









Information for users of Spanish genetic resources

The competent authority in Spain who implements Nagoya protocol in Spain is the Ministerio para la Transición Ecológica y el Reto Demográfico (MITECO), Subdirección General de Biodiversidad Terrestre y Marina del MITECO.

1. Who must request the authorization for Access to Spanish genetic resources?

All users (regardless of their nationality) who wish to get access after the 15th of March 2017 to Spanish genetic resources from wild taxa whose activities involves the **utilization** of genetic resources must apply for an authorization. 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 the 13th of December, on natural heritage and biodiversity.

The Royal Decree 124/2017, of 24th of February, regulates access to genetic resources from wild taxa *in situ*, i.e., in their natural environment, and *ex situ*, out of their natural environment.

2. Are there exemptions to RD124/2017?

Yes, there are several exemptions, described in the Royal Decree 124/2017, and also available in the following <u>link</u>. As far as MARINE genetic resources are concerned, users are exempted from obtaining an auhtorization under the following circumstances:

-Access to genetic resources from fisheries regulated by law of "Pesca Marítima del Estado" from 26 March. Notwithstading this, should access be requested with a different purpose to fisheries or aquaculture exploitation and/or beyond research in the fisheries or oceanographic domain (according to Law 33/2001), those genetic resources would fall within Royal Decree 124/2017 scope.

-Access to Spanish genetic resources exclusively with taxonomic purposes according to definition on Article 2.3 of Royal Decree 124/2017, of 24 February. For this matter, "exclusively with taxonomic purposes" implies the application of principles and methods of identification, delimitation and classification of living beings, requiring the study of their filogenetic relationships and evolutionary and ecological process leading to biodiversity and using morphological, physiological, genetic, behavioural and environmental. It is important to highlight that transmission to third parties will only be allowed when the purpose remains being exclusively taxonomic. Otherwise an authorization will have to be requested.











In you are unsure whether your research is using genetic resources falling under the scope of Royal Decree 124/2017, you should contact the National Focal Point at bzn-protocolonagoya@miteco.es.

3. How does the Spanish access regulation apply to Spanish genetic resources from wild taxa found in Spanish ex situ collections?

The user / institution / company that already has the genetic resources in its own collection can make use of them without having to request access authorization. However, the third party that accesses after March 15, 2017 to a Spanish genetic resource deposited in a collection, company, institution or research center for its use, even if the resource had been acquired before that date, must request administrative authorization of access in accordance with the provisions of RD 124/2017, of February 24.

In the event that there was an authorization from the competent authority at the time of collection of the genetic resources that explicitly allowed the transfer to third parties of the material for its use, as understood in the context of the Nagoya Protocol, it will not be mandatory to request an access authorization.

4. How to request an authorization for access to Spanish genetic resources from wild taxa?

The authorization request is different if the research is for non-commercial or commercial purposes. In the case of research for non-commercial purposes, the information is in the <u>link</u> and on this page you can request authorization to access electronically. To access these telematic procedures, the user must previously be provided with a digital certificate (only possible for Spanish citizens).

5. How can I request authorization for access to Spanish genetic resources if I do not have a digital certificate?

If the user does not have a digital certificate or is a foreign citizen or institution, he or she must fill the application form (pdf), which contains the same information that must be filled in electronically, and send it in order to facilitate and expedite the presentation of the request to bzn-protocolonagoya@mapama.es. Once the user has received confirmation that the application is complete and adequate, he/she can send the final version of the application (the original document duly signed) to the following postal address, so that it can be registered and dealt with:

SUBDIRECCIÓN GENERAL DE BIODIVERSIDAD TERRESTRE Y MARINA Ministerio para la Transición Ecológica y el Reto Demográfico Plaza San Juan de la Cruz S/N, 28071 Madrid (Spain)











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 submitted at:

- 1. CORREOS post office
- 2. Spanish embassies and consulates abroad
- 3. Registry offices
- 4. Other venues established by the regulations currently in force

6. How long does the competent authority have to issue the access authorization?

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.

7. Is there anything else that can help me correctly fill out my authorization request?

When presenting the request, the user must specify whether the application is presented as a "Private" (signed by a researcher in a personal capacity) or institutional (signed by the legal representative of an institution). In the "Private" option, it is mandatory to attach a document accrediting the entity to which you are affiliated, for example, a letter of support or a copy of the request for funding of the research project signed by the legal representative of the aforementioned entity.

In the "Participating institutions" section, users must indicate all the institutions and researchers who will use / analyze the samples.

In the Section "Ubicación en las que se a recolectar o colección ex situ de la que se va a obtener" ("Location where it is going to be collected or ex situ collection from which it is going to be obtained") there are two possibilities. When collecting samples from the wild, users must specify GPS coordinates of the sampling point of the genetic resource. In the case of ex situ collections, users must indicate the identifier of the strain or genetic resource and the name of the culture collection.

8. And if I still have doubts, where can I find more information?

On the MITECO website there is a section with questions and answers about the request and authorization for access to genetic resources (<u>link</u>) or you can ask ECIMAT staff (service "Supply of Marine Biological Resources" for assistance.

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