

BRAZIL

EASY ABS GUIDE

This Easy ABS guide was developed by the **GNP-HuB project** in collaboration with the **ABS authorities from Brazil**. It aims to help researchers understand Brazilian ABS measures and the steps to become Nagoya-Protocol-compliant. This guide focuses on non-commercial use of genetic resources and associated traditional knowledge.

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ABS general overview

The Brazilian ABS legislation does not require an ABS permit before obtaining or utilizing a genetic resource. Instead, and in the absence of access to associated traditional knowledge (aTK), users must formally establish a Brazilian partner who should register them in **SisGen**. A **registration of shipment** is required *before* transferring samples outside Brazil for new research and/or development abroad. A **registration of access** is required *before* requesting intellectual property rights or publishing of results. The registration of access does not imply benefit sharing commitments.

In situations of **public health emergency**, the Ministries of Health and Environment, in a joint Ordinance, can establish a simplified procedure for shipping genetic heritage.

Regarding genetic resources for food and agriculture, species included in annex 1 of the **ITPGRFA** are excluded of the ABS measures in Brazil, when used for a purpose covered by the treaty.

Party to the Nagoya Protocol since:
2021

Access regulated since:
2000 - the ABS procedures were simplified in 2015 with the Law N°13.123

ABS National Focal Point:

Genetic Heritage Management Council (**CGEN**)
Luiz Eduardo Andrade de Souza, Biodiversity Division, Ministry of Foreign Affairs of Brazil dbio@itamaraty.gov.br

SisGen contact: sisgen@mma.gov.br

SisGen (the National System for Genetic Heritage and Associated Traditional Knowledge Management) is the Brazilian virtual platform to manage ABS registrations and notifications. But only Brazilian citizens can login, that is why foreigners need a Brazilian partner to register their research.

Soon, SisGen will enable foreigners to make their own registrations in association with a Brazilian institution.

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What is the scope of the ABS measures for non-commercial research?

What genetic resources are covered?

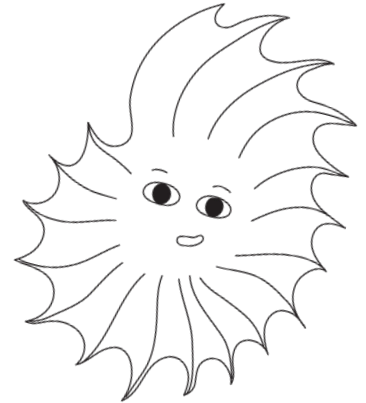
- native
- endemic
- wild
- introduced (non-native) *
- domesticated *
- cultivated *

In Brazil, genetic heritage refers to genetic material, genetic information and substances from the metabolism (derivatives or biochemical compounds).

*For introduced, domesticated, and cultivated species that are not native to Brazil, ABS measures only apply when they form spontaneous populations and have acquired distinctive characteristic properties in the country, or when are considered landraces or creole breeds selected or developed by Indigenous peoples, traditional communities, or traditional farmers in the Brazilian territory.

For example, a researcher wants to study the genetic composition of coffee plants harvested in a farm in Brazil. As this species is cultivated and not native to Brazil, then it is out of the scope of the Brazilian ABS legislation and registration in SisGen is not needed.

Microorganisms are considered part of the existing Brazilian genetic heritage when they have been isolated from substrates of the national territory, the territorial sea, the exclusive economic zone or the continental shelf.



What non-commercial academic research activities are covered?

- evolution
- gene function
- gene expression
- genome editing
- gene characterization
- biochemical characterization
- biogeography
- population genetics
- genome sequencing
- taxonomy
- species identification/ barcoding
- phylogeny
- bioprospection

What areas in the country are covered?

- *ex situ* collections*:
 - within the country
 - outside the country
- all country

Notes: For marine areas, the Brazilian Biodiversity law applies to the continental shelf, territorial waters, and the exclusive economic zone.

*If the genetic resource is also found in *in-situ* conditions within Brazil's jurisdiction.

Are there exceptions to any of the three previous questions?

Access to human genetic resources at any point in time as well as research activities completed before 2000 are excluded.

The following activities are not considered access **when they are not an integral part of research or technological development** (art 107, Decree 8772):

- Filiation or paternity test, sexing technique and karyotype or DNA analysis and other molecular analysis for identification of a species or specimen.
- Tests and clinical diagnostic examinations for the direct or indirect identification of etiological agents or hereditary diseases in an individual
- Extraction, by milling method, crushing, or bleeding that results in fixed oils.
- Purification of fixed oils resulting in a product whose characteristics are identical to those of the original raw material.
- Tests which aim to assess rates of mortality, growth, or multiplication of parasites, pathogens, pests, and disease vectors.

- Processing extracts, physical separation, pasteurization, fermentation, pH assessment, total acidity, soluble solids, bacterial and yeast counts, molds, fecal coliforms, and total genetic heritage samples.
- Physical, chemical, and physical-chemical characterization to determine nutritional information of foods.
- Comparison and extraction of information of genetic origin in national and international databases.

What types of ABS permits are required?

Research activities	Type of permit	National Competent Authority	Requirements
Shipment of samples outside Brazil for new research and/or development abroad.	Registration of shipment made by the Brazilian partner through SisGen .	Genetic Heritage Management Council (CGen), presided by the Ministry of Environment and Climate Change of Brazil cgen@mma.gov.br	<p>Foreigners must have a formal Brazilian partner.</p> <p>Users must show the following documents at the moment of shipment:</p> <ul style="list-style-type: none"> - a receipt of the shipment registration in SisGen - a copy of the MTA signed by both sender and recipient - the Shipment Invoice
Non-commercial utilization. When access (research or technological development) to GR <i>doesn't</i> result in a finished product or reproductive material for economic exploitation.	Self-declaratory registration of access through SisGen .		<p>Foreigners must have a formal Brazilian partner to register them in SisGen, it does not imply research collaboration.</p> <p>Registration before specific trigger points: request for intellectual property rights or publication of results.</p>
Commercial utilization. When access (research or technological development) to GR <i>results</i> in a finished product or reproductive material for economic exploitation.	Self-declaratory access registration and notification through SisGen .		<p>Foreign companies need a Brazilian legal person number or a local partner to use SisGen.</p> <p>Notification when a final product or reproductive material is about to reach the market</p>

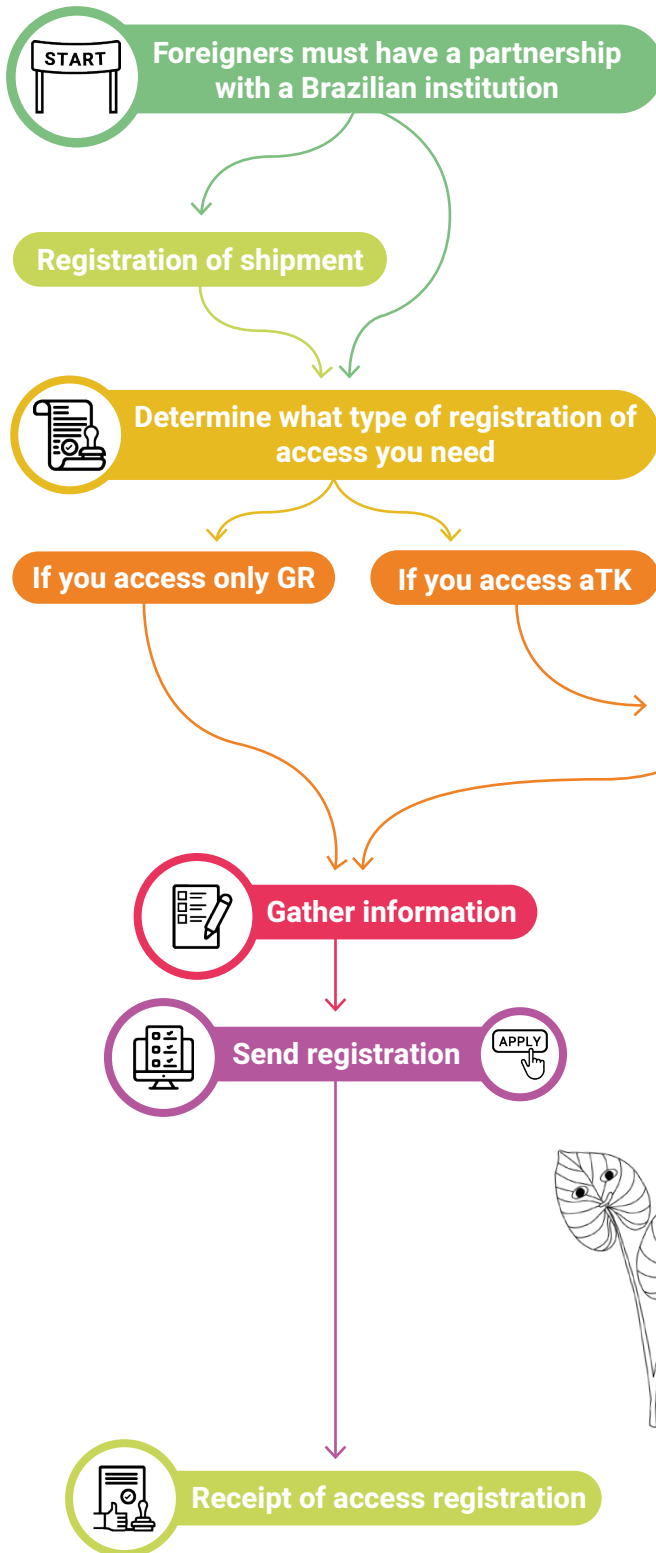
A notification is required for the commercialization of a finished product or reproductive material. Registration is sufficient for the commercialization of intermediate products.



BRAZIL



ABS procedure for non-commercial utilization of genetic heritage and associated traditional knowledge



Sign a formal agreement (e.g. MoU) to establish a Brazilian partner.



You just need a prior **registration of shipment** if you will transfer the sample outside Brazil for new research and/or development abroad.

For **non-commercial use** of all types of GR and/or aTK a **registration of access** on SisGen is needed. There are 3 options: only GR, only aTK or both.

You have to get registered by a Brazilian partner **before requesting intellectual property rights or publishing research results.**

If the source of aTK is identifiable, a Prior Informed Consent from the provider of aTK is needed.



Fill out the forms and complete requirements. This should be done by the Brazilian partner on **SisGen** virtual platform.

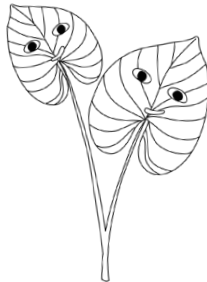
Partner sends the forms and requirements through SisGen virtual platform.

According to the law:

- it is not needed to pay a fee
- you do not have to wait for the authorities to check the documentation
- you are not obliged to share benefits for non-commercial use (no MAT needed)

SisGen automatically delivers a *receipt of access registration*.

At this moment, Brazil is not generating IRCCs. You can use the *receipt of access registration* to show compliance.



Relevant links:



[ABS Law 13.123, of 2015](#)



[ABS Decree 8772, of 2016](#)



[Genetic Heritage Management Council \(CGen\)](#)



[SisGen User Manual](#)

How long does it take, on average, to obtain an ABS permit?

■ less than 3 month

Note: The access registration in case of non-commercial use could take less than an hour, once you have all the required information. However, the process to officially establish a Brazilian partner usually takes a month or two.

How long is the permit valid for?

As the access registration is not required prior to the activities, but it is in fact a registration of results, it is valid for everything that happened before the registration took place and was disclosed during registration. Therefore, there is no need for an extension. Some modifications are possible if new activities are included.

Are there other non-ABS - permits needed? Which ones? (e.g. to collect, to export)

Yes, other permits that might apply, as appropriate:

- For collection of biological material, [more info](#).
- For the collection, by foreigners, of data and scientific materials in Brazil, [more info](#).
- For export and import of biological material (when not for research and development under ABS measures), [more info](#).
- For import and export of CITES species, [more info](#).
- For entry into [Indigenous land](#) and [Protected Areas](#).



Do the national ABS measures address traditional knowledge? How?

Yes.

What is considered aTK in Brazil?

It is the information or practice of Indigenous populations, traditional communities, or traditional farmers about the properties, or the direct or indirect uses associated with genetic heritage.

Please note that if you use aTK for research or technological development, **even if obtained from secondary sources** (e.g., street markets, publications, inventories, films, scientific articles, registries, and other forms of systematization or records), you are required to obtain prior informed consent from an Indigenous population, traditional community, or traditional farmer holder of the aTK and make a registration of access on SisGen.

Procedure:

- Foreigners have to sign a formal agreement to establish a Brazilian partner.
- If the source of aTK is identifiable, you require a Prior Informed Consent from the provider of aTK.
- The Brazilian researcher makes the registration of access on SisGen.
- If there are modifications, the Brazilian partner/user must update the registration.
- If the use is not commercial, there are no benefit-sharing obligations.

Keep in mind! Country-special features and practical considerations

- **Access in ex-situ collections:** according to the Brazilian ABS legislation, access means carrying out research or technological development on Brazilian genetic heritage samples. This means that a access registration or notification in SisGen might be needed when you obtain and use Brazilian GR from an *ex-situ* collection, independently of when the material was collected and left the country or whether the genetic resource is located in a foreign collection outside of Brazil, since the triggering event is research and development. In consequence, the utilization of material deposited in *ex situ* collections decades ago may be under the scope of the Brazilian ABS measures, if research and development happened under the temporal scope.
- **Describing new species:** to officially describe new species, the nomenclature codes may require biological vouchers to be deposited in *ex-situ* collections, which must be freely distributable to third parties with no restrictions. Under the Brazilian ABS law, a registration or notification is required for new research or development using genetic heritage obtained from *ex-situ* collections, and this may be considered a restriction. This may lead to some researchers facing difficulties when describing new species from Brazil.

Benefit-sharing

What kind of benefits does the country usually request from non-commercial research projects?

Even though registration of access is required, **there is no obligation of benefit-sharing for non-commercial research.**

In case of commercialization of finished products or reproductive material (without access to aTK), users can choose between monetary and non-monetary benefit-sharing.

If the user chooses to share the benefits through **monetary means**, a deposit to the National Benefit-Sharing Fund equal to 1% of net revenue must be made:

- No agreement is required.
- Users must disclose the annual net revenue from the commercialization of the product.
- An invoice is issued and the user pays on an annual basis

If the non-monetary benefit-sharing option is chosen, such as a conservation or social project, training or technology transfer, an agreement is needed and benefit-sharing must be equivalent to 0.75% of net revenue.

For uses of aTK, benefit-sharing obligations vary depending on whether the source of aTK is identifiable or not:

- **identifiable:** a freely negotiated Benefit-Sharing agreement with the provider of aTK is needed (for monetary and/or non-monetary benefits), plus 0.5% of the net revenue must be deposited in the National Benefit-Sharing Fund.
- **unidentifiable:** impossible to be linked to at least one indigenous population, traditional community, or traditional farmer that creates, develops, holds or maintains that knowledge. Benefit-sharing agreement is not needed, and 1% of net revenue must be deposited in the National Benefit-Sharing Fund.

Non-identifiable aTK should not be confused with aTK that has been published or widely disseminated. Even though the aTK is obtained from secondary sources, the user must try to identify at least one Indigenous population, traditional community or traditional farmer that creates, develops, holds or maintains that knowledge.

Micro-businesses, small businesses, micro individual entrepreneurs, traditional farmers and their cooperatives **are exempt** from benefit-sharing obligations, but the notification is still needed.



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