

Access to genetic resources and associated traditional knowledge and sharing of the benefits arising from their utilization (ABS)

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The regulation for access and sharing of the benefits arising from the utilization of genetic resources and their associated traditional knowledge (ABS) controls the relationships between the provider and the user of genetic resources and associated traditional knowledge. Who is affected by the regulation in France? What is its scope? What are the procedures to be followed?

The Nagoya Protocol and its transposition into French Law

Adopted in October 2010, the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization (ABS) entered into force on 12 October 2014. This protocol establishes an international legal framework based on three sections:

- **Access to genetic resources and their associated traditional knowledge with a view to their utilization:** States can decide to make this access subject to their prior informed consent or to the consent of the traditional communities involved;

- **Benefit sharing:** the benefits must be shared fairly and equitably, subject to conditions established by mutually agreed terms between the user and the provider country or the traditional community involved;
- **Compliance:** the States Parties must adopt measures to ensure that access to genetic resources and to the associated traditional knowledge used under their jurisdiction complies with the internal regulations of the provider countries for access and benefit sharing.

The law of 8 August 2016 on reclaiming biodiversity, nature, and landscapes led to ratification of the Nagoya Protocol in France, and established measures to implement these three sections. Accordingly, a national access and sharing system for the benefits arising from the utilization of genetic resources and their associated traditional knowledge (ABS system) was introduced.

Why is France regulating access to its genetic resources and to their associated traditional knowledge?

France has a rich biodiversity that needs to be preserved. Genetic resources offered by this biodiversity are at the heart of research and development activities, in many fields. Through the benefit-sharing arising from the utilization of genetic resources, the ABS regulation in France aims to make the development of these activities a lever towards the preservation of biodiversity and sustainable development in the territories where the resources come from. Requiring prior informed consent for access to genetic resources also contributes to promote conditions of access and utilization that respect biodiversity.

Furthermore, traditional communities in overseas territories hold traditional knowledge associated with genetic resources. The ABS legislation also makes it possible to ensure that their utilization is preceded by the prior informed consent of such communities and by mutually agreed terms on the sharing of benefits with the user, that shall benefit directly these communities.

The ABS legislation also contributes to improve legal security between provider and user, and to strengthen the traceability of resources and transparency of utilizations. Therefore, it offers more favorable conditions for the development of projects using genetic resources in a sustainable way and taking an active part in the preservation of biodiversity and sustainable development.

Who is affected by the national ABS system?

The national ABS system applies to mainland France and its overseas territories. This system is not applicable in French Polynesia and New Caledonia, which have developed their own regulations in accordance with their statutes and competences. In addition, only the provisions concerning the utilization of the associated traditional knowledge apply to the Wallis and Futuna Islands.

Users

A user is a French or foreign natural person or a legal entity working for the public or private sector, who or which utilizes genetic resources or traditional knowledge associated to these genetic resources.

Utilization of genetic resources is defined as research and development activities on the genetic or biochemical composition of genetic resources, in particular through the application of biotechnologies, and the valorization of these genetic resources as well as the applications and marketing arising from them;

Utilization of associated traditional knowledge means studying and making use of it (e.g. making use of knowledge related to the medicinal properties of a plant held by a traditional community).

Providers

Two categories of providers are established:

- The French State, for genetic resources under national sovereignty;
- The traditional communities of French Guiana and Wallis and Futuna, for the associated traditional knowledge that they hold.

Organisation of the national ABS system and procedures to be followed

The ABS system in France comprises:

- **A general scheme** for wild genetic resources and their associated traditional knowledge;

- **Specific schemes for:**

- ✓ genetic resources of related wild species
- ✓ genetic resources originating from domestic or cultivated species
- ✓ genetic resources that are subject to forestry
- ✓ genetic resources collected by laboratories for the purposes of preventing, monitoring and combating health hazards relating to animals, plants and food safety
- ✓ genetic resources collected by laboratories for the purposes of the prevention and control of serious human health hazards

Fields not covered by the national ABS scheme

- Human genetic resources.
- Genetic resources collected outside the national territory and outside areas under French sovereignty or jurisdiction.
- Genetic resources covered by international instruments specialised in access and sharing of the benefits, such as the International Treaty on Plant Genetic Resources for Food and Agriculture.
- Genetic resources of species utilized as models in research and development (e.g. white laboratory rats). Species that fall under that exclusion are listed on a [decision of September 3rd, 2019](#).

- Genetic resources and their associated traditional knowledge that contribute to safeguarding defense and national security interests.
- Some associated traditional knowledge (for instance those that cannot be attributed to one or more traditional communities or which have well-known properties that have been used for a long time and repeatedly outside of the traditional communities that share them) as well as the exchange and utilization of genetic resources and associated traditional knowledge within and between traditional communities of inhabitants, for personal or non-commercial purposes.

Fields not covered, on an experimental basis, by the national ABS scheme

Microorganisms from mainland France are excluded from the general ABS scheme for a period of three years, as of August 30, 2019. This experimentation was defined by article 129 of law n ° 2019-486 of 22 May 2019. [Decree no.2019-916](#) specifies its monitoring and evaluation conditions. Users must, annually and before August 1 of each year, send the Ministry information on the work carried out under this experimentation. The document below is made available by the Ministry for this purpose. The information gathered will be used for monitoring and evaluating the experimentation in order to identify the follow-up to be given.

- [Survey on the experimental exemption applicable to microorganisms of mainland France](#)

Procedures to be followed regarding the general ABS scheme

In order to utilize **french genetic resources** with **no direct commercial purposes** (e.g.: fundamental research project, R&D phase aiming to determine the properties of certain molecules...), an **ABS declaration** is required and must be addressed to the ministry of environment through [CERFA form 15786](#).

In order to utilize **french genetic resources** with **direct commercial purposes**, an **ABS authorization request** is required and must be addressed to the ministry of environment through a [CERFA form 15785](#).

In order to utilize **associated traditional knowledge**, an authorization request is required through [CERFA form 15784](#).

These declaration and authorisation forms have to be filled in and returned to apa@developpement-durable.gouv.fr

The operation of these three distinct procedures is described on the [Access and Benefit-Sharing Clearing-House](#).

Enforcement of European ABS regulations: due diligence obligation by users

In accordance with the “compliance” section of the Nagoya Protocol, the European Union regulation 511/2014 and its implementing regulation 2015/1866 seek to ensure that genetic resources and their related associated traditional knowledge utilized within the European Union are

accessed in accordance with the internal ABS regulations of the countries providing these resources. These regulations establish a due diligence obligation on the part of users, as well as a mechanism of checkpoints at the stage of research funding on the one hand and at the final product development stage on the other hand. These require a declaration to be submitted by the users to the competent national authorities, certifying that they have fulfilled the due diligence obligation.

How does this apply for french users?

- At the stage of final development of a product:

The appropriate authority is the Ministry in charge of environment. The required due diligence declaration must be made on the [DECLARE platform](#) set up by the European Commission.

- At the stage of research funding:

The competent authority is the Ministry in charge of research. The required due diligence declaration should be made on the [platform](#) set up by this Ministry.

- [Send an email to the Ministry in charge of research](#)

Contact information for the Competent National Authority

Ministère de la transition écologique

Direction générale de l'aménagement, du logement et de la nature

Direction de l'eau et de la biodiversité

Sous-direction de la protection et de la restauration des écosystèmes terrestres

Bureau de l'encadrement des impacts sur la biodiversité - Mission APA

1, place Carpeaux - 92055 La Defense Cedex - France

- [Send an email to the Competent National Authority](#)

ABS Regulations

International level

- [Convention on Biological Diversity \(CBD\)](#)
- [Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization \(ABS\)](#)

European level

- [EU Regulation No. 511/2014 of 16 April 2014 on compliance measures for users from the the Nagoya Protocol on Access To Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union](#)
- [EU Implementing Regulation 2015/1866 of the Commission 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](#)
- [Guidance document on the scope of application and core obligations of EU Regulation 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 Eq](#)

- [Presentation of European regulations on the website of the Commission](#)

National level

- [Title V of Law No. 2016-1087 of 8 August 2016 on Reclaiming Biodiversity, Nature and Landscapes](#)
- [Decree No. 2017-848 of 9 May 2017, regarding access to genetic resources and their associated traditional knowledge and sharing the benefits arising from their utilisation](#)
- [Book IV, chapter II, section 3 of the French Environmental Code](#)

French Polynesia and New Caledonia

- [Book III, title IV of the Environmental Code of French Polynesia](#)
- [Environmental Code of New Caledonia - North Province](#)
- [Environmental Code of New Caledonia - South Province](#)
- [Environmental Code of New Caledonia – Loyalty Islands Province](#)

ABS documentation

- [Access and Benefit-Sharing Clearing-House \(ABSCH\)](#)
- [Presentation of the ABS on the website of the Biodiversity Research Foundation](#)