

Nagoya Protocol on Access and Sharing Benefits Arising from the Utilisation of Genetic Resources

The *Nagoya Protocol to the Convention on Biological Diversity* is an international agreement establishing binding legal obligations relating to access to genetic resources and benefit sharing. The Protocol is supplementary to the Convention and only applies to those state Parties that have ratified it. The Protocol, which has been signed by more than 90 countries and ratified by more than 50 countries, came into force on the 10th of October 2014. Country Parties to the Convention that have not ratified the Protocol are still bound by obligations on access and fair and equitable benefit sharing set out in the Convention (see *Access to Genetic Resources under the Convention on Biological Diversity*, Fact Sheet Int-7).

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 a means to secure the conservation of biological diversity and the sustainable use of its components.

Scope

The Nagoya Protocol applies to utilisation of genetic resources covered by the Convention, to traditional knowledge associated with genetic resources and to the benefits arising from their utilisation. The Convention applies to genetic resources provided by countries of origin (i.e. countries which possess those resources in in-situ conditions) or by Parties who have obtained those resources in accordance with the Convention. 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, genetic resources outside areas of national jurisdiction and resources covered by specialised international access and benefit sharing instruments that do not run counter to the objectives of the Convention and the Protocol. This includes genetic resources covered by the *International Treaty for Plant Genetic Resources* (International Treaty) when utilised for the purpose of research, breeding and training for food and agriculture (Fact Sheet Int-6) and pandemic influenza covered by the *International Health Regulations (2005)*.

Benefit Sharing

Parties to the Nagoya Protocol are required to adopt measures to ensure there is fair and equitable benefit sharing for all utilisation of genetic resources and associated 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, provision of research results)

The obligation for benefit sharing is triggered by 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.
- Traditional knowledge associated with genetic resources held by Indigenous and local communities.

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

New utilisations of genetic resources accessed following the entry into force of the Convention 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 national legislation and institutional policies. Botanical gardens, part of the International Plant Exchange Network (IPEN), for example, do not differentiate between pre- and post-Convention collections. Meanwhile European Union legislation limits benefit-sharing obligations to resources accessed after the 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 is subject to prior informed consent and mutually agreed terms, with:

- Countries of origin or by Parties who have obtained those resources in accordance with the Convention.
- Indigenous and local communities for genetic resources over which they have established rights.
- Indigenous and local communities for access to traditional knowledge associated with genetic resources.

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

Multilateral Benefit Sharing Fund

The Protocol provides the possibility for the creation of a multilateral fund to provide for fair and equitable benefit sharing in relation to genetic resources and derivatives of interest to the scientific or commercial sector that may cross national boundaries and be available from a range

of sources. The concept of a multilateral fund was inspired in part by the multilateral access and benefit system set up by the International Treaty.

Compliance

The Nagoya Protocol requires states to adopt measures to support compliance with the domestic benefit-sharing legislation or regulatory requirements of the Party providing genetic resources, and/or the country in which Indigenous or local communities whose traditional knowledge has been accessed or utilised are located. To this end the European Union and Switzerland have both adopted implementing legislation requiring users of genetic resources and traditional knowledge to demonstrate due diligence in ensuring compliance with relevant domestic access legislation in provider countries.

The Protocol creates a system for monitoring compliance through checkpoints at one or more stages of resource use, including: research, development, innovation, pre-commercialisation or commercialisation. The Protocol envisions that evidence of prior informed consent and mutually agreed terms may be given by a standardised international certificate of compliance issued by relevant national authorities. The Standard Material Transfer Agreement utilised by the *International Treaty* and the *International Health Regulations (2005)* may be considered as a certificate of compliance.

Parties are obliged to 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 access and benefit sharing obligations.

To aid national implementation the Protocol calls for support for Parties to establish national focal points and competent national authorities; establishment of an international Access and Benefit-sharing Clearing-house; and capacity-building, awareness-raising and technology transfer.

Further information is available on the official CBD website at <http://www.cbd.int/abs/>.

This fact sheet was produced as part of a collaboration between the CGIAR Consortium and the Australian Centre for Intellectual Property in Agriculture (ACIPA) to research international intellectual property issues relating to agriculture.

This fact sheet is for information purposes only. It is designed to assist in general understanding of legal rights and obligations: It is not tailored to any particular fact, situation or requirements and should not be relied upon for legal advice.

Further Fact Sheets are available on the ACIPA website <http://acipa.edu.au/fact-sheets.html>.