



USER GUIDANCE

Title: Registration of genetic resources

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| 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

As the competent authority for access and benefit sharing of genetic resources, the Plant Protection Directorate is duty bound to facilitate the registration of national collections of genetic resources into the EU’s register of collections.

As the national administration for the purpose of the International Treaty on Genetic Resources for Food and Agriculture (ITPGRFA), the Plant Protection Directorate is also tasked to maintain records of national genetic resources and to work towards the identification, evaluation and characterisation of useful germplasm in the context of agriculture and climate change.

For the scope of fulfilling this task, “collections of genetic resources” are loosely understood to consist of *in situ* or *ex situ* specimens or samples of a plant, animal, or other organism, of a given species, variety, breed, or similar, or its parts, as the case may be, which have conservation or agricultural or conservation value.

The registration of genetic resources is a procedure by which basic information about the source, location and history of the target genetic resource is collected. It is important that this information is as correct and up to date as possible.

Public or private entities may register their genetic resources collections in two registers:

Register A: For the registration of national collections of genetic resources from gene banks in a database which feeds into the EU's register of collections; and

Register B: For acknowledging authentic traditional genetic resources which are held by private individuals and which merit conservation under some of the measures of the Rural Development Programme.

The registration of collections of genetic resources and the maintenance of up-to-date register that reflects the state of affairs at a given point in time is an essential function in the management and conservation of genetic resources of importance in the context of agriculture and climate change.

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;
- Subsidiary Legislation 549.111;
- 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 public or private entities which function as holders of Genetic Resources.

These are gene banks, research and academic entities and professional users in possession of living collections consisting of populations of an animal breed, plant variety, or other non-human organisms that are indigenous, endemic, traditional, or relic in nature, that originated in Malta, or were naturalised before 12 October 2014 according to EU Regulation 511/2014 and S. L. 549.111.

Procedure of application

Application options

Application form (Genetic resources registration form) may be:

- Downloaded from https://www.servizz.gov.mt/en/Pages/Environment_Energy_Agriculture-andFisheries/Agriculture/Horticulture/WEB05291/default.aspx
- Requested by phone by calling freephone 80072310 or number 22926535.
- Requested by e-mail on: plantprotection@gov.mt • Collected in person from 110, Annibale Preca Street, Lija.

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.

|| 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.

Contact Information	<p>Focal points are required to reach the repository where the genetic resource is being held. Their names and other contact details should be provided to facilitate communication between the ABS competent authority and the collection holder.</p>
Genetic Resource Information	<p>This section requests information about the genetic resource which is being registered.</p> <ol style="list-style-type: none"> 1. Its common name in English and, if possible, in Maltese should be provided. 2. For ease of identification, scientific names should be provided down to the lowest category as possible (genus, species and subspecies). If this is a Maltese breed of animal, provide the breed name. If it is a Maltese landrace or cultivated variety or similar, provide the variety name. 3. If the genetic resource is one for which its natural source is Malta, the country of origin indicated in the form should be Malta. However, sometimes it may be the case that local collection holders keep collections originating from other countries, therefore such distinction should be clearly indicated. 4. The unique identifier of the collection (collection ID) given following international standards should be provided. Whether the collection is intended to provide a germplasm supply to breeders should also be indicated. 5. Information about the unique features characterizing the target genetic resource should be provided, to clearly indicate which traits make it different from other similar breeds or varieties. At least three features should be listed, if possible. 6. The genetic resources held in a repository generally form a sample of a larger population or may be the remaining few specimens of a specific breed. Different collections may each consist of a different sampling unit (e.g. individuals, seeds, buds, eggs or other tissues). The type of samples and their quantity (i.e. the sampling size) should be indicated. 7. Indicate if the collection being registered is a complete collection or only partial and belonging to a larger collection.
Repository Information	<p>The repository may be a gene bank, a farm, a conservation body, or similar entity, which is responsible for the management and conservation of the genetic resource. Its contact information is required by the competent authority to facilitate communication and management. The repository ID, which may be a FAO INSTCODE or some other internationally recognized code used to identify the repository institution, should be indicated.</p>

Breeding Entity Information	New breeds or varieties may arise as a result of breeding programmes or of continuous selection by farmers as genetic resources are passed down within families as heritage. The entity which contributed to the creation of the genetic resources can vary from a local farm to a breeding company, and it should be identified together with its contact information provided. In some instances, farms function both as repositories and breeders, therefore the repository information and the breeding entity information may be the same. The breeding entity ID , which may be a FAO INSTCODE or some other internationally recognized code used to identify the breeding institution, should be indicated.
Breeding Information	Some local genetic resources are the product of breeding programmes involving other foreign or local genetic resources. Where the recent ancestry of the target genetic resource can be identified, this should be provided, indicating the names of the parental lines (i.e. the parentage), the entity providing parents (i.e. the parental repository), the year of crossing , and the breeding method used (e.g. self-fertilisation, marker assisted back-crossing, mutation breeding, etc.)
Complementary documents for the registration of collections in the EU Register of Collections	(a) Codes of conduct, guidelines or standards, whether national or international, developed by associations or organisations, and adhered to by the collection, and information relating to the collection's instruments for the application of those codes of conduct, guidelines or standards; (b) Relevant principles, guidelines, codes of conduct or manuals of procedures, developed and applied within the collection, and any additional instruments for their
(Register B)	application; (c) Certification of the collection under relevant schemes, whether national or international; (d) Information about participation of the collection in any international collection networks, and about associated applications for inclusion in the register of collections filed by partner collections in other Member States (optional); (e) Any other relevant documentation.
Appendix	For collections involving individual tagged specimen, the applicable specimen tags may be included in the space provided.

|| 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 of request; in case of walk-ins, it is given immediately.

- An acknowledgement of receipt of application for registration is sent to customer within twenty-four (24) hours of receipt by post. In the case of walk-ins, the acknowledgement is given immediately.
- The application is vetted within five (5) working days from receipt.
- If the application is incomplete, the responsible official will request the applicant for further information or for clarifications within the same five (5) days from receipt of application. The PPD assists the applicant to provide the missing information.
- A Certificate of Registration is issued within three (3) working days of the completion of the vetting of a complete application.
- The Holder of the Genetic Resources is on the same working day, informed and asked to collect a copy of the Certificate of Registration from the offices of the PPD in Lija.
- In cases where even following consultation with other competent authorities, technical difficulties persist, e.g. the pedigree of the animals cannot be confirmed, the application is rejected, and the applicant is informed within three (3) working days of the completion of the vetting of a complete application.

|| Compliance requirements

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

Applications must include:

- the contact information;
- information on the genetic resources;
- repository information;
- breeding entity information;
- breeding information
- herd book, if applicable;
- DNA certificate or morphological characterisation by a professional expert, if applicable.

|| Other requirements

For registration of the collection in Register B, complementary documentation as proof that the collection is compliant with the requirements of Regulation (EU) 511/2014 Article 5 and Commission Implementing Regulation (EU) 2015/1866 Article 2 and Annex I.

| Related documents

Registration of Genetic Resources Application Form.
User Check-list for the registration of genetic resources.