

INSTITUTE OF AGRICULTURAL RESEARCH'S GENETIC RESOURCES ACCESS POLICY

1. INSTITUTIONAL BACKGROUND

Instituto de Investigaciones Agropecuarias (INIA, Institute of Agricultural Research) is a private law non-profit Corporation dependent on the Chilean Ministry of Agriculture, whose mission is to generate and share knowledge and strategic technologies on a global scale in order to develop innovation and improve the competitiveness of the food and agriculture sector.

Since its foundation in 1964, within the framework of the Chilean Ministry of Agriculture's mandate to support the national agriculture, INIA has been concerned about the conservation of the genetic resources of the country by carrying out collections, preserving and characterizing germplasm. This has enabled INIA to manage important germplasm collections of the essential and strategic crops, as well as microorganisms. Historically, INIA has used these genetic resources (GRs) in plant breeding programs and integrated disease, insect and weed control for the agricultural development of the country. As a result, INIA has developed an important number of breeding materials, commercial varieties and biocontrollers, contributing to the national agricultural development.

Under the mandate of the Chilean Ministry of Agriculture (Resolution N° 676 from 01. 22. 1985) and with the aim of respond and comply with the International Undertaking on Plant Genetic Resources (FAO 1983), INIA created the Genetic Resources Program in 1985.

Subsequently, in 1990, with the support of the Japan International Cooperation Agency (JICA) and the Chilean State, INIA designed and built 4 seed banks, structuring a plant germplasm bank network. This effort allowed the creation of scientific, technical and infrastructure basis that strengthened the activities of INIA's Genetic Resources Program.

Likewise, since 2001, INIA has been systematically developing the collection of native plant seeds, efforts focused specially on those endemic plant and endangered species.

In 2010, INIA, with funding from the Chilean Agriculture Ministry, created the **“Germplasm Bank Network in accordance with international standards”**. This network includes four phylogenetic banks and one microbial bank distributed throughout the country.

With the creation of INIA's bank network, a response to the international commitments met by the Chilean State in this matter is given, before the OECD, FAO and the Convention on Biological Diversity.

The Bank Network project accounted for the necessity to strengthen the management systems for the optimal preservation of the national genetic resources in germplasm banks.

2. DEFINITIONS

The definitions presented below are based mainly on the ones provided by the Convention on Biological Diversity (Decree N° 1963 of the Chilean Ministry of Foreign Affairs, 1995) and the Environmental Bases Law (Law 19.300 of 1994), with the clarifications that were considered necessary for the development this document.

Material Transfer Agreement (MTA): An agreement held between INIA and parties external to the institution, national or international, for the transfer and exchange of genetic resources, its progeny or derivatives of the biodiversity maintained under *ex situ* or *in situ* preservation conditions.

Commercial use and Commercialization: This involves a patent request, obtaining or transferring Intellectual Property Rights or any other tangible or intangible rights by selling or licensing, or any other form that declares property; the beginning of product development; the management of market research and seeking for premarket approval, and/or selling any by-product.

Appropriate Technical Committee: INIA's higher court, which will analyze and solve the genetic access request of materials that are strategic for INIA or the country. This committee will be led by the National Deputy Director of INIA's Research and Development. Furthermore, it includes the GR Coordinator, the head of Intellectual property and ad hoc researchers.

Free, Prior and Informed Consent: A basic and fundamental element of the ability of a community and individuals to hold and execute Treaties and Agreements, in order to exercise sovereignty and to protect lands and natural resources, and also to create and participate in processes that fix violations committed against its land rights and against rights recognized on the treaties. The right to Free, Prior and Informed Consent is key for the establishment of conditions and criteria that are acceptable in States negotiations above all, and any other matter concerning lands and the way of living of a community.

Derivative: It is understood as a biochemical compound that exists naturally, produced by gene expression or by biologic or genetic resources metabolism, even if they do not have functional units of heredity.

Fair and Equitable Benefits Distribution: Participation of the economic, environmental, scientific and technological, social or cultural benefits resulting from the research, bioprospecting or the economic leverage of the elements and genetic biodiversity resources between the stakeholders involved in the access and preservation of the genetic resources, with a special focus on local and native communities.

Biological Diversity: It involves the variability among living organisms from all sources, including, among others, terrestrial and marine ecosystems, and other aquatic ecosystems and ecological complexes they are part of.

Genetic Material: Any material or element from vegetal, animal, microbial origin or of other kind that contains functional units of heredity.

Material Transfer Notification (MTN): An INIA's internal document for transferring and exchanging elements and genetic resources, their progeny or biodiversity derivatives, maintained under *ex situ* or *in situ* conditions.

Biological Resources: Living environmental components that are susceptible to human use. The biological components are part of the biological diversity. Precisely, biological resources refers to genetic resources, organisms or a part of them, populations or any other biotic component of ecosystems that have a value or actual or potential utility for humanity.

Genetic Resources: Part of the genetic material of vegetal (phytogenetic), animal (zoogenetic), microbial, or of any other kind of biodiversity that has a known use, even if it is effectively exploited by humans (current value) or not (potential value).

Genetic Resources Use: This is understood as performing research and development activities about the genetic and/or biochemical composition of genetic resources.

3. INTERNATIONAL AGREEMENTS; LEGISLATION AND REGULATIONS IN FORCE WITHIN CHILE IN RELATION TO GENETIC RESOURCES

The current Policy is based on international agreements and treaties that have been signed by the Chilean State, and also the related national legislation, specifically:

The **Convention on Biological Diversity**, signed by Chile in 1992 and ratified via Executive Order, 1963 (Diario Oficial de Chile, N°35.160, May 6th, 1995). The objectives of the Agreement are the preservation of the biological diversity, the sustainable use of its components, and the fair and equitable share in

the benefits that derives from the use of genetic resources with, among other things, an appropriate access to those resources, together with an appropriate transfer of relevant technologies, considering all rights over those resources and technologies (Art. 1). Article 15, that regards the access to genetic resources on which, among other things, recognizes the sovereign rights of the States on genetic resources and their authority to control the access to their genetic resources, is particularly relevant to this Policy (Art. 15.1). It states that the Parties shall create conditions to facilitate other Parties to access genetic resources, without the imposition of restrictions contrary to the objectives of the Agreement (Art. 15.2.). Access to genetic resources shall be on mutually agreed terms (Art. 15.4.), and subjected to prior informed consent by the Contracting Party that provides the resources (Art. 15. 5).

FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Chile signed the International Treaty in November 2002 and was ratified in May 2016. The specific objectives of the Treaty are "the preservation and sustainable use of plant genetic resources for food and agriculture, and fair and equitable distribution of the benefits arising from their use in harmony with the Convention on Biological Diversity, for a sustainable agriculture and food safety". The Treaty designed and currently drives a Multilateral Access and Benefit Sharing System, aiming to facilitate the resources exchange between the Contracting Parties. This multilateral access system can be applied only to species considered strategic for global agriculture, which are listed in the Appendix 1 of the treaty.

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 (2010). The Protocol aims at the "fair and equitable share in the benefits arising from the use of genetic resources, even through the appropriate access to genetic resources and through the appropriate transfer of relevant technologies, considering all rights over those resources and technologies". The scope of the Nagoya Protocol is genetic resources comprised on article 15 of the Agreement and the benefits arising from the utilization of such resources. This Protocol shall be also applied to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge. This protocol entered into force on October 12th 2014 and Chile signed it in 2010 but has not ratified it yet.

The Industrial Property Law No. 19.039 from 1991 establishes the obligation to protect heritage, both biological and genetic, and national traditional knowledge, when industrial property rights are consent (Article 3). The Chilean law provides that plants and animals and procedures for plants and animals production that are essentially biological, are not considered as an invention, and therefore are excluded from patent protection. However, microorganisms and microbiological procedures that meet the general requirements for the award of patents can be protected (Article 37). Likewise, it is excluded from patent protection the "Part of living beings as found in nature, natural biological processes, biological material existing in nature or material that can be isolated, including genomes or

germplasm. Nevertheless, procedures that use one or more of the biological materials mentioned above and products directly obtained by such procedures, provided that they comply with the requirements established in Article 32–of this Law, insofar as the biological material is adequately described and the industrial application thereof is explicitly outlined in the patent application” (Article 37f). Finally, article 38 of the law says “Patents may not be granted for inventions whose commercial exploitation must necessarily be prevented to protect public order, State security, morality or proper practice, people or animal life or health, or to preserve plants or the environment, provided that such exclusion is not solely for the purposes of a legal or administration provision that prohibits or regulates such exploitation.”

Law No. 19.342 regulating the rights of breeders of new plant varieties in Chile, and that is consistent with the UPOV Act, International Union for the Protection of New Varieties of Plants from 1978, of which Chile is a signatory. This law stipulates, among other matters, that a breeder can claim protection of a plant variety if this is New, Distinct, Uniform and Stable.

4. CONCERNED PARTIES

- Ministry of Agriculture and related services.
- Ministry of Environment.
- National and international Botanic Gardens.
- National and international Universities.
- Institutes and Centers of Research at National and International levels.
- INIA researchers.
- National and international companies.
- Non-governmental organizations.
- Indigenous communities.
- Farmers.

5. APPLICATION FIELD

This Institutional Policy comprises everything related to the terms and conditions of access, bioprospecting and transfer of wild and cultivated genetic resources, their progeny or derivatives; even if they are from vegetal, microbial or animal origin, collection products, genetic introduction or breeding preserved in INIA’s germplasm banks. The scope of this Policy also includes that regarding the remuneration of benefits arising from the use and development of genetic resources transferred by INIA.

Genetic resources generated by INIA are, besides, subject to particular conditions stated in INIA's Intellectual Property Policy, which shall be negotiated case by case.

6. GUIDING PRINCIPLES

1. Genetic Resources Sovereignty. - Genetic resources as a component of natural resources are sovereignty of States that own or conserve them.
2. Respect for international Treaties. - The agreement and full respect for international treaties and agreements signed and ratified by the Chilean State in the field of conservation, access and use of genetic resources.
3. Interdependence on Genetic Resources. - Genetic resources are essential for food safety and agriculture maintenance, and so it is for development of new products and medicines. In this context, countries and institutions depend on germplasm from other countries and institutions for agricultural development and scientific research.
4. The access to genetic resources shall be based on a mutual agreement previously agreed between the requiring party and the one that has genetic resources available (prior informed consent). This according to international obligations and considering the interests of other parties, as the Government, indigenous and local communities, individuals, NGOs and the scientific community.
5. The access to genetic resources shall be based on agreements that help the encouragement and strengthening of scientific research, preferably in the country; moreover, it should provide fairly and equitably remuneration of the benefits generated from the use of transferred genetic resources.
6. Good faith. – It is taken as a starting point that any natural or legal person requesting access, acts in good faith when providing all reliable information necessary to resolve and give adequate response to the request.

7. OBJECTIVES

The general objective of this policy is to provide an institutional framework under which INIA will deal with requests for genetic material collected and/or maintained in its germplasm banks, and the terms and conditions under which it may grant access to these materials.

Specific objectives

- a) To establish and have institutional rules and procedures for processing access requests to germplasm held by INIA.
- b) To promote protection, research and sustainable use of genetic resources incorporated in the Bank Network.
- c) To secure an immediate but properly controlled access to the germplasm held by INIA.

8. GENETIC RESOURCES ACCESS

- 8.1 INIA will treat expeditiously and transparently any access request, without imposing restrictions that are contrary to what is stated in international agreements and treaties signed and ratified by the Chilean State in this field and related national laws. It will also consider institutional policies related to this matter.
- 8.2 INIA will analyze all access requests and decide considering its strategic objectives and aiming to fulfill the institutional mission, in the context of the State policies of Chile.
- 8.3 Requests for access to genetic resources shall be made by legal entities; requests made by individuals will be exceptionally addressed.
- 8.4 Requests for access to GRs will be analyzed and resolved according to INIA's National Program to safeguard those resources according to the following criteria:
 - When GRs **incorporated to the INIA's Bank Network** are requested, this will be carried out through Global Grin and it will be resolved by the Coordinator of the National Program of GRs. However, if the material is "strategic", it will be resolved by the Appropriate Technical Committee.
 - When GRs **NOT incorporated to the INIA's GRs Program** are requested by outsiders to INIA, the request will be executed by email, letter and written notification, as appropriate and addressed to the respective Coordinator, who will resolve. In the case of requests made by the personnel of INIA, the request will be sent by email or memorandum to the respective investigator who must resolve it.
- 8.5 The amount of germplasm to transfer will depend on the species involved and it will be defined by INIA according to international standards. Under no circumstances complete collections will be transferred.
- 8.6 INIA will establish categories of access to genetic resources according to criteria established by the Appropriate Technical Committee. In spite of the aforementioned, some limitations on access are detailed in Article 9.
- 8.7 If the request is approved, the applicant will be notified and a MTN (Material Transfer Notification) or a MTA (Material Transfer Agreement) shall be signed prior to the release of the genetic resource, as appropriate. Likewise, depending on the magnitude of the requested

material, INIA may request the applicant to cover the replacement costs of the transferred material, required sanitary analysis and dispatch.

- 8.8 INIA may establish germplasm collection agreements for conservation and research, which contains a contract for access to genetic resources collected in order to safeguard the institutional interests and the interests of the Chilean State on these resources. The aforementioned shall be executed without contravening national legislation and/or current Policies and regulations currently in force in Chile regarding this matter.

9. ACCESS RESTRICTIONS

- 9.1 INIA, through the Appropriate Technical Committee, may limit or restrict access to some genetic resources, if they are native and/or endemic, endangered or considered strategic for the country.
- 9.2 The genetic resource from INIA programs, such as pure lines and advance lines are considered private material and are owned by the institution. Therefore, they are not freely available. INIA may grant access to these within the framework of cooperation agreement for specific research.
- 9.3 Wild or cultivated, progeny and derivative genetic resources, as well as the information generated from these, obtained in the framework of specific projects and that may be under investigation or used by INIA researchers, will have the status of access with reserve. They may be distributed, provided there is an express authorization by the Appropriate Technical Committee.
- 9.4 All genetic resource in custody or that has been collected and kept in INIA's Bank Network by request of third parties, will not be available for distribution, unless that Party authorizes it in writing.

10. COMMERCIAL USE OF GENETIC RESOURCES

- 10.1 INIA distributes germplasm only for research and development purposes. Therefore, INIA will trade, under no circumstances genetic, resources classified as public in nature and reserved.
- 10.2 INIA will give, under no circumstances, access to genetic resources to requestors who consider direct marketing of these resources.

11. ACCESS TO INFORMATION AND ASSOCIATED DATA

As a scientific institution, for INIA is important to promote access to its collections to the scientific and preservation community. Thus, the information regarding collections held in INIA's germplasm banks and that are considered as public varieties, will be freely accessible and, therefore, arranged in their

online databases. Included in this are passport information, characterization, images and any information arising from the research of genetic resources preserved in its germplasm banks.

All unpublished information generated within the framework of projects or agreements in progress or finished, using genetic resources collected or preserved by INIA, may be available in online databases, as long as the Appropriate Technical Committee authorizes explicitly and in writing.

12. APPROPRIATE TECHNICAL COMMITTEE

Committee created to evaluate and sanction access requests to genetic resources from externals to INIA and their unpublished information, that are considered strategic for the institution and/or the country.

Function:

Analyze and resolve access requests to genetic resources strategic for INIA or the country.

Structure:

Director: National Deputy Director of Research and Development.

Executive Secretary: National Coordinator of the Genetic Resources Program.

Additional members:

1. Intellectual Property Manager.
2. Bank Managers, as appropriate.
3. National Programs Coordinators, as appropriate.
4. Researchers, as appropriate.