

Nagoya Protocol – Access and use of genetic resources

General information

What is the Nagoya Protocol about?

The Nagoya Protocol on **Access and Benefit-Sharing (ABS)** is an international agreement aimed at a fair and equitable sharing of the benefits arising out of the utilization (research and/or development) of genetic resources (and/or traditional knowledge associated with them), cf. <https://www.cbd.int/abs/>

What genetic resources are involved?

- A genetic resource is **any material of plant, animal, microbial** or other (non-human) origin that contains **functional units of heredity**, or **derivatives** of a genetic resource (e.g. enzymes, proteins, metabolites) with actual or potential value.
- **Excluded** are organisms that are the subject of special treaties (e.g. International Treaty on Plant Genetic Resources for Food and Agriculture => 35 food and 29 feed plant species e.g. wheat and other cereals, apple, strawberry, field bean, various cabbage species; however vines are not listed), and any kind of human genetic material.
- **Utilization** of genetic resources means **conducting research and/or development activities** on the genetic and/or biochemical composition of these resources or their derivatives.
- Applies to any genetic resource collected within the scope of the Nagoya Protocol as of **October 14, 2014**.

Signatory countries to the Nagoya Protocol

- 141 members, 1 ratified but not yet an official member (Costa Rica)
- Not signed by: Italy, Poland, USA, Australia, New Zealand, Russia and other countries yet national ABS regulations may apply, so please contact VF 1 to check.
- For details on the participating countries please refer to <https://absch.cbd.int/en/>

What does this mean for research?

- During the project proposal process please check whether you are within the scope of the Nagoya Protocol - see the **checklist**.
- Before acquiring a genetic resource, the user must be granted **access** obligations by the provider country (the country where the genetic resource is located in situ) in the form of a **PIC (Prior Informed Consent)**.

- Conclusion of **benefit-sharing** obligations in the form of **mutually agreed terms (MAT)**: contractual obligations between the provider country and the user of the genetic resource (**MTA - Material Transfer Agreement**):
 - **MATs** specify monetary and / or non-monetary benefit-sharing measures.
 - **MATs** regulate what can be done with the genetic resource (commercial or non-commercial research), who will be the user of this resource, for how long it will be used, whether resources can be passed on to other scientists, etc.
- If users of a genetic resource have PIC and MAT, the provider country can issue an **Internationally Recognized Certificate of Compliance (IRCC)** to prove the legality of the access and the establishment of the MATs and can decide on the publication on the ABS Clearing House website.

Further steps:

- Fill in checklist
- Contact VF1 to jointly review the necessary steps
- Create a Material Transfer Agreement (MTA) and all other necessary documents.
- File original MTA in JU, upload to FIS

What does this mean for the HGU?

- Since 2018, compliance checks have been carried out by the competent national authority of the country in which the resource is accessed and used (in Germany: Bundesamt für Naturschutz).
- VF1 checks whether users of genetic resources have fulfilled their due diligence obligations.
- Project principal investigator of the HGU is responsible for obtaining the necessary documents and their documentation:
 - Completion of the Nagoya checklist by project principal investigator
 - Project principal investigator contacts VF1 to jointly review the necessary steps
 - Project principal investigator fills out application form for MTA, followed by preparation of a Material Transfer Agreement (MTA) etc. by the legal department.
 - Signed original MTA filed in the legal department, uploaded to FIS by project principal investigator.

- Violations of EU Regulation No. 511/2014 (Regulation on measures for users to comply with the provisions of the Nagoya Protocol) constitute administrative offenses, fines of up to EUR 50,000 possible.

Further information

The **German Nagoya Protocol HuB** (HuB: Hilfe und Beratung) offers help to the academic research sector in Germany to understand the obligations arising from the implementation of the Nagoya Protocol. <https://www.nagoyaprotocol-hub.de/?lang=de>