CBD's complex procedures. This agreement established a multilateral benefit-sharing system for all genetic resources listed under its first Annex.

In 2018, accounting for this complexity, the parties of the Protocol decided that more information would be necessary about possible situations that would require the use of the ABS multilateral mechanism (decision NP-3/13). This is because although there is a clear expectation on the usage possibilities for transboundary species and for which prior consent cannot be granted, as per article 10, the parties did not expect that all the necessary elements to create a multilateral mechanism established within the scope of the Protocol would be present.

Adding to this construction, the Subsidiary Body on Implementation (SBI), during the second part of its third meeting in March 2022, recommended a text to be discussed regarding the Parties' Meeting on the Nagoya Protocol. The document proposes different text options to be discussed and encourages members to institute an *ad hoc* working group to study possible categories for a multilateral benefit-sharing system, as well as the primary setbacks and challenges of the current bilateral system¹⁵. It is worth noting that the text suggests payment of 1% of the retail price for commercial gains obtained from the use of genetic resources for the purposes of benefit-sharing.

The document further suggests the institution of a Global Biodiversity Fund, which will be operated by the Global Environmental Facility (GEF), an existing financial mechanism to help implement CBD projects. The values would be used in projects to support biodiversity conservation activities and the sustainable use of their components¹⁶.

Despite the SBI's recommendations, the Protocol's Parties have yet to decide on the theme.

14 *Ibidem*.

15 UNITED NATIONS. Environment Programme. **Convention on Biological Diversity**. CBD/SBI/REC/3/17. Available at <https://www.cbd.int/doc/recommendations/sbi-03/sbi-03-rec-17-en.pdf>. Accessed on: Aug. 31, 2022.

16 *Ibidem*.

4.2 DIGITAL SEQUENCE INFORMATION

The ABS regime was prepared considering tangible biological resources. The typical idea of biopiracy refers to seeds, plants or animals illegal exported to another country and taken to laboratories for product development. However, due to recent developments in biology, biotechnology and computer science, genetic information was acquired and shared in an intangible format.

This change is also due to the advances in molecular biology and computation algorithms that resulted in the discovery of new DNA sequencing methods. The next generation sequencing (NGS) technologies, for instance, can generate DNA sequencing data at a low cost and much faster than previous technologies. With NGS, it is possible to resequence entire genomes and transcriptomes¹⁷ more efficiently and cheaper than before, with greater depth.

In this context, a new concern emerged for providing countries: digital biopiracy. According to attorney and professor Margo Bagley, providing countries fear that, once access to a physical sample is authorized, genetic information will be digitally sequenced and sent to publicly accessible genetic banks, such as GenBank or the European Nucleotide Archive. Since access to these data banks currently do not require PIC or MAT, users may take advantage of the genetic information without complying with ABS rules¹⁸. In summary, providers fear that the new genetic sequencing technology and the fluidity of information may hamper the compliance with ABS rules.

The emergence of technological changes to research methods and to the way genetic information is shared drove debates on whether DSI must be considered genetic resources within CBD and the Nagoya Protocol. Since the convention establishes that a “genetic resource” is a genetic material of substantial or potential value, certain members interpreted that the treaty must cover only physical biological samples¹⁹.

17 CONFEDERAÇÃO NACIONAL DA INDÚSTRIA. Sequencing techniques developed themselves at the same time as computer data processing capabilities. As such, there was an expansion of a field known as omics, which involves mapping DNA and RNA sequences, as well as protein and metabolite sequences at a molecular level. The integration of these different omics is what is known today as Biology. In: **Bioeconomia e a indústria brasileira**. Brasília: CNI, 2020. Available at: https://static.portaldaindustria.com.br/media/filer_public/cd/ed/cded4159-a4c5-474d-9182-dd901b317e1c/bioeconomia_e_a_industria_brasileira.pdf. Accessed on: Aug. 5th, 2021.

18 BAGLEY, Margo. Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology (February 2016). **Virginia Public Law and Legal Theory Research Paper** n° 11, Emory Legal Studies Research Paper 11.

19 UNITED NATIONS. Convention on Biological Diversity. CBD/DSI/AHTEG/2020/1/3. **Digital Sequence Information on Genetic Resources: Concept, Scope and Current Use**. Available at: <https://www.cbd.int/doc/c/fe/f9/2f90/70f037ccc5da885dfb293e88/dsi-ahteg-2020-01-03-en.pdf>. Accessed on: July 15, 2021.

As previously mentioned, the Nagoya Protocol was designed primarily to further implement the CBD's third objective: fair and equitable sharing of benefits arising from the use of genetic resources.. If, due to new technologies, the genetic resources become accessible without PIC and MAT and/or economically explored without proper counterparts, due to the lack of access to a physical sample, the Protocol will not be able to fulfill the purposes for which it was created.

In order to better understand this issue, in December 2016, the 13th Parties Conference of the CBD and the Second Parties' Meeting on the Nagoya Protocol established an *ad hoc* group of technical DSI specialists (AHTEG). In addition, the CBD's Executive Secretariat requested a survey of facts and a study to clarify the terminology and assess the use of the DSI. The COP also encouraged the parties, indigenous peoples, local communities, relevant NGOs and stakeholders provide their comments on the subject.

The DSI study was released in 2018 and showed that the technique has been broadly used in laboratories. However, some researchers believe that access to physical materials is still required in most cases. At present, only a small part of the commercial survey is based on tangible samples, but academic groups are still interested in collecting field and *ex situ* sample²⁰. The use of digital sequencing also revealed a new genetic manipulation technique, which is considered the next step in genetic engineering based on DSI: synthetic biology²¹.

However, the AHTEG report indicates that the most important point remained inconclusive, and that is how the term "genetic resources" is defined. Some experts state that the definition includes DSI; others believe that genetic resources refers primarily to tangible materials; while others stated that the DSI must not be considered a genetic resource, but must be covered by the Nagoya Protocol.

The complexity of this subject, the constant technological advances and the lack of an accurate definition of DSI encouraged the COP to adopt Decision 14/20 during its 14th meeting in November 2018²². The resolution requested four studies on DSI and established a new *ad hoc* group of technical experts.

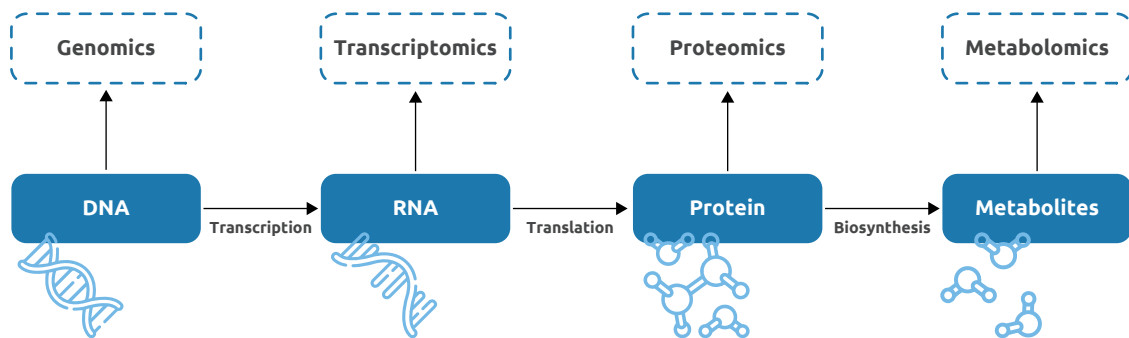
20 Fact Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on the Biological Diversity and the Nagoya Protocol. Available at <https://www.cbd.int/doc/c/e95a/4ddd/4baea2ec772be28edcd10358/dsi-ahteg-2018-01-03-en.pdf>. Accessed on: July 15, 2021.

21 The COP understands that synthetic biology consists in developing modern biotech with a combination of science, technology and engineering. In other words, it involves the use of genetic engineering to modify/redesign genetic structures in order to create new features that are not found in nature. One example is the use of steviol glycoside by the food industry. This molecule provides a sugary flavor found in steviol leaves, and was broadly potentialized at a chemical level using synthetic biology. Available at: <https://bch.cbd.int/synbio/#:~:text=The%20COP%20also%20acknowledged%20that,design%2C%20redesign%2C%20manufacture%20and%2F>. Accessed on: July 15, 2021.

22 Available at: <https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-20-en.pdf>. Accessed on: October 30, 2021.

One of the studies requested by the Executive Secretariat provided a scientific base analysis on the concept and the scope of DSI. The study systematizes, in several groups, the different types of biological information that could make it up. The explanation is based on the “central dogma of molecular biology”, in which the DNA is converted into RNA, which turns into proteins and finally transforms into metabolites. The first group includes only the DNA and RNA (strict scope); the second covers DNA, RNA and proteins (intermediary scope); the third includes DNA, RNA, proteins and metabolites (intermediary scope); and the fourth is the broadest concept, including traditional knowledge, environmental influences, among others. These groups were organized to facilitate a future decision by the COP regarding the scope of DSI. Moreover, the method is important to identify the source of the information.

FIGURE 4 – Dogma of molecular biology and omic sciences



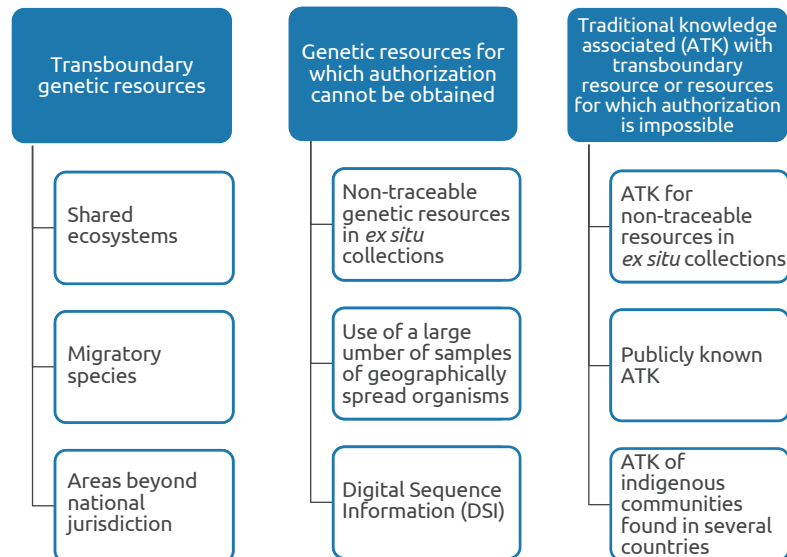
Source: Author

Based on the studies and AHTEG’s results, the Open-ended Working Group on the Post-2020 Global Biodiversity will make recommendations for the 2nd part of the COP-15, which is expected to be held in Canada in December 2022. The group will also consider potential policies to incorporate DSI into the Protocol which were already discussed during webinars on the subject organized by the CBD Executive Secretariat²³.

In order to better understand item 4, Figure 5 summarizes the most problematic application situations of the Nagoya Protocol’s bilateral system.

²³ Available on: <https://www.cbd.int/article/dsi-webinar-series-2020>. Accessed on: August 10, 2021.

FIGURE 5 – Genetic transboundary resources for which authorization or prior consent is impossible to obtain



Source: Author

4.3 MULTIPLE ACCESS

Scientists handling DSI at a practical level state that a single genetic sequence holds little value for researching and developing new products. The use and comparison of various genetic sequences from different species through data processing (biological computing) is what allows value to be generated from the information for the purposes of genetic improvement, development of new molecules, identification of new organisms, and other applications.

Since the primary way of accessing the DSI is through gene banks, multiple accesses can be made through this tool. In Brazil, the domestic ABS legislation includes DSI as part of the genetic heritage. In this case, if a Brazilian company wants to use DSI of various species native to Brazil as part of its R&D process, said company must carry out multiple accesses, which must comply with Brazilian law.

However, several genetic sequences from different origins are often applied to develop a single product. The formalization of access to all these sequences results in uncertainty, delay, and expense²⁴. Consequently, in this situation, the use of a multilateral mechanism, as determined by Article 10 of the Protocol, would be more appropriate.

²⁴ Bagley, Margo; Perron-Welch. Study to Identify Specific Cases of Genetic Resources and Traditional Knowledge Associated with Genetic Resources that Occur in Transboundary Situations or for Which it is not Possible to Grant or Obtain Prior Informed Consent. As requested in decision NP-3/13 (paragraph 5(a)) by the Third Meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Nagoya Protocol. March 2020 Available at <https://www.cbd.int/abs/art10/2019-2020/study.shtml>. Accessed on August 2nd, 2021



UNITED NATIONS  NATIONS UNIES

5. OVERVIEW OF THE NAGOYA PROTOCOL'S IMPLEMENTATION IN OTHER COUNTRIES

Up until now, 138 parties ratified the Protocol, including China, India, EU countries and almost every country in South America (except for Chile, Paraguay and Colombia)²⁵.

The ABS Clearing-House²⁶, available on the CBD's website, as mentioned earlier, is an essential tool to obtain information regarding procedures, relevant authorities, and national legislation about ABS in countries that signed the Protocol. Thus, it will be used as a reference database to assess how this treaty is implemented.

Analysis of the Protocol's implementation across the world took into account the following points:

- a) designation of a national authority as a focal point, that is an authority in charge of providing information on specific access and benefits sharing requirements at a national level;
- b) existence of a competent national authority to grant access authorization and assess potential benefits sharing contracts;
- c) existence of laws, regulations or general policies on ABS;
- d) existence of a specific ABS procedure²⁷; and
- e) checkpoints and designation of a body in charge of monitoring ABS rules, either through national standards or standards of other countries who signed the Protocol.

If all these mechanisms are presented, it means the country has been working internally to effectively apply the rules of the Protocol.

For this reason, the degree of implementation of the treaty was analyzed in two groups of countries: one includes the largest potential providers, represented by 13 member countries with approximately 70% of the planet's biodiversity, while the other includes some of the largest potential users. This group is made up of the primary users of Genbank's

²⁵ Available at: <https://www.cbd.int/abs/nagoya-protocol/signatories/>. Accessed on: July 15, 2021.

²⁶ xxxxxx

²⁷ The difference between items "c" and "d" is that, in some cases, countries may only mention the theme in a general manner in its internal laws, but do not detail what procedure must be followed to access genetic resources or share benefits. In other countries, the theme is outlined in greater detail.

DSI, as per a recent CBD study regarding the subject²⁸. These countries were selected because a significant number of accesses to genetic resources are found in them, and it is important to observe how deeply the Protocol's mechanisms are implemented and the compliance with standards in the accessed resources' countries of origin.

The most biologically diverse countries in the world are Brazil, Colombia, Ecuador, Peru, Venezuela, Bolivia, Mexico, United States, China, Indonesia, Australia, the Philippines, Malaysia, South Africa and the Democratic Republic of the Congo²⁹. However, since the US, Colombia and Australia are not part of the Protocol, they have been excluded from the analysis. The other countries comprise the group of largest potential providers.

According to the data available in ABS Clearing-House on this group, Bolivia, China, Indonesia, the Philippines, and Malaysia are notable for the low degree of implementation of the Protocol. These countries only designated a national focal point, but did not reference a national authority or legal, administrative, or political measures on the subject. South Africa and Peru fulfilled all analyzed requirements and are already among the countries with the highest degrees of implementation. Compared to them, Brazil is at an intermediary position along with India, as it still lacks specific designated checkpoints.

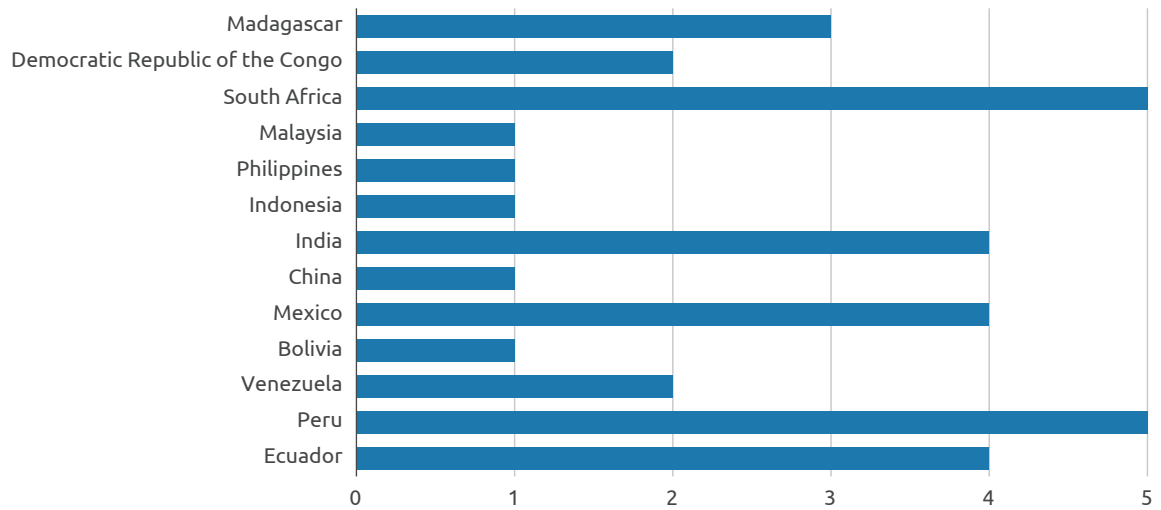
As indicated above, in addition to these megadiverse countries, the degree of implementation in countries that are more likely to be users rather than providers was also analyzed. As criteria for this selection, the study sponsored by the 14th COP, within the scope of the CBD, was used as reference. The study identified countries with the highest number of DSI users, including US, China, India, Japan, Germany, UK, France, Brazil, Spain and Russia³⁰. However, since the US and Russia are not part of the Protocol, they have been excluded from the analysis. Brazil's implementation will be analyzed in its own section.

According to the information available on ABS Clearing-House, France and Spain present advanced levels of implementation. In addition to EU regulations these countries have their own national laws and a designated checkpoint to comply with ABS rules. They are followed by the UK and Germany, while China shows the lowest levels of implementation.

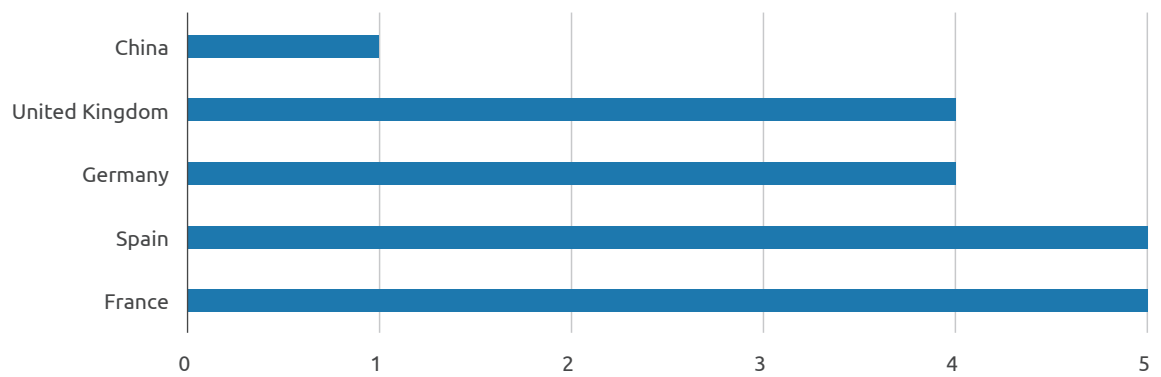
28 Dröge, Gabriele; Scholz Amber Hartman; Huang, Sixing; Rohden, Fabian. Combined Study on DSI in public and private databases and DSI traceability. Available at <https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf>. Accessed on: July 1st, 2021.

29 Available at: <https://news.mongabay.com/2016/05/top-10-biodiverse-countries/>. Accessed on: August 5th, 2021.

30 Dröge, Gabriele; Scholz Amber Hartman; Huang, Sixing; Rohden, Fabian. Combined Study on DSI in public and private databases and DSI traceability. Available at <https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf>. Accessed on July 15th, 2011.

FIGURE 6 – Degree of implementation in megadiverse countries.

Source: Author

FIGURE 7 – Degree of implementation in countries with the highest number of DSI users.

Source: Author

5.1 MEGADIVERSE COUNTRIES

The analysis included certain countries with access and benefit-sharing standards to achieve a broad view of the access requirements and sharing methods. Since these are the most biologically diverse countries, the industry must pay close attention to these processes. The mechanisms are highly diverse between countries and no pattern can safely be used as universal reference.

MEXICO

For which activities will access authorization be required?

Mexico does not have any specific laws regarding benefits sharing and access. According to information from ABS Clearing-House, the *Ley de Desarrollo Rural Sustentable* and the *Ley de Desarrollo Forestal Sustentable* outline, at a general level, the access to genetic resources, while the *Ley General del Equilibrio Ecológico e la Protección al Ambiente* outlines how benefits are shared.

What national authorities are in charge?

Dirección General de Vida Silvestre, Subsecretaría de Gestión para la Protección Ambiental, Secretaría de Medio Ambiente y Recursos Naturales (SEMARNAT), Comisión Nacional para el Desarrollo de los Pueblos Indígenas (CDI) and Comisión Nacional de Áreas Naturales Protegidas.

What mechanisms are used to benefit-sharing?

Generic obligations are outlined in the *Ley General del Equilibrio Ecológico y la Protección al Ambiente*. The benefit-sharing arising from access to genetic resources must be analyzed on a case-by-case basis and defined according to a common agreement between parties.

Primary applicable law: *Decreto Promulgatorio del Protocolo de Nagoya sobre Acceso a los recursos genéticos y participación justa y equitativa en los beneficios que se deriven de su utilización al convenio sobre la diversidad biológica, Ley General de Desarrollo Forestal Sustentable and Ley de Desarrollo Rural Sustentable*. Available at: <https://absch.cbd.int/countries/MX>. Accessed on: August 4th, 2021.

ECUADOR

For which activities will access authorization be required?

Acquisition, use, handling, investigation, import, export, as well as distribution and sale of genetic species from local wildlife, fauna and flora. When it comes to collection or access for the purposes of technological R&D for the cosmetics, personal hygiene and perfume industry, a special procedure must be followed, and all individuals or legal entities, be them national or international, required authorization by the competent Regional District to carry out scientific research on fauna and flora in areas deemed as *Patrimonio Nacional de Áreas Naturales*.

What national authorities are in charge?

Ministerio del Ambiente y Agua.

What mechanisms are used to benefit-sharing?

Based on the information provided by the interested party, the authority must prepare a technical report. The following will be considered to determine the benefits to be paid: commercial applicability of the research, its budget and involved players (*Reglamento Código Organico Economía Social de Los Conocimientos*, 2016).

Primary applicable law: *Reglamento Al Regimen Comun Sobre Acceso a los Recursos Geneticos Decreto Ejecutivo 905*. Available at: <https://www.ucuenca.edu.ec/images/DIUC/Documentos/PropiedadIntelectual/LeyesYReglamentos/Reglamento-al-Rgimen-Comn-sobre-acceso-a-los-Recursos-Genticos.pdf>. Accessed on: August 4th, 2021; and *Reglamento Código Organico Economía Social de Los Conocimientos* Available on: <https://www.ambiente.gob.ec/wp-content/uploads/downloads/2018/05/Codigo-Organico-Economia-Social-de-los-Conosimientos.pdf>. Accessed on: September 23, 2021.

PERU

For which activities will access authorization be required?

For all activities involving the use (R&D) of genetic resources native to Peru, including derivative products, their intangible components and genetic resources of migratory species found in national territory through natural causes.

What national authorities are in charge?

El Servicio Nacional Forestal y de Fauna Silvestre (SERFOR) del Ministerio de Desarrollo Agrario y Riego, El Instituto Nacional de Innovación Agraria (INIA) del Ministerio de Desarrollo Agrario y Riego, Ministerio de la Producción and El Servicio Nacional de Áreas Naturales Protegidas por el Estado (SERNANP). The competent authority will be chosen depending on the genetic resource that's been accessed (article 12 of Supreme Decree 019 – 2021 MINAM).

What mechanisms are used to benefit-sharing?

Payment is required to benefit-sharing when there is access to genetic heritage or their subproducts, including intangible components. The parties (i.e., interested parties and the Competent National Authority) must negotiate fair and equitable sharing of benefits arising from the use of this component. Peru's standards do not mention any specific values or margins to be followed. As for traditional collective knowledge, the amount required to share benefits must be greater than 10% of gross sales resulting from products developed with collective knowledge. This amount shall be directed to the *Fondo para el Desarrollo de los Pueblos Indígenas*.

Primary applicable law: Supreme Decree n. 019 – 2021 MINAM. Available at: <https://cdn.www.gob.pe/uploads/document/file/2035623/DS.%20019-2021-MINAM%20con%20anexos.pdf>. Accessed on: September 11th, 2022; and *Ley 27811 que establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológico*. Available at: <https://sinia.minam.gob.pe/download/file/fid/37540>. Accessed on: September 11th, 2022.

INDIA

For which activities will access authorization be required?

For activities involving the acquisition of biological resources in India or access to associated traditional knowledge for the purposes of commercial R&D or biological research and use. The law determines a fee must be paid. Access authorization is not required for collaborative research projects between Indian and foreign institutions.

Access authorization is required for individuals who are not citizens of India, Indian non-residents, corporations, associations or organizations not founded or registered in India or registered in the country but have non-Indian equity.

What national authorities are in charge?

National Biodiversity Authority.

What mechanisms are used to benefit-sharing?

Payment varied between 0.1% and 5% of the purchase of the genetic product. In case of unidentifiable providers, the amount is directed to the National Biodiversity Fund.

In 2020, India launched an electronic system to monitor and issue access permits for genetic resources. The system allows government authorities to permanently review and approved issued forms (<https://abs-sustainabledevelopment.net/story/training-workshop-on-it-monitoring-tool-for-abs-in-india/>).

Primary applicable law: *Biological Diversity Act 2002, Biological Diversity Rules 2004 and Guidelines on Access of biological resources*. Available at: <https://absch.cbd.int/countries/IN>. Accessed on: July 15, 2021.

SOUTH AFRICA

For which activities will access authorization be required?

Biological prospection activities and export of biological resources. The term “indigenous biological resources” refers to any genetic resource. Prior informed consent is required for associated traditional knowledge.

What national authorities are in charge?

National Department of Environmental Affairs.

What mechanisms are used to benefit-sharing?

The law does not outline any amounts, suggesting these can be freely negotiated between the parties. There is also a Bioprospecting Trust Fund to which payments must be made. Payments to all stakeholders must come from this fund.

Primary applicable law: Biodiversity Act n. 10 of 2004 and Regulation on bioprospecting Access and benefit sharing 2008. Available at <https://absch.cbd.int/countries/ZA/MSR>. Accessed on: July 15, 2021.

DEMOCRATIC REPUBLIC OF THE CONGO

For which activities will access authorization be required?

According to Article 54 of the *Loi Relative a la Conservation de la Nature*, activities resulting from the exploration of genetic resources and traditional knowledge for commercial, scientific or other purposes.

What national authorities are in charge?

Ministère de l'Environnement et Développement Durable.

What mechanisms are used to benefit-sharing?

Sharing can be made through monetary or non-monetary means. No amounts or rules are defined. However, Article 61 indicates that the State has the right to receive 16% of the monetary benefits for associated access to genetic resources by the local community.

Primary applicable law: *Loi n. 14/003 Relative a la Conservation de la Nature*, 2014. Available at <https://cd.chm-cbd.net/implementation/fol320521/loi-relative-la-conservation-de-la-nature/>. Accessed on: July 15, 2021.

MADAGASCAR

For which activities will access authorization be required?

Access to genetic resources and traditional knowledge from Madagascar. It is worth noting that foreign users require a prior collaboration agreement for projects from a Malagasy public research authority.

What national authorities are in charge?

Direction du Systeme des Aires Protégées, as per the ABS Clearing-House.

What mechanisms are used to benefit-sharing?

Benefits may be monetary or non-monetary, as the type and amount of the benefit will be determined on a case-by-case basis. No amounts are pre-determined.

Primary applicable law: *Décret n. 2017 066 du 31 janvier 2017*. Available at https://absch.cbd.int/api/v2013/documents/1E13DEBB-A5F3-91A9-1CD0-D41D2B61A650/attachments/Madagascar_decret_ressources_genetiques_2017_066.pdf. Accessed on: August 5th, 2021.

Considering that national legislations are not uniform, the Protocol, as a multilateral international instrument on the subject, can harmonize ABS rules for specific cases. The result can be the creation of a less complex environment than one where the user has to comply with multiple domestic laws. An alternative that is still possible may be the definition of guidelines or reference models that can be adopted by countries, at their discretion.

It is also notable that the ABS Clearing-House need to be constantly updated so it does not present incomplete information. As an example, Brazil's Decree no. 8,772/2016 and Mexico's a *Ley General del Desarrollo Forestal Sustentable* and *Ley del Desarrollo Rural Sustentable*, which outline the biological resources system, are not listed.

5.2 DEVELOPED COUNTRIES AND DSI USERS

The compliance mechanisms for access to genetic resources and associated traditional knowledge in developed countries using DSI were also analyzed. Since these countries ratified the Protocol some time ago, it is interesting to note the instruments that have been used to ensure compliance with the laws of providing countries. Hence, Brazil could leverage the best practices to implement the agreement.

FRANCE

What national authorities were designated by the country?

There are many authorities in charge, including: *Ministère de l'Enseignement supérieur, de la Recherche et de l'Innovation* *Ministère de la transition écologique et solidaire*; *Direction générale de l'aménagement, du logement et de la nature* *Direction de l'eau et de la biodiversité* *Bureau de l'encadrement des impacts sur la biodiversité*.

What are the applicable laws?

EU Regulation 511/2014, *Loi de Biodiversité* 2016 – 1087 and *Décret* n° 2017 – 848.

Are there any checkpoints for compliance with ABS laws of countries of origin?

Yes, based on EU Regulation 511/2014, checkpoints will be a requirement for getting research funding by the *Ministère de l'Enseignement supérieur, de la Recherche et de l'Innovation* and the *Ministère de la Transition Ecologique e Solidaire*.

Are there any sanctions for violations?

The Biodiversity Law (*Loi Biodiversité*) outlines penalties in case of irregular access. Thus, violators are subject to one year in prison and a 150,000-euro fine in case of the following:

- (1) use or access to genetic resources or traditional knowledge without compliance with the law and articles 3 and 4 of EU Regulation 511/2014. In this case, fines of up to 1 million euros are applicable for commercial use.
- (2) failure to seek, maintain or provide relevant information about access and benefit-sharing arising from genetic resources and associated traditional knowledge.

Finally, the law also determines a complementary sentence that prohibits violators from requesting access to genetic resources or traditional knowledge for up to five years.

Available at: <https://absch.cbd.int/countries/FR>. Accessed on: August 5th, 2021.

GERMANY

What national authorities were designated by the country?

Federal Agency for Nature Conservancy.

What are the applicable laws?

EU Regulation 511/2014, National Strategy on Biological Diversity, Patent Act and Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) n° 511/14.

Are there any checkpoints for compliance with ABS laws of countries of origin?

Yes, the Federal Agency for Nature Conservancy oversees receiving users' due diligence certificates in case of (1) funding requests and (2) final stages of produce development (due diligence procedure under EU Regulation 511). Moreover, authorities may also perform an *ad hoc** inspection of users

Are there any sanctions for violations?

Yes, the Act Implementing the Nagoya Protocol, under section 4 (2) 4, outlines that access to genetic resources and traditional knowledge that violates the law and the EU Regulation may be subject to punishment with up to 50,000-euro fine.

**Ad hoc* inspection has a specific purpose, that is, the environmental authority performs a purpose-specific visit to check whether the company is complying with ABS laws.

Available at: <https://absch.cbd.int/countries/DE> Accessed on: August 5th, 2021.

SPAIN

What national authorities were designated by the country?

The primary authority is the *Dirección General de Biodiversidad, Bosques e Desertificación del Ministerio para Transición Ecológica y el Reto Demográfico*. There are other competent authorities specific for autonomous communities.

What are the applicable laws?

EU Regulation 511/2014, *Ley 42/2017*, known as *Ley del Patrimonio Natural y de La Biodiversidad* and the *Real Decreto 124/2017 relativo al acceso a los recursos genéticos procedentes de Taxones silvestres y al control de la utilización*.

Are there any checkpoints for compliance with ABS laws of countries of origin?

Yes, the *Ministerio de la Transición Ecológica*. Article 72 of *Ley 42/2007* establishes that the measures for compliance for proper access will be handled according with EU Regulation 511/2014.

Are there any sanctions for violations?

Yes, according to *Ley 42/2007*, irregular access to genetic resources and traditional knowledge (article 80 (1) u. v) may be deemed severe or very severe infraction. As per article 81, very severe infractions may be subject to fines of up to 2 million euros. Severe infractions may be subject to fines of up to 200,000 euros.

Available at: <https://absch.cbd.int/countries/ES> Accessed on: August 5th, 2021.

As members of the European Union, France, Germany and Spain generally follow the procedures established under EU Regulation 511 of April 16th, 2014³¹. The regulation suggests a declaratory monitoring system and mentions two possible moments to check the due diligence certificates for access to genetic resources and traditional knowledge: (1) during the research funding request phase; and (2) in the final product development stage, prior to entry-to-market in the EU. Article 9 also outlines inspections by competent national authorities in case of suspicion of irregular access to resources or inspections based on risk assessment for user-developed activities.

Understanding due diligence

Due diligence is a preventive procedure to seek and analyze information to identify situations of risk (either financial, legal or reputational) for companies. The expression became famous for its application in mergers and acquisitions, but it is currently being applied in different areas. The certificate shows that companies worked preventively and were diligent in their legal compliance.

It is also worth noting that article 11 of the Regulation indicates that countries must also determine sanctions. However, the regulation does not establish what these sanctions should be, and member nations are free to establish the penalties they deem necessary. The charts present different punishments. For example, France determines one year in prison and a 150,000 euro fine, while Germany establishes fines of up to 50,000 euros in case of irregular access to genetic resources and ATK.

In a recent publication on the subject by the EU, the Protocol's application guide clarifies that the due diligence process (which is already widely used by companies across the world during mergers and acquisitions) must be applied to genetic resources and ATK and adapted accordingly. The document also indicates that the purpose is to gather and use information systematically³².

The UK is still a member of the Protocol even after its departure from the EU. However, its laws about the subject are vague and generic, potentially making it difficult for domestic users to comply with them.

31 Regulation n° 511/2014 to implement the Nagoya Protocol in the EU and to enable Union-wide ratification of the Protocol. Available at: <https://eur-lex.europa.eu/legal-content/PT/TXT/?uri=CELEX%3A32014R0511>. Accessed on: September 20, 2021.

32 Guidance document on the scope of application and core obligations of Regulation (EU) n° 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 (2021/C13/01). Available at [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112\(02\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02)&from=EN). Accessed on: August 5th, 2021.

UNITED KINGDOM

What national authorities were designated by the country?

The following authorities were designated after the country's departure from the EU: Office for Product Safety and Standards and Department for Business, Energy & Industrial Strategy.

What are the applicable laws?

Nagoya Protocol (Compliance) Regulations 2015, the Nagoya Protocol (Compliance) Amendment (EU Exit) Regulations 2018, and the Environment and Wildlife (Legislative Functions) (EU Exit) Regulations 2019.

Are there any checkpoints for compliance with ABS laws of countries of origin?

Yes, the Office for Product Safety and Standards. The authority shall carry out inspections according to risk analysis, on a case-by-case basis.

Are there any sanctions for violations?

Yes, the Nagoya Protocol (Compliance) Regulations 2015 establishes civil and penal sanctions in case of compliance notes or stop notices from competent authorities are violated. There are no limits imposed on fines.

Available at: <https://absch.cbd.int/countries/GB>. Accessed on: August 5th, 2021.

Although considered one of the major users of DSI, Japan has yet to designate a national authority to the ABS Clearing house to monitor ABS rules in the country. The most likely explanation is that PIC is not required to access Japanese genetic resources. It is important to emphasize that the survey made in this study did not find any sanctions for regulating access to genetic resources and ATK from other countries. Therefore, among users countries analyzed, Japan has the lowest degree of implementation.

JAPAN

What national authorities were designated by the country?

At present, no national authorities have been designated and the Japanese government does not demand PIC to access genetic resources.

What are the applicable laws?

There are two documents with instructions to apply the protocol, but none of them are binding.

Are there any checkpoints for compliance with ABS laws of countries of origin?

Yes, the Ministry of Environment.

Are there any sanctions for violations?

If there are any, this information was not provided to the ABS Clearing-House or the Guideline on Access to Genetic Resources and Fair and Equitable Sharing of Benefits.

Available at: <https://absch.cbd.int/countries/JP>. Accessed on: August 5th, 2021.

Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization. Available at: http://abs.env.go.jp/pdf/english_guidelines.pdf

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6. IMPLEMENTATION OF THE NAGOYA PROTOCOL IN BRAZIL

As previously stated, the Protocol imposes a series of obligations upon countries; Brazilian law regarding access to national genetic resources, Federal Law No. 13,123/2015 and its regulations make up an important part of the obligations defined in the Protocol for accessing national genetic resources and traditional knowledge associated with them in Brazil, as well as benefit-sharing.

However, there is still plenty of work to be done regarding how the Protocol's obligations are to be fulfilled, particularly when it comes to the need to ensure compliance of activities using exotic genetic resources and associated traditional knowledge to laws in their countries of origin. Moreover, there are specific cooperation and stimulation duties that must be equally observed.

The following topics outline the specific obligations to be fulfilled to implement the Protocol in Brazil, as well as potential pathways to do so. Other relevant matters were also defined to ensure implementation in the country, although they are not Protocol obligations necessarily.

6.1 TEMPORAL GOAL

As explained in a study published by the Brazilian National Confederation of Industry, titled "Analysis of regulatory impacts due to the ratification of the Nagoya Protocol in the Brazilian industry" (*Análise dos impactos regulatórios da ratificação do Protocolo de Nagoia para a indústria nacional*)³³, during the discussions regarding the text of the Protocol, the parties did not reach a consensus about when the rules should become valid, which led to discussions about how to better interpret the treaty. The disagreements showed three different positions on the matter:

³³ *Análise dos impactos regulatórios da ratificação do Protocolo de Nagoia para a indústria nacional*. CNI. Oct. 2020 Available at <https://www.portaldaindustria.com.br/publicacoes/2020/10/importancia-da-ratificacao-do-protocolo-de-nagoia-para-industria-brasileira/>. Accessed on: August 5th, 2021.

- The first position, supported primarily by some of the provider countries, stated that the Protocol would have retroactive effects and that it is applicable to genetic resources that have entered the country at any moment. This position is contrary to Article 28 of the Vienna Convention on the Law of Treaties, which stipulates non-retroactivity, except in cases when the treaty specifically states otherwise.
- The second position states that the Protocol must be applied to genetic resources that enter a country starting when the CBD is made effective in each country; and
- The third position states that the Protocol must be applied to genetic resources that enter a country after it is made effective in each country.

Analysis of foreign laws indicates that most countries adopted the third position, but there is at least one country who took an intermediary stance, as per the table below.

Option 1	Option 2	Option 3
Presently, no countries believe that the Protocol will be applied to resources that have been accessed at any moment.	Argentina presented an interpretation along with its ratification instrument that appears to indicate that the Protocol would be applicable to resources accessed after the CBD is made effective.	Japan and the UK adopted the position that the Protocol shall only be applicable to genetic resources or traditional knowledge associated to genetic resources that were accessed (that is, obtained), starting at the date the Protocol is made effective in the country.

Considering the national context, the best position Brazil could take is **option 3**, which would ensure legal security for users. This means establishing that the Protocol applies to genetic resources and ATK obtained starting at the date when it is made effective in the country, that is, June 2nd, 2021. Although the Protocol was not internalized, starting on this date, Brazil could be held accountable at an international level³⁴.

Another equally legitimate option, although controversial at a global level, is to consider that the Protocol shall only be applicable after publishing an executive decree that will disclose the text nation-wide. Considering that Brazil has been a member of the Protocol since June 2021, the Brazilian tradition, overseen by the Federal Supreme Court³⁵, dictates that it may only be a requirement in internal plans once it is enacted in a decree published by the Executive Branch. This happened, for instance, during the process to internalize the Convention on Biological Diversity (CBD).

34 VARELLA, Marcelo D. *Direito Internacional Público*. 8.ed. São Paulo: Saraiva Educação, 2019.

35 (...) Analysis of the Brazilian Federal Constitution indicates that execution of international treaties and their incorporation into the internal judicial system stems, in the system adopted in Brazil, from a subjectively complex action, resulting from the decisions of two homogeneous powers: the National Congress, which makes decisions on treaties, agreements or international laws at a definitive level upon legislative decrees (CF, article 49, I) and the President, who can not only execute these international rights actions (CF, article 84, VIII), but also enact, as Head of State, upon decree. The procedure to incorporate international treaties, following the international convention execution phases, and their approval in congress and ratification by the Head of State, is concluded once the President expedites the decree, whose edition includes three basic, inherent effects: (a) enactment of the international treaty; (b) official publication of its text; and (c) execution of the international act, which then becomes binding and mandatory in the internal positive law plan. Precedents. (ADI 1480 MC, Rapporteur: Celso de Mello, en banc court, judged on 9/4/1997, DJ 18-05-2001 PP-00435 EMENT VOL-02031-02 PP-00213).

6.2 CHECKPOINTS

One of the most relevant matters to consider when implementing the Protocol is the definition of a checkpoint. According to article 17, item 1(a), the parties shall designate one or more control points. Thus, countries must designate a body in charge of receiving information on the source of genetic resources, obtaining prior consent from provider countries, mutually agreed terms and benefit-sharing, as needed. Moreover, this body may be authorized to impose sanctions in case of violations or inform another competent body to do so.

When negotiating the text of the Protocol, the provider countries insisted on designated intellectual property offices as checkpoints. As no consensus was reached, it was decided that each country will be allowed to choose an authority in charge of checking the applicable ABS rules.

Analysis of foreign laws indicates that countries have been adopting the following options to implement this subject:

Option 1	Option 2	Option 3
In Japan, the Ministry of Environment acts as the checkpoint.	Peru has two checkpoints: the National Institute of Intellectual Property (<i>Instituto Nacional de Defensa de la Competencia y la Protección de la Propiedad Intelectual</i>) and the National Commission against Biopiracy (<i>Comisión Nacional contra la Biopiratería</i>).	France involves two ministries in the monitoring process: the Ministry of Higher Education, Research and Innovation (<i>Ministère de l'Enseignement Supérieur, de la Recherche et de l'Innovation</i>) and the Ministry of Ecological Transition (<i>Ministère de la Transition Écologique</i>).

Moreover, there is a possibility to determine specific moments to control compliance with the corresponding laws. The European Union, for instance, established two potential control opportunities: (a) granting research funds; and (2) the final product development phase.

Considering that the Ministry of Environment already centralizes matters regarding access to genetic resources and associated traditional knowledge through the Genetic Heritage Management Council (CGen, *Conselho de Gestão do Patrimônio Genético*), it is recommended to use the ministry's own structure as a checkpoint through existing departments or by creating new ones. Controls can be achieved using a purpose-built, seamless system, allowing users to report the regular use of exotic genetic resources providing the minimum information on access as per the Nagoya Protocol, detailed in the list presented in item 6.3.

6.3 DUE DILIGENCE AND INTERNATIONALLY RECOGNIZED CERTIFICATE OF COMPLIANCE

As with other member nations, Brazil must adopt effective, proportionate measures to ensure genetic resources or associated traditional knowledge have been accessed in Brazilian territory as per the other party's laws or ABS regulations. For instance, in case PIC and MAT are covered in these rules, Brazil must ensure users comply with these obligations.

Due to the high number of accesses to genetic resources and ATK for R&D purposes, a purpose-built monitoring system for each access would make these activities unfeasible because of the high investments in human resources and the ineffectiveness of the process, particularly when considering the development of products that access genetic resources of many different species.

Considering these points and the EU's experience, a monitoring system would be the most appropriate as it would be founded upon due diligence and the issuance of an International Compliance Certificate for more specific cases. It should be stressed that it is possible to establish specific stages to check compliance with the corresponding law, as per item 6.2.

According to the European model, companies shall implement due diligence processes to access genetic resources and associated traditional knowledge. Just as due diligence processes are commonly used when contracting suppliers and third-party intermediaries to mitigate the risks of corruption, the company shall establish an internal process to archive information of the genetic resources being used.

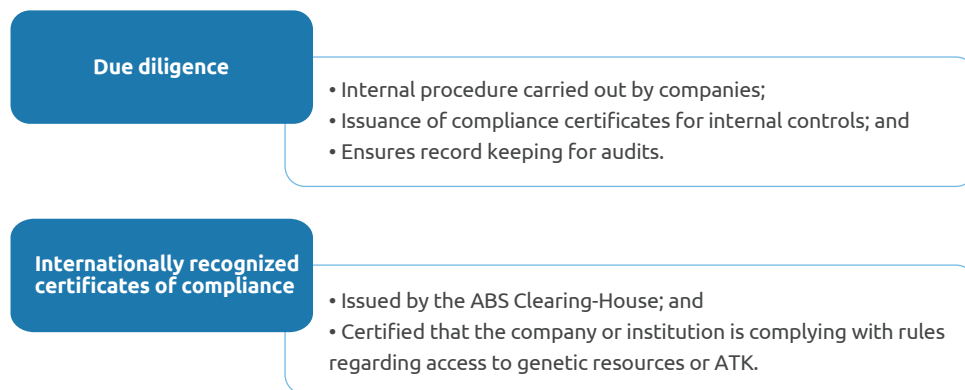
As a means to ensure legal security, a law could determine the applicable elements for the due diligence process, as per the minimum information needed for the internationally recognized certificate of compliance according to article 17 of the NP.

The elements include:

- subject-matter or genetic resources covered by the certificate;
- provider;
- person or entity to whom prior informed consent was granted;
- confirmation that prior informed consent was obtained;
- confirmation that mutually agreed terms were established;
- commercial and/or non-commercial use;
- issuing authority;
- date of issuance;
- unique identifier of the certificate.

At the end of the analysis, the company may issue a compliance certificate for the access. Furthermore, the company shall also maintain archives of this data for a certain period established by law. In the EU, for example, this obligation refers to a 20-year period. Throughout this term, the government authority may carry out inspections in case it is suspected that the company or institution is accessing the resources in violation of ABS standards. An audit by sampling will be carried out at the time, during which the company or institution must present certain due diligence processes that were carried out.

FIGURE 8 – Methods to prove compliance with the Nagoya Protocol

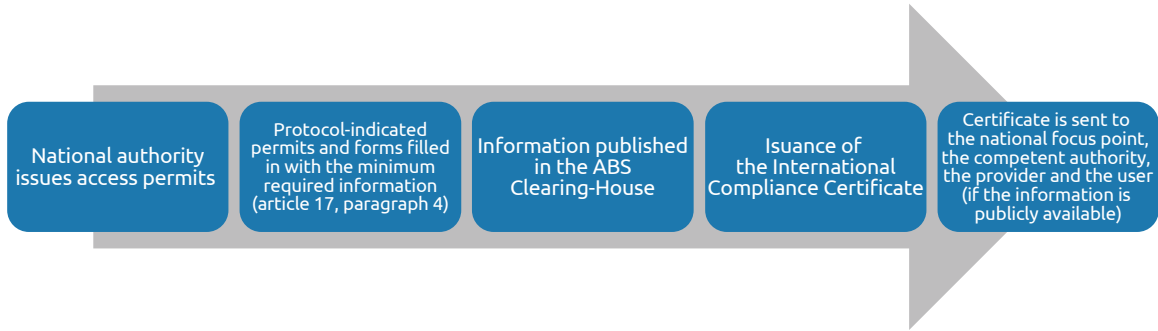


Source: Author

Regarding the international certificate, article 17 of the Protocol also establishes that the checkpoints must be responsible for receiving the International Compliance Certificate. In case the company required official evidence that the resource was accessed according to ABS standards and if it has access documentation, the company may request/obtain an international certificate for the specific resource from the ABS Clearing-House.

In the case of Brazilian genetic resources, the sole paragraph of article 4 of Decree No. 8,772/2016 already determines the issuance of an International Compliance Certificate by CGen upon the user's request, as evidence that the resources were accessed in compliance with national laws.

FIGURE 9 – Framework of how the International Compliance Certificate is issued

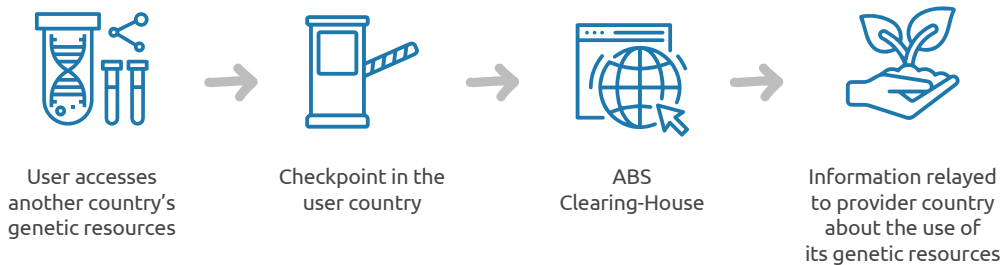


Source: Convention on Biological Diversity

Many international certificates were already published in the ABS Clearing-House. Presently, India, Spain, Kenya, and South Africa issued the most certificates³⁶. Moreover, if the user does not have a certificate, the user may prove compliance with ABS rules by providing the necessary information.

Another lesser known, but still extremely important aspect for implementing the Protocol and ensuring its transparency is the *checkpoint communiqué*. This mechanism allows users to become aware of how their genetic resources are being used outside their territory. The ABS Clearing-House once again bridges communications in this case. At present, Japan is the only country that implemented this mechanism. Since the country does not have a designated national authority and does not require PIC to access its resources, it is possible to conclude that the focus of implementation in Japan is on monitoring access to foreign genetic resources.

FIGURE 10 – Checkpoint communiqué framework.



Source: Author

36 *ABS Clearing-House: the key to a successful relationship*. Available at <https://community.abs-sustainabledevelopment.net/wp-content/uploads/2019/04/2.-ABSCH-UNDP-Istanbul.pdf>. Accessed on: September 1st, 2021.

6.4 EXCEPTIONS

It is recommended that internal laws establish situations in which the treaty shall not be applicable due to other, more specific rules. Inspired by EU Regulation 511/2014, situations in which it is suggested not to apply the Protocol include:

1. Human genetic resources;
2. Genetic resources to which the International Treaty on Plant Genetic Resources for Food and Agriculture is applicable;
3. Cases in which ABS rules regarding the Influenza virus are applicable (Pandemic influenza preparedness framework for the sharing of influenza virus and access to vaccines and other benefits); and
4. Emergency threats to human health, fauna and flora, as determined at a national and international level (as was the case of Covid-19, caused by a new species of coronavirus).

6.5 DEFINING APPLICABLE SANCTIONS AND COMPETENT INSPECTION AUTHORITIES

As part of the system to monitor the Protocol, article 17, item 1(a)(ii) outlines the need for members to establish appropriate, effective, proportionate measures for when ABS rules are violated. Hence, each country must determine suitable sanctions to be applied by the checkpoint.

Decree No. 8,772/2016, through articles 78 to 91, establishes infractions and fines related to irregular access to genetic resources and ATK of Brazilian origin. The fine is an administrative sanction of up to BRL 10,000,000.00 (ten million Brazilian reais). Moreover, other sanctions may be applied according to the violation and circumstances, as follows:

- 1 - Warning or seizure:
 - a) of samples containing accessed genetic heritage;
 - b) of instruments used in obtaining or processing genetic heritage or associated traditional knowledge that have been accessed;
 - c) of products stemming from access to genetic heritage or associated traditional knowledge; or
 - d) products obtained from information on associated traditional knowledge;

- 2 - Temporary suspension of manufacturing or sale of the finished product or reproductive material stemming from access to the genetic resource or associated traditional knowledge until the situation rectified;
- 3 - Embargo on the specific activity related to the infraction;
- 4 - Partial or full closure of the establishment, activity or business;
- 5 - Suspension of permits or authorizations; or
- 6 - Cancellation of permits or authorizations.

The Brazilian Institute of Environment and Renewable Resources (IBAMA, *Instituto Brasileiro do Meio Ambiente e Recursos Renováveis*), Navy Command, Ministry of Agriculture, Livestock and Supplies (MAPA, *Ministério da Agricultura, Pecuária e Abastecimento*) are the competent inspection authorities.

In order to ensure Brazil complies with the obligations of the Protocol, internal laws shall also disclose what sanctions must be imposed on users of foreign genetic resources who do not comply with the country of origin's laws. At the initial stage of the implementation, since companies are still adapting to the Protocol, inspections must be primarily for educational purposes, as was the case with the Brazilian General Data Protection Law (LGPD, *Lei Geral de Proteção de Dados*, Law No. 13,709/2018). This law has been effective since September 2020, but the National Data Protection Agency (*Agência Nacional de Proteção de Dados*) only began applying fines on August 1st, 2021.

Another interesting point to consider when it comes to how the sanctions are applied lies in the implementation of an internal due diligence procedure by companies. For instance, article 5, paragraph 4 of Decree No. 8,420/2015, which regulated the anti-corruption law, refers to this specific aspect for companies that provide the existence and operation of an integrity program.

It will also be essential to determine what shall be the competent authorities in charge of exercise policing powers in these cases. The role would be similar to that of IBAMA, MAPA or Navy Command for national genetic resources and associated traditional knowledge. The inspection of the compliance with these obligations shall be bound to prior qualification of the designated entity.

Analysis of foreign laws indicates that countries have been adopting the following options to implement this subject:

Option 1	Option 2	Option 3
In the Philippines, India, France and the UK, there are two types of penalties for violating ABS rules: administrative fines and criminal sanctions ³⁷ .	South Korea applies administrative fines for light violations and criminal sanctions for severe or repeated violations ³⁸ .	Spain applies administrative fines.

National legislation must create reasonable, proportionate administrative sanctions to ensure compliance with foreign legislation. Moreover, due to legal equality, national legislation shall not establish sanctions that are more severe than those of Federal Law 13,123/2015 and Federal Decree No. 8,772/2016.

Therefore, during the initial stages of implementation of the requirements regarding compliance with foreign laws, research companies and entities will still be in the qualification and adaptation stages, so it is recommended that inspections are educational instead of punitive, allowing companies to rectify non-compliances within a certain deadline.

6.6 QUALIFICATION MECHANISMS

Public agencies acting as checkpoints for compliance with ABS rules must be prepared to receive this demand. If the Ministry of Environment's Department of Genetic Heritage or another agency designated in this ministry becomes in charge of this, for example, they will need to invest in training human resources, as these agencies do not routinely work with these subjects.

Research companies and institutions must also train employees to maintain organized archives containing all information on accessed genetic resources. Thus, workshops, lectures, training sessions and expert-conducted courses should facilitate the implementation process.

6.7 TRANSBOUNDARY RESOURCES

Brazil shares a part of its biodiversity with its neighboring countries. Thus, it is essential that clear rules are defined on how to approach the following situations:

- Transboundary genetic resources or associated traditional knowledge obtained in Brazil;

³⁷ Sirakaya, Aysegul. Balanced Options for Access and Benefit-Sharing: Stakeholder Insights on Provider Country Legislation. *Frontiers in Plant Science*. October 2019 Available at <https://www.frontiersin.org/articles/10.3389/fpls.2019.01175/full>. Accessed on: October 1st, 2021.

³⁸ Ibidem.

- Transboundary genetic resources or associated traditional knowledge found in Brazil but obtained in a different country; and
- Transboundary genetic resources or associated traditional knowledge found in Brazil but obtained in an unknown location.

No specific treatment regarding the subject in another country has been determined, most likely because there are questions on how to approach it on an international level. In order to ensure legal security to users when a subject is not solved internationally, the following alternatives may be adopted:

TABLE 7 – Alternatives for access to transboundary genetic resources and associated traditional knowledge

Status	Solution
Genetic resources or associated traditional knowledge obtained in Brazil	Law No. 13,123/2015 is the sole law applied.
Genetic resources or associated traditional knowledge found in Brazil but obtained in a different country	Laws from the country of origin are the sole laws applied.
Genetic resources or associated traditional knowledge found in Brazil but obtained in an unknown location	Option 1: no laws are applied until the subject is defined internationally, at a global or bilateral level.
	Option 2: Brazilian or foreign laws are applied at the user's discretion.

6.8 AWARENESS

Brazil must adopt measures to raise awareness on the importance of genetic resources and associated traditional knowledge, as well as other matters related to access and benefit-sharing. The Protocol even provides examples of how awareness can be raised, as seen in item 3.3 of this study.

In order to implement the NP's suggestions, Brazil could create a specific qualification program, which should provide the articulation among entities representing the business sector, traditional communities and the academic sector or to ensure growth and penetration.

6.9 INCENTIVES TO PROVIDERS AND USERS

The protocol establishes that the parties must encourage the adoption of the following practices. Hence, Brazilian law could outline the measures found in the table below:

TABLE 8 – Best practices to implement the Nagoya Protocol

Theme	Best practice
Mutually agreed terms	<ul style="list-style-type: none"> • Encourage the inclusion of dispute solution mechanisms; • Use legal resources in the judicial system and in case of disputes; and • Facilitate access to legal means and use of mechanisms related to mutual acknowledgment and execution of foreign sentences and arbitrations.
Template contract clauses	<ul style="list-style-type: none"> • Promote the development, update and use of contract clauses (in individual sectors and across many sector) for mutually agreed terms.
Purpose of the resources	<ul style="list-style-type: none"> • Encourage users and providers to direct benefits stemming from the use of genetic resources towards conservation of biological diversity and sustainable usage of its components.
Codes of conduct, guidelines and best practices	<ul style="list-style-type: none"> • Encourage the development, update and use of volunteer codes of conduct, guidelines and best practices.

6.10 DIGITAL SEQUENCE INFORMATION

At present, the CBD does not define how the Protocol is applicable regarding the use of digital sequence information. Therefore, international laws that internalize the Protocol upon international clarification must regulate this specific.



7. FINAL REMARKS

The accelerated loss of biodiversity is of the most difficult challenges being faced today. Thus, political, scientific and legal efforts from the international community are required to approach this issue. The Nagoya Protocol is one of the most recent tools created to help this task, by promoting access and benefit-sharing related to genetic resources and associated traditional knowledge, which is one of the key goals of the Convention on Biological Diversity.

The internalization of the Nagoya Protocol by Brazil requires an Executive decree and a law to monitor access to genetic resources and associated traditional knowledge from foreign countries. Since the Protocol grants ample freedom to countries, the Brazilian government should pay close attention to the best international practices. This should ensure the effective implementation of the treaty, promoting the conservation of biodiversity without forcing national players (be them industry, academic or community representatives) to deal with needless bureaucratic procedures that could hinder their competitiveness or research development efforts.

Many questions still need to be answered in international debates, as is the case of DSI, transboundary resources, migratory species and multiple accesses. As a member of the Protocol, Brazil also participates in these debates and must defend positions of natural interest during the next Conferences of Parties.

Considering the Protocol's primary obligations imposed on Brazil as a user country, potential paths to be taken by the government to implement it include:

- a) Defining checkpoints;
- b) Defining processes to monitor access to foreign genetic resources and ATKs;
- c) Defining what information companies must archive and the maximum time allowed for the government to request this information; and
- d) Defining applicable sanctions for violations.

This possible direction will allow the matter progress further at the Executive and Legislative branches and in civil society, while ensuring the interests of the national industry are aligned with the conservation of biodiversity, the sustainable use of its components and the fair and equitable benefit-sharing.



8. APPENDIX - SYSTEMATIZATION OF POSSIBILITIES AND SUGGESTIONS FOR IMPLEMENTING THE NAGOYA PROTOCOL IN BRAZIL

Aspects to be defined for implementation of the Nagoya Protocol in Brazil	Possibilities and suggestions
Identifying situations in which information on access to genetic resources and ATK shall be required	Inspections can be carried out based on the activity's risk, suspicions of irregularity or during pre-determined moments, as in the EU (Regulation No. 511/2014).
Defining checkpoints	ANVISA, CNPq and MAPA are authorities with the potential of acting as checkpoints.
Accurately identifying information that could be required during an inspection.	Similar demand to article 4, item 3 of EU Regulation 511/2014. (i) date and time of access; (ii) description of the genetic resources and associated traditional knowledge that was used; (iii) means through which the genetic resource or ATK were directly obtained, as well as subsequent users; (iv) whether there are any rights or obligations regarding access and benefits sharing; (v) access permits (as applicable); and (vi) existence of mutually agreed terms.
Defining exceptions to the Protocol	Inclusion of authorization to access the genetic material of the Covid-19 virus and other emergency calamities or public health situations, as well as human genetic resources and genetic resources for the food industry and agriculture, to which the International Seed Treaty is applied.
Defining applicable sanctions	Educational inspection so that the designated checkpoints can apply fines. Moreover, more beneficial dosimetry could be considered for companies who prove their implementation of a well-structured due diligence process.
Implementing qualification mechanisms	Development of a step-by-step guide to facilitate access to foreign species, specifying not only the procedure, but also what information companies must archive and the necessary due diligence.



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