NATUR VÅRDS VERKET

SWEDISH ENVIRONMENTAL PROTECTION AGENCY

The Nagoya Protocol and the EU ABS Regulation

Contents

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Working Group at the Swedish Environmental Protection Agency: Louise Bednarz, Jessica Henecke Dahl, Johan Linnander, Pernilla Åhrlin **Editor:** Erik Klefbom **Graphic Production & Illustration:** AB Typoform **Photo:** IBL Bildbyrå **ISBN:** 978-91-620-8800-2 **Print:** Arkitektkopia March 2018

Introduction

The Nagoya Protocol is an international agreement on genetic resources and associated traditional knowledge. The protocol regulates how genetic resources are collected, how they are utilised in research and product development, and how profits are distributed from this use.

The Nagoya Protocol, which is legally binding and entered into force on 12 October 2014, provides a legal framework for "fair and equitable sharing of benefits that arise from the utilisation of genetic resources". The aim is to create greater legal certainty for both the country providing the resources and their users.

Biodiversity is a global asset with enormous value for current and future generations. It is important to preserve and to conduct research on biological diversity, not only for environmental reasons, but also for economic and social values. Utilisation of genetic resources and associated traditional knowledge may provide a significant part for developing products and future applications in the health, agriculture, plant breeding and biotechnology sectors.

ABS (Access and Benefit Sharing) is a principle enshrined in both the Convention on Biological Diversity (CBD) and the Nagoya Protocol. It aims to create incentives for the protection and sustainable use of biodiversity. In this context, ABS mean a fair and equitable sharing of the benefits that arise from the utilisation of genetic resources and traditional knowledge.

GENETIC RESOURCES

Genetic resources may be plants, animals or parts thereof such as seeds, spores, sperm, as well as yeast cells, viruses and bacteria. They can be used in the development of products such as pharmaceuticals, cosmetics and biofuel. A genetic resource can also be utilised in basic research in ecology and bio-medicine.

The Convention on Biological Diversity defines genetic resources as "genetic material of actual or potential value" and "any material of plant, animal, microorganism or other origin containing functional units of heredity".

Genetic resources play an important and increasingly significant role in several economic sectors such as food production, forestry and the development of pharmaceuticals, cosmetics and bio-based energy sources. Genetic resources are also important in measures taken to restore damaged ecosystems and biodiversity.

TRADITIONAL KNOWLEDGE RELATING TO GENETIC RESOURCES

The traditional knowledge of indigenous peoples and local communities with traditional lifestyles can provide important clues leading to scientific discoveries. It includes knowledge, innovations and practices for the conservation and sustainable use of biodiversity. In many cases, this knowledge has been passed down orally through generations, and can be found in stories, legends, folklore, rituals, songs and laws.

The definition of associated traditional knowledge will depend on the ABS legislation of the provider country. Therefore, if users are uncertain whether their research includes traditional knowledge, it is important for them to contact the country from which the genetic resources and associated traditional knowledge are accessed or originated.

Glossary

User: Physical or legal person utilising genetic resources or associated traditional knowledge.

Use of genetic resources: Research and development activities related to the genetic and/or biochemical composition of genetic resources, including through the use of biotechnology as defined in Article 2 of the Convention on Biological Diversity.

Prior informed consent (PIC): Informed consent provided in advance by the provider country or indigenous peoples/local community in the provider country. Prior informed consent should be based on prior information from the user on how the genetic resources and/or associated traditional knowledge will be used and the purpose of its use. The genetic resources and/or traditional knowledge may only be accessed after prior informed consent has been given to the user.

Genetic Resources: Genetic material of actual or potential value.

Heredity: Any material from plants, animals, micro-organisms- or other sources containing functional units of genetic material.

Internationally recognised certificate of compliance (IRCC): A permit or equivalent document issued at the time of admission as proof that the genetic resources and/or associated traditional knowledge is obtained in accordance with prior informed consent (PIC) and on mutually agreed terms (MAT).

Illegally collected genetic resources: Genetic resources and associated traditional knowledge not acquired in accordance with national law or statutory requirements for access and sharing of benefits in the provider country that is party to the Nagoya Protocol.

Collection: A private or publicly owned set of collected samples of genetic resources and associated information that is compiled and stored.

User Association: An organisation established in accordance with the requirements of the Member State in which it is located, and which represents the interests of users, and which participates in developing and monitoring the best practices referred to in Article 8 of the Implementing Regulation (EU No 2015/1866).

Due diligence: Users must demonstrate that they have accessed the genetic resources and/or associated traditional knowledge related to genetic resources under applicable national ABS legislation in the provider country and, if necessary, entered into an agreement (MAT) to ensure fair and equitable distribution of potential benefits according with applicable legislation or statutory requirements.

Access: Acquisition of genetic resources or associated traditional knowledge of a party to the Nagoya Protocol.

Associated traditional knowledge: Traditional knowledge held by indigenous or local peoples, which is relevant to the use of genetic resources, and is described as such in the prior informed consent (PIC) and mutually agreed terms (MAT).

Mutually Agreed Terms (MAT): A contractual agreement between the country providing genetic resources, or associated traditional knowledge, and a user. This establishes special conditions for the fair and equitable sharing of the benefits arising from the utilisation of genetic resources or/and of associated traditional knowledge. The agreement may also include additional terms for such use and as well for future applications and marketing.

The ABC of the Nagoya Protocol

ACCESS

Accessing genetic resources and associated traditional knowledge according to the Nagoya Protocol means to acquire them according to national access legislation in a provider country that is a party to the Nagoya Protocol.

Countries that regulate access to their genetic resources and associated traditional knowledge must make these rules clear and transparent.

When using genetic resources and associated traditional knowledge accessed from countries with their own legislation on ABS, such as Peru, Kenya and India, the user must comply with the provisions of this legislation.

BENEFIT-SHARING

An important purpose of the Nagoya Protocol is to ensure fair and equitable sharing of the benefits arising from the utilisation of genetic resources and/or associated traditional knowledge. Therefore, mutually agreed terms (MAT) must be established in which the rights of countries with access to genetic resources and associated traditional knowledge, as well as indigenous peoples and local communities are considered in terms of the distribution of benefits. Benefits may be monetary or non-monetary, such as royalties and the sharing of research results.

COMPLIANCE

The Nagoya Protocol requires a compliance system aimed at creating greater legal certainty for users as well as those providing genetic resources and associated traditional knowledge. Therefore, in the EU there is the EU ABS Regulation (No. 511/2014). According to the regulation if the utilisation occurs in the EU, the users need to submit a **due diligence** declaration to the competent national authority in the country where the utilisation takes place. This means that users must declare that they have the required permits i.e. prior informed consent (PIC), mutual agreed terms (MAT) if required or an internationally recognised certificate (IRCC). When undertaking research or product development in Sweden, you submit a due diligence declaration to the Swedish Environmental Protection Agency (EPA). It is the responsibility of the Swedish EPA to review and check these due diligence declarations.

ABSCH (Access and Benefit-Sharing Clearing House)

The Access and Benefit-Sharing Clearing-House (ABSCH) is a digital platform and website established by the CBD Secretariat. Here you will find information about which countries are party to the Nagoya Protocol, National Focal Points (NFP), Competent National Authorities (CNA), and National Legislation (MSR). ABSCH is a important tool for both users and countries that provide genetic resources and associated traditional knowledge.

If you do not find the information you are looking for, contact the country's national focal point or the country's competent authorities for the Nagoya Protocol.

Learn more about ABSCH: **https://absch.cbd.int**

Implementation of the Nagoya Protocol and EU ABS Regulation in Sweden

Sweden is a party to the Nagoya Protocol since 7 December 2016. The Nagoya Protocol requires a compliance system and thus there is an obligation for users in the EU to submit due diligence declarations and keep and transfer the relevant information to subsequent users. The rules and conditions are set out in the EU ABS Regulation (EU No. 511/2014) which entered into force on 12 October 2014 and in the Implementing Regulation (No 2015/1866).

The EU Commission has published a horizontal guidance document which provides guidance on the provisions, scope and core obligations of the EU ABS Regulation. This horizontal guidance document is available on the Swedish Environmental Protection Agency's website on the Nagoya Protocol. The EU Commission is currently developing sector specific guidance documents for - biotechnology, pharmaceuticals, cosmetics, food and feed, plant breeding, animal breeding, biological control and biostimulants, research institutions and collections.

In Sweden there is a supplementary regulation to the EU ABS Regulation called the Swedish Ordinance on the use of genetic resources and associated traditional knowledge. It entered into force on 1 October 2016 (Regulation (SFS 2016: 858) and provide provisions and obligations in Sweden in regards to the Nagoya Protocol.

Sweden has no legislation that governs access for genetic resources and associated traditional knowledge. This means that users do not need prior informed consent (PIC) or mutually agreed terms (MAT) to use Swedish genetic resources. However, certain species are covered by other legislations e.g. the Swedish Species Protection Ordinance (2007:845) that restrict or prohibit all uses. For example, if users are to collect species from a protected area e.g. national parks, you will need permits from the county administrative boards or in some cases from the municipalities.

1993 **Convention on Biological Diversity**
2010 **The Nagoya Protocol is adopted**
2014 **The Nagoya Protocol enters into force**
2016 **Sweden becomes a party to the Nagoya Protocol**

When is the user in scope of the EU ABS Regulation?

WHO IS THE USER?

A user is a natural or legal person that utilizes genetic resources and/or associated traditional knowledge. The definition does not differentiate between different types of legal persons, organisations of different sizes or the objective of the utilisation. Therefore, the regulations are applicable to all kind of research e.g. basic research, applied research, commercial research and product development. A natural or legal person who only keeps, sends or sells genetic resources is not considered to be a user.

MATERIAL SCOPE

The EU ABS Regulation (EU No. 511/2014) applies to genetic resources e.g. biological material of plants, animals or microbial or other origins containing functional units of heredity, as well as associated traditional knowledge.

The Regulation also applies to derivatives which were acquired at the same time as the genetic resource. Derivatives are defined as naturally occurring biochemical compositions that result from the genetic expression or metabolism of biological or genetic resources, although they do not contain functional units of genetic material. Examples of these are enzymes, proteins and essential oils.

There are genetic resources which are excemt to the Nagoya Protocol and EU ABS Regulation. These are human genome, certain plant genetic material (see Appendix 1 of the International Treaty on Plant Genetic Resources, ITPGRFA), pandemic influenza virus (PIP) and genetic material collected from international waters.

GEOGRAPHICAL SCOPE

Genetic resources and associated traditional knowledge are only in scope of the protocol and regulation if they acquired in a country that is a party to the Nagoya Protocol and has ABS legislation. This legislation also needs to apply to the specific genetic resource or associated traditional knowledge that has been acquired.

The use of genetic resources and associated traditional knowledge is only covered by the EU ABS Regulation if utilisation occurs in a country in the EU. A country must exercise sovereign rights over the resources and associated traditional knowledge for them to be in scope of the Nagoya Protocol and the EU ABS Regulation. This means that materials, from for example, international waters and areas covered by the Antarctic Treaty are not affected by these rules.

TIMING

Genetic resources and associated traditional knowledge are only considered in scope of the Nagoya protocol and EU ABS regulation if they have been accessed after 12 October 2014. If access has been made earlier, the EU ABS regulation does not apply – this also applies in cases where the utilisation started after this date. It is important to note that there may be national legislation that users still need to comply with even though the acquisition was made before 12 October 2014.

Declare due diligence

The users must demonstrate that they comply with the ABS law of the provider country related to genetic resources and associated traditional knowledge. This is done in three documents:

- Prior Informed Consent (PIC)
- Mutually Agreed Terms (MAT)
- Declaration of due diligence.

The first two documents (PIC and MAT) together constitute an Internationally Recognized Certificate of Compliance (IRCC). The third document, declaration of due diligence, is the core of the EU ABS Regulation. A declaration of due diligence shows that the user has complied with the ABS legislation of the provider country.

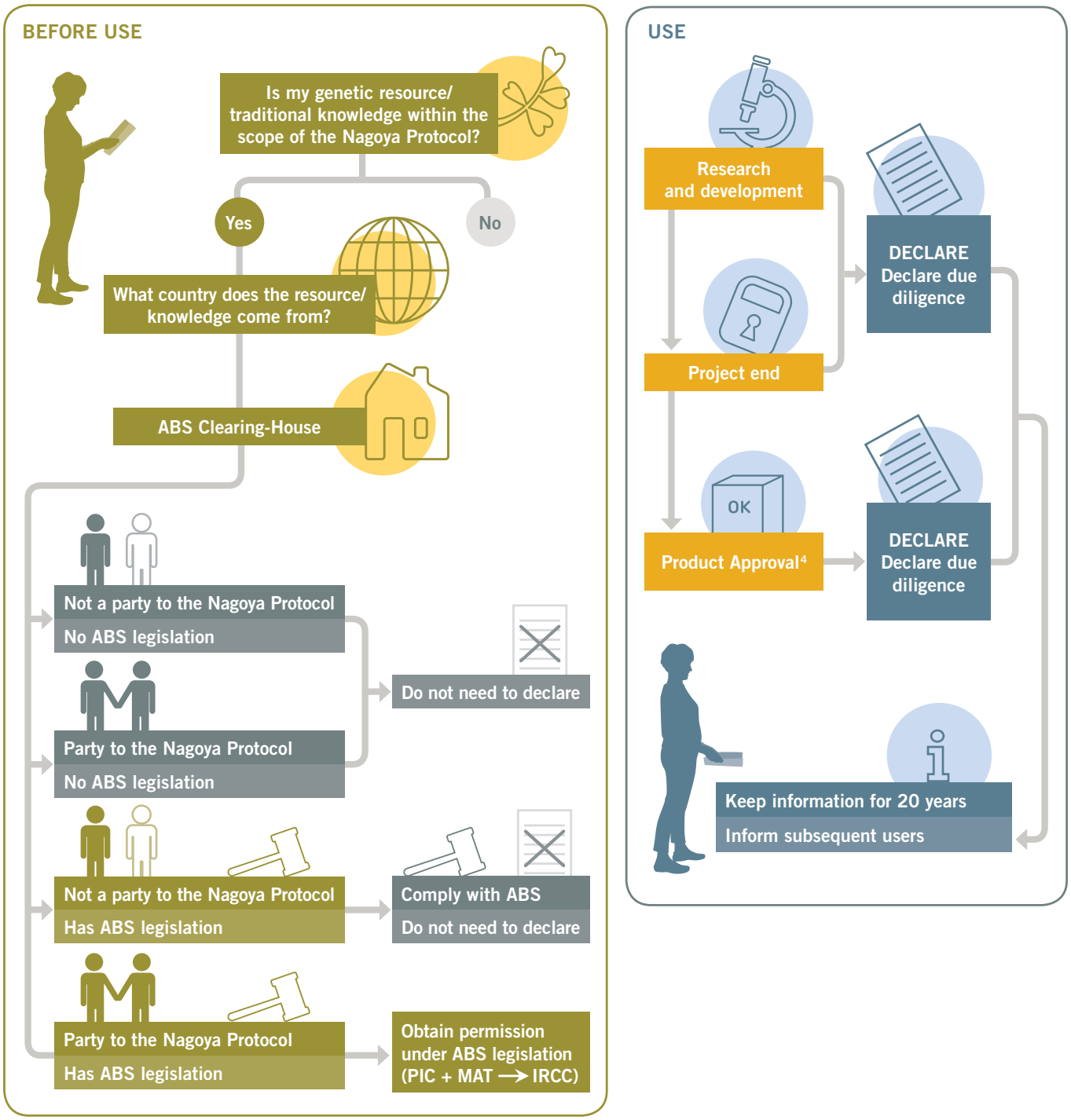
The user shall declare due diligence on two occasions:

1. After the first instalment of research funding has been received or at the latest by the end of the project or when the final report is submitted. This applies even if there is no further product development.
2. In the final stage of development of a product.

The conditions for these are set in the Implementing Regulation (EU No. 2015/1866).

In addition to declaring due diligence, information must be kept for 20 years after use, and the information must be forwarded to subsequent users.

Declaration of due diligence is made in the EU's web-based tool "DECLARE": **www.naturvardsverket.se/declare.** Note that the requirements for when/if traditional knowledge related to genetic resources should be declared differ between the EU ABS Regulation and the Swedish Ordinance on genetic resources and associated traditional knowledge (SFS 2016: 858). According to the Swedish Ordinance the user needs to declare due diligence even if the associated traditional knowledge was not accessed at the same time as the genetic resource.


BEFORE USE
Is my genetic resource/ traditional knowledge within the scope of the Nagoya Protocol?
Yes
No
What country does the resource/ knowledge come from?
ABS Clearing-House
Not a party to the Nagoya Protocol
No ABS legislation
Do not need to declare
Party to the Nagoya Protocol
No ABS legislation
Not a party to the Nagoya Protocol
Has ABS legislation
Comply with ABS
Do not need to declare
Party to the Nagoya Protocol
Has ABS legislation
Obtain permission under ABS legislation (PIC + MAT → IRCC)
USE
Research and development
DECLARE Declare due diligence
Project end
OK
Product Approval[4]
DECLARE Declare due diligence
Keep information for 20 years
Inform subsequent users

Before use

WHAT IS A GENETIC RESOURCE/TRADITIONAL KNOWLEDGE?
Determine if the subject of your research is considered as a genetic resource and/or associated traditional knowledge. Please note that there are some biological materials which are excemt from the EU ABS Regulation. Read more about genetic resources on page 4, as well as under the heading "When is the user in scope of the EU ABS Regulation?".

FIND INFORMATION ON ABSCH ON THE COUNTRY YOU WISH TO ACQUIRE FROM
Find out which rules apply in the country you plan to access your resource and/or knowledge. To do this, visit the ABSCH web site (www.absch.cbd.int). Here you will also find contact information for the competent authority that issues PIC (prior informed consent) and MAT (Mutual Agreed Terms) the provider country. Read more about ABSCH on page 7.

OBTAIN ACCESS PERMIT ACCORDING TO ACCESS LEGISLATION
Apply for prior informed consent (PIC) for access to the resource/knowledge and to establish mutually agreed terms (MAT). This is done through the competent authority of the provider country and/or the indigenous/local peoples who holds the associated traditional knowledge. These two documents (PIC and MAT) together constitute an internationally recognised certificate of compliance (IRCC). Read more about these on page 5.

During use

DECLARE DUE DILIGENCE
Declare due diligence to the Swedish Environmental Protection Agency via the "DECLARE" tool found at **www.naturvardsverket.se/declare.** This should be done after the first instalment of the research funding is received or at the latest at the end of the research stage. A declaration must also be submitted at the final stage of a product development. In Article 6 of the EU ABS Regulation it is stated when the submission should be made regarding the final stage of product development.

Registered Collections

There is a possibility for collections within the EU to become a so-called registered collection of genetic resources and associated traditional knowledge. A registered collection must meet the criteria set out in Article 5 of the EU ABS Regulation (EU No. 511/2014) and in Annex 1 of the Implementing Regulation (EU No. 2015/1866). The entirety or parts of the collection can be registered. Anyone wishing to register a collection (with material acquired after 12 October 2014) should ensure that there is data on traceability and any conditions of utilisation.

If users utilise genetic resources and/or associated traditional knowledge from a registered collection, it means that they do not need to acquire separate access permits (PIC and MAT) when genetic resources or associated knowledge of the collection is used.

This applies only when the new use of the genetic resource or knowledge is covered by the original access permits and agreements issued for the genetic resources and/or the associated traditional knowledge.

Best practices

An association of users can agree on common procedures to meet the due diligence requirements, known as best practices, and obtain approval from the EU Commission. For a best practice to be approved, the criteria set out in Annex IV of the Implementing Regulation must be met (EU No 2015/1866).

The role of the Swedish Environmental Protection Agency

The Swedish Environmental Protection Agency is the only competent authority in Sweden for the Nagoya Protocol and the EU ABS Regulation. This means it has a responsibility to review and check the due diligence of users. The Swedish Environmental Protection Agency is also responsible for verifying applications for the registration of collections and making regular checks on these. The role also includes providing advice and guidance on the use of genetic resources and associated traditional knowledge.

THE NAGOYA PROTOCOL AND THE EU ABS REGULATION

Genetic resources play an increasing role in developing and producing food, cosmetics and pharmaceuticals. This may relate to plant parts, seeds and bacteria.

The Nagoya Protocol is an international agreement that governs the use of such genetic resources and traditional knowledge linked to the resource.

This leaflet contains a brief description of the laws and regulations governing the collection and use of these genetic resources, who is considered to be a user? What is a genetic resource and associated traditional knowledge? What does it mean to declare due diligence?

The leaflet also sets out the most important steps that researchers and product developers need to take in order to meet their obligations.

NATUR VÅRDS VERKET

Swedish Environmental Protection Agency 106 48 Stockholm. Visiting address: Stockholm – Valhallavägen 195, Östersund – Forskarens väg 5 hus Ub. Tel: 010 698 10 00, Fax: 010 698 10 99, e-mail: registrar@naturvardsverket.se Internet: www.naturvardsverket.se **Orders** Ordertel: 08 505 933 40, e-mail: natur@cm.se Postal address: Arkitektkopia AB, Box 11093, 161 11 Bromma. Internet: www.naturvardsverket.se/publikationer