USER GUIDANCE

Title: Authorisation to access and use genetic resources

Issue date: 30 September 2020

Update: N/A

Version: V1 dated 30 September 2020

Contents

Introduction

Genetic resources are protected by international agreements to which both the EU and Malta are parties. These legally binding agreements recognise that countries have sovereign rights over genetic resources on their territory and encourage them to facilitate the access to these resources "for environmentally sound uses". In addition, any benefits arising from the use of these genetic resources should be shared with the country providing these resources. This is the concept of "access and benefit sharing" (ABS).

Overview

The authorisation to access and use genetic resources is one of the functions of the Plant Protection Directorate as the competent authority for access and benefit sharing (ABS) of genetic resources.

This procedure is a means for the competent authority to implement the concept of access and benefit sharing which began to be clarified at international level in 1998, and was translated into a legally-binding international agreement through the Nagoya Protocol to the Convention on Biological Diversity (CBD) on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation. 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 utilisation of genetic resources, as well as their associated traditional knowledge, thereby contributing to the conservation and sustainable use of biodiversity.

Genetic resources and knowledge, innovations and practices of indigenous and local communities associated with these resources have in the past been utilised 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.

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.

The purpose 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.

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.

As the competent authority for the ABS, and the focal point between Malta, the European Commission and the ABS Clearing House, the Plant Protection Directorate 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 Certificates of Compliance to the ABS-CH for the establishment of Internationally

Recognised Certificates of Compliance (IRCC);
- Carrying out functions related to registers of collections under Article 5 of the Basic Regulation;
- 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.

In accordance to national law, the ABS Advisory Committee has been established to examine applications for the utilisation 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.

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 utilisation. In this context, 'utilisation' 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.

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

- Obtain Prior Informed Consent (PIC) from the Plant Protection Directorate;
- Enter an agreement with the provider of genetic resources based on Mutually Agreed Terms (MAT) with the involvement of the Directorate;
- Obtain an Internationally Recognized Certificate of Compliance (IRCC) as evidence that PIC and MAT requirements have been fulfilled.

In the context of rules and provisions governing the access of genetic resource, the aim of this service is to grant access to genetic resources or permit the use of knowledge associated with such genetic resources, for research and commercial purposes, by users.

Legal basis

- The Convention on Biological Diversity (CBD)
- The Nagoya Protocol
- 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.
- Legal Notice 379 of 2016
- The International Treaty on Genetic Resources for Food and Agriculture (ITPGRFA).

Definitions

'ABS', an acronym for "Access and Benefit-Sharing", refers to the way in which genetic resources or traditional knowledge associated with such resources is accessed and how the benefits that result from the utilisation of such resources and associated traditional knowledge are shared with the countries and/or indigenous and local communities providing them.

'Access and Benefit-sharing Clearing-House' refers to the global information portal that identifies information that Parties either must or may submit to the Clearing-House.

‘Biodiversity’ refers to the variability that exists among living organisms from all sources including among other things, terrestrial, marine and other aquatic ecosystems and the ecological complexes which they are part of. It includes diversity within species, between species and their ecosystems.

‘Competent National Authorities’ refers to domestic administrations established by governments and responsible for granting access to their genetic resources.

‘Genetic resources’ means all genetic material of actual or potential value. Essentially, the term encompasses all living organisms (plants, animals and microbes) that carry genetic material potentially useful to humans. Genetic resources can be taken from the wild, domesticated or cultivated. They are sourced from: natural environments (in situ) or human-made collections (ex situ) (e.g. botanical gardens, gene banks, seed banks and microbial culture collections).

‘Internationally recognised certificate of compliance’. Domestic access permits that are made available to the Clearing-House are recognised as "internationally recognised certificates of compliance". These certificates serve as evidence of acquisition in accordance with applicable rules.

‘Mutually Agreed Terms’ (MAT) establishes that specific benefit-sharing conditions must be "mutually agreed" between providers and users of genetic resources. Given their "mutually agreed" nature, MAT are contractual arrangements and will normally be set out in private law contracts.

‘Prior Informed Consent’ (PIC) refers to the administrative permit given by the competent national authority of a provider country to a user, prior to accessing genetic resources.

‘Providers of genetic resources’ Within the exercise of their sovereignty, states will determine who holds rights over genetic resources in their domestic legal order and who has the authority to grant access to genetic resources or traditional knowledge associated with genetic resources and who should be involved in the negotiation of mutually agreed terms with potential users etc.

‘Users of genetic resources’ refers to a diverse group, including botanical gardens, industry researchers such as pharmaceutical, agriculture and cosmetic industries, collectors and research institutes. They seek access for a wide range of purposes, from basic research to the development of new products.

Designated authority

The Genetic Resources within the Plant Protection Directorate.

Eligibility

This service is open to Users of Genetic Resources. These are individuals or entities that wish to access and use genetic resources and their derivatives as stipulated in S.L. 549.111.

Procedure of application

Application options

Application form (Genetic resources registration form) may be:

- Requested by phone by calling freephone 80072310 or number 22926535.
- Requested by e-mail on: plantprotection.mafa@gov.mt
- Collected in person from 110, Annibale Preca Street, Lija.
- Or filled on line through the eForm at servizz.gov:

Filled applications are to be submitted by post or by hand.

Any additional documents, missing information, and approvals, are to be obtained by the customer before the application can be processed further. These can be sent by email, by post, or by hand.

|| Application details

The application form for the registration of collections of genetic resources is built around basic information about the source, location and history of the target genetic resource. The quality of information required is further explained in the table below.

It is important that all information submitted in the application is up to date.

Personal details of the applicant	Applicants are required to provide personal details, contact details, and the details of the company or institution they are acting on behalf of, if applicable.
Information on genetic resources and source	This section requests information about the genetic resources or associated derivatives which are required to be accessed for utilization. 1. Species name 2. Projected quantity to be used 3. Functional Unit 4. Source locality coordinates and name
Utilisation activities of genetic resources	This section requests information on the type of utilization to be carried out on the genetic resource or associated derivative: • Research, development or both • Industry for which utilization is the objective: cosmetics, medicine, plant breeding, animal breeding, biostimulants, conservation, biological control, food/feed/beverages, others
Project description	This section requests information about the project that shall be undertaken: • Title of project; • Justification of project; • Brief project outline; • Dates of collection activity of the GR • Number of persons to be involved in the collection activity • Type of vehicles and means by which the site where the GR occurs will be accessed • Description of potential negative ecological impacts of the collection activity • Information on the intended use of the GR / aTK • Brief description of what the research and development will involve • Address of the research facility where product research will take place • Planned starting date of the research phase • Planned ending date of the research phase • Address of the development facility where product development will take place • Planned starting date of the development phase • Planned ending date of the development phase • Contact details of stakeholders involved in research or development • Role of stakeholders involved in research or development • The GR / aTK is intended to be transferred to third parties during the

	research or development • Contact details of third parties involved in research or development • Role of third parties in research or development • Budgetary value of the project • Name of the entity funding the project • Address of the entity funding the project • Funding scheme reference ID • Amount to be received in funding • Expected date of receipt of the first instalment of research funding, grant or other financial contribution • Monetary and other benefits expected to be derived from the completion of the project and commercialization • Name of the country in which the product is to be placed on the market.
Supplementary documentation	These are documents that are to be submitted with the application, including: • Copy of the Curriculum Vitae of the individual(s) leading the collection of GR / aTK • Copy of the Curriculum Vitae of the individual(s) leading the research or development • Copy of memorandum of association of the legal person • Copy of a letter by the company director authorising the applicant to act as representative of the legal person • Permission to access from privately owned land • Copy of Prior Informed Consent and Mutually Agreed Terms documentation of the preceding user, if the GR / aTK is to be transferred to the applicant • Copy of Internationally Recognized Certificates of Compliance of the preceding user, if the GR / aTK is to be transferred to the applicant • Detailed Project Description • Complementary application to an assistant authority

|| Service availability

During normal opening hours:

Summer (16th June to 30th September): 07:30 – 13:00
Winter (1st October to 15th June): 07:30 – 15:30

|| Service delivery timelines

- In cases where the application form is requested rather than downloaded, it is sent to the customer within twenty-four (24) hours, except in cases where the applicant walks in, in which case, the application form is printed and handed immediately.
- Filled-in applications received by email or post are acknowledged within twenty-four (24) hours of receipt. In the case of walk-ins, this acknowledgement is given immediately.
- On the basis of an administrative check and a technical verification, and within five (5) working days from receipt of application, the responsible official informs the customer of the outcome, as follows:
    - the application has been accepted and no further information is required; or
    - the application is on hold because it is incomplete or information/documents are missing; or
    - the use of genetic resources falls outside the scope and does not require a PIC

    - the application cannot be accepted.
- Within ten (10) working days from receipt of complete application, the responsible officer issues the permit to the user, by email.
- The user may wish to re-negotiate the benefit sharing conditions set therein. The user is entitled to twenty (20) working days after the process is initiated to reach an agreement. If agreement is not reached after this deadline, the permit is automatically terminated.
- Within twenty-four (24) hours of conclusion of this exercise, the responsible official issues the International Recognised Certificate of Compliance (IRCC) through the Access and Benefit Sharing Clearing House website.
- The User is immediately informed by email that the digital certificate has been issued, and can be printed. The responsible official also notifies the User and issues the IRCC by email.

|| Compliance requirements

The application may be submitted in original; electronic scanned signatures are also accepted, as long as they are followed by submission of the originals.

Application must be accompanied by supporting documents, whichever are applicable:

- Copy of the Curriculum Vitae of the individual(s) leading the collection of genetic resources or associated derivatives
- Copy of the Curriculum Vitae of the individual(s) leading the research or development
- Copy of memorandum of association of the legal person
- Copy of a letter by the company director authorising the applicant to act as representative of the legal person
- Permission to access from privately owned land
- Copy of Prior Informed Consent and Mutually Agreed Terms documentation of the preceding user, if the genetic resources or associated derivatives is to be transferred to the applicant
- Copy of Internationally Recognized Certificates of Compliance of the preceding user, if the genetic resources or associated derivatives is to be transferred to the applicant3
- Detailed Project Description
- Complementary application to an assistant authority

|| Other requirements

User is bound to submit annual progress reports and obligatory declarations according to permit and legislation.

IRCC Certificates are not sent by post to Users.

Related documents

Authorisation to access and use genetic resources Application Form.
User check-list for the authorisation to access and use genetic resources.