Nagoya Protocol

on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization

Division I 1.3

What is the Nagoya Protocol?

The Nagoya Protocol is a legally binding international agreement on access to genetic resources and traditional knowledge associated with them and the fair and equitable sharing of benefits arising from their utilisation (Access and Benefit-Sharing - ABS). It is based on the Convention on Biological Diversity (CBD).

The Nagoya Protocol contains:

- international standards for national ABS legislation: in particular, requirements for prior informed consent (PIC) shall be clear and transparent;
- an obligation to negotiate mutually agreed terms (MAT) on benefit-sharing (where relevant, involving indigenous and local communities), unless otherwise determined by the provider state;
- an obligation of Parties to take measures to provide for user compliance with PIC and MAT; and
- institutional provisions, such as the establishment of an ABS Clearing-House and the obligation of Parties to designate a national focal point and one or more competent national authorities.

What is the scope of the Regulation (EU) No 511/2014 and the German Implementing Act?

Genetic resources and traditional knowledge associated with them, if

genetic resources are subject to the sovereign rights of a country
+ access takes place in a country that is Party to the Nagoya Protocol
+ this Party has regulated ABS
+ access takes place as of 12 October 2014
+ utilisation within the EU

= Scope of application of the Regulation (EU) No 511/2014 and the German Implementing Act

The Basic Regulation and the German Implementing Act do not apply, if any of the prerequisites listed above are not met.

However, existing ABS legislation of the provider country must still be upheld!

How is the Nagoya Protocol implemented within the EU and Germany?

EU:
- (Basic) Regulation (EU) No 511/2014 of 16 April 2014
- (Implementing) Regulation (EU) 2015/1866 of 13 October 2015

Germany:
- Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No 511/2014 (entry into force on 1 July 2016)

Access	Benefit-sharing	Compliance
Rules set by each respective EU Member State	Rules set by each respective EU Member State	Harmonized rules at the EU level

In-situ access to genetic resources in Germany is not tied to any ABS obligations.

What are users of genetic resources and of associated traditional knowledge obliged to do?

Due diligence obligation:
Users are obliged to act with the necessary level of care to determine whether their utilisation is legal. This is the case, if access to the resources (or traditional knowledge) took place in accordance with the relevant legal or other requirements of the provider country, and if benefits are shared fairly and equitably upon MAT. This includes a duty to carry out risk management based on three main elements:

Documentation obligation	Risk assessment obligation	Options for mitigating risks
According to the Basic Regulation documents must be: • obtained, • kept (for 20 years after utilisation has ended), • transferred to subsequent users.	In the event of insufficient information or uncertainties about the legality of access and utilisation: • PIC and MAT or equivalent documents must be obtained retrospectively, or • utilisation must be discontinued.	• Acquiring genetic ressources from registered collections as foreseen in the Basic Regulation. • Using best practices recognized in accordance with the Basic Regulation or the Nagoya Protocol.

Due diligence declaration:
In addition to exercising due diligence, the Basic Regulation also stipulates that users are obliged to make due diligence declarations at two stages of the research and development chain:

- In the phase of research funding, whether from public or private sources, a declaration is to be made after the first instalment of funding has been received and all the genetic resources have been acquired, but no later than at the project end.
- In the final phase of product development, a declaration has to be made (e.g. before market approval or authorisation is sought, or before it is placed for the first time on the market).

The content of the declarations, which have to be submitted to the competent national authority, is drawn from the Implementing Regulation.

Assistance to checks:
Users must offer all assistance necessary to facilitate checks of their compliance with due diligence and declaration obligations.

Who is responsible in Germany?

National focal point:
Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU)

Federal Ministry for the Environment, Nature Conservation and Nuclear Safety

Competent national authority:
Federal Agency for Nature Conservation (BfN)
Division I 1.3
Konstantinstr. 110
D-53179 Bonn
E-Mail: Nagoya-CNA@bfn.de
Tel: +49 (0) 228 8491-1211
Fax: +49 (0) 228 8491-1229
Web: www.abs.bfn.de

Federal Agency for Nature Conservation

Federal Office for Agriculture and Food

ROBERT KOCH INSTITUT

German Patent and Trade Mark Office

In agreement with:
Federal Office for Agriculture and Food (BLE), Robert Koch Institute (RKI)
In cooperation with:
German Patent and Trade Mark Office (DPMA)

Where to find more information?

- On ABS in GER at: www.abs.bfn.de
- On ABS worldwide at: https://absch.cbd.int