

ONLINE SURVEY ON INFORMATION SYSTEMS, REGISTERS AND DATABASES

This document does not refer to Traditional Cultural Expressions or folklore, as they are the responsibility of the Ministry of Culture and Sport.

1. Is there any formal domestic or customary legal system in your country requiring, or at least relating to, the establishment and/or maintenance of an information system on GRs, TK and/or TCEs:

As indicated on the website of the Ministry for the Ecological Transition and the Demographic Challenge,¹ access to genetic resources from wild taxa and the controlled use of genetic resources and associated traditional knowledge are regulated in Spain under Act No. 42/2007, on natural heritage and biodiversity, as amended by Act No. 33/2015 (which entered into force on October 7, 2015), and Royal Decree No. 124/2017 of February 24, on access to and controlled use of genetic resources from wild taxa (which entered into force on March 15, 2017). Those regulations ensure the compliance of Spain with 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 and with Regulation (EU) No. 511/2014 of the European Parliament and of the Council of April 16, 2014 on the same matter.

Under Article 71 of Act No. 42/2007, authorization to obtain access to Spanish genetic resources must be obtained from the competent authority. Articles 72 and 74 regulate the controlled use of genetic resources and associated traditional knowledge in Spain. Articles 80 and 81 establish the infringements and sanctions arising from non-compliance with the obligations and procedures set forth in the Act on this matter.

All the relevant procedures are set forth in detail in Royal Decree 124/2017.

They include the procedures for, on the one hand, obtaining access to Spanish genetic resources from wild taxa for commercial and non-commercial purposes and the fair and equitable sharing of benefits and, on the other hand, controlling the use of genetic resources and associated traditional knowledge in Spain.

Since its entry into force, access to and use of Spanish genetic resources has been subject, by virtue of the Nagoya Protocol, to the procedures of prior informed consent, the negotiation of mutually agreed conditions and the obtaining, as proof of compliance both requirements, of access authorization granted by the competent authority. This serves to underscore the value of Spanish biodiversity as a source of innovation in the economy, making the use of genetic resources an incentive and a new source of innovative financing for biodiversity conservation.

Under Royal Decree No. 124/2017, the dual profile of Spain, not only as a source of genetic resources but also as a user of genetic resources from home and abroad, is also acknowledged. It therefore contains the internal procedures for control and monitoring, making it possible to detect the illegal use of genetic resources and associated traditional knowledge in Spain, in accordance with the relevant European Union regulations.

The competent authorities for implementing Regulation (EU) No. 511/2014, with regard to

¹ [Regulations on access to and use of genetic resources \(miteco.gob.es\)](https://www.miteco.gob.es/). Last accessed on February 15, 2023 (Spanish only).

compliance with the Nagoya Protocol in the European Union, are also set forth in the Decree.

With regard to follow-up and compliance measures, Royal Decree No. 124/2017 sets forth specific procedures for requesting and collecting due diligence declarations by users when they:

- (a) are beneficiaries of research funds that use Spanish or foreign genetic resources and associated traditional knowledge in Spain;
- (b) are in the final stages of preparing a product developed through the use of genetic resources and associated traditional knowledge; and
- (c) apply for a patent.

The regulation provides for the establishment of the Committee on access to and use of genetic resources and associated traditional knowledge in Spain in order to promote cooperation and collaboration between the different competent authorities.

It also provides for the establishment of a national information system to coordinate information relating to the regulation's scope of application. That information will be taken into account in the drafting and implementation of the national plan to monitor the legal use of genetic resources and associated traditional knowledge in Spain. The aim of the plan will be to reduce the risk of the use anywhere in the country of genetic resources and associated traditional knowledge obtained unlawfully either in Spain or in third countries party to the Nagoya Protocol.

Article 14(5) of Royal Decree No. 124/2017 provides that, as the national focal point for the Nagoya Protocol, the Directorate for Environmental Assessment and Quality and the Natural Environment, under the Ministry of Agriculture and Fisheries, Food and the Environment, shall forward the information received under sections 1, 2 and 3 (on due diligence) to the Nagoya Protocol Access and Benefit-sharing Clearing House (ABS Clearing House) and, where appropriate, to the European Commission and the competent national authorities referred to in Article 13(2) of the Protocol.

Furthermore, Article 23(2) of the Patents Act (No. 24/2015 of July 24) states that, when biological material of plant or animal origin is referred to in an application to patent an invention, the application must state the geographical origin or source of the material, if known. Such information shall be without prejudice to the patent's validity.

In the cases provided for in Regulation (EU) No. 511/2014, the patent application shall also contain, as determined by the regulations, the information that users of such resources are obliged to keep in accordance with the provisions of the aforementioned regulation. Such information shall be without prejudice to the patent's validity.

Moreover, the issue of the establishment or maintenance of an information system on genetic resources would appear to be regulated by the following instruments, to which Spain is a signatory:

- Article 14(2) of the Nagoya Protocol provides that each party shall provide all the information required thereunder to the ABS Clearing House, as well as information required pursuant to decisions adopted by the Conference of the Parties serving as the meeting of the Parties to this Protocol. Such information shall include:
 - (a) legislative, administrative and policy measures on access and benefit sharing;
 - (b) information about the national focal point and the competent national authority or authorities; and
 - (c) permits or their equivalent, issued at the time of access as evidence of the decision to

grant prior informed consent and that mutually agreed terms have been established.

Article 14(3) provides that additional information, if any and as appropriate, may include:

- (a) the relevant competent authorities of indigenous and local communities, and any information deemed appropriate;
- (b) model contractual clauses;
- (c) methods and tools developed to monitor genetic resources; and
- (d) codes of conduct and best practices.

- Article 7(3) and (4) of Regulation (EU) No. 511/2014, on monitoring user compliance, provides that:

3. The competent authorities shall transmit the information received on the basis of paragraphs 1 and 2 of this Article to the Access and Benefit-Sharing Clearing House, established under Article 14(1) of the Nagoya Protocol, to the Commission and, where appropriate, to the competent national authorities referred to in Article 13(2) of the Nagoya Protocol.

4. The competent authorities shall cooperate with the Access and Benefit-Sharing Clearing House to ensure the exchange of the information listed in Article 17(2) of the Nagoya Protocol for monitoring the compliance of users.

- Royal Decree No. 429/2020 of March 3, under which the regulations on access to plant genetic resources for food and agriculture and those cultivated for other purposes are approved, and which amends various royal decrees on plant products. Article 8(7) provides that the Directorate for Agricultural Production and Markets, under the Ministry of Agriculture, Fisheries and Food, shall communicate to the national focal point of the Nagoya Protocol, through the national information system on access to and the use of genetic resources and associated traditional knowledge in Spain and in accordance with Royal Decree No. 124/2017, the access authorizations issued, with the aim of transferring that information to the ABS Clearing House. That communication shall be made within a maximum period of one month after the authorization is granted.

2. Is your country party to any international or regional legal instrument (such as a convention, treaty or declaration) that requires the establishment of or participation in information systems for the protection, promotion and/or safeguarding of GRs, TK and/or TCEs? If so, please indicate which international or regional legal instrument.

See Article 14 of the Nagoya Protocol and Article 7(3) and (4) of Regulation (EU) No. 511/2014, referred to in the previous question.

3. Does any information system(s) of GRs, TK and/or TCEs exist in your country (whether IP-related or not)? If so, please provide a description of such information system(s).

The web portal of the Ministry for the Ecological Transition and the Demographic Challenge → Biodiversity and Forests → Data and Inventory Portal includes, among other things, the following:

- Spanish Inventory of Natural Heritage and Biodiversity.
- National Forest Inventory.
- Spanish Inventory of Terrestrial Species.
- Spanish Inventory of Traditional Knowledge related to Biodiversity (the need to be aware of,

preserve and promote traditional knowledge and practices that are of interest for biodiversity is enshrined in Act No. 42/2007). Article 74 states that the authorities shall draw up traditional knowledge inventories with a view to deepening awareness of and preserving such knowledge).

- Spanish Inventory of Marine Habitats and Species.

Phylogenetic resources are regulated by Title IV of Act No. 30/2006 of July 26, on seeds, nursery plants and phylogenetic resources. Article 51 addresses mechanisms to protect and promote farmers' rights. It further specifies that the authorities, within the scope of their competence, shall, with a view to promoting the use and preservation of genetic resources in danger of disappearing, adopt measures to protection, preserve and develop traditional knowledge of interest for phylogenetic genetic resources for food and agriculture.

In that regard, the authorities are entrusted under the Act with a mandate to preserve, maintain and promote traditional knowledge and stimulus to establish an inventory of traditional knowledge on cultivated plants (agricultural biodiversity).

The Ministry of Agriculture, Fisheries and Food has set up the Spanish Inventory of Traditional Knowledge on Agricultural Biodiversity: [phylogenetic resources for agriculture and food \(mapa.gob.es\)](http://mapa.gob.es), called CONECT-e.² Its developers include the Autonomous University of Barcelona, Autonomous University of Madrid and Madrid Institute of Rural, Agricultural and Food Research and Development.

CONECT-e (CONocimiento ECológico Tradicional), which means “sharing traditional ecological knowledge” is a participatory citizen science platform for collecting and sharing traditional knowledge relating to plants, animals, fungi, traditional crop varieties and ecosystems. It is a wiki-like platform allowing anyone to sign up and share the traditional knowledge and practices acquired from their elders. CONECT-e is divided into five main categories: plants, traditional crop varieties, ecosystem management, animals and climate change (the latter two are still under development). Under each category, you can search for information by file, content or location, and select a series of filters that will help you to find the information that you are looking for.

4. Which IP-related objectives are sought to be achieved through this information system(s)?

To provide documentary, legal and administrative information on the various types of industrial property, genetic resources or traditional knowledge, and the Nagoya Protocol.

5. What types of information are included in such an information system, including potentially sensitive categories of information such as sacred TK/TCEs and/or secret TK/TCEs?

Technical and legal information on the status of industrial property case files, industrial or technical information on Spanish genetic resources and traditional knowledge and administrative information relating to the Nagoya Protocol.

6. What are the roles of various stakeholders in the establishment of the information system(s)?

- **Who characterizes and documents genetic resources?** Patent examiners with regard to

² Online platform (Spanish only): <https://www.miteco.gob.es/es/ceneam/recursos/pag-web/conecte.aspx>.

patent applications. Any other information is administered by Ministry for the Ecological Transition and the Demographic Challenge officials.

- **Who writes down, films, records, translates and compiles TK and/or TCEs?** The Ministry for the Ecological Transition and the Demographic Challenge.
- **Who administers the information system/database/register(s)?** Patents are administered by the Spanish Patent and Trademark Office (SPTO) and any other information is administered by the Ministry for the Ecological Transition and the Demographic Challenge.
- **Who can add new entries/registrations?** SPTO.
- **What role do Indigenous Peoples, as well as local communities as appropriate, play?** Not applicable.

7. Which are the principles and modalities regulating access to competent information? As indicated in the answer to question one, the principles governing access to competent information are prior informed consent, the negotiation of mutually agreed terms and the procurement, as evidence of having complied with both of those requirements, of access authorization granted by the competent authority.

- **Who retains control of the information system?** SPTO in the case of industrial property.
- **Who is authorized to access the content?** Any interested user.
- **Are there tiered levels of access to different categories of content?** Yes, for patents.

8. What are the involvement and rights of Indigenous Peoples, as well as local communities, in the process of the establishment, functioning and management of the information system(s)? Not applicable.

9. What is the legal effect of inclusion of GRs, TK and/or TCEs, as may be, into the information system? For example, does inclusion establish IP rights? No, it is purely informative and is used for the study of prior art in the case of patents.

10. How are disputes resolved (for example, competing claims by more than one community to a certain body of GRs, TK or TCEs)? How are transboundary GRs, TK and/or TCEs dealt with? Not applicable.

11. Are there interoperability standards between the existing information systems in your country and other information systems or services? Do these interoperability standards concern: (i) data formats (e.g., XML, data fields, etc.); (ii) content data (e.g., characterization, function, technical use of GRs, TK or TCEs); (iii) rights metadata (e.g., right holder, subject matter, date of documentation, etc.); or (iv) structures of the information systems and services (e.g., APIs, etc.)? If so, please provide a description of these standards. There are no regulations in that regard.

12. Do you have any other views or experiences relating to the establishment, functioning and management of information systems? Not applicable.

13. Do you have any suggestions for future work under the auspices of the WIPO IGC and/or by the WIPO Secretariat on these issues? Not applicable.