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Biodiversity

Frequently asked questions regarding the application and authorization to access to Spanish genetic resources from wild taxa:

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1. Who must apply for an authorization to access to Spanish genetic resources from wild taxa?

Users of Spanish genetic resources from wild taxa whose activities involves the **utilization** of genetic resources. In this context, ‘**utilization 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 as defined in the Law 42/2007, of 13 December, on natural heritage and biodiversity.

The European Commission is preparing several sectorial guidance documents on the interpretation of the term utilization within the scope of the Regulation (EU) No 511/2014, which are foreseen to be published soon. It is recommended that users consider these guidelines to establish whether activities carried out with genetic resources constitute ‘utilization’, and therefore fall within the scope of this bylaw.

The bylaw 124/2017, of 24 February, regulates the access to genetics resources from wild taxa in situ, i.e. in their natural habitats, and ex situ, i.e. outside their natural habitats.

Access to the following Spanish genetics resources for their utilization does not fall in the scope of the bylaw 124/2017, of 24 February

- a) Plant genetic resources for agriculture and food regulated by the Law 30/2006, of 26 July, on seeds and plants from garden center and plant genetic resources.
- b) Fishery resources regulated by the Law 3/2001, of 26 March, on state maritime fishery.
- c) Zoogenetic resources for agriculture and food.

Additionally, access authorization is not necessary when:

- a) Users access to Spanish genetic resources for exclusively taxonomic purposes, according to the definition of ‘exclusively taxonomic purposes’ in article 2.3 of the bylaw 124/2017, of 24 February. These genetic resources may only be transferred to subsequent users under the same terms they were accessed, that is with exclusively taxonomic purposes. Otherwise, an access authorization is required.
- b) Collection and preservation of samples in germplasm banks or ex situ collections for exclusively conservation purposes.
- c) Users that carry out activities of production and commercialization of seeds and forest plants regulated by the Bylaw 289/2003, of 7 March, on commercialization of forest breeding material, as long as the use of these genetic resources does not constitute utilization and the user do not transfer them to subsequent users for different uses.

2. How to acquire an access authorization for Spanish genetic resources from wild taxa?

The Bylaw 124/2017, of 24 February, establishes proceedings and access authorizations for both the utilization for non-commercial research purposes and the utilization for commercial purposes.

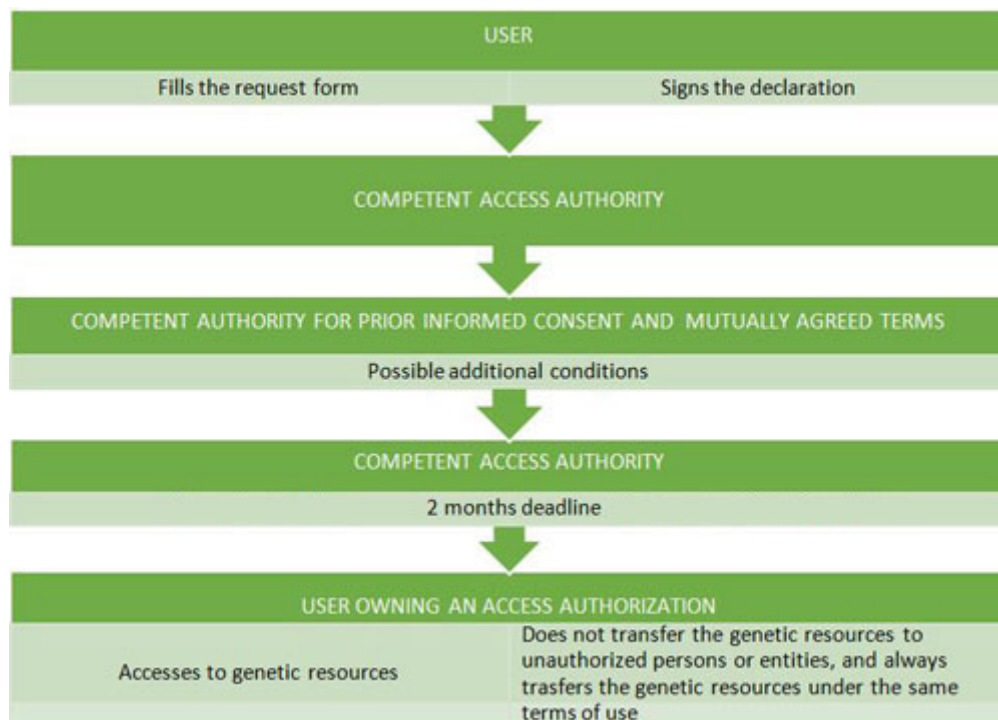
In both cases, an access authorization is required **previously to the access** to genetic resources

A) Access for the utilization for non-commercial research purposes.

The access application, together with a signed declaration by the user, will be addressed to the competent access authority (see section 1.3.).

The competent access authority will examine the access application and the user declaration, and will request the opinion of the responsible authority for providing prior informed consent and establishing mutually agreed terms who may establish conditions to the access.

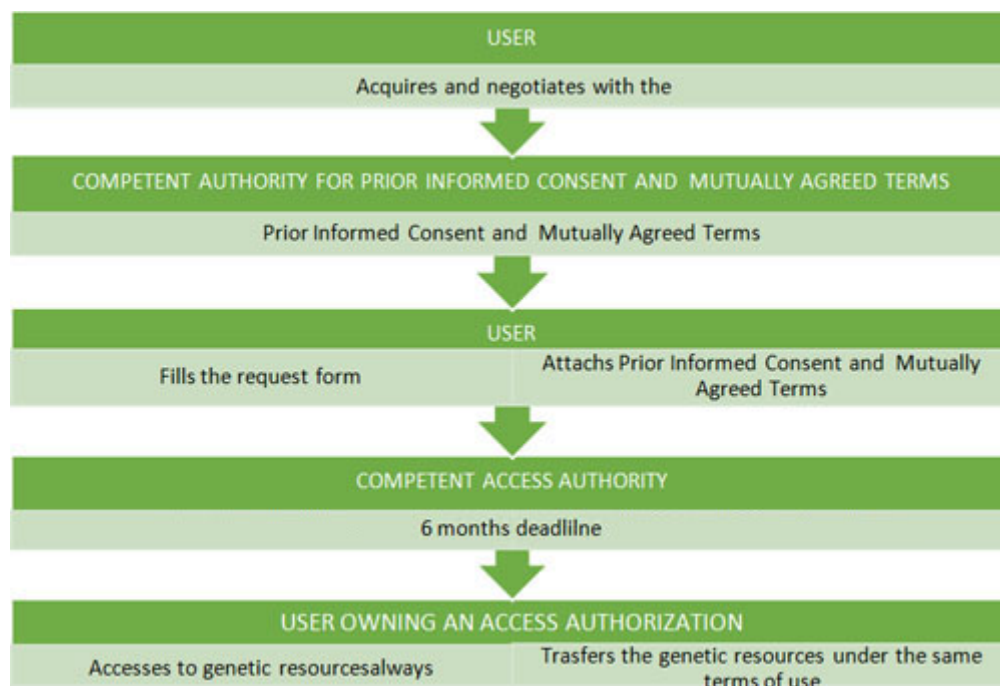
Finally, the competent access authority will grant the access authorization.



B) Access for the utilization for commercial purposes.

User must obtain the prior informed consent and the mutually agreed terms from the corresponding competent authority previously to submit the access application.

The access application together with the prior informed consent and the mutually agreed terms will be addressed to the competent access authority, who will examine the documents and grant the access authorization.



3. Who are the competent authorities to apply prior informed consent and negotiate mutually agreed terms, and the competent access authorities?

Both the competent authorities to apply **prior informed consent** and negotiate **mutually agreed terms**, and the competent access authorities depend on the nature of the requested genetic resources from wild taxa. Next table shows the relationship between the genetic resources and the corresponding competent authorities:

Genetic Resource	Competent authority for prior informed consent and mutually agreed terms	Competent access authority
Marine genetic resources	Dirección General de Sostenibilidad de la Costa y del Mar del MAPAMA	Dirección General de Calidad y Evaluación Ambiental y Medio Natural del MAPAMA
Genetic resources in public domain	Authority of the General Administration of the State to which that public domain is assigned	Dirección General de Calidad y Evaluación Ambiental y Medio Natural del MAPAMA
Genetic resources in state institutions of ex situ conservation	Managing authority of the state institution of ex situ conservation	Dirección General de Calidad y Evaluación Ambiental y Medio Natural del MAPAMA
Genetic resources from terrestrial wild taxa distributed along the territory of more than one autonomous community	Authority established by the autonomous community where the genetic resource is accessed	Dirección General de Calidad y Evaluación Ambiental y Medio Natural del MAPAMA
Others (e.g. endemic species in an autonomous community)	Authority established by the autonomous community where the genetic resource is accessed	Authority established by the autonomous community where the genetic resource is accessed

Since the bylaw 124/2017, of 24 February, has just come into force, the autonomous communities are still in the process of appointing their competent authorities. This website will be updated with the information on the designations of those competent authorities.

4. Where to apply for an access authorization to Spanish genetics resources from wild taxa?

The application to both access for the utilization for non-commercial research purposes and access for the utilization for commercial purposes can be accessed at the Ministry of Agriculture and Fisheries, Food and Environment (MAPAMA)'s website:

https://sede.mapama.gob.es/portal/site/se/procedimientos-intermedio?theme_id=5

Users must own a digital certificate to do the online application.

According to article 16.4 of the Law 39/2015, of 1 October, on the Public Administration and the Common Administrative Procedure, the access application can be also submitted at:

- a) CORREOS post office
- b) Spanish embassies and consulates abroad
- c) Registry offices
- d) Other venues established by the regulations currently in force

When the access application is not submitted through the online system at MAPAMA's website, it must be addressed to the competent access authority.

When the access is for the utilization for commercial purposes, users must obtain the prior informed consent and the mutually agreed terms from the corresponding competent authority previously to submit the access application.

Attention: Access authorization to Spanish genetic resources does not exempt users from the obligation to obtain as many others authorization established by other currently regulations in force.

5. How long will take for the access authority to grant the access authorization?

1) In the case of access for the utilization for non-commercial research purposes, the access authority will grant the access authorization in a period of two months since it receives every documents relating to the access application. If users have not been notified after this period it is understood that the authorization has been granted by positive administrative silence.

2) In the case of access for the utilization for commercial purposes, the access authority will grant the access authorization in a period of six months since it receives the access application. If users have not been notified after this period it is understood that the authorization has been granted by positive administrative silence

6. For how long an access authorization is valid?

If an expiration date takes place, it will appear on the access authorization. The access authorization will be valid only for the authorized utilization of the genetic resources for which it has been granted. To carry out a different utilization to that authorized, the user will have to apply for a new access authorization. Specially, if an access authorization was granted for a non-commercial utilization, and the research and development result in a commercial utilization, the user must apply for a new access authorization.

Furthermore, the access authorization will also include the information relating to the sampling number of the genetic resource and the dates for sampling. If additional samplings are required, the user must apply for a new access authorization.

7. What are the penalties for utilizing Spanish genetic resources without obtaining the required access authorization?

The access to Spanish genetic resources without obtaining the required access authorization as described in the Bylaw 124/2017, of 24 February, is considered an administrative infringement:

- *Very serious infringement* when profits are higher than 100.000 euros. In this case, the user may be fined 200.001 to 2.000.000 euros.

- *Serious infringement* when profits are lower than 100.000 euros. In this case, the user may be fined 3.001 to 200.000 euros.

Access authorization to Spanish genetic resources does not exempt users from the obligation to obtain as many others authorizations established by other currently regulations in force.