

ABS IN BRAZIL

Rules | Specific requirements | Practical considerations

New rules on ABS

On 17 November 2015, a new legal framework on ABS entered into force in Brazil. Law 13.123, which had been under discussion for over 10 years, fully revoked prior rules, which had been adopted on 29 June 2000 and published as Medida Provisoria 2.186, on 23 August 2001. It aimed to overcome the many concerns raised over the years over rules that - while enabling access to genetic resources and associated traditional knowledge - established burdensome requirements and did not include special considerations for scientific research.

Law 13.123 is regulated by Decree 8.772 (11 May 2016). Additionally, Decree 8.973, adopted in January 2017, approved the restructuring of activities for the management of genetic heritage within the Ministry of Environment.

Full implementation of the ABS framework in Brazil now requires the launch of electronic system for registration (see box on SisGen), which is expected in the first semester of 2017.

This fact sheet was produced by the Union for Ethical BioTrade (UEBT), in partnership with GSS Sustentabilidade e Bioinovação and Tozzini Freire Advogados.

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Overview

Brazil is one of the most biodiverse countries in the world; the number of known plant, animal and fungi species in the country already surpasses 200.000 and only 11% of its biodiversity is thought to have been surveyed. In addition, Brazilians cherish their ecosystem and biological resources and speak of 'sociobiodiversity' to reflect its intrinsic links with social, cultural and economic values.

It is thus not surprising that Brazil is an important actor in international discussions on access to genetic resources and fair and equitable sharing of benefits derived from their utilisation (also known as ABS). Brazil has also pioneered national implementation of ABS principles, through a 2001 provisory measure that was the basis of numerous ABS permits and agreements and a 2015 law that overhauled the ABS system and established an innovative, registration-based approach.

The new system, which also features a national fund for benefit sharing and an option for monetary benefit sharing based on the income derived from research or development, is in force and expected to soon become operational.

What resources and activities involve 'access to genetic resources'?

Brazilian rules set requirements for access to genetic heritage and associated traditional knowledge. As defined, these terms focus on research or product development based on native and some non-native species, as well as with traditional knowledge on uses and properties of these species:

Access

Research or technological development conducted on a sample of genetic heritage or associated traditional knowledge. Either of these activities triggers access requirements. That is, the development and/or formulation of new or enhanced materials, products or processes for economic exploitation - even if it does not involve research - is considered 'access'.

- ✓ Research and technological development is covered whether conducted in Brazil or abroad.
- ✓ Sending samples abroad for research and development, even if only for laboratory services, is covered.
- ✗ Certain activities are excluded such as production of fixed oils and extracts or testing for pH or bacteria - as long as no research or development is involved.

Genetic heritage

Information of genetic origin from plant, animal or microorganisms, including metabolic substances. This definition covers physical (molecules or substances) and intangible (genetic or biochemical information taken from a sample) components.

- ✓ All native species are considered part of Brazilian genetic heritage, including traditional local and Creole plant varieties or animal breeds and microorganisms isolated in Brazilian territory.
- ✗ Non-native species are not included, unless they have been introduced in Brazil, grow spontaneously, and have developed distinctive properties.

Traditional knowledge

Information or practices of indigenous peoples or traditional communities or traditional farmers on the properties or direct or indirect uses of genetic heritage. That is, information on the properties or uses of Brazilian genetic heritage that facilitates research and development.

- ✓ Traditional knowledge that has been published or otherwise disseminated – for example, in books, films, databases and other types of instruments – is covered. However, note different procedures apply depending on whether traditional knowledge has an identifiable origin or not.

International rules

Brazil is party to the following international treaties relevant for ABS principles and rules:

- Convention on Biological Diversity (CBD) – ratified 1994.
- International Treaty for Plant Genetic Resources for Food and Agriculture – ratified 2006.
- International Union for the Protection of New Varieties of Plants Convention (UPOV) – acceded 1999.

Brazil signed the Nagoya Protocol in 2011, but has not yet gone through the ratification process. Given concerns with the national rules on ABS in force at the time, it has chosen to prioritise revising and implementing its new legal framework on ABS prior to ratification.



What are access requirements?

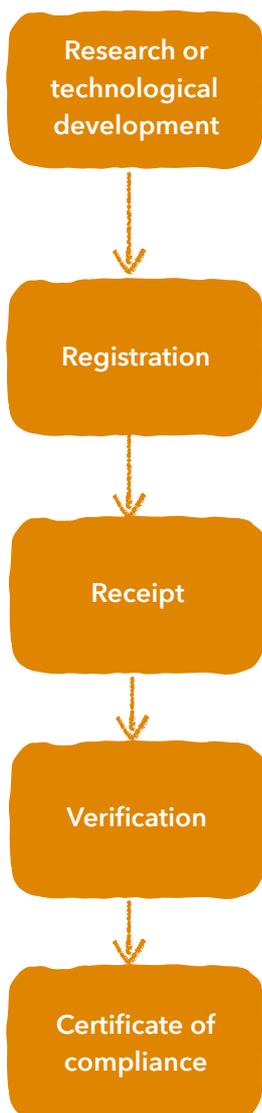
Under the new Brazilian law, access to genetic heritage does not require prior informed consent as such. Access to genetic heritage is, instead, subject to an electronic registration system (referred to as SisGen). Companies conducting access to genetic heritage must declare and provide details of the activities, information and materials involved. The same approach applies to traditional knowledge, in cases where such knowledge does not have an identifiable origin.

If access activities involve traditional knowledge with an identifiable origin - that is, when it can be linked to a specific indigenous people, traditional community or traditional farmer - prior informed consent is still required and must be secured prior to registration.

SisGen

The National System for the Management of Genetic Heritage and Associated Traditional Knowledge (referred to as SisGen) is charged with the register of access to genetic heritage or associated traditional knowledge, among other tasks. Information in the system will be public, except where the user has requested and provided legal justification for confidentiality. SisGen is managed by the CGen Executive Secretary, but is not yet operational.

What is the procedure for access to genetic resources?



Research or technological development involving genetic heritage may be started without prior procedure. However, registration must have taken place prior to sending samples abroad, applying for intellectual property rights, commercialising intermediate or final products, or publishing research results. Also, foreign companies and institutions may only conduct such research and development in partnership with local institutions.

Entities conducting research or technological development activities must register electronically. SisGen requires information on topics such as the user and its local partners; the objectives, expected or obtained results and potential application of research or development; and the type and source of genetic heritage or associated traditional knowledge accessed.

Once the registration form is completed, SisGen automatically issues a receipt. This document constitutes the written proof of registration and allows the user to apply for intellectual property rights, market intermediate products, publish or otherwise disclose research results, and notify a final product.

Registration is also followed by a process of verification – an evaluation of the information provided by the user conducted by the Council for the Management of Genetic Heritage (referred to as CGEN). This process involves consultation of relevant regional and expert bodies and may detect irregularities or the need for additional information.

Upon request of the user, CGEN may issue a certificate of legal compliance for activities of access to genetic heritage. Such a certificate will be discussed and issued by the CGEN plenary, according to its internal procedures.

What activities trigger benefit sharing?

In the new Brazilian ABS framework, engaging in activities considered to be ‘access’ does not necessarily trigger benefit sharing requirements. Indeed, benefit sharing conditions are only triggered if access to genetic heritage or associated traditional knowledge leads to commercialising a final product and if such access added significant value to such product.

- ✓ A final product does not require any additional production process and is ready to be used final consumer – whether an entity or an individual. In agriculture, reproductive material is deemed a final product.
- ✓ Adding significant value means that genetic heritage or associated traditional knowledge either determine the product’s functional characteristics (for example, an active ingredient used in pharmaceutical or cosmetic products) or its market appeal (for example, product marketing or packaging refers to associated traditional knowledge).
- ✗ There are a number of exceptions to benefit sharing requirements, including intermediate products, final products or reproductive material developed by traditional farmers, cooperatives or small businesses; the licensing of intellectual property rights; and final product or reproductive material resulting from access to non-native species (unless these species grow spontaneously and have distinctive characteristics or are traditional plant varieties).



CGen

The Council for the Management of Genetic Heritage (referred to as CGen) is the multi-stakeholder body charged with coordinating the development and implementation of policies for ABS. It brings together representatives of public institutions, business, academia and indigenous peoples and traditional communities. It is responsible for setting technical norms and guidelines (for example, for the National Fund for Benefit Sharing), monitoring access, accrediting ex situ collections, managing the notification of final products, and creating and maintaining SisGen.

Traditional knowledge of identifiable origin

Access to traditional knowledge that is linked to specific indigenous peoples, traditional communities or traditional farmers, requires prior informed consent and mutually agreed terms. This is the case whether such traditional knowledge has been accessed directly (for example, through interviews with traditional communities) or indirectly (for example, traditional knowledge available in scientific publications, databases or cultural inventories).

Proof of prior informed consent and benefit sharing agreements must be presented to SisGen. It is important to note that, in line with the scope of benefit sharing for genetic heritage, benefit sharing agreements for traditional knowledge of identifiable origin are only signed once if there is final product. In this case, it is the manufacturer of the final product who negotiates and shares benefits directly with the providers. However, in addition, 0,5% of the net income from sales of the final product must be paid to the National Fund for Benefit Sharing, as a recognition of the collective nature of traditional knowledge.

What are benefit sharing requirements?

Under the Brazilian ABS framework, there is an option for monetary or non-monetary sharing of benefits derived from access to genetic heritage.

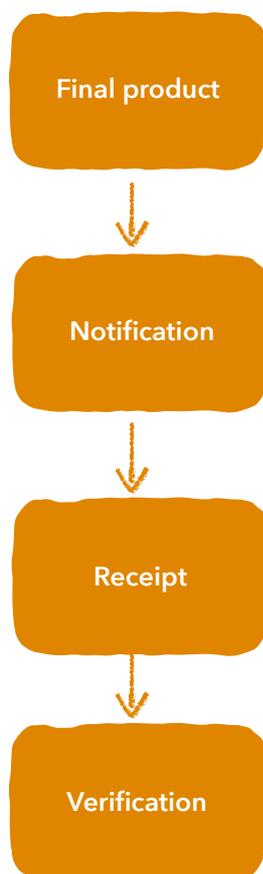


Monetary benefits are set at 1% of the net income from the sales of the final product. Nevertheless, business associations may negotiate a lower percentage in cases where the competitiveness of the sector requires it. Payments are made into the National Fund for Benefit Sharing (referred to as FNRB).



Non-monetary benefits are set at 0.75% of the net income from the sales of the final product. In case of opting for non-monetary benefits, a company would need to sign an agreement with the Ministry of Environment to define the activities that will constitute such benefit sharing, including projects on the conservation or sustainable use of biodiversity, transfer of technologies, training and capacity building, and preferential terms for acquisition of products. It would be up to the company sharing benefits to select the specific groups or projects to be supported through non-monetary benefit sharing. This agreement must be presented within 365 days from the notification.

What is the procedure for benefit sharing?



Benefit sharing requirements are only triggered by the intent to commercialise a final product derived from access to genetic heritage or associated traditional knowledge (see above).

Prior to the commercialisation of the final product, the manufacturer must notify SisGen and provide:

- Information on applicant, final product or reproductive material, sector of application, relevant registrations (e.g. SisGen, ANVISA, IBAMA or INPI), and geographical scope of manufacture and commercial distribution;
- Declaration on whether genetic heritage or associated traditional knowledge used in the final product determines the product's functional characteristics or its market appeal.
- Choice of which type of benefit sharing mechanisms it seeks to apply.

Once the notification form is completed, SisGen automatically issues a receipt, on the basis of which the applicant is able to prove notification and move forward with the economic exploitation of the final product or reproductive material.

With notification, CGen also conducts a process of verification – an evaluation of the information provided by the user.

What about activities conducted prior to this ABS framework?

Law 13.123 makes it compulsory to regularise any activities such as access to genetic heritage or associated traditional knowledge, transfer of samples abroad or economic exploitation of a product resulting from access carried out without proper authorisations under the previous ABS framework (that is, between June 30, 2000 and November 16, 2015). The time period foreseen for such regularisation is one year, counting from the launch of SisGen.

Regularisation procedures differ according to the activities. If access involved only research activities, companies are only required to register these activities in SisGen. If access led to commercialisation of a final product, a commitment to share benefits must be signed. This commitment must cover all benefits accrued from the time the product was launched - but it does not extend beyond a maximum of five years. Signature of this commitment suspends applicable sanctions for lack of compliance. Once legal requirements have been met, including registration, notification, signature and fulfilment of a benefit sharing agreement, sanctions are significantly reduced or extinguished, depending on the types of activities conducted.

Access to genetic heritage and associated traditional knowledge that was carried out before 30 June 2000 is not subject to ABS requirements.



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