



FREQUENTLY ASKED QUESTIONS REGARDING THE APPLICATION AND AUTHORIZATION TO ACCESS TO SPANISH PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

1. Is there any policy in Spain regulating access to the Spanish plant genetic resources for food and agriculture?

Yes. The **Royal Decree 429/2020, of 3 March 2020, approving the Access to Plant Genetic Resources for Food and Agriculture and those Cultivated for Other Purposes Regulations, and amending various royal decrees on plant products**, regulates the access to the Spanish plant genetic resources for food and agriculture, including crop wild relatives, those species that may be potential donors of characters of interest, and plant genetic resources cultivated for purposes other than food and agriculture.

The regulation is based on the access and benefit sharing mechanisms established by the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty)¹ and 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 (Nagoya Protocol)², which have been ratified by Spain.

By virtue of this Royal Decree, as of May 11th, 2020, any person interested in accessing these resources must request and obtain, prior to access, the corresponding access authorization.

All plant varieties that according to their own regulations can be commercialized are excluded from the regulation. Likewise, no authorization is required for the collection and maintenance of samples in *ex situ* collections exclusively for conservation purposes.

2. What is the process to obtain the access authorization as per the Royal Decree 429/2020, of 3 March 2020?

See decision tree on access procedures.

The Royal Decree establishes the following three different procedures for requesting access based on the type of plant genetic resource in question and the intended use:

A. Requesting access under the scope of the International Treaty:

This procedure is to be followed by access seekers who are based in a country that is a Party to the Treaty and that interested in plant genetic resources included in the **International Treaty's Multilateral system of access and benefit-sharing**. These resources are those listed in Annex I of the International Treaty, conserved *in situ* or *ex situ*, that are in the public domain and are under the control of the government (at the national or sub-national level). In addition, the intended use of the requested resources

¹ The full text of the International Treaty is available through the following url: <http://www.fao.org/3/a-i0510e.pdf>

² The full text of the Nagoya Protocol is available through the following url: <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-es.pdf>



must be their **conservation and sustainable use for research, breeding and training for food and agriculture**.

Access to these resources, as well as their transfer to third parties and the sharing of the benefits derived from their use, will only be subject to the terms and conditions established in the Standard Material Transfer Agreement (SMTA) of the International Treaty.

Access under the terms and conditions of the SMTA is also allowed for plant genetic resources not included in the Annex I of the International Treaty for users based on countries that are signatories of the International Treaty as long as the intended use of the resources is the conservation and sustainable use for research, breeding and training for food and agriculture.

The access request form is available at the following link:

<https://sede.mapa.gob.es/portal/site/seMAPA/navTablonAnuncios>

B. Requesting access under the scope of the Nagoya Protocol:

This access procedure is to be followed by access seekers interested in plant genetic resources, conserved *in situ* or *ex situ*, that are not included in the Treaty's Multilateral System and/or when the intended use of the resources is other than their conservation and sustainable use for research, breeding and training for food and agriculture.

Access to these resources is provided based on the provisions of Article 2 of the Nagoya Protocol as long as the intended use of the resources is their "use". Otherwise, the procedure C, below, is the one to be followed. The Nagoya Protocol defines "use" as *carrying out research and development activities on the genetic or biochemical composition of genetic resources, including through the application of biotechnology according to the definition stipulated in article 2 of the Convention on Biological Diversity*.

Access seekers are encouraged to check the European Commission's 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 2021/C 13/01³.

Access authorization is not necessary when the access to the Spanish plant genetic resources is *exclusively* for *taxonomic purposes*⁴, according to the definition of 'exclusively taxonomic purposes' in article 2.3 of the Royal Decree 124/2017, of 24 February, relative to the access to genetics resources from wild taxa and to the control of the utilization. These genetic resources may only be transferred to subsequent users under the same terms they were accessed. That is for exclusively taxonomic purposes. Otherwise, an access authorization is required.

Two different procedures are established depending on whether the intended use of the resources is for commercial purposes or not. The access request forms are available at the following links:

³ Available at:

<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1612445983959&uri=CELEX%3A52021XC0112%2802%29>

⁴ Exclusively taxonomic purposes (definition in Art. 2.3. Royal Decree 124/2017, of 24 February): *Application of principles and methods for identification, delimitation and classification of living beings, which requires the study of their phylogenetic relationships as well as the evolutionary and ecological processes that have generated biodiversity using morphological, physiological, genetics, behavioral and environmental data.*



- When the intended use of the requested plant genetic resource is for non-commercial purposes:

https://sede.mapa.gob.es/portal/site/seMAPA/ficha-procedimiento?procedure_suborg_responsable=79&procedure_id=674&by=theme

- When the intended use of the requested plant genetic resource is for commercial purposes:

https://sede.mapa.gob.es/portal/site/seMAPA/fichaprocedimiento?procedure_suborg_responsable=79&procedure_id=677&by=theme

C. Access procedure when the criteria established in paragraphs A) or B) above are not met.

The provisions of Law 30/2006, of 26 July, on seeds, nursery plants and plant genetic resources apply. The access procedure is established in Chapter I, Section 3^a of Royal Decree 429/2020, of 3 March.

D. Access to Spanish plant genetic resources by farmers for direct use.

Ex situ germplasm collections may provide small quantities of plant genetic resources to farmers, for their cultivation on their own farm, provided that the genetic resources are not registered varieties.

The amount of seeds that may be provided will be established by the National Commission on access to plant genetic resources. The agreed amounts will be published on the website of the Ministry of Agriculture, Fisheries and Food. That said, under some justified circumstances, access to these resources may be denied.

3. Who are the competent authorities to grant access? and to provide the prior informed consent (PIC) and negotiate the mutually agreed terms (MAT)?

The competent access authority and the authority responsible for providing the prior informed consent (PIC) and for negotiating the mutually agreed terms (MAT) are established by the Royal Decree 429/2020, of 3 March.

The table below shows the different procedures for requesting access to Spanish plant genetic resources, as established by the Royal Decree 429/2020, of 3 March, and the competent authorities involved in each of them.

Access procedure	Requirements	Competent authority
Access to plant genetic resources as established in the International Treaty	Standard Material Transfer Agreement (SMTA)	Plant genetic resources conserved <i>In situ</i> : Authority designated by the Autonomous Communities Plant genetic resources conserved <i>ex situ</i> : Collection manager



<p>Access to plant genetic resources as established in the Nagoya Protocol for <u>non-commercial uses</u></p>	<p>Access authorization</p> <p><i>Report</i></p>	<p>All resources: General Directorate of Agricultural Productions and Markets of the Ministry of Agriculture, Fisheries and Food</p> <p>Plant genetic resources conserved <i>in situ</i>: Authority designated by the Autonomous Communities</p> <p>Plant genetic resources conserved <i>ex situ</i>: Collection manager</p>
<p>Access to plant genetic resources as established in the Nagoya Protocol for <u>commercial uses</u></p>	<p>Access authorization</p> <p>Prior Informed Consent (PIC)</p> <p>Mutually Agreed Terms (MAT)</p>	<p>All resources: General Directorate of Agricultural Productions and Markets of the Ministry of Agriculture, Fisheries and Food</p> <p>Plant genetic resources conserved <i>in situ</i>: Authority designated by the Autonomous Communities</p> <p>Plant genetic resources conserved <i>ex situ</i>: Collection manager</p>
<p>Access to plant genetic resources when neither of the two previous procedures is applicable</p>	<p>Material Transfer Agreement (MTA)</p>	<p>Plant genetic resources conserved <i>in situ</i>: Authority designated by the Autonomous Communities</p> <p>Plant genetic resources conserved <i>ex situ</i>: Collection manager</p>

4. What are the steps in each procedure?

A. Access procedure under the scope of the International Treaty:

The corresponding form must be completed and submitted online. The online forms are available at the Electronic Office of the Ministry of Agriculture, Fisheries and Food:

<https://sede.mapa.gob.es/portal/site/seMAPA/navTablonAnuncios>

Submissions can also be made through any of the alternative channels established in article 16.4 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations.

The request must be addressed to the competent authority designated by the autonomous community where the requested plant genetic resource is located, in the



case of plant genetic resources conserved *in situ*, or to the manager of the germplasm collection, in the case of plant genetic resources conserved *ex situ* (See table above).

B. Access procedure under the scope of the Nagoya Protocol:

The corresponding form must be completed online. The online forms are available at the Electronic Office of the Ministry of Agriculture, Fisheries and Food:

<https://sede.mapa.gob.es/portal/site/seMAPA/procedimientos>

Submissions can also be made through any of the alternative channels established in article 16.4 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations.

Two different procedures are established depending on whether the intended use of resources is for commercial purposes:

1) *Requesting access to Spanish plant genetic resources to be used for non-commercial purposes.*

The access request must be addressed to the competent authority for granting access through the Electronic Office of the Ministry of Agriculture, Fisheries and Food (or through any of the alternative channels established by article 16.4 of Law 39/2015, of 1 October, of the Common Administrative Procedure of Public Administrations). The request form will be accompanied by a statement of responsibility made by the access seeker containing the following commitments:

- To not use the requested plant genetic resources for commercial purposes;
- To request a new authorization for access if the research and development results in a possible commercial use;
- To not transfer the plant genetic resource to any unauthorized person and, in the case of transmitting the resource to third parties, to do it under the same conditions as established by the statement of responsibility;
- Provide a written report to the Competent Authority including the final outcomes of the investigation.

The competent authority will review the request and the access seeker's declaration of responsibility, and will require a **Report** from the responsible authority to provide the PIC and negotiate the MAT, who may establish conditions for granting the access to the resources.

The competent authority for providing the PIC and negotiating the MAT will be designated by the government of the autonomous community in whose territory the requested plant genetic resource is located, in the case of plant genetic resources conserved *in situ*, or the manager of the collection of germplasm, in the case of plant genetic resources conserved *ex situ* (See table).

After reviewing the Report, the competent access authority will grant, where appropriate, the access authorization.

2) *Requesting access to Spanish plant genetic resources to be used for commercial purposes.*

Prior to submitting the access request, the PIC should be obtained and the MAT negotiated.



The competent authorities to provide the PIC and negotiate the MAT are designated by the government of the autonomous community where the requested plant genetic resource is located, in the case of plant genetic resources conserved *in situ*, or by the manager of the collection, when the resources are conserved *ex situ* (See table).

Once that PIC and MAT have been obtained, the access request should be submitted to the **competent access authority** through the Electronic Office of the Ministry of Agriculture, Fisheries and Food (or through any of the alternative channels included in article 16.4 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations). The submission should include the application form duly completed, the PIC and the MAT.

After reviewing the documentation, the competent access authority will grant, where appropriate, the access authorization.

C. Requesting access to plant genetic resources when the criteria established in paragraphs A) or B) above are not met.

The access procedure for these plant genetic resources will follow the provisions contained in Law 30/2006, of 26 July, on seeds, nursery plants and plant genetic resources.

Access seekers must contact the **competent authority** designated by the autonomous community where the requested plant genetic resource is located, in the case of plant genetic resources conserved *in situ*, or the collection manager, in the case of plant genetic resources conserved *ex situ* (See table).

5. Where can you request authorization for accessing Spanish plant genetic resources?

Online submission forms for requesting access for accessing Spanish plant genetic resources are available at the Electronic Office of the Ministry of Agriculture, Fisheries and Food, as well as in the section "Plant Genetic Resources for Food and Agriculture" of the webpage of the same Ministry.

To be able to access these procedures online, a personal digital certificate is needed.

As per article 16.4 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, access requests may also be submitted at:

- a. The post office.
- b. Diplomatic representations or Consular offices of Spain abroad.
- c. Registration assistance offices.

Regardless of the channel selected for submitting the access authorization request, it must be addressed to the corresponding competent access authority.

6. How long will take to the Competent Access Authorities to issue the access authorization?

Access requests that fall under the scope of the International Treaty will be granted quickly. The transfer of the requested material will be free of charge, and when a fee is charged, it will not exceed the corresponding minimum costs.

For access requests that fall under the scope of the Nagoya Protocol, two time frames are established depending on the intended use of the requested plant genetic resource:



- **Access authorizations for non-commercial uses:** Once the competent authority has received all the requested documents, the authorization will be granted within three months from the date when the request was made. If the authorization has not been granted after this period, it will be understood that the request has been approved by default.
- **Access authorizations for commercial uses:** Once the competent authority has received the access request, the authorization will be granted within six months from the date when the request was made. If the authorization has not been granted after this period, it will be understood that the request has been approved by default.

7. For how long is an access authorization valid?

If it expires, the expiration date will appear on the access authorization. The access authorization will be valid only for the utilization of the plant genetic resources for which it has been granted. To carry out a different utilization to that authorized, the user has to apply for a new access authorization. In particular, if the access authorization was granted according to the provisions of the Nagoya Protocol for non-commercial uses, and the research and development result in a commercial use, the user must apply for a new access authorization for use with commercial purposes.

Access authorizations for plant genetic resources conserved *in situ* will include the number of samples that will be collected and the specific dates when the collecting missions will take place. If additional samplings are required, the user must apply for a new access authorization.

Please note: Obtaining an access authorization does not exempt from the obligation to obtain any other authorizations established by any other regulations currently in place.

8. How does this regulation affect *ex situ* collections of Spanish companies, institutions or research centers that conserve plant genetic resources of Spanish origin?

Any plant genetic resource of Spanish origin that is found in a Spanish *ex situ* collection or under the power of disposal of a company, institution or research centre or of any natural or legal person, that has been collected and deposited or stored prior to the entry into force of the Royal Decree 429/2020, of 3 March, and which is accessed by a third party for use after May 11, 2020, falls within the scope of the Royal Decree.

Therefore, the user/institution/company that already has the genetic resources in their own collection can use them without having to request access authorization. However, any third party interested in accessing them after May 11, 2020, must request an access authorization, in accordance with the provisions of Royal Decree 429/2020, of 3 March.

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

9. What are the penalties for using Spanish plant genetic resources without having obtained the required access authorization?

Access to Spanish plant genetic resources without obtaining the required access authorization is considered an administrative infringement as per the Royal Decree 429/2020, of 3 March, The regime of infringements and sanctions established in articles 80.1.v) and 81 of Law 42/2007, of 13 December, on natural heritage and biodiversity,



and in Title VI of Law 30/2006, of 26 July, of seeds, nursery plants and plant genetic resources, respectively, will apply, when appropriate, as follows.

- *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.