

Introduction to the Nagoya protocol UNamur - ADRE

The Convention on Biological diversity:

- The Nagoya protocol originates from the [Convention on Biological Diversity](#) (CBD) which is a multilateral and legally binding international convention. The CBD is one of the three “Rio Conventions”, the outputs of the Rio de Janeiro Earth Summit in 1992 (the 3 conventions are the [United Nations Framework Convention on Climate Change](#), the [Convention on Biological Diversity](#) and the [United Nations Convention to Combat Desertification](#)).
- There are now 194 Parties to the CBD, including EU (and Belgium).
- The objectives of the CBD are:
 - o 1. The conservation of biological diversity;
 - o 2. The sustainable use of the components of biological diversity;
 - o 3. **The fair and equitable sharing of the benefits arising out of the utilization of genetic resources.**
- The article 15 of the CBD defines the “access to genetic resources and the benefit-sharing of their utilization”. It:
 - o Recognizes the sovereign right of states over their natural resources;
 - o Requests parties to facilitate access to genetic resources and sharing of their utilization on the basis of prior informed consent and mutually agreed terms.

The Nagoya Protocol

- The [Nagoya Protocol](#) is a complementary agreement to the Convention on Biological Diversity and aims mainly at the implementation of the third objective of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity.
- The Nagoya Protocol was adopted in 2010 in Nagoya and now comprises 124 parties (see [here](#) the signatories).
- **It entered into force on October 12, 2014 (= effective date).**
- **Objective:** *“The objective of this Protocol is 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, ..., thereby contributing to the conservation of biological diversity and the sustainable use of its components.”*
- The application of the Nagoya Protocol is based on:
 - o A **Prior Informed Consent** to access to genetic resources.
 - o Establishment of **Mutually Agreed Terms** for fair and equitable benefit-sharing.
 - o **Monitoring** of the **compliance**.

- **Definitions:**
 - “**Biological resources**” includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.
 - “**Genetic resources**” means genetic material of actual or potential value.
 - “**Genetic material**” means any material of plant, animal, microbial or other origin containing functional units of heredity.
 - “**Derivative**” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.
 - “**Utilization of genetic resources**” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.
 - “**Biotechnology**” means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
 - “**Country of origin of genetic resources**” means the country that possesses those genetic resources in in-situ conditions.
- **Scope:** The Nagoya Protocol shall apply to **genetic resources** within the scope of Article 15 (defining the access to genetic resources) of the Convention and to the benefits arising from the utilization of such resources. The Nagoya Protocol shall also apply to **traditional knowledge** associated with genetic resources.
- **Exclusions:**
 - If another specialized/specific international access and benefit-sharing instrument applies (e.g., framework of International Treaty on Plant Genetic Resources, WHO’s Pandemic Influenza Preparedness Framework).
 - Human genetic resources.

EU implementation of the Nagoya Protocol:

- **Access and Benefit-Sharing are implemented at the Member States level** and require the establishment of **Prior Informed Consent and Mutually Agreed Terms** with the country of origin of the genetic resource.
- The compliance to the Nagoya Protocol is implemented by the European Commission through two regulations:
 - Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.
 - Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices

- **Key features of EU regulation:**
 - Users have to exercise **due diligence** (= taking “reasonable measures”) to ensure that genetic resources were accessed and used in accordance with applicable legal requirements and benefits are fairly and equitably shared upon mutually agreed terms, based on applicable legal requirements.
 - Attesting of due diligence by **keeping and transferring** to subsequent users the relevant information related to the access and benefit-sharing until **20 years after end of utilization**.
 - Monitoring of compliance is done mainly at two checkpoints → filling of due diligence declarations:
 - **Funding** (public and private) of research (one due diligence per project).
 - Final stage of product development.
 - **Facilitating compliance:** Articles 5 and 8 of Regulation (EU) No 511/2014 provide for voluntary tools, namely registered collections and best practices, to assist users in complying with their due diligence obligation.
- **Geographic scope:**
 - Genetic resources coming from Parties to the Protocol.
 - **Access legislation in place** (information can be found on ABS Clearing House website <https://absch.cbd.int/> or via the provider country’s National Focal Point).
 - Areas beyond national jurisdiction are out of scope.
- **Temporal scope:**
 - Genetic resources accessed after entry into force of the Nagoya Protocol (October 12, 2014).
 - **No retroactive effect.**
 - **Time of access** and not time of utilization determines applicability.

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