



MINISTRY FOR AGRICULTURE, FISHERIES,
AND ANIMAL RIGHTS

PLANT PROTECTION DIRECTORATE

User Guide

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

Introduction

Genetic resources and knowledge, innovations and practices of indigenous and local communities associated with these resources have in the past been utilized by various industries with inadequate sharing of benefit with the sovereign countries or entities providing the genetic resources or associated traditional knowledge ('provider countries'), and with insufficient legal certainty and transparency. Commitments to ensure the fair and equitable sharing of benefits arising from their utilization were foreseen in the United Nations' Convention on Biodiversity (CBD) but were never uniformly applied in concrete terms.

The concept of the access and benefit sharing began to be clarified at the international level in 1998, and guidelines for their implementation began to be drafted in 2000 by the establishment of an Ad Hoc Open-ended Working Group on Access and Benefit-sharing. This group met eleven times from 2005 to 2010 to negotiate an international regime on Access and Benefit-sharing. At its ninth meeting, the Working Group accepted a draft Protocol as the basis for further negotiations.

The group continued to negotiate on the basis of this text until its last meeting which was held on 16 October 2010, in Nagoya, Japan. The product of this meeting was the **Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (ABS)**, known colloquially as the Nagoya Protocol.

The Nagoya Protocol is a protocol to the United Nations' Convention on Biodiversity (CBD) first signed by world leaders in 2010. The European Union, as a party to the CBD, approved the Protocol on 16 May 2014; therefore enabling it to come into force on 12 October 2014.

The Nagoya Protocol is intended to put into practice the third objective of the CBD, which includes the fair and equitable sharing of benefits arising out of the utilization of genetic resources, as well as their associated traditional knowledge, thereby contributing to the conservation and sustainable use of biodiversity.

Within the EU, the Nagoya Protocol is being implemented through **Regulation (EU) no 511/2014 of the European Parliament and of the Council of 16 April 2014** (referred to as the ‘Basic Regulation’) and **Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015** (referred to as the ‘Implementing Regulation’). These two legal instruments form the basis for decisions taken at EU and member state level. The EU law has entered into force on 9 June 2014 and has applied since the 12 October 2014.

Genetic material and genetic resources

Genetic resources comprise genetic material of actual or potential value, from natural or cultivated stocks (e.g. seed banks or botanical gardens). These resources are typically used by a wide range of sectors in nature-based research and development as a basis for innovation, such as for new medicines, chemicals or cosmetics. These guidelines apply to genetic resources for which Malta has sovereign rights.

The ABS laws and their requirements do not apply to the following:

- (a) human genetic resources;
- (b) genetic resources used as bulk commodities (such as agriculture, fisheries or forestry products, whether for direct consumption or as ingredients);
- (c) genetic resources acquired prior to the entry into force of the Nagoya Protocol;
- (d) the genetic resources for which the Nagoya Protocol’s access and benefit sharing obligations are addressed by other international instruments¹;
- (e) genetic resources that Malta determines do not require Prior Informed Consent;
- (f) marine resources found in Areas Beyond National Jurisdiction (ABNJ); and
- (g) derivatives² accessed independently of genetic resources.

National implementation

The scope of the ABS is to enable the recognition of sovereign rights of states over their natural resources and give them the authority to determine access to their genetic resources or the traditional knowledge associated with genetic resources held by indigenous and local communities. The ABS law facilitates conservation of biological diversity and sustainable use of genetic resources, while providing legal certainty and transparency for both providers and users of genetic resources.

All the parties to the Nagoya Protocol are periodically required to communicate certain information to the **ABS Clearing House (ABS-CH)**, which is a platform for exchanging information on access and benefit-sharing established by Article 14(1) of the Protocol, as part of the Clearing House of the CBD established under Article 18, paragraph 3 of the Convention.

¹ The EU ABS Regulation is not applicable to genetic resources addressed by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) or the Pandemic Influenza Preparedness (PIP) Framework in those EU countries which are both parties to those specialized instruments and the Nagoya Protocol. However, the EU ABS Regulation would be applicable in such cases if the intended utilization of the genetic resource is not covered by either specialized instrument.

² According to Article 2(e) of the Nagoya Protocol a ‘derivate’ means ‘a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity’ (e.g. proteins, lipids, enzymes, nucleic acids and other organic compounds).

Malta acceded the Nagoya Protocol on 1 December 2016 and became Party to the Protocol on 1 March 2017. Malta has incorporated the EU ABS law through **Legal Notice 379 of 2016**, which was published on 15 November 2016. Under regulation 4, this legal instrument establishes the **ABS Competent Authority** which acts as the focal point between Malta, the European Commission and the ABS Clearing House.

The ABS Competent Authority is responsible for:

- Processing of applications for access to genetic resources or their associated traditional knowledge;
- Granting of access to genetic resources through **Prior Informed Consent (PIC)** following consultation with the relevant assistant authorities, where applicable;
- Drafting and negotiating **Mutually Agreed Terms (MAT)** for the access and utilization of genetic resources;
- Issuing of **Internationally Recognized Certificates Of Compliance (IRCC)**;
- Relaying information about collections and utilization of genetic resources to the European Commission and the ABS-CH in line with Articles 5(2) and 7(3) of the Basic Regulation;
- Providing advice on applicable procedures and measures relating to Malta and EU ABS laws;
- Carrying out monitoring and enforcement to ensure the correct implementation of ABS laws.

Three Assistant Authorities are established under the said legal notice to provide information to the ABS Competent Authority as well as to provide advice on the granting of Prior Informed Consent to users for access to genetic resources which fall under their remit. The Assistant Authorities support the ABS Competent Authority in the drafting of the Mutually Agreed Terms. These comprise of:

- (a) the **Environment and Resources Authority (ERA)** for wildlife, as laid down under the Environment Protection Act, with the exception of birds protected through the provisions of the Conservation of Wild Birds Regulations, 2006;
- (b) the **Wild Birds Regulation Unit (WBRU)** for birds, as laid down under the Conservation of Wild Birds Regulations, 2006;
- (c) the **Department of Fisheries and Aquaculture (DFA)**, as laid down in the Fisheries Conservation and Management Act.

An **ABS Advisory Committee** will be established under national law to examine applications for the utilization of genetic resources where technical support is required for decision making and implementation of ABS laws at national level. This Committee consists of experts or technical people from various fields, and includes a representative from each of the following entities:

- the ABS Competent Authority
- the Assistant Authorities;
- the Directorate of Environment and Climate Change;
- the Ministry responsible for the economy;
- the Medicines Authority;
- the Continental Shelf Department;
- the Veterinary Services Directorate; and
- the Ministry responsible for research and development:

The chairperson for this committee shall be appointed by the Permanent Secretary of the Ministry responsible for the environment.

Users and utilization

Within the scope of the Basic Regulation and the European Commission's guidance document 2016/C 313/01³, a 'user' is a natural or legal person accessing the genetic resource and/or associated traditional knowledge for the scope of utilization. In this context, 'utilization' means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention on Biodiversity.

Legal obligations for users

All users, irrespective of the size of the enterprise, are obliged to show **due diligence** to ensure that genetic resources which they intend to utilize have been accessed in line with the requirements of ABS laws. Best practices developed by users are important in identifying due diligence measures which are economical and in compliance with ABS legal requirements.

To facilitate interpretation by providers and users of genetic resources, in addition to the guidance document 2016/C 313/01, the EU has carried out consultations at various levels to produce a series of guidance documents for different sectors to simplify the interpretation of the different activities within the context of the term 'utilization' and indicate which type of utilization actions fall inside or outside the scope of the EU ABS law.

In order to be granted access to genetic resources over which Malta has sovereign rights or to be permitted to utilize traditional knowledge associated with genetic resources held by local communities, users are required to:

- obtain Prior Informed Consent (PIC) from the ABS Competent Authority;
- enter an agreement with the provider of genetic resources based on Mutually Agreed Terms (MAT) with the involvement of the ABS Competent Authority;
- obtain an Internationally Recognized Certificate Of Compliance (IRCC) as evidence that PIC and MAT requirements have been fulfilled;

The EU ABS law places a specific focus on the obligation by users to submit due diligence declarations to the ABS Competent Authority overseeing the access to the genetic resource or associated traditional knowledge. For this reason, a user is required to provide due diligence declarations⁴ to the ABS Competent Authority, as applicable, after the first installment of research funding has been received and in the final phase of product development, in compliance with Articles 4, 7(1) and 7(2) of the Basic Regulation and Articles 5 and 6 of the Implementing Regulation.

³ Doc. 2016/C 313/01: Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the 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.

⁴ Template due diligence declarations are defined under Annexes II and III of the Implementing Regulation.

In addition, the users are required to permit checks and verifications requested by the ABS Competent Authority. Failure to abide by due diligence requirements or the obligation to seek, keep and transfer information and documentation to subsequent users may lead to administrative penalties. In cases where inconsistencies in the user's implementation of ABS laws are identified, the ABS Competent Authority may require users to comply with remedial conditions within stipulated timeframes and may also impose administrative penalties.

Offences and penalties

Persons that are found guilty of offences or attempting to commit offences against the Legal Notice may be penalized with a fine between €800 and €4,658.75. The identification of subsequent offences may lead to higher fines between €6,000 and €10,000, or even comprise imprisonment for a period not exceeding 2 years.

Application process for access to genetic resources

The application process for access and utilization of genetic resources or their associated traditional knowledge consists of 3 major steps and 3 - 4 key players, namely: the applicant user, the genetic resource provider, the ABS Competent Authority and, possibly, one or more of the assistant authorities. If so required, the ABS Competent Authority may further be assisted by the ABS Advisory Committee.

Users requesting access to genetic resources over which Malta has sovereign rights are required to obtain Prior Informed Consent from the ABS Competent Authority. If such consent is given, in order for users to be allowed to utilize the genetic resources for which prior informed consent has been given, they must accept the terms and conditions under mutual agreement with the ABS Competent Authority. A schematic representation of this process is provided in **Figure 1** and is further explained in the following sections.

Prior informed consent (PIC)

The applicant for Prior Informed Consent must fill in and submit an application to the ABS Competent Authority at least six months prior to the intended utilization. The ABS Competent Authority will evaluate the application, and involve the Assistant Authorities to which the genetic resources are pertinent, if applicable. The PIC applications must contain information and documentation required by the relevant authorities to make an informed decision whether to grant consent.

The ABS Competent Authority may request additional information or documentation, or summon the Advisory Committee, to help it reach a decision.

At least the following documents are required:

- Curriculum Vitae of the individual(s) leading the collection of GR / aTK;
- Curriculum Vitae of the individual(s) leading the research or development;
- Detailed project description of the access and utilization activities;

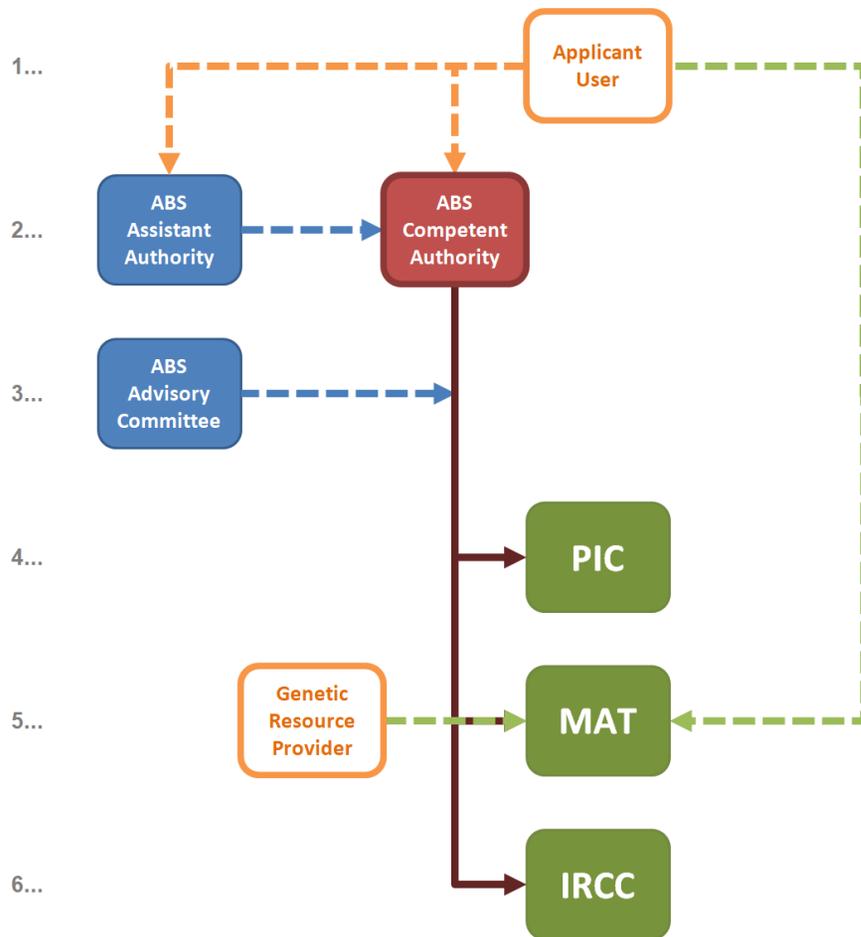
- The name of the repository of genetic resources as well as the identification codes to be assigned to the genetic resources collected, if known at time of application;
- Permission from the third party to enter and collect genetic resources from privately owned land, if applicable;
- Nature Permit from the authority managing the environment if the genetic resource is protected or to be accessed from a protected site.

Mutually agreed terms (MAT)

Once the application is approved, a permit establishing terms of access and utilization is provided, without prejudice to the requirements of other permit requirements stipulated by international and national law. The applicant is provided with a time window to renegotiate the terms of the permit if standards conditions are not agreeable. The established MAT permit should guarantee that the benefits arising from the utilization of genetic resources, as well as any subsequent application and commercialization will be shared in a fair and equitable way with Malta.

Internationally Recognized Certificate Of Compliance (IRCC)

Once the MAT are established, the ABS Competent Authority will provide the user of the genetic resources with an Internationally Recognized Certificate Of Compliance as evidence of the decision to grant prior informed consent and the establishment of mutually agreed terms with the ABS Competent Authority in line with the requirements of the Nagoya Protocol. The certificate of compliance will be available also on the Access and Benefit-Sharing Clearing House. Applicants are therefore required to indicate in advance what aspects of their project they wish to remain confidential at the international level.



1. Individuals or entities that wish to access genetic resources or their associated traditional knowledge for utilization are required to request consent from the ABS Competent Authority (ABS-CA.)

2. The ABS-CA will receive Prior Informed Consent (PIC) applications for genetic resources under their responsibility as stipulated in Subsidiary Legislation 549.111.

3. If required the ABS-CA will present the applications received to the ABS-Advisory Committee for consultation before deciding on applications for the access and utilization of genetic resources or associated traditional knowledge.

4. Prior Informed Consent may be granted to users that wish to access genetic resources relevant under the Access and Benefit Sharing framework after applications have been evaluated.

5. Access is granted through a permit based on Mutually Agreed Terms (MAT) between the user and the provider of the genetic resource or associated traditional knowledge. The user has the option to negotiate the key terms of the permit.

6. Information about the permit releases is transmitted to the ABS-Clearing House (ABS-CH) for international recognition. The certificate will constitute an Internationally Recognized Certificate of Compliance (IRCC) under the terms of the Nagoya Protocol. The user may thereafter start utilization.

Figure 1 – Process for access to Malta's genetic resources for their utilization.