Scope of application

"Utilisation 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. The latter refers to any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use.

Utilisation only falls within the scope of Regulation (EU) No 511/2014 if

- it occurs in an EU Member State,
- the genetic resource (or the associated traditional knowledge) is subject to the sovereign rights of a state,
- that state is a Party to the Nagoya Protocol and has laid down ABS provisions, and
- the genetic resources (or the associated traditional knowledge) were accessed as of 12 October 2014.

Information on ABS in Germany and the EU can be found at:
www.abs.bfn.de

Information on ABS worldwide can be found on the ABS Clearing-House at:
https://absch.cbd.int/

Contact point

The Federal Agency for Nature Conservation (BfN) is the Competent National Authority for the implementation of the Nagoya Protocol and Regulation (EU) No 511/2014 in Germany. As such it is the first contact and consulting body for all users and for collections of genetic resources in Germany. The BfN is also responsible for

- checking user compliance with the due diligence obligation,
- receiving due diligence declarations,
- receiving and reviewing requests for inclusion in the register of collections, as well as subsequent checks of registered collections.

Contact

Federal Agency for Nature Conservation
Division I 1.3
Konstantinstr. 110
D-53179 Bonn
Email: Nagoya-CNA@bfn.de
Tel: 0228/8491-1211
Fax: 0228/8491-1229
Web: www.abs.bfn.de

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Federal Agency for Nature Conservation

Nagoya Protocol

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

Background

The basis for the Nagoya Protocol is the international legally binding Convention on Biological Diversity (CBD) which entered into force in 1993. The Convention has three main objectives:

- the conservation of biological diversity,
- the sustainable use of its components,
- the fair and equitable sharing of the benefits arising from the utilisation of genetic resources (Access and Benefit-sharing - ABS).

The Nagoya Protocol fleshes out the ABS obligations under the CBD, both for genetic resources and for the traditional knowledge associated with them. The main elements of the Nagoya Protocol are:

- international “standards” for national access regulations, in particular requirements for prior informed consent (PIC) of the provider country,
- obligation of users of genetic resources (or the associated traditional knowledge) to negotiate mutually agreed terms (MAT) on benefit-sharing with the providers and, where relevant, with indigenous and local communities,
- obligation of Parties to take measures to provide for user compliance with PIC and MAT, and
- institutional provisions such as establishing an ABS Clearing-House and the obligation of Parties to designate a national focal point and one or more competent national authorities.

Entry into force of the Nagoya Protocol and Regulation (EU) No 511/2014: 12 October 2014

Implementation

The Nagoya Protocol is implemented in the European Union through Regulation (EU) No 511/2014, which entered into force at the same time as the Nagoya Protocol on 12 October 2014. The Regulation prescribes directly binding obligations on the users of genetic resources (or associated traditional knowledge) to comply with the Nagoya Protocol. Further detailed provisions are set out in Implementing Regulation (EU) 2015/1866.

Supplementary provisions for Germany are laid down in the national Act Implementing the Obligations under the Nagoya Protocol, Transposing Regulation (EU) No 511/2014 and Amending the Patent Act.

EU Member States may decide to legislate on access to genetic resources (or to traditional knowledge associated with them) within their national jurisdiction. Germany has not introduced any provisions of this kind.

However, utilising genetic resources or their associated traditional knowledge within the EU is subject to obligations to exercise and declare due diligence and to assist compliance checks.

Obligations of users

Users of genetic resources (or the traditional knowledge associated with them) must comply with the following:

- Exercising due diligence

The provision on due diligence (Article 4 Regulation (EU) No 511/2014) prescribes risk management based on three pillars: documentation (i.e. seeking, keeping and transferring to subsequent users particular documents or information), risk reduction (e.g. by obtaining genetic resources from registered collections) and risk assessment (e.g. relating to inadequate information or uncertainties about the legality of access and utilisation).

- Declarations of due diligence

On receipt of research funding, recipients must declare that they have exercised due diligence. Another such declaration must be submitted at the final stage of product development.

- Assisting compliance checks

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