Nagoya Protocol on Access and Benefit-Sharing

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The Nagoya Protocol advances one of the three objectives of the Convention on Biological Diversity (CBD), namely 'the fair and equitable sharing of the benefits arising from the utilization of genetic resources'. The Protocol promotes equity in the sharing of benefits from the use of genetic resources and encourages the reinvestment of benefits into the conservation and sustainable use of biodiversity and ecosystems. Binding obligations established under the Protocol aim at creating greater legal certainty and transparency as well as more equitable partnerships between users and providers of genetic resources and associated traditional knowledge. The Protocol has the potential to leverage tangible impacts in provider countries and foster sustainable development for present and future generations.

Why are we talking about access and benefit-sharing?

The entry into force of the Convention on Biological Diversity (CBD) in 1993 marks a fundamental shift in how genetic resources are considered by the international community. Prior to the CBD, free access to genetic resources had prevailed. However, developments in biotechnology since the mid-1970s made the search for new and unforeseen uses for genetic resources possible. This attracted greater attention to the value of these resources. Like many other resources in the world, genetic resources are not evenly distributed. In the early 1980s, several countries started restricting access to the genetic resources under their jurisdiction and calling for increased control over their genetic resources[1].

During the negotiations of the CBD, many developing countries wanted the value and contribution of genetic resources to be recognised and the benefits resulting from their use to be shared more fairly and equitably. The fair and equitable sharing of benefits arising out of the utilisation of genetic resources came to be one of the three objectives of the CBD, together with the conservation of biological diversity, and the sustainable use of its components. The concept aimed at re-directing benefit flows back to countries providing genetic resources, while creating incentives for the conservation and sustainable use of biological diversity.

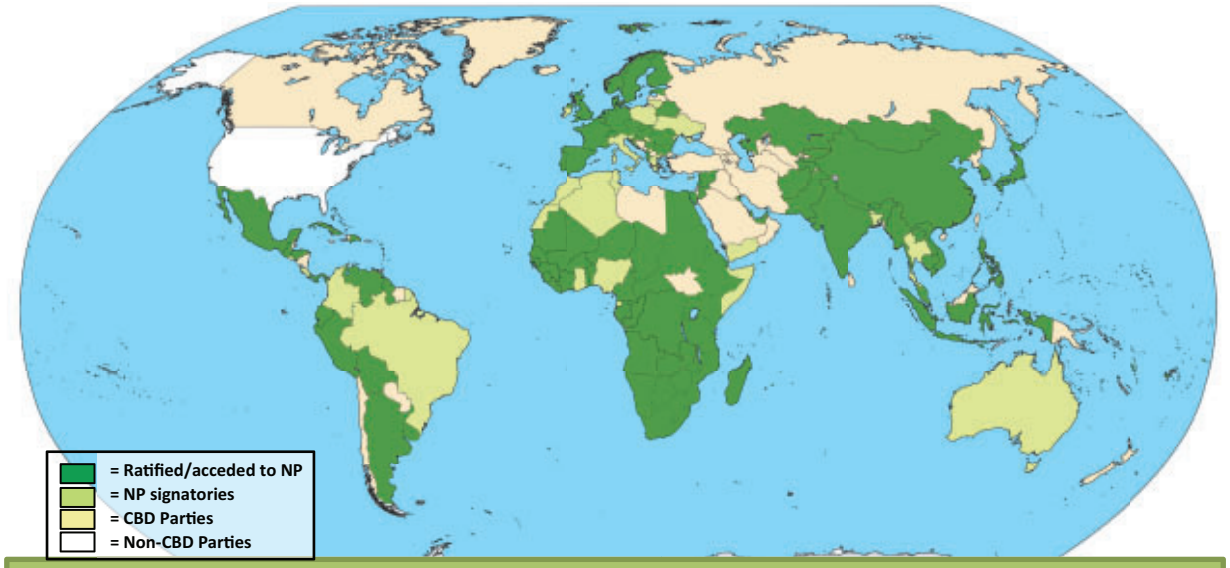
What are the access and benefit-sharing principles of the CBD?

The CBD established the concept of access and benefit-sharing (ABS), which refers to how genetic resources may be accessed, and how the benefits resulting from their use are shared between the people, institutions or countries using the resources (users) and the people or countries that provide them (providers)[2].

Using genetic resources, whether from plants, animals or micro-organisms, refers to the process of researching their beneficial properties and using them to increase scientific knowledge and understanding, or to develop commercial products. Users of genetic resources are required to obtain permission, the prior informed consent (PIC), of the country providing access to the genetic resource and negotiating and agreeing on the terms and conditions of access and utilisation of this resource through the establishment of mutually agreed terms (MAT). This agreement is also to address the sharing of benefits arising from the utilisation of the resource.

Why is the Nagoya Protocol important?

Access to genetic resources can lead to benefits for both users and providers. ABS ensures that the way in which genetic resources, and associated traditional knowledge, are accessed and used,



119 Countries that of July 2019 have ratified/acceded to the Nagoya Protocol: Afghanistan, Albania, Angola, Antigua and Barbuda, Argentina, Austria, Belarus, Belgium, Benin, Bhutan, Bolivia, Botswana, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Central African Republic, Chad, China, Comoros, Congo, Côte D'Ivoire, Croatia, Cuba, Czech Republic, Democratic Republic of the Congo, Denmark, Djibouti, Dominican Republic, Ecuador, Egypt, Eritrea, Estonia, Eswatini (Kingdom of), Ethiopia, European Union, Fiji, Finland, France, Gabon, Gambia, Germany, Guatemala, Guinea, Guinea Bissau, Guyana, Honduras, Hungary, India, Indonesia, Japan, Jordan, Kazakhstan, Kenya, Kuwait, Kyrgyzstan, Lao PDR, Lebanon, Lesotho, Liberia, Luxembourg, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Marshall Islands, Mauritania, Mauritius, Mexico, the Federated States of Micronesia, Mongolia, Mozambique, Myanmar, Namibia, Nepal, Netherlands, Niger, Norway, Pakistan, Palau, Panama, Peru, Philippines, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Rwanda, Saint Kitts and Nevis, Samoa, Sao Tome and Principe, Senegal, Serbia, Seychelles, Sierra Leone, Slovakia, South Africa, Spain, Sudan, Sweden, Switzerland, the Syrian Arab Republic, Tajikistan, Togo, Tuvalu, Uganda, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, Uruguay, Vanuatu, Venezuela (Bolivarian Republic of), Viet Nam, Zambia and Zimbabwe

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Figure 1. World map of ratifications/accessions to the Nagoya Protocol.

maximises the benefits for users, providers and the communities where those resources are found.

In 2010, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation was adopted as a supplementary agreement to the Convention to advance its third objective, building on the provisions of the CBD.

The Nagoya Protocol establishes an international, legally binding framework to promote the transparent and effective implementation of access and benefit-sharing at the national level. The Protocol helps establishing more predictable conditions for access to genetic resources while also helping to ensure benefit-sharing when genetic resources leave the country providing the genetic resources. Thus, the Nagoya Protocol helps to create trust between users and providers of genetic resources by providing a clear transparent framework for access and benefit-sharing and further legal certainty.

The Nagoya Protocol entered into force in October 2014, after ratification by 50 countries. As of 9 July 2019, 119 Parties [once a country ratifies an intergovernmental treaty, they become a Party to the treaty] to the CBD had ratified the Protocol (Figure 1)[3]. The Protocol receives broad support from both developed and developing countries in different regions. Ratification of the Nagoya Protocol enables countries to shape future priorities and guidance for the implementation of the Nagoya Protocol and also helps to build trust between users and providers.

What does the Nagoya Protocol provide for?

The Nagoya Protocol covers genetic resources, including microorganisms, plants, and animals, as well as traditional knowledge associated with genetic resources. It sets out a new regime with core obligations for its contracting Parties to take measures in relation to access, benefit-sharing and compliance. The compliance obligations are one of the main innovations of the Protocol. The Protocol also establishes an ABS Clearing-House to facilitate the exchange of information.

Access

Access to genetic resources is subject to the PIC of the provider country unless otherwise determined by that country. Parties that require PIC must establish clear and transparent procedures for accessing genetic resources and are to issue a permit when access is granted. The Protocol also regulates access to genetic resources for their utilisation. The term 'utilisation of genetic resources' is defined to mean 'to conduct research and development on the genetic and/or biochemical composition of genetic resources,

including through the application of biotechnology as defined in Article 2 of the Convention'[4].

Benefit-sharing

Under the Nagoya Protocol, benefits arising from the utilisation of genetic resources as well as subsequent applications and commercialisation are to be shared in a fair and equitable way with the provider country. This sharing is upon mutually agreed terms. The benefits to be shared may be monetary or non-monetary, such as training and education, transfer of technology, or sharing of research results [the Nagoya Protocol includes an annex with an indicative list of types of benefits that can be shared].

Compliance

With a view to support benefit-sharing once genetic resources have left the provider country and are being utilised by scientific or research institutions or industries in another country, the Protocol contains obligations to support compliance with the ABS requirements of the provider country and with the contractual obligations between users and providers of genetic resources reflected in mutually agreed terms. In addition, the Protocol puts in place a system to monitor the utilisation of genetic resources, based on permits (internationally recognised certificates of compliance) and checkpoints. Parties are to establish at least one checkpoint in order to monitor the utilisation of genetic resources by users within their jurisdiction.

ABS Clearing-House

The Nagoya Protocol establishes the ABS Clearing-House as a platform for exchanging information on ABS[5]. The Clearing-House is a key tool for facilitating implementation of the Protocol. Parties must publish information on their access and benefit-sharing procedures and the permits they issue in the ABS Clearing-House, so they become internationally recognised certificates of compliance. The certificate serves as evidence that a user has accessed a genetic resource legally and in accordance with the ABS measures of the provider country [more information on internationally recognised certificates of compliance and the monitoring system established by the Protocol is available at: https://vimeo.com/263320356/513f748f8a].

How does the Nagoya Protocol address non-commercial research?

During the negotiations of the Nagoya Protocol, the scientific community expressed concerns about the impact that ABS provisions could have on non-commercial research. The Protocol requires Parties to create conditions to promote and encourage research that contributes to the first and second objective of the CBD – that is conservation and sustainable use of biological diversity[6].

What does the Nagoya Protocol mean for users of genetic resources?

The Nagoya Protocol, in order to be operational, must be implemented by Parties through national legislative, administrative and/or policy ABS measures. National ABS requirements vary from country to country due to different national priorities and circumstances. It is the countries through their national ABS measures that determine the specific application of the Nagoya Protocol in their country and define which activities are covered by their ABS legislation.

Users of genetic resources need to follow the ABS requirements of: (1) the country providing the genetic resource; and (2) the country where utilisation of the genetic resource (i.e. research and development) takes place. Users from a country that is not a Party to the Nagoya Protocol still need to comply with the legislation of the country providing the genetic resources. The most convenient way to find national information on those ABS requirements is through the country profiles on the ABS Clearing-House[7]. Consulting the relevant ABS measures can help users to understand how to comply with ABS requirements. However, many countries are in various stages of developing their legal and institutional frameworks for ABS and making that information available on the ABS Clearing-House. To find more information on the requirements that would apply to a specific case or activity, users of genetic resources are encouraged to contact the ABS national focal point or the competent national authority(ies) in a country. The contact details as well as information on each country's ABS requirements are available in the country profile page on the ABS Clearing-House.

The publication 'ABS is genetic resources for sustainable development'[8] provides some specific examples of biodiscoveries as well as ABS measures and approaches in 27 countries

Conflicts of interest

The authors declare no conflicts of interest.

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Biographies

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Brazil, example of a non-Nagoya Protocol country

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Brazil was one of the first countries to regulate access to genetic resources, and to associate traditional knowledge and benefit sharing through Provisional Act 2186-16 of 23 August 2001 for purposes of scientific research, bioprospecting, and technological development. After almost 15 years of many criticisms and demands from civil society and other sectors, Law 13,123 was sanctioned on 20 May 2015[1] and entered into force on 17 November 2015, revoking Provisional Act 2.186.

The Law, known as the Biodiversity Law, regulates Article 1, Article 8(j), Article 10(c), Article 15, and Article 16, items 3 and 4 of the Convention on Biological Diversity (CBD), besides regulating part of Article 225 of the Brazilian Federal Constitution. It provides for access to genetic resource (known in Brazil as genetic heritage), for protection and access to associated traditional knowledge, and for benefit-sharing for conservation and sustainable use of biodiversity and creates the Genetic Heritage Management Council (CGen), the Brazilian National Competent Authority for ABS. Therefore, despite the fact that Brazil has not yet ratified the Nagoya Protocol (NP) on Access to Genetic Resources and the Fair and Equitable Distribution of Access and Benefit Sharing (ABS), the Law 13,123 is aligned with this international agreement.

The construction process of this new legislation was complex, considering the different interests and points of view of the various sectors of civil society, represented by academia, business sector, and holders of associated traditional knowledge, as well as those of the different ministries. The Law is regulated through Decree No. 8,772 of 11 May 2016 and to enable compliance with the legislation, the National System of Genetic Resource Management and Associated Traditional Knowledge (SisGen) was developed by the Ministry of Environment.

The Law 13,123 has a broader scope than the previous legislation and involves research, technological development, and economic exploitation of products arising from access to genetic resources (GR) and associated traditional knowledge (ATK). Due to the new definitions of GR [genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms], access to GR [research or technological development carried out on genetic heritage samples] and research [experimental or theoretical activity carried out on genetic heritage or associated traditional knowledge with the objective of building new knowledge by means of a systematic process that creates and tests hypothesis, describes and interprets fundamentals of observed phenomena and facts], the Law includes activities such as basic research related to taxonomy, phylogeny, epidemiology, and ecology, among others, as well as the obtention of genetic sequence from GR and their use.

Brazil set a precedent when it included genetic information in the scope of its ABS legislation, taking into account that in the last two meetings of the Conference of the Parties to the CBD (COP 13 and COP 14) and of the Parties to the NP (COP-MOP 2 and COP-MOP 3) the issue of Digital Sequence Information (DSI) was discussed