umweltbundesamt
ENVIRONMENT AGENCY AUSTRIA

INFORMATION SHEET FOR USERS OF GENETIC RESOURCES

Checklist included

Federal Ministry
Republic of Austria
Climate Action, Environment,
Energy, Mobility,
Innovation and Technology

VIENNA 2022

INFORMATION SHEET FOR USERS OF GENETIC RESOURCES

Regulation (EU) No 511/2014 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 Utilisation in the Union" (hereinafter referred to as EU ABS Regulation) has been directly applicable to all individuals in the EU since 12 October 2014.

For **users of genetic resources** and **traditional knowledge** associated with genetic resources this entails inter alia the obligation to verify if the genetic resources have been **accessed in compliance with applicable legislation or regulatory requirements** (due diligence obligation), and whether benefits arising from the utilisation of genetic resources have to be fairly and equitably shared upon mutually agreed terms.

According to Article 3 (2) of the EU ABS Regulation, the term **"genetic resources"** means genetic material of actual or potential value. **'Genetic material'**, according to Article 3 (2), means any material of plant, animal, microbial or other origin containing functional units of heredity.

According to Article 3 (4) of the EU ABS Regulation **"user"** means a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources.

According to Article 3 (5) of the EU ABS Regulation, **"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.

If there is no such utilisation, the requirements of the EU ABS Regulation do not apply in Austria and consideration of the enclosed checklist is not necessary. For example, the collection and identification, as well as the description of observed characteristics and the archiving of genetic resources do not constitute utilisation in the meaning of the EU ABS Regulation. For these activities, it is therefore not necessary to take the measures set out in the EU ABS Regulation.

The **obligations under Article 4** of the EU ABS Regulation specify, inter alia, that genetic resources have to be accessed and used in accordance with applicable access and benefit-sharing legislation or regulatory requirements and that such access and utilisation has to be documented appropriately.

Article 7 of the EU ABS Regulation requires all recipients of research funding involving the utilisation of genetic resources and traditional knowledge associated with genetic resources to submit a due diligence declaration. Such a due diligence declaration has also to be submitted at the stage of final development of a product. These **due diligence declarations at the stage of research funding or at the stage of final development of a product** demonstrate that the users have exercised due diligence in accordance with the obligations laid down

in Article 4 of the EU ABS Regulation. Article 5 of Implementing Regulation (EU) 2015/1866 provides detailed rules on the due diligence declaration.

In adopting the **Implementing Regulation (EU) 2015/1866** of 13 October 2015, the European Commission has laid down rules for the implementation of the EU ABS Regulation as regards the "register of collections", monitoring user compliance and "best practices". These rules are applicable to the utilisation of genetic resources and to any access to genetic resources that precedes their utilisation.

Annex II to the Implementing Regulation (EU) 2015/1866 provides a template for a due diligence declaration which is to be submitted through the **web tool DECLARE** (https://webgate.ec.europa.eu/declare/web/domain).

Competent National Authority

The Federal Minister for Climate Action, Environment, Energy, Mobility, Innovation and Technology is the only Competent National Authority (CNA) for Austria (Federal law Gazette I No. 36/2019).
Email: Abt-VI-9@bmk.gv.at

National Focal Point

Dr. Andrea H. Nouak
Federal Ministry Republic of Austria for Climate Action, Environment, Energy, Mobility, Innovation and Technology
Division VI/9, International Environmental Affairs
Email: andrea.nouak@bmk.gv.at

Further information

Umweltbundesamt GmbH (Environment Agency Austria)
Team Biodiversity and Nature Conservation
Email: abs@umweltbundesamt.at

Important documents and links

- Regulation (EU) 511/2014
  https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0511&from=de
- Implementing Regulation (EU) 2015/1866
  https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1866&from=EN
- Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 (2016/C 313)
  https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0827(01)&from=DE
- Austrian Federal Act (Federal Law Gazette I No. 36/2019) on the implementation of obligations under the Nagoya Protocol and under Regulation (EU) No. 511/2014
  https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20010647

- Register of Austrian laws (RIS): offers a search function, however most legislation is only available in German: https://www.ris.bka.gv.at/
- DECLARE Web Tool
  https://webgate.ec.europa.eu/declare/web/domain
- Umweltbundesamt website on Access and Benefit Sharing
  https://www.biodiv-abs.at/
- The Access and Benefit Sharing Clearing-House (ABSCH):
  https://absch.cbd.int/
- Austria´s country profile at the ABSCH:
  https://absch.cbd.int/countries/AT

CHECKLIST FOR USERS OF GENETIC RESOURCES IN AUSTRIA

1 – Determine whether Regulation (EU) 511/2014 applies (hereinafter referred to as EU ABS Regulation)

Check the following questions:

- Is the genetic resource **used in Austria**?
- Was the genetic resource (or traditional knowledge associated with the genetic resource) accessed in a country that is a Party to the Nagoya Protocol after 12 October 2014?
- Does that Party to the Nagoya Protocol have a**ccess measures on genetic resources and benefit-sharing?**

If the answer to one of these questions is **NO, no further steps are required** and the genetic resource may be utilised in compliance with the general restrictions under public and private law.

2 – Compliance with legal requirements for collections or acquisitions from third parties

Before collecting, acquiring or using a genetic resource, the legal requirements that apply to these activities in the respective country of origin have to be clarified.

Information can be found, for example, on the website of the Access and Benefit Sharing Clearing House (ABS Clearing House, https://absch.cbd.int/). Although every effort has been made to ensure that the information contained on the ABS Clearing House's website is complete, the information provided on some Parties to the Nagoya Protocol is still not sufficient. It is therefore recommended that you undertake further research on the situation in the respective Contracting Party.

To ensure compliance with the requirements of the Nagoya Protocol, the Austrian Federal Act on the implementation of obligations under the Nagoya Protocol and Regulation (EU) No. 511/2014 (Federal Law Gazette I No. 36/2019) designates the Federal Minister for Sustainability and Tourism, currently the Federal Minister for Climate Action, Environment, Energy, Mobility, Innovation and Technology as competent authority, while also laying down rules on penalties.

Collections in Austria

Austria has not established access legislation applicable to genetic resources on the Austrian territory or to issues of benefit-sharing in the course of the implementation of the Nagoya Protocol. Access to genetic resources in Austria is therefore free. However, there are general restrictions imposed by public and private law (e.g. nature conservation law, property law) that have to be complied with.

There are many Austrian statutory provisions (in agriculture, forestry, hunting, fishing, soil and nature conservation, patent law and the civil code) that contain rules on the access to genetic material and on the collection, utilisation and transport of genetic material. There are general rules on the collection of genetic material that apply in Austria, either under public law (e.g. nature conservation laws) or private law (e.g. property rights), and that have to be complied with. See also https://www.biodiv-abs.at/regelungen: "Related rules/ Themenverwandte Regelungen".

Access through third parties (collections, traders)

Access to genetic resources stored in collections created for the purpose of ex situ conservation (i.e. the conservation of species outside their natural habitat) or access through traders may be subject to the requirements or restrictions applicable in the country providing the genetic resource. This has to be checked on a case-by-case basis.

In these cases, too, care should be taken to obtain information within the meaning of the due diligence obligation prescribed in Article 4 (3) of the EU ABS Regulation.

Where genetic resources are obtained from a collection registered under Article 5 of the EU ABS Regulation, the user is considered to have exercised due diligence as regards the seeking of information. The register of collections can be accessed through the European Commission's website. It has the following address: https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Register%20of%20Collections.pdf

3 – Use of best practices

Pursuant to Article 8 of the EU ABS Regulation, best practices are recognised by the European Commission and listed in a register. These procedures can help users to comply with their due diligence obligations. If a suitable method is available, its use is recommended.

The register of recognised best practices can be accessed through the European Commission's website https://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm. It has the following address: https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Register%20of%20Best%20Practices.pdf

4 – Process documentation

For the purpose of demonstrating compliance with the due diligence obligation, the activity or process falling within the scope of the EU ABS Regulation has to be documented in accordance with Article 4 (3) of the EU ABS Regulation. The information and relevant documents have to be kept for 20 years after the end of the period of utilisation. This is part of the due diligence obligations of users.

Any additional information such as relevant correspondence should also be documented and kept, and transfers of genetic resources to subsequent users also have to be documented.

5 – Receipt of research funding

For each research funding grant received a declaration of due diligence within the meaning of Article 7 (1) of the EU ABS Regulation has to be submitted. The declaration should be made to the European Commission through the online system DECLARE (https://webgate.ec.europa.eu/declare/web/domain).

According to Article 5 (2) of the EU Implementing Regulation 2015/1866, the due diligence declaration must be submitted no later than the time of the final report, or in absence of such a report, at the project end. A template for a due diligence declaration can be found in Annex II to the EU Implementing Regulation 2015/1866 (see "Important documents and links").

6 – Development of a product

At the stage of final development of a product developed, a due diligence declaration pursuant to Article 7 (2) of the EU ABS Regulation must be submitted. The declaration should be made to the European Commission through the online system DECLARE (https://webgate.ec.europa.eu/declare/web/domain).

According to Article 6 (2) of the EU Implementing Regulation 2015/1866, the due diligence declaration has to be submitted only once, prior to the first of the following events occurring: market approval or authorisation, placing a product on the market for the first time, and transferring the result of the utilisation to another person. A template for a due diligence declaration can be found in Annex III to the EU Implementing Directive 2015/1866 (see "Important documents and links").

7- Change of use

If there is a change in the use of a genetic resource in the course of the research and development activities (e.g. development of another product based on the same genetic resource), the permits and contractual arrangements required under the Nagoya Protocol must be renegotiated and/or adjusted.

8 – Procedure in the event of ambiguities

Should there be any ambiguity regarding the lawfulness of an access to a genetic resource or its utilisation, the information and relevant documents required to demonstrate compliance with the due diligence obligation must be obtained retrospectively, or the use has to be discontinued.

Imprint

Owner and Editor: Umweltbundesamt GmbH
Spittelauer Lände 5, 1090 Vienna/Austria