

Access to Spanish genetic resources from wild taxa



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Brief introduction



Convention on Biological Diversity

- Into force on 29 December 1993
- 196 parties to the CBD
- Spain ratified it on 21 December 1993

It has 3 main objectives:

1. The conservation of biological diversity
2. The sustainable use of the components of biological diversity
3. **The fair and equitable sharing of the benefits arising out of the utilization of genetic resources**



Brief introduction

Nagoya Protocol

- Into force on 12 October 2014
- 113 Parties
- Spain ratified it on 3 June 2014

Article 1. OBJECTIVE

The objective of this Protocol is the **fair and equitable sharing of the benefits arising from the utilization of genetic resources**, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby **contributing to the conservation of biological diversity and the sustainable use of its components.**



Brief introduction



Nagoya Protocol

“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 Article 2 of the Convention;



Brief introduction



Nagoya Protocol

Nagoya
Protocol

Access to genetic resources or to traditional knowledge associated to genetic resources



To be decided by the Party in the exercise of sovereign rights over natural resources

Compliance with domestic legislation or regulatory requirements on access and benefit-sharing



Compulsory for the Party



Brief introduction



European Union (EU)

- Spain is a member state of the EU
- The EU is Party to the CBD and to the Nagoya Protocol

EU ABS normative

Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

Commission implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices.



Brief introduction



European Union (EU)

**EU ABS
Regulation**

Access to genetic resources or to traditional knowledge associated to genetic resources

Compliance with domestic legislation or regulatory requirements on access and benefit-sharing



Brief introduction



European Union (EU)

Scope of EU ABS Regulation

Genetics Resources

Traditional knowledges
associated to GR

- + to genetic resources over which the origin country exercises sovereign rights
- + when the origin country is Party to the Nagoya Protocol
- + where ABS measures have been established by this Party, with those measures applying to the specific genetic resource (or aTK) in question
- + to genetic resources which were accessed as of 12 October 2014



Brief introduction



European Union (EU)

Obligations of users

Users shall exercise **due diligence** to ascertain that GR and aTK which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements.

Checks on user compliance

- In accordance with a periodically reviewed plan developed using a risk-based approach.
- When a competent authority is in possession of relevant information regarding a user's non-compliance.



Brief introduction



European Union (EU)

Due diligence declaration checkpoints

1) at the stage of
research funding

2) at the stage of final
development of a
product

Spanish ABS legislation



Provider Country Measures on ABS Taken by
Developed Countries, Tokyo 13 Feb 2019



Spanish biodiversity act

Natural Heritage and Biodiversity Act (Law 42/2007) amended by Law 33/2015.
Into force on 07 Oct 2015.

Article 71

Access to Spanish genetic resources from wild taxa subject to PIC, MAT and access authorization.

National Focal Point: Ministry for the Ecological Transition (MITECO).

Benefits arising from the utilization of Spanish genetic resources will be mainly direct towards the conservation and sustainable use of biodiversity in Spain.

Articles 72 & 74

Control of the utilization of genetic resources and associated traditional knowledge in Spain (Compliance measures for the implementation in Spain of EU Regulation 511/2014).

Articles 80 & 81

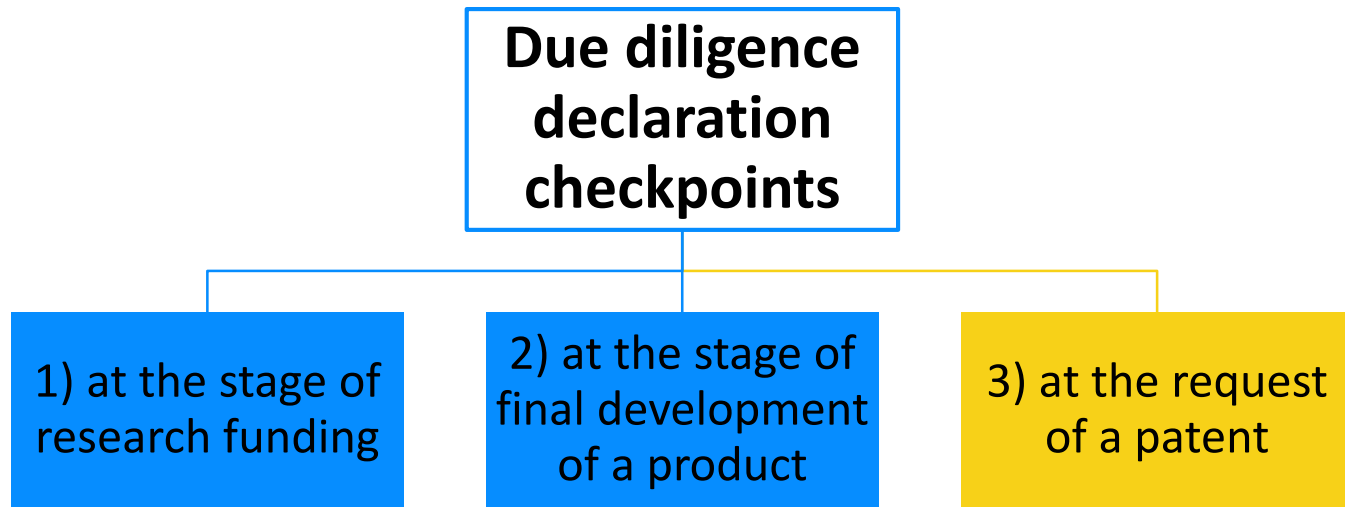
Infringements and penalties.



Spanish biodiversity act

Control of the utilization of genetic resources in Spain

In accordance with the EU ABS Regulation but adding a third checkpoint:





Spanish ABS bylaw

Laying down detailed rules for the implementation of articles 71, 72, 74, 80 and 81 of the Spanish Biodiversity Act



Establishing rules governing compliance in accordance with the EU ABS Regulation and the Commission Implementing Regulation



Royal Decree 124/2017, of 24 February, on access to genetic resources from wild taxa and on control of the utilization.



Spanish access regulation entered into force on 15 March 2017

Access to Spanish genetic resources from wild taxa



Provider Country Measures on ABS Taken by
Developed Countries, Tokyo 13 Feb 2019



Access to Spanish genetic resources

Scope:

- Spanish and foreign users of Spanish genetic resources.
- Spanish genetic resources, *in situ* and *ex situ*, from wild taxa.

Outside of the scope :

- Plant genetic resources for agriculture and food regulated by Law 30/2006.
- Fishery resources for food and aquiculture exploitation regulated by Law 3/2001.
- Zoogenetic resources for agriculture and food.
- Exclusively taxonomic purposes (definition in Art. 2.3.)



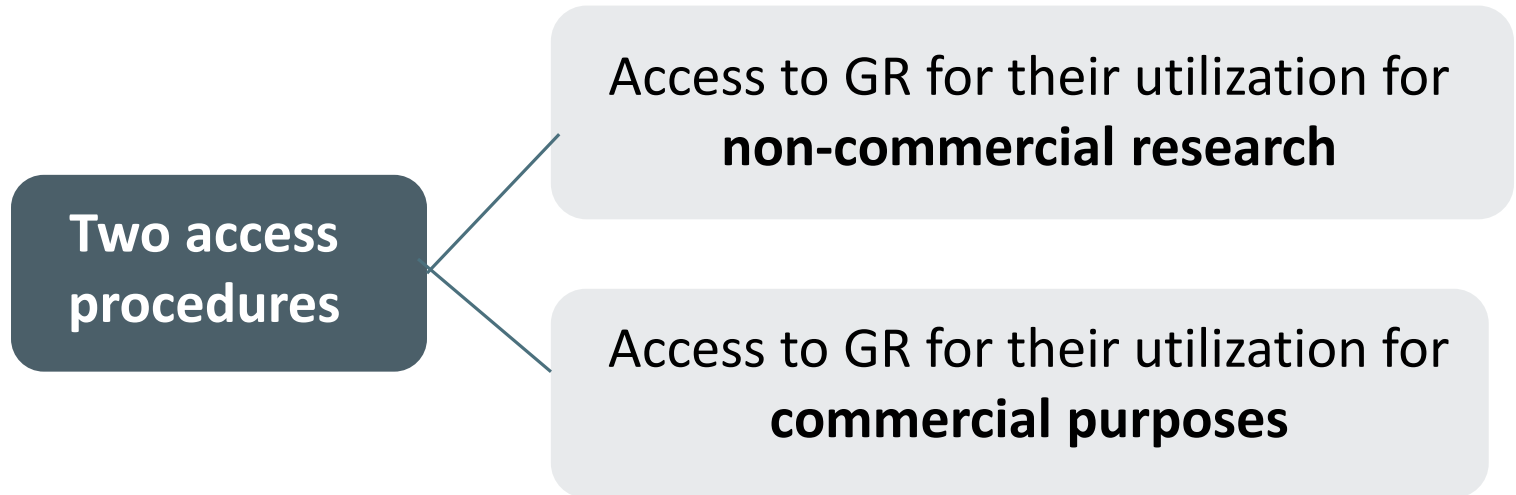
Exclusively taxonomic purposes

(definition in Art. 2.3. Spanish ABS bylaw)

«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».



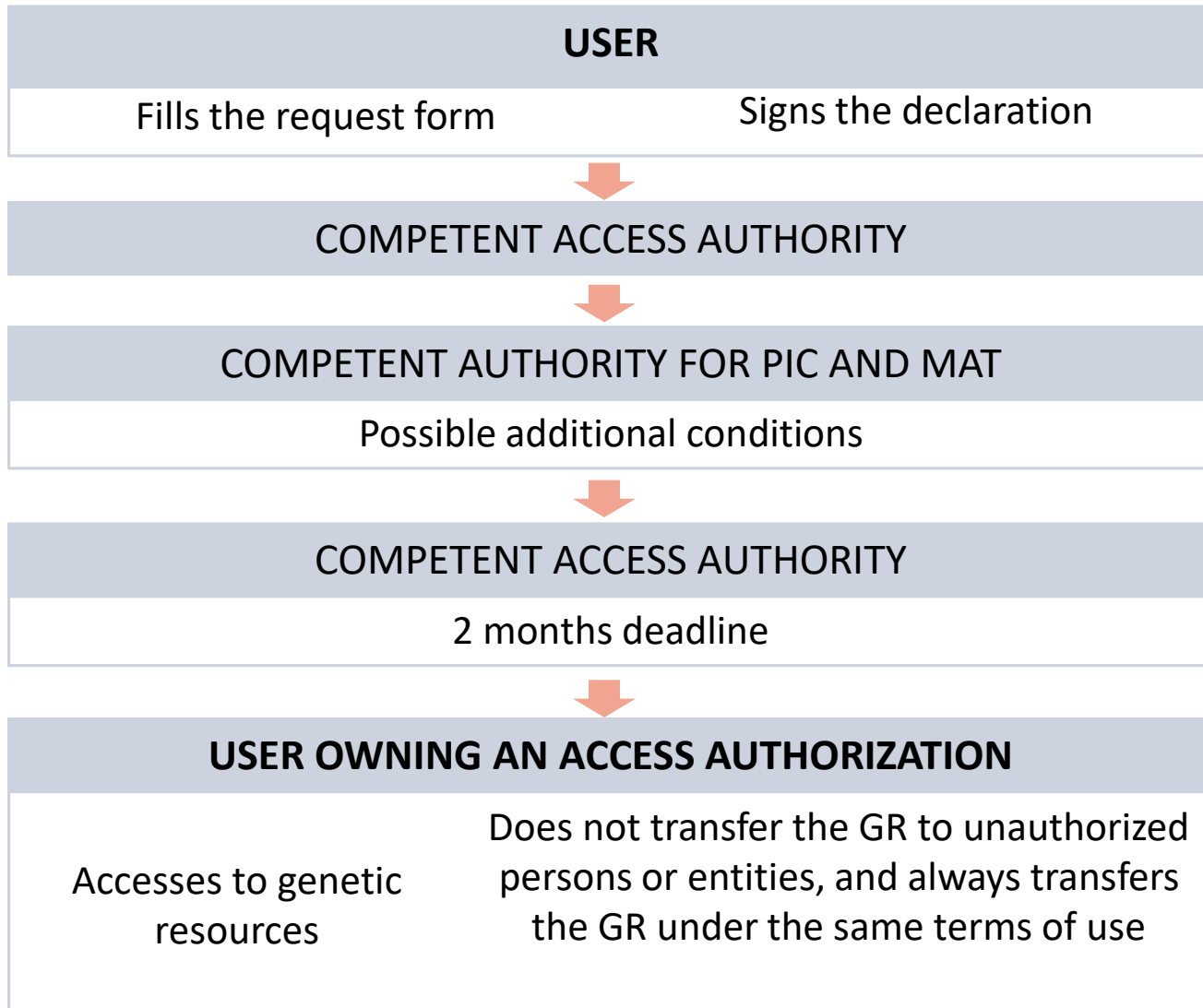
Access to Spanish genetic resources



- ☞ **In both cases the user is obliged to get an access permit before accessing the GR.**
- ☞ **The access permit is independent from other permits/authorizations.**

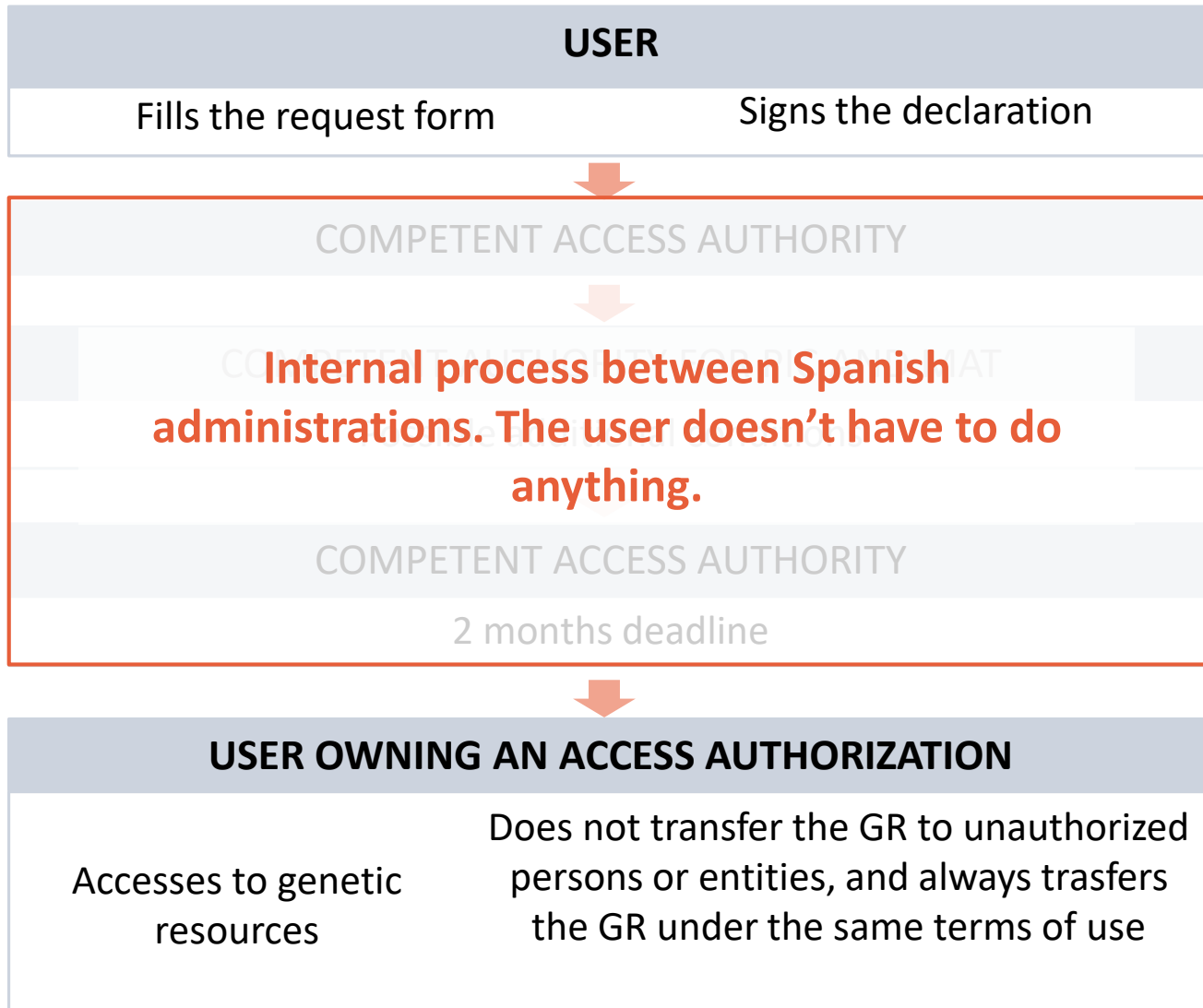


Access for the utilization for non-commercial research



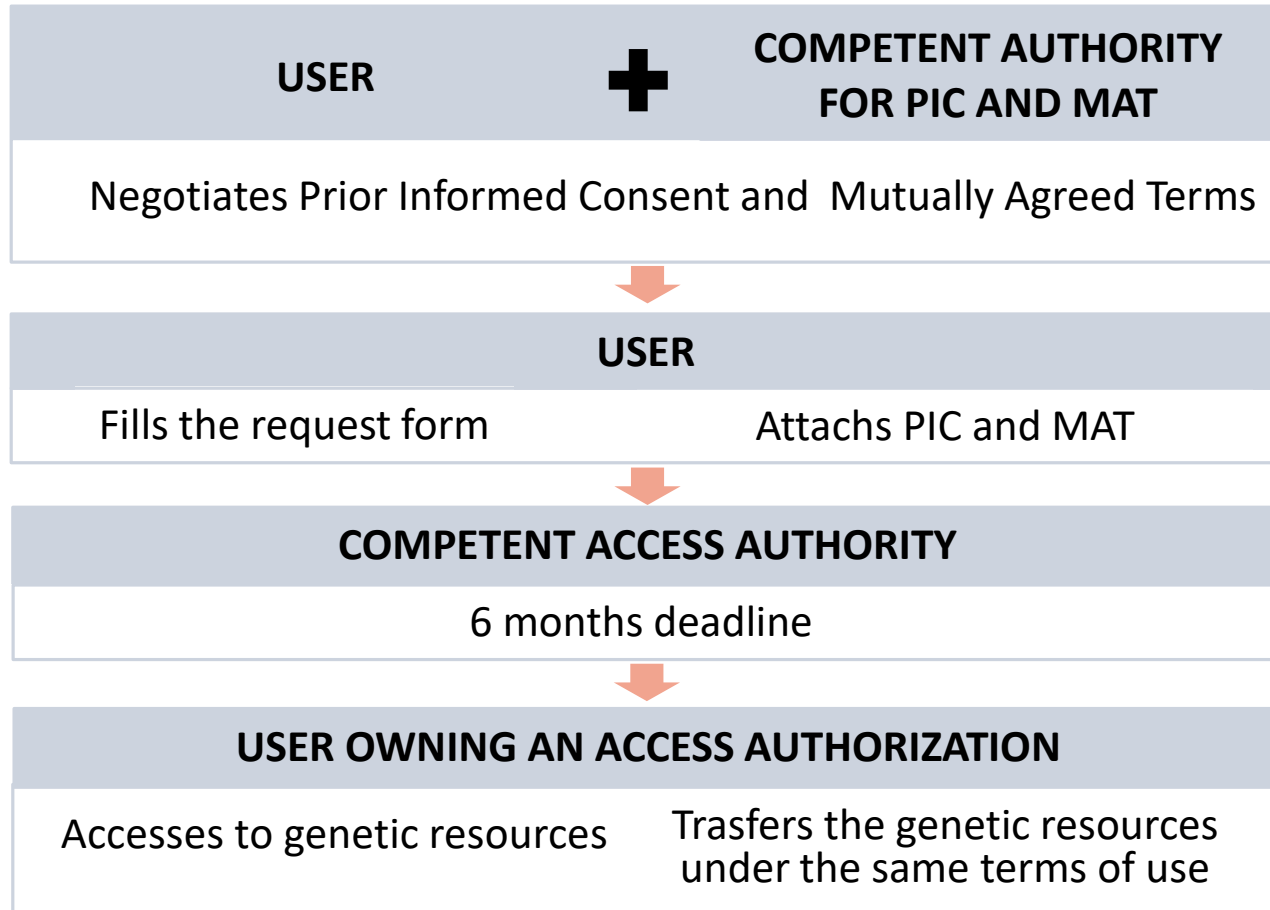


Access for the utilization for non-commercial research





Access for the utilization for commercial purposes



 **Guidelines for negotiating MATs under development.**



Competent authorities

Genetic Resource	Competent authority for PIC and MAT	Competent access authority
Marine genetic resources	Dirección General de Sostenibilidad de la Costa y del Mar of MITECO	Dirección General de Biodiversidad y Calidad Ambiental of the Ministry for the Ecological Transition (MITECO)
Genetic resources in public domain	Authority of the General Administration of the State to which that public domain is assigned	
Genetic resources in state institutions of <i>ex situ</i> conservation	Managing authority of the state institution of <i>ex situ</i> conservation	
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	
Others (e.g. endemic species in an autonomous community)	Authority established by the autonomous community where the genetic resource is accessed	

☞ **One National Competent Authority (MITECO).**

☞ **Several Regional Competent Authorities (autonomous communities).**



Competent authorities

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Marine genetic resources	Dirección General de Sostenibilidad de la Costa y del Mar of MITECO	
Genetic resources in state institutions of <i>ex situ</i> conservation	Authority of the General State Administration that public domain is assigned to the state institution of <i>ex situ</i> conservation	Dirección General de Medio Ambiente y Calidad Ambiental of the Ministry for the Ecological Transition (MITECO)
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	
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

Users don't need to know every Spanish competent authority, they just may contact the Spanish National Focal Point.

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Information

<https://www.miteco.gob.es/es/biodiversidad/temas/recursos-geneticos/>

The screenshot shows the website header with the Spanish Government logo and the Ministry of Ecological Transition. The main navigation bar includes links for 'Ministerio', 'Áreas de actividad', 'Participación pública', 'Cartografía y SIG', 'Estadísticas', 'Sede electrónica', and 'Sala de prensa'. A breadcrumb trail reads 'Inicio > Biodiversidad > Recursos genéticos'. On the left, a 'Temas' sidebar lists various biodiversity topics, with 'Recursos genéticos' highlighted. The main content area is titled 'Recursos genéticos' and features a large DNA double helix image. Below this, three columns provide information: 'Normativa internacional' with a leaf icon and a link to international norms; 'Normativa española' with a DNA icon and links to Spanish norms and FAQs in both Spanish and English; and 'Sede electrónica' with a link to electronic procedures.

**Thank you for your
kind attention!**



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