

Regulating access to genetic resources (Spain)

Workshop Access to genetic resources and benefit sharing
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Spanish Biodiversity Act

- ▶ Amendments to the Natural Heritage and Biodiversity Act (Law 42/2007) (Law 33/2015, BOE 225, 22/09/2015) (into force on 07/10/2015):
 - ▶ Art. 71. Access to Spanish Genetic Resources.
 - ▶ Art. 72. Control of the utilization of GR in Spain (Compliance measures for the implementation in Spain of EU Regulation 511/2014).
 - ▶ Art. 74. Control of the utilization of TK in Spain (Compliance measures for the implementation in Spain of EU Regulation 511/2014).
 - ▶ Arts. 80 and 81. Infringements and penalties.

Spanish Biodiversity Act

- ▶ Access to Spanish genetic resources (new art. 71):
- ▶ Regulates access to Spanish genetic resources (in accordance with the CBD, Nagoya Protocol and ITPGRFA), which will be subject (through a *Real Decreto* = bylaw/regulation) to PIC, MAT and to obtaining an access permit.
- ▶ Establishes a simplified procedure for access to genetic resources for non-commercial research purposes in their utilization (change of intent requires new permit).



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Spanish Biodiversity Act

- ▶ Access to Spanish genetic resources (new art. 71):
- ▶ Establishes the competent authorities for access to Spanish genetic resources:
 - ▶ Autonomous Communities (regions);
 - ▶ Central government in the following situations:
 - ▶ Marine genetic resources;
 - ▶ Genetic resources that are under the State public domain;
 - ▶ Genetic resources in State ex situ collections;
 - ▶ Genetic resources for which the distribution area covers more than one Autonomous Community (region).



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Spanish Biodiversity Act

- ▶ Access to Spanish genetic resources (new art. 71):
- ▶ Outside of the scope:
 - ▶ Access for taxonomic purposes, as long as there is no utilization of the genetic resource and subject to restrictions in their transfers;
 - ▶ Plant Genetic Resources for food and agriculture covered by Law 30/2006;
 - ▶ Fisheries genetic resources covered by Law 3/2001;
 - ▶ Animal genetic resources for food and agriculture covered by its specific legislation.



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Spanish Biodiversity Act

- ▶ Access to Spanish genetic resources (new art. 71):
- ▶ National Focal Point: Ministry for Agriculture, Food and Environment.
- ▶ Centralised system, through the National Focal Point, for the notification of access permits to the ABS-CH.
- ▶ Benefits arising from the utilization of Spanish genetic resources will be mainly direct towards the conservation and sustainable use of biodiversity in Spain (Spanish Fund for the Natural Heritage and Biodiversity).
- ▶ Establishes a specialized committee on ABS (regional competent authorities and interested Ministries) under the State Commission for Natural Heritage and Biodiversity.



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- ▶ Access to Spanish Genetic Resources, *in situ* and *ex situ*.
- ▶ Monitoring the utilization of GR and TK utilized in Spain (in compliance with EU Regulation 511/2014): Designation of competent authorities under EU regulation 511/2014; Exercise due diligence by users; Checks on user compliance; Inclusion of Spanish collections in the EU Register of collections.
- ▶ Spanish information system (IT tool) on access to and utilization of genetic resources and associated traditional knowledge in Spain.
- ▶ Cooperation of the Spanish public competent administrations.



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- ▶ Access to Spanish Genetic Resources (Scope):
- ▶ Access to Spanish Genetic Resources, in situ and ex situ;
- ▶ Outside of the scope:
- ▶ Taxonomic purposes;
- ▶ The collection of material and its maintenance in germoplasm banks or ex-situ collections with the exclusive purpose of its conservation;
- ▶ The production and commercialization



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- ▶ Access Competent authorities:
- ▶ National Focal Point will inform about competent authorities.
- ▶ DG Natural Environment of the Ministry of Agriculture, Food and Environment (access permit): GR under the competent authority of the Central Government
- ▶ PIC and MAT, depend on the genetic resource:
 - ▶ For Marine GR: DG for the Coastal and Marine Sustainability;
 - ▶ For GR that are under the State public domain: the authority that exercises the State public domain;
 - ▶ For GR in State ex situ collections: the State institution managing the collection;



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▶ For GR for which the distribution area covers more th

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- ▶ Access procedures:
- ▶ Access to GR for their utilization for non-commercial research
- ▶ Access to GR for their utilization for commercial purposes

In both cases the user is obliged to get an access permit before accessing the genetic resource. The access permit is independent from other permits/authorizations.



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Access to GR for their utilization for non-commercial research:

- ▶ Address to the access competent authority the access request form (Annex I) attaching a declaration of responsibility explicitly stating that:
- ▶ The user has no intention to utilize the GR for commercial purposes.
- ▶ In case there is a change of intent during the utilization of the GR, the user will request a new access permit for commercial purposes.
- ▶ Transfer to third users will take place, if allowed in the terms of the permit, under the same conditions as originally granted.
- ▶ The user will provide a written report with the final results of the research to the competent authority granting the access permit.



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Access to GR for their utilization for non-commercial research (cont.):

- ▶ The authority granting PIC & MAT could add specific benefit-sharing conditions, i.e.:
- ▶ Duplicates of the samples to be deposited into a Spanish ex situ collection.
- ▶ Spanish researchers to participate in the research in cases of access being granted to foreign researchers
- ▶ The access competent authority has a maximum of 2 months to grant the access permit (if the application is complete) [Annex II establishes the minimum content of the access permit, in line with the Nagoya Protocol and its mechanisms].



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- ▶ Access to GR for their utilization for commercial purposes:
- ▶ Address to the access competent authority the access request form (Annex III) attaching PIC and MAT by the responsible authority.
- ▶ Guidelines for the negotiation of MATs (under development).
- ▶ The access competent authority has a maximum of 6 months to grant the access permit [Annex IV establishes the minimum content of the access permit, in line with the Nagoya Protocol and its mechanisms].



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- ▶ **Access to GR in emergency situations:**
- ▶ **The declaration of emergency or alert situations could entail an exceptional authorisation of access, on a provisional basis providing immediate access to the GR**
- ▶ **The exceptional authorisation is conditioned to the later negotiation of MATs and obtaining the definitive access permit (maximum period of 6 months)**



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- ▶ Spanish information system (IT tool) on access to and utilization of genetic resources and associated traditional knowledge in Spain.
- ▶ Cooperation of the Spanish public competent administrations: specialized committee on ABS (regional competent authorities and interested Ministries) under the State Commission for Natural Heritage and Biodiversity.



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Thank you for your kind attention!



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