

Nagoya Protocol on Access to Genetic Resources and Benefit Sharing

The Nagoya Protocol on Access to Genetic Resources is an international agreement establishing binding legal obligations relating to the access and use of genetic resources. The Protocol is supplementary to the Convention on Biological Diversity (CBD) and only applies to those States that have ratified it. The Protocol, which has been ratified by 120 countries, came into force on 12 October 2014. Contracting Parties to the CBD that have not ratified the Protocol are still bound to fulfil their access and benefit sharing obligations under the Convention (*see* Fact Sheet 14: Access to Genetic Resources under the Convention on Biological Diversity).

The Nagoya Protocol is designed to implement the third objective of the Convention: ‘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.’ The Protocol views benefit sharing, access, technology transfer, and funding as means of securing the conservation of biological diversity and the sustainable use of its components.

Scope of the Nagoya Protocol

The Nagoya Protocol applies to genetic resources derived from plants, animals, or microorganisms; traditional knowledge associated with these genetic resources; and benefits that arise from their utilisation. The Protocol also applies to the use of derivatives, defined as naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources, even if they do not contain functional units of heredity. The Nagoya Protocol does not apply to human genetic resources or genetic resources outside areas of national jurisdiction.

The Protocol does not also apply to the genetic resources covered by specialised international access and benefit sharing instruments, including pandemic influenza covered by the International Health Regulations (2005); and plant genetic resources that are covered under *Annex 1* of the International Treaty on Plant Genetic Resources for Food and Agriculture. The only exception here is that the use of these resources must be for the purpose of utilisation and conservation for research, breeding, and training for food and agriculture. If the use of these resources is for the purpose of chemical, pharmaceutical and/or other non-food/feed industrial uses, the Nagoya Protocol may apply (*see* Fact Sheet 12:

International Treaty on Plant Genetic Resources for Food and Agriculture).

Benefit sharing

Parties to the Nagoya Protocol are required to adopt domestic measures to ensure the fair and equitable benefit sharing for the utilisation of genetic resources and traditional knowledge. Benefit sharing must be based on mutually agreed terms and may be both monetary and/or non-monetary (e.g., royalties, milestone payments, access to resultant technologies, sharing of research results, and access to scientific information, including biological inventories and taxonomic studies).

The obligation for benefit sharing is triggered by the utilisation of:

- genetic resources, i.e. conducting research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology;
- derivatives;
- genetic resources over which Indigenous and local communities have established rights under national law; and/or
- traditional knowledge associated with genetic resources held by Indigenous and local communities.

Benefit sharing obligations extend to subsequent applications and commercialisation of genetic resources, derivatives, and traditional knowledge.

Any new utilisation of genetic resources, derivatives or traditional knowledge that have been accessed following the entry into force of the CBD but prior to the Nagoya Protocol entering into force may also be subject to benefit-sharing obligations. This is not clearly defined by the Protocol and users will need to pay close attention to relevant national legislation and institutional policies. Botanical gardens, part of the International Plant Exchange Network (IPEN), for example, do not differentiate between pre- and post-CBD collections. Meanwhile, European Union legislation limits benefit-sharing obligations to resources accessed after the Nagoya Protocol entered into force.

Access obligations

Parties under the Protocol are required to adopt domestic measures with a view to ensuring that access to genetic resources and knowledge is subject to prior informed consent from and mutually agreed terms with relevant providers, including:

- countries of origin or Parties who have obtained those resources in accordance with the CBD;
- Indigenous and local communities for resources and knowledge over which they have established rights.

The obligations to seek prior informed consent and to negotiate mutually agreed terms for access to and utilisation of genetic resources are set by national access legislation and other national legislative and administrative measures. They may also include relevant customary laws and protocols of Indigenous and local communities and directly applicable international legal instruments.

Compliance

The Nagoya Protocol requires Parties to adopt measures to provide that genetic resources and/or traditional knowledge used in their jurisdiction have been accessed in accordance with the domestic access legislation or regulatory requirements of the other Party. To this end, the European Union and Switzerland have both

adopted legislation requiring users of genetic resources and/or traditional knowledge to demonstrate due diligence in ensuring compliance with relevant domestic access legislation in provider countries.

The Protocol also requires Parties to:

- establish a national focal point and one or more competent national authorities to provide access permits and to ensure compliance with the Protocol;
- create a system for monitoring compliance through the designation of checkpoints at one or more stages of resource use, including: research, development, innovation, pre-commercialisation or commercialisation;
- cooperate in cases of alleged violation of relevant national law and policy;
- encourage alternative dispute resolution in access contracts; and
- provide access to justice in cases of failure to comply with obligations on access and benefit sharing.

Internationally recognised certificate of compliance

To ensure compliance with the Protocol, Parties are required to make available all access permits or their equivalent to the Access and Benefit-sharing Clearing-House. Under the Protocol, an access permit issued by a national authority and made available to the Clearing-House shall constitute an internationally recognised certificate of compliance. Such certificates are important because they serve as evidence that genetic resources were accessed based on prior informed consent and that mutually agreed terms were established in accordance with domestic access and benefit sharing laws or other relevant regulatory requirements.

When it is not confidential, the internationally recognised certificate of compliance must contain the following minimum information:

- Issuing authority;
- Date of issuance;
- The provider;
- Unique identifier of the certificate;
- The person or entity to whom prior informed consent was granted;

- Subject-matter or genetic resources covered by the certificate;
- Confirmation that mutually agreed terms were established;
- Confirmation that prior informed consent was obtained; and
- Commercial and/or non-commercial use.

This fact sheet is only for information purposes, and to assist you in understanding your legal rights and obligations in a general sense. It is not tailored to any particular fact, situation or specific requirements, and must not be relied on as legal advice.

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