Application of the Nagoya Protocol

The Nagoya Protocol applies to the use of genetic resources and traditional knowledge associated with these genetic resources (see the introductory note to the Nagoya Protocol).

What is the biological material concerned?

- **"Any material of plant, animal, microbial or other origin (but not of human origin) containing functional units of heredity"**;
- To which access was made **after October 12, 2014** (including if such access was achieved indirectly through an intermediary);
- For which access and benefit-sharing are **not governed by another specialized and recognized international instrument** (examples of treaties that could lead to an exception in point 5 of this document) ;
- Which is "**used**", in particular on which activities of "**Research and Development on the genetic and/or biochemical composition are carried out, in particular by the application of biotechnology**";
- Coming from a geographical area under national jurisdiction, of which the supplier country is a party to the Nagoya Protocol (129 countries: https://absch.cbd.int/) and has defined modalities of access to its genetic resources.

In practice?

For biological material originating from a country party to the Nagoya Protocol and for which access in that country of origin was achieved after October 12, 2014, it should therefore be determined whether:

- This country of origin has established procedures for accessing its genetic resources by referring to the site Access and Benefit-sharing Clearing House (ABS Clearing House) ;
- The use that is made of this resource falls within the scope of the Nagoya Protocol.

For the latter, there is no specific list of activities that may or may not fall within the scope of the Nagoya Protocol. Nevertheless, the guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 gives some indications on this matter.

This text specifies in particular:

> *Typically, the results of basic research are published and as such they may become the basis for further applied research with commercial relevance. Researchers involved in basic research may not necessarily be aware of it at that stage, but their findings may still turn out to have commercial relevance at a later stage.* ***Depending on the specific activity undertaken, both basic and applied research may be considered as "utilisation" in the sense of the Protocol and Regulation.*** *Similarly, various types of scientific institutions can be concerned by the Regulation.*
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> *There are nonetheless certain upstream activities which are related to (or carried out in support of) research but should not as such be considered "utilisation" in the meaning of the Regulation — e.g. the maintenance and management of a collection for conservation purposes, including*

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storage of resources or quality/phytopathology checks, and verification of material upon acceptance.

Similarly, the mere description of a genetic resource in phenotype-based research such as morphological analysis normally would also not amount to "utilisation".

However, if the description of a genetic resource is combined with research on that resource, i.e. to discover specific genetic and/or biochemical properties, this would qualify as "utilisation" in terms of the Protocol and the Regulation. *As a type of 'litmus test', users should ask themselves whether what they are doing with the genetic resources creates new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development. If this is the case, the activity goes beyond mere description, should be considered research and therefore falls under the term "utilisation".*

When the biological material meets the above conditions, the international provisions of the Nagoya Protocol apply and it is appropriate to act in accordance with Regulation (EU) No 511/2014 and its implementing regulation (2015/1866). These regulations define what users of genetic resources must do in order to comply with access and benefit-sharing (ABS) rules.

This includes:

- Prior Informed Consent: access to genetic resources must be subject to the "prior informed consent" (PIC) of the provider country, unless the latter decides otherwise.
- Benefit sharing: the use of genetic resources under the jurisdiction of a state party to the protocol must always give rise to the sharing of benefits, whatever they may be. This sharing is governed by the "mutually agreed terms of use" (MAT).

Contact :

To help you determine if your research projects fall within the scope of the Nagoya Protocol and take the necessary actions, you can contact:

At UNamur:

ADRE Legal Advisor – Benjamin Vandeberg – benjamin.vandeberg@unamur.be

The SPW Wallonie :

SPW Agriculture - Département du Développement - Direction de la Qualité et du Bien-être animal – Damien Winandy - damien.winandy@spw.wallonie.be

Webpage: S'informer sur le Protocole de Nagoya et ses obligations

The National Focal Point :

Belgium National Focal Point – Salima Kempenaer – salima.kempenaer@health.fgov.be