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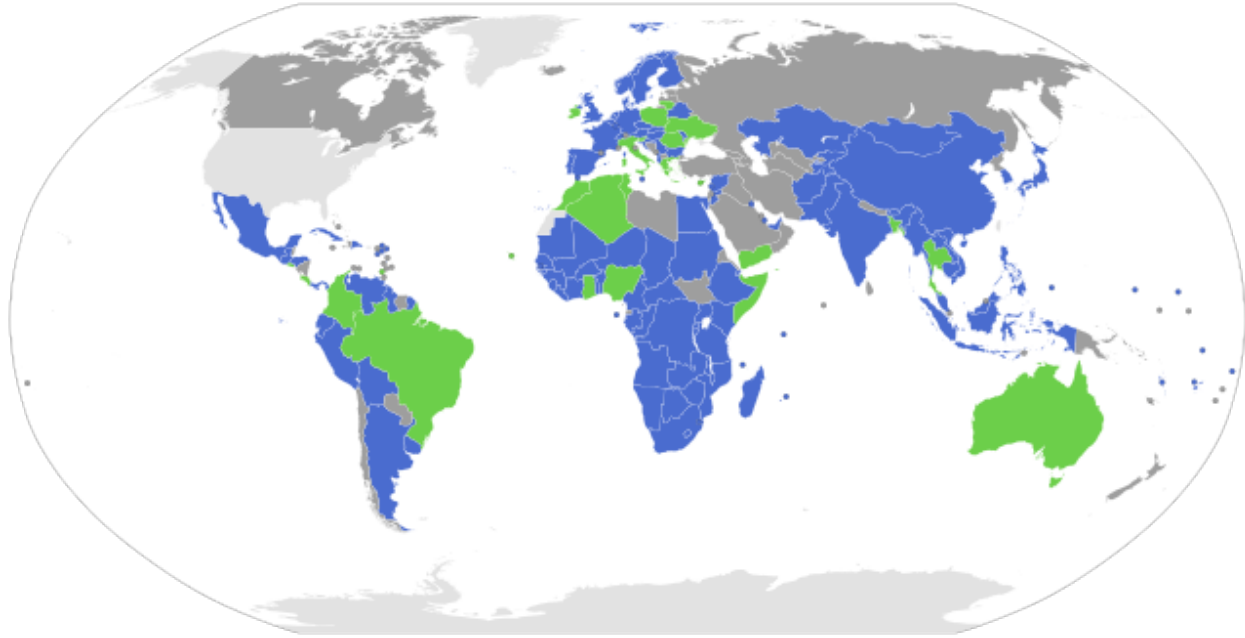
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LAW

ENVIRONMENTAL LAW II

**A REVIEW OF THE NAGOYA PROTOCOL ON ACCESS
TO GENETIC RESOURCES AND THE FAIR AND
EQUITABLE SHARING OF BENEFITS ARISING FROM
THEIR UTILIZATION TO THE CONVENTION ON
BIOLOGICAL DIVERSITY**

The **Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity**, also known as the **Nagoya Protocol on Access and Benefit Sharing (ABS)** is a 2010 supplementary agreement to the 1992 Convention on Biological Diversity (CBD). It is a multilateral environmental agreement adopted under the auspices of the Convention on Biological Diversity. It was adopted by the Conference of the Parties to the Convention of Biological Diversity at its tenth meeting on 29th October, 2010 in Nagoya, Japan. The Protocol entered into force on 12th October, 2014 which was 90 days after the fiftieth instrument of ratification was deposited with the CBD. The Protocol has been ratified by 123 parties, which includes 122 United Nations member states and the European Union.



- parties
- signed, but not ratified
- non signatory, but **Biological Diversity Convention party**
- non signatory, **non-Biological Diversity Convention party**

The objective of the Nagoya Protocol is for the benefits arising from the utilization of genetic resources and associated traditional knowledge to be shared fairly and equitably with the providers and holders of said resources and knowledge, so as to contribute to the conservation and sustainable use of biodiversity. The Protocol thus reinforces and supports the three objectives of the CBD which are:

- a. The **conservation** of biodiversity
- b. The **sustainable** use of the components of biodiversity
- c. The **fair and equitable sharing of benefits** arising out of the utilization of benefits arising out of the utilization of genetic resources

Its aim is the implementation of the third objective of the CBD: **the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity.** The term 'genetic resource' is not directly defined in the Nagoya Protocol. However, based on the definition in the CBD, genetic resource means any material of plant, animal, microbial or other origin that contains functional units of heredity (i.e. genes) and is of actual or potential value. The Nagoya Protocol does not apply to human genetic resources. Under the Nagoya Protocol, utilization

means any research and development carried out on the genetic and/or biochemical compositions of genetic resources. Utilization does not include the direct use of genetic resources to produce commodities such as oils, fragrances, and extracts. Some examples of utilization are:

- Research to identify active compounds for the development of medicines, cosmetics, agricultural chemicals;
- Taxonomic research for the identification of new species;
- Genetic modification.

The Nagoya Protocol gives provider countries the rights to control access to genetic resources found within their jurisdiction. The aim of this is to re-establish a provider country's control over these resources. There are 2 categories of provider country:

1. An originating country where the genetic resource exists in situ, i.e. a country in which the genetic resource exists in its natural habitat.
2. An originating country where the genetic resource exists ex situ, i.e. a country in which the genetic resource exists outside of its natural habitat. A country falling within this category must have obtained the genetic resource from an originating country under the CBD.

The Nagoya Protocol is a landmark agreement in the international governance of biodiversity and is relevant for a variety of commercial and non-commercial sectors involved in the use and exchange of genetic resources. The Nagoya Protocol is based on the fundamental principles of access and benefit-sharing enshrined in the CBD. These principles are based on potential users of genetic resources obtaining the **prior informed consent** (PIC) of the country in which the genetic resource is located before accessing the resources, and negotiating and agreeing on the terms and conditions of access and use of this resource through the establishment of **mutually agreed terms** (MAT).

The Nagoya Protocol applies to genetic resources that are covered by the CBD, and to the benefits arising from their utilization. The protocol also covers traditional knowledge associated with genetic resources that are covered by the CBD and the benefits arising from its utilization. The Nagoya Protocol sets out obligations for its contracting parties to take measures in relation to access to genetic resources, benefit-sharing and compliance. Under the access obligations, domestic-level access measures aim to:

- a. Create legal certainty, clarity, and transparency
- b. Provide fair and non-arbitrary rules and procedures for access to their genetic resources
- c. Establish clear rules and procedures for prior informed consent and mutually agreed terms
- d. Provide for issuance of a permit or equivalent when access is granted
- e. Consider the importance of genetic resources for food and agriculture for food security, e.t.c.

As regards the benefit-sharing obligations, domestic-level benefit-sharing measures aim to provide for the fair and equitable sharing of benefits arising from the utilization of genetic resources with the contracting party providing genetic resources. Utilization includes research and development on the genetic or biochemical composition of genetic resources, as well as subsequent applications and commercialization. Sharing is subject to mutually agreed terms. Benefits may be monetary (eg. royalties or licence fees), but they may also be non-monetary. Examples of non-monetary benefits include training and education, cooperation in research and development, transfers of technology, access to scientific information, joint ownerships of intellectual property rights, and preferential access to products developed from genetic resources.

Specific obligations to support compliance with the domestic legislation or regulatory requirements of the contracting party providing genetic resources, and contractual obligations reflected in mutually agreed terms, are a significant innovation of the Nagoya Protocol. Contracting parties are to:

- a. Take measures providing that genetic resources utilized within their jurisdiction have been accessed in accordance with prior informed consent, and that mutually agreed terms have been established, as required by another contracting party
- b. Cooperate in cases of alleged violation of another contracting party's requirements
- c. Encourage contractual provisions on dispute resolution in mutually agreed terms
- d. Ensure an opportunity is available to seek recourse under their legal systems when dispute arises from mutually agreed terms.
- e. Monitor the use of genetic resources after they leave a country by designating effective checkpoints at every stage of the value-chain: research, development, innovation, pre-commercialization , or commercialization, e.t.c

Article 1 of the Protocol sets out its objective which is to ensure the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components. Its scope as set out under Article 3 covers genetic resources and the benefits arising from the utilization of such resources. It also provides that the Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

Article 8 provides concessions for developing countries in the development and implementation of their access and benefit-sharing legislation or regulatory requirements, by mandating parties among other things, to create conditions to promote and encourage research, which contributes to the conservation and sustainable use of biological diversity in developing countries, pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, and also take into consideration the need for expedited access and

fair and equitable sharing of genetic resources. Also, under Article 8, parties shall consider the importance of genetic resources for food and agriculture and their special role for food security. Article 13 sets out the role of national governments, which includes the establishment of National Focal Points and National Authorities. In addition, Article 14 establishes an Access and Benefit-Sharing Clearing House, which is to serve as a means for sharing information. In particular; it is to provide access to information made available by each party relevant to the implementation of the Protocol.

In terms of monitoring and compliance, Article 17 provides that to support compliance, each party is to take measures, to monitor and to enhance transparency about the utilization of genetic resources. Additionally, under Article 29, parties are to monitor the implementation of their obligations under this Protocol, and shall report to the Meeting of the Parties to the Protocol on measures that they have taken to implement this Protocol. Article 30 sets out the procedures and mechanisms to promote compliance. It provides that the parties shall consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of the Protocol and to address cases of non-compliance. These procedures and mechanisms are to include provisions to offer advice or assistance.

The Nagoya Protocol addresses traditional knowledge associated with genetic resources with provisions on access, benefit-sharing and compliance. It also addresses genetic resources where indigenous and local communities have the established right to grant access to them. Parties to the Nagoya Protocol are to take measures to ensure these communities' prior informed consent, and fair and equitable benefit-sharing, keeping in mind customary laws and procedures as well as customary use and exchange of genetic resources. By setting-out clear provisions on access to traditional knowledge associated with genetic resources, the Nagoya Protocol will assist in strengthening the ability of indigenous and local communities to benefit from the use of their knowledge, innovations and practices. The Nagoya Protocol will also provide incentives for the promotion and protection of traditional knowledge by encouraging the development of community protocols, minimum requirements for mutually agreed terms and model contractual clauses related to access and benefit-sharing of traditional knowledge associated with genetic resources.

Implementation of the Nagoya Protocol is to be co-ordinated by a newly formed international body known as the Access and Benefits Sharing (ABS) Clearing House. The Nagoya Protocol's success relies on its effective implementation at the domestic level. Supporting mechanisms provided by the Nagoya Protocol will assist its contracting Parties with implementation, these include:

- The establishment of national focal points and competent national authorities to serve as contact points for obtaining information, granting access and cooperation between Parties.
- An Access and Benefit-sharing Clearing-House, which is a web based platform to share information to support the implementation of the Nagoya Protocol. Each Party to the Nagoya Protocol shall provide, for example, information on domestic ABS requirements,

on national focal points and competent national authorities, as well as make available permits or their equivalent issued at the time of access.

- Capacity-building to support key aspects of implementation. Based on a country's self assessment of national needs and priorities this can include capacity to:
 - a. Develop domestic ABS legislation to implement the Nagoya Protocol
 - b. Negotiate mutually agreed terms
 - c. Develop in-country research capacity
- Awareness-raising through promotion of the Nagoya Protocol and an exchange of experiences and information, with and among key stakeholders, including indigenous and local communities, the research community, and others.
- Technology transfer, primarily through collaboration and cooperation in technical and scientific research and development programmes, including biotechnological research.
- Targeted financial support for capacity-building and development initiatives through the Nagoya Protocol's financial mechanism, the Global Environment Facility (GEF).

The following steps are required to be taken in order to comply with the Nagoya Protocol:

1. A provider country informs the clearing house of its national provisions with regards to access and benefits sharing (ABS) information. The clearing house will keep this information up-to-date.
2. . The clearing house acts as an intermediary. If a user wishes to access a genetic resource from a provider country, the user should contact the clearing house for details of how to agree mutually agreed terms with the provider country.
3. From the information provided by the clearing house, the user contacts the relevant government department in the provider country and obtains permission for either non-commercial or commercial use (details can be made confidential and, therefore, not open to inspection by third parties). If noncommercial use is initially agreed, terms can be re-negotiated at a later date if commercialization appears likely.
4. The provider country issues to the user a national permit. Additionally, the provider country files the national permit at the clearing house.
5. An internationally recognized certificate of compliance (IRCC) is issued electronically by the clearing house. The IRCC acts as proof that the genetic resource has been accessed in accordance with the Nagoya Protocol.
6. Proof of compliance with the Nagoya Protocol must be issued when certain events are triggered. Such events include, receipt of research funding, commercialization of a product and applying for market approval in the EU. Compliance can be proved by presenting the IRCC when required.
7. Details of the triggering event are communicated by the user to the clearing house which in turn contacts the provider country to report on the progress of the research and development of their genetic resources. This step gives the provider country an opportunity to negotiate new terms in light of the recent events, e.g. a commercialization agreement if the initial agreement was only for noncommercial use.

Users of genetic resources or traditional knowledge are obliged to exercise due diligence to ascertain that:

- any genetic resources and traditional knowledge utilized by the user has been accessed from a provider country party to the Nagoya Protocol in accordance with the applicable access and benefit-sharing legislation or requirements, and
- mutually agreed terms between the user and the provider country result in fair and equitable benefits to both parties, in accordance with applicable access and benefit-sharing legislation or requirements.

The Nagoya Protocol aims to foster the provision and use of genetic resources in a fair and equitable way. It seeks to facilitate appropriate access to genetic resources by appropriate transfer of relevant technologies, in order to contribute to the conservation of biological diversity and the sustainable use of its components. The Nagoya Protocol aims at providing a legal framework that creates clarity, transparency and legal certainty for the equity relationship of the CBD. ABS can help increase knowledge of value of natural resources, create incentives for conserving biodiversity, provide conditions for research & development on genetic resources and for conservation & sustainable use of biodiversity, respect, preserve and maintain traditional knowledge associated with genetic resources.

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