

BIO DIVERSITY



Law Handbook

Study carried out by Escolhas Institute

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Law Handbook

Introduction

The objective of the Biodiversity Law Handbook is to present, in simple and accessible language, Federal Law No. 13,123/2015 (the Brazilian “Biodiversity Law”) and the legal instruments that were drafted to implement it, in particular Federal Decree No. 8,772/2016 and the regulations of the Genetic Heritage Management Council (Conselho de Gestão do Patrimônio Genético - CGen) and the Ministry of the Environment.

The Handbook is designed especially for those who intend to carry out research and development on components of Brazilian biodiversity and associated traditional knowledge, or to explore products resulting from these activities, in Brazil and abroad. These groups of people are defined within the multilateral Access and Benefit Sharing (ABS) system, as well as in the Brazilian Biodiversity Law, as users, a category that may include companies, researchers, and traditional communities. This guide will also aid those who simply wish to better understand the Brazilian regulations on this subject.

The translation of this Handbook into English aims to help fill the gap of quality information accessible to foreigners on the Brazilian legal framework for access to genetic resources and traditional knowledge. For instance, the National System for the Management of Genetic Heritage and Associated Traditional Knowledge (SISGen) was launched as a virtual platform in 2017 but still does not have a version in English. This is not only symptomatic of a language barrier, but mainly of an ABS system that was installed largely due to concerns with biopiracy* and consequently imposes counterparts for the access of foreigners to genetic resources originated in Brazilian territory. Though based on justifiable and important concerns, this posture toward access to components of its biodiversity has led foreigners to avoid researching and developing products with Brazilian species, as well as generated difficulties for Brazilian scientists conducting part of their research abroad.

Nonetheless, this publication comes at a turning point in this scenario. With the recent ratification of the Nagoya Protocol by Brazil, the country will have to improve its ability to inform international stakeholders on how to comply with the national rules on access to genetic resources. This goes beyond reporting to the ABS Clearing House (ABSCH), the platform created by the Nagoya Protocol to exchange information about ABS legislation in each member country. It requires the capacity-building of Brazilian public, private, academic, and civil society organizations in the principles and requirements of the legislative framework so they can better explain them to international stakeholders with whom they will be engaging more frequently and directly. The translation of this Handbook seeks to offer one more tool among the many that will be necessary to support this capacity-building effort.

The Biodiversity Law Handbook is divided into seven parts: (1) Contextualization; (2) Basic concepts; (3) SISGen: registration and notification; (4) Benefit sharing; (5) Governance; (6) Compliance and (7) Transitional provisions.

We hope that this material will ease the understanding of this still new and challenging topic and help foster the sustainable use of biodiversity, in accordance with the national legislation, and the fair and equitable sharing of the benefits that derive from this use, which are central objectives of the Convention on Biological Diversity (CBD).

* The first Brazilian legislation on the subject, Provisional Measure (Medida Provisória) nº 2.052, was created in the year 2000 with the intention of suppressing biopiracy and guaranteeing the equitable sharing of benefits arising from research and development with Brazilian species. This legislation was repeatedly reenacted as Provisional Measure nº 2.186-16/2001, which remained in place until the Biodiversity Law was approved in 2015.

Index

1. General Context

1.1. What the Biodiversity Law is and its intended use	10
1.2. The Biodiversity Law and the Convention on Biological Diversity	11
1.3. Who needs to comply with the Biodiversity Law?	12
1.4. The situation of foreigners	13
1.5. Main obligations under the Biodiversity Law	14

2. Basic concepts

2.1. Genetic heritage and traditional knowledge	18
2.2. Official list of species of Brazilian biodiversity?	19
2.3. Associated traditional knowledge	20
2.4. Access	21
2.5. Activities that do not configure access when they are not an integral part of R&D	22
2.6. Transferring and Sending	24
2.7. Finished product, intermediate product and reproductive material	25

3. SISGen: registration and notification

3.1. The National System for the Management of Genetic Heritage and Associated Traditional Knowledge (SISGen), access registration and product notification	28
3.2. Flowchart of registration and notification in SISGen	29
3.3. Research using associated traditional knowledge	30
3.4. The system	31
3.5. User registration versus institutional regist	32
3.6. Access registration: necessary information	33
3.7. Finished product notification: required information	35
3.8. Transferring: required information	37
3.9. Sending for provision of services: required information	38

4. Benefit sharing

4.1. Modalities	42
4.2. Attribution of responsibility for payment	43
4.3. Finished product	44
4.4. Value and destination	45
4.5. Sectoral agreement	48
4.6. Benefit Sharing Agreement (BSA): when to enter?	49
4.7. Benefit Sharing agreement (BSA): content	50
4.8. Exemptions	51

5. Governance

5.1. General structure	54
5.2. Composition and duties of the Genetic Heritage Management Council (CGen)	55
5.3. Department of Genetic Heritage (DPG): assignments	56
5.4. National Benefit Sharing Fund (FNRB)	57
5.5. FNRB Steering Committee	58

6. Compliance

6.1. Administrative infractions and sanctions	62
6.2. Inspection	63

7. Transitional provisions

7.1. Adaptation and legalization	66
7.2. How to adapt and legalize?	67



General Context

What the Biodiversity Law is and its intended use

Federal Law No. 13,123 / 2015, also known as the Biodiversity Law, aims to regulate research and development activities that draw on the genetic heritage of species that make up Brazilian biodiversity and the traditional knowledge associated with it in order to promote their sustainable use and the fair and equitable sharing of benefits arising from these activities. This Law defines the use of biodiversity components for research and development purposes as “access” to genetic heritage or associated traditional knowledge.

It is worth noting that there is a difference between the definition of access under Brazilian Law and the use given to that word in the context of the CBD. In Brazilian Law, access means research and development. In the CBD, this word is used to describe the act of obtaining a sample for further research and development.

See below how the Law defines genetic heritage and access to genetic heritage and associated traditional knowledge (art. 2, I, II and III *):

- (i) Genetic Heritage - information of genetic origin of plant, animal, microbial or other species nature, including substances derived from the metabolism of these living beings;
- (ii) Associated traditional knowledge of identifiable origin - information or practice of the indigenous population, traditional community, or traditional farmer about the direct or indirect properties or uses associated with the genetic heritage; and
- (iii) Associated traditional knowledge of non-identifiable origin - associated traditional knowledge in which there is no possibility of linking its origin to at least one indigenous population, traditional community, or traditional farmer.

We will always refer to Brazilian biodiversity as a synonym for national genetic heritage, that is, all the information about the genetic origin of a plant, animal, microbial or other species, including substances from the metabolism of these living beings.

* Whenever an article is mentioned in the Handbook without specification, it is because we are referring to the Biodiversity Law.

The Biodiversity Law and the Convention on Biological Diversity

It is common for users to ask themselves if only Brazil has specific legislation on this topic. The answer is no. In fact, countless countries have regulations for access to their genetic heritage, including Australia, South Africa, Colombia, Mexico, and Spain. They all have a common origin: the Convention on Biological Diversity.

The Convention on Biological Diversity (CBD) is the most important international treaty for the conservation and sustainable use of biodiversity. It acknowledges that countries are sovereign over the genetic resources of biodiversity found in their territory and can set standards for access and demand sharing of the benefits arising from it. It was based on this convention that Brazil - and several other countries - drafted internal laws on the subject (art. 15.1. of the CBD).



Convention on
Biological Diversity

The current Biodiversity Law is the second Brazilian legal framework on the subject. Before it was drafted, we had Provisional Measure 2.186-16/2001, which was in force for almost 15 years, until it was revoked in 2015. This older legislation had numerous problems that discouraged the carrying out of research on biodiversity and, consequently, the sharing of resulting benefits. Therefore, after extensive debate between the government and civil society, it was replaced by the current Biodiversity Law.

Who needs to comply with the Biodiversity Law?

The Biodiversity Law applies to any individual or entity (companies, universities, communities, etc.) that carries out research and development activities using Brazilian biodiversity (art. 11, I and II). Some examples of economic sectors potentially subject to the Law are: cosmetic, pharmaceutical, food, chemical, pesticide, and energy.

Who needs to comply with the Law?

- Companies
- Universities
- Communities
- Researchers
- Others



Sectors of interest:

- Cosmetics
- Pharmaceutical
- Chemical
- Sanitizing
- Energy
- Foods
- Others

The Law also applies to those who, even without access, economically exploit a finished product or produce reproductive material arising from access to the genetic heritage or associated traditional knowledge (art. 11, III). Any of them can be referred to as a user (art. 2º, XV, of the Biodiversity Law).

The situation of foreigners

The Biodiversity Law also applies to foreign individuals or legal entities that intend to carry out activities to access the genetic resources of Brazilian biodiversity or associated traditional knowledge. They must observe the following specific rules:



- Foreign individuals are **prohibited** from accessing Brazilian genetic heritage or associated traditional knowledge. They must always act through a legal entity (art. 11, §1).
- The legal entity headquartered abroad can obtain access, but it must be **associated** with a national institution for scientific and technological research, whether public or private (art. 12, II). This institution can be a Brazilian company, university or research entity such as Fiocruz and Embrapa. It is up to the foreign entity to contact the partners of interest and verify the possibility of association.



The Biodiversity Law does not specify how this association should take place, giving the parties significant freedom. This can be accomplished, for example, through a collaboration contract for the development of joint research. In this type of association, it is up to the Brazilian entity to register the access in the National Management System for Genetic Heritage and Associated Traditional Knowledge (SISGen).

Main obligations under the Biodiversity Law

The three main obligations established by Law are as follows:



- **Registration:** research and development activities using the genetic heritage of biodiversity and the traditional knowledge associated with it must be registered on an electronic platform called the National Management System for Genetic Heritage and Associated Traditional Knowledge (Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado - SISGen), even when the objective is that those activities be carried out abroad. This platform can be accessed at www.sisgen.gov.br (art. 12).



- **Notification:** finished products and reproductive materials developed from research and development with the genetic heritage of biodiversity and associated traditional knowledge must be notified prior to the start of their commercialization. As with registration, notification must take place through SISGen (art. 16, I).



- **Benefit sharing:** the manufacturer of the finished product or producer of the reproductive material must share the benefits resulting from its economic exploitation (arts. 17 and 18).

These obligations will be detailed throughout this Handbook.



Basic concepts

Basic concepts of the Biodiversity Law: genetic heritage and traditional knowledge

We have seen that the Biodiversity Law deals with research and development activities using national genetic heritage and associated traditional knowledge, which are defined as follows:

- Genetic heritage - information on the genetic origin of plant, animal, microbial or other species, including substances from the metabolism of these living beings;
- Associated traditional knowledge - information or practice of the indigenous population, traditional community or traditional farmer about the direct or indirect properties or uses associated with the genetic heritage.

In practice, this means that the following are considered to be part of the Brazilian genetic heritage:

- Native species;
- Domesticated or cultivated species that have naturally developed their own distinctive characteristics;
- Microorganisms isolated from substrates in the national territory, the territorial sea, the exclusive economic zone, or the continental shelf;

Stay tuned! If the research or development does not involve Brazilian genetic heritage, the Biodiversity Law does not apply (e.g., research on soybeans, corn, sugar cane, shea, etc.).



Official list of species that integrate Brazilian biodiversity

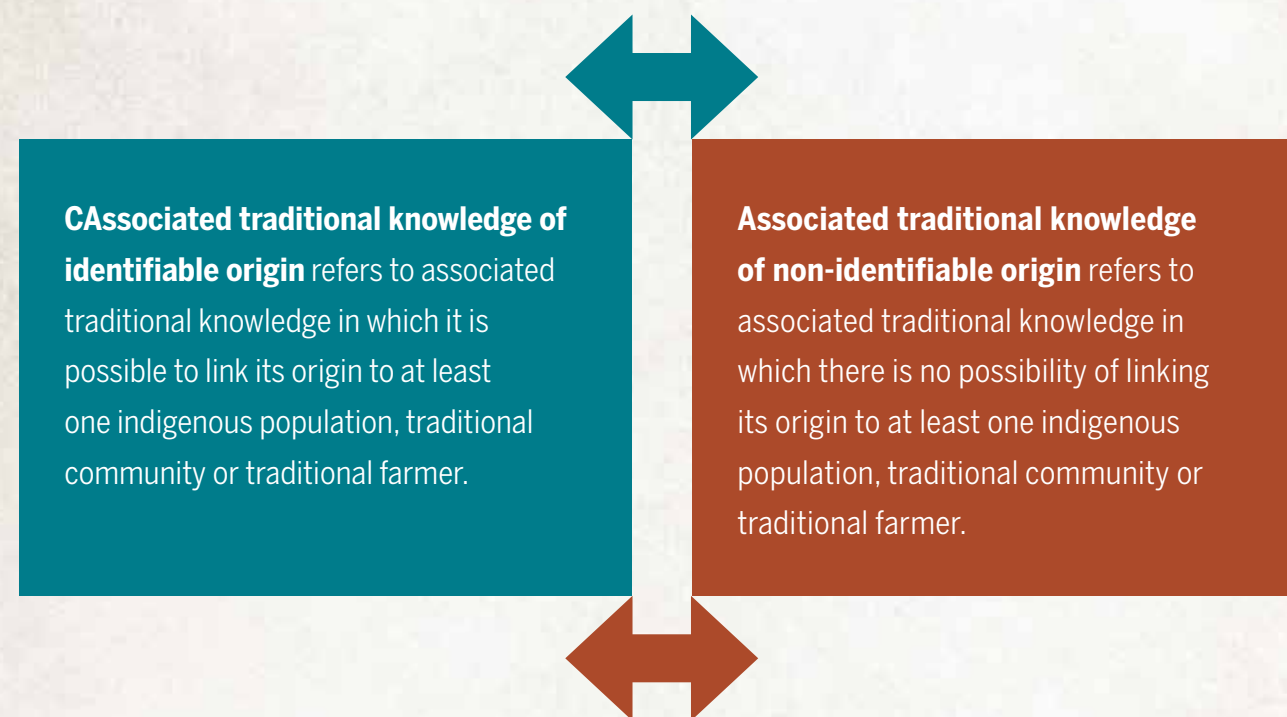
Unfortunately, there is no official list of species that make up the national genetic heritage, and each user must collect this information on their own to verify whether the Biodiversity Law applies or not to their activities. The most commonly used reference to research the origin of a species is Flora do Brasil 2020 (Brazilian Flora 2020), which can be accessed at <http://floradobrasil.jbrj.gov.br>. Below, we provide an example of querying this list for jabuticaba (*Plinia cauliflora*).

The screenshot shows the 'FLORA DO BRASIL 2020 - ALGAS, FUNGOS E PLANTAS' website. The search bar is empty, and the results section on the right shows the 'Flora do Brasil 2020' title and a brief description of the project. The search results are currently empty.

The screenshot shows the search results for 'Angiospermas'. The results list several species, including 'Plinia cauliflora'. The results are displayed in a table with columns for 'Nome', 'Descrição', and 'Imagens'. The 'Plinia cauliflora' entry is highlighted.

Basic concepts of the Biodiversity Law: associated traditional knowledge

In the case of traditional knowledge, the Biodiversity Law recognizes two modalities: identifiable origin and non-identifiable origin

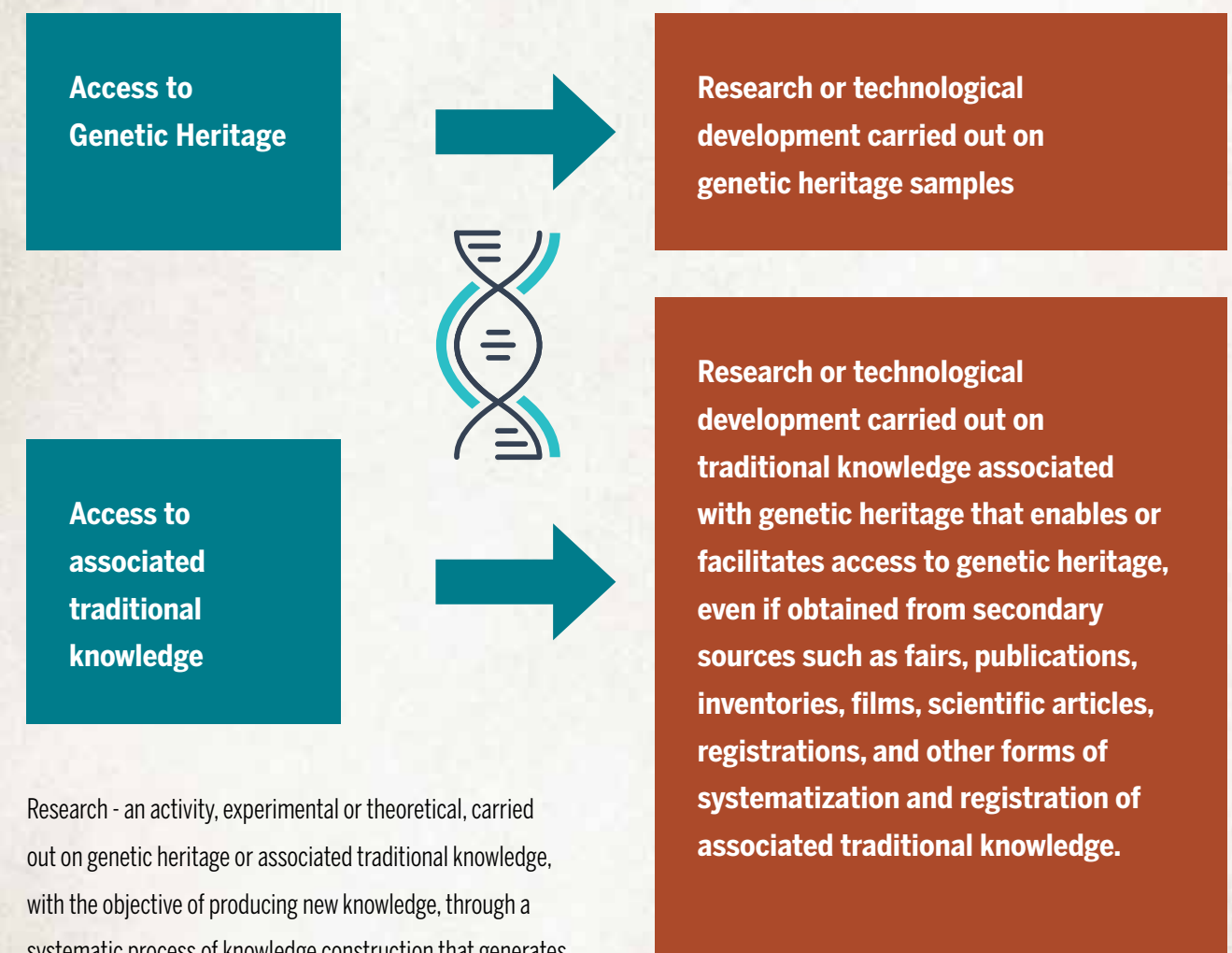


Beware! Access to associated traditional knowledge of non-identifiable origin follows rules similar to access to genetic heritage, but access to traditional knowledge of identifiable origin is subject to its own rules. The main difference is that, in the latter, the user must obtain prior consent from the traditional community that is providing the knowledge (art. 9) and negotiate a benefit sharing agreement with its representatives.



Basic concepts of the Biodiversity Law: access

Another basic definition of the Biodiversity Law is that of access, since it is the occurrence of access, together with the presence of the national genetic heritage and/or associated traditional knowledge, that determines the applicability of the Law. For example, the simple sale of a fruit in natura at a street market is not subject to the Law, as it does not involve the activity of access. Let's take a closer look at these concepts:



Research - an activity, experimental or theoretical, carried out on genetic heritage or associated traditional knowledge, with the objective of producing new knowledge, through a systematic process of knowledge construction that generates and tests hypotheses and theories, describes and interprets the fundamentals of observable phenomena and facts (art. 2, X).

Technological development - systematic work on genetic heritage or associated traditional knowledge, based on existing procedures, obtained through research or practical experience, carried out with the aim of developing new materials, products or devices, perfecting or developing new processes for economic exploitation (art. 2, XI).

Activities that do not configure access when they are not an integral part of R&D

The following activities are not considered to be access to genetic heritage if they are not part of a research and development process (art. 107 of Federal Decree 8.772 /2016 and Technical Guideline No. 9/2018):

- Affiliation or paternity test, sexing technique and karyotype or DNA analysis and other molecular analyzes aimed at the identification of a species or specimen;
- Clinical diagnostic tests and examinations for the direct or indirect identification of aetiological agents or hereditary pathologies in an individual;
- Extraction by grinding, pressing, or bleeding method resulting in fixed oils;
- Purification of fixed oils resulting in a product whose characteristics are identical to those of the original raw material;
- Test that aims to measure mortality rates, growth or multiplication of parasites, pathogens, pests and disease vectors;
- Comparison and extraction of information of genetic origin available in national and international databases;
- Extract processing, physical separation, pasteurization, fermentation, pH assessment, total acidity, soluble solids, bacteria and yeast counts, molds, fecal coliforms and total genetic heritage samples;
- Physical, chemical and physical-chemical characterization for determining the nutritional information of foods;

- Technical reports that include inventory, survey or monitoring of genetic heritage, for the purposes of environmental licensing, assessment of the potential for exploitation of natural resources or actions for environmental recovery and restoration of degraded areas;
- Identification or confirmation of identification - taxonomy of the genetic heritage to be incorporated into the collection of an ex situ collection;
- Physical, chemical, physical-chemical or biochemical characterization of extracts, waxes, butters and oils;
- Quality control tests on products from access to genetic heritage or associated traditional knowledge, as well as proficiency tests carried out in laboratories; and
- The carrying out of tests that use genetic heritage exclusively as target organisms.

Basic concepts of the Biodiversity Law: sending and shipping

Some access activities may require the transfer of samples abroad to carry out small tests or even as part of a co-development. These activities are called by the Law transferring or sending, depending on the case:

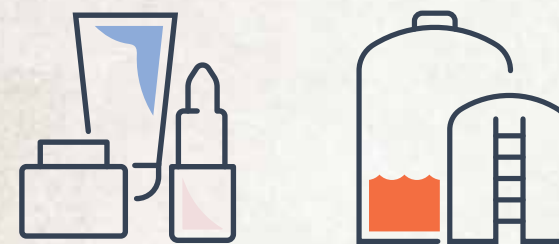
Transferring is the shipping of a sample of genetic heritage to an institution located outside the country for the purpose of access, in which the responsibility for the sample is transferred to the recipient (art. 2, VIII).

Sending is the shipping of a sample containing genetic heritage for the provision of services abroad as part of research or technological development in which the responsibility for the sample lies with those who perform the access in Brazil (art.2º, XXX).

As can be seen, transferring and sending are similar categories, since both involve the shipment of genetic heritage samples abroad to carry out research and development. Yet there are differences. The main one being that, in the case of transferring, there is effectively a **transfer of responsibility** over the sample whereas in sending this does not occur, the sender remains responsible. There are also differences in the procedure to be followed in one case and in the other, the most striking being that, in transferring the registration at SISGen must occur before it being carried out, while in sending this is not necessary (art. 11, §2).

Basic concepts of the Biodiversity Law: finished product, intermediate product, and reproductive material

The Biodiversity Law imposes different rules for sharing benefits to be complied with by users who economically exploit a finished product, reproductive material, or intermediate product (the latter is exempt). We will talk about these rules later, but it is important to know what is meant by each one:



Finished product – a product that does not require any type of additional production process, stemming from access to genetic heritage or associated traditional knowledge, in which the component of genetic heritage or associated traditional knowledge is one of the main elements of adding value to the product, which can be used by the end consumer, whether individual or legal entity.

Intermediate product - product whose nature is to be used in the production chain, which will aggregate it in its production process, as an input, excipient, and raw material, for the development of another intermediate product or finished product.



Reproductive material – material for plant propagation or animal reproduction of any genus, species, or cultivation from sexual or asexual reproduction. Seeds and semen, for example.



SISGen

SISGen, access registration, and product notification

One of the greatest innovations of the Biodiversity Law was to allow the control of the activities developed within its scope to be carried out through an electronic system: the National System for Access to Genetic Heritage and Associated Traditional Knowledge (Sistema Nacional de Acesso ao Patrimônio Genético e ao Conhecimento Tradicional Associado - SISGen). The system provides a friendly environment through which the user provides the data required by Law and, as a rule, does not need to wait for a reply from the authorities before he/she can carry out research or exploit the products. The following activities must be registered/notified at SISGen (art. 12):

- Access to genetic heritage and the traditional knowledge associated with it;
- Transferring a sample of genetic heritage abroad;
- Sending a sample of genetic heritage to provide services abroad;
- Notification of finished product or reproductive material;

These registrations/notifications must occur before carrying out one of the following activities (whichever takes place first) (art. 12, paragraph 2)

- Transferring;
- Request for any intellectual property rights;
- Commercialization of the intermediate product;
- Dissemination of results, final or partial, through scientific or communication media;
- Notification of finished product or reproductive material developed as a result of access.

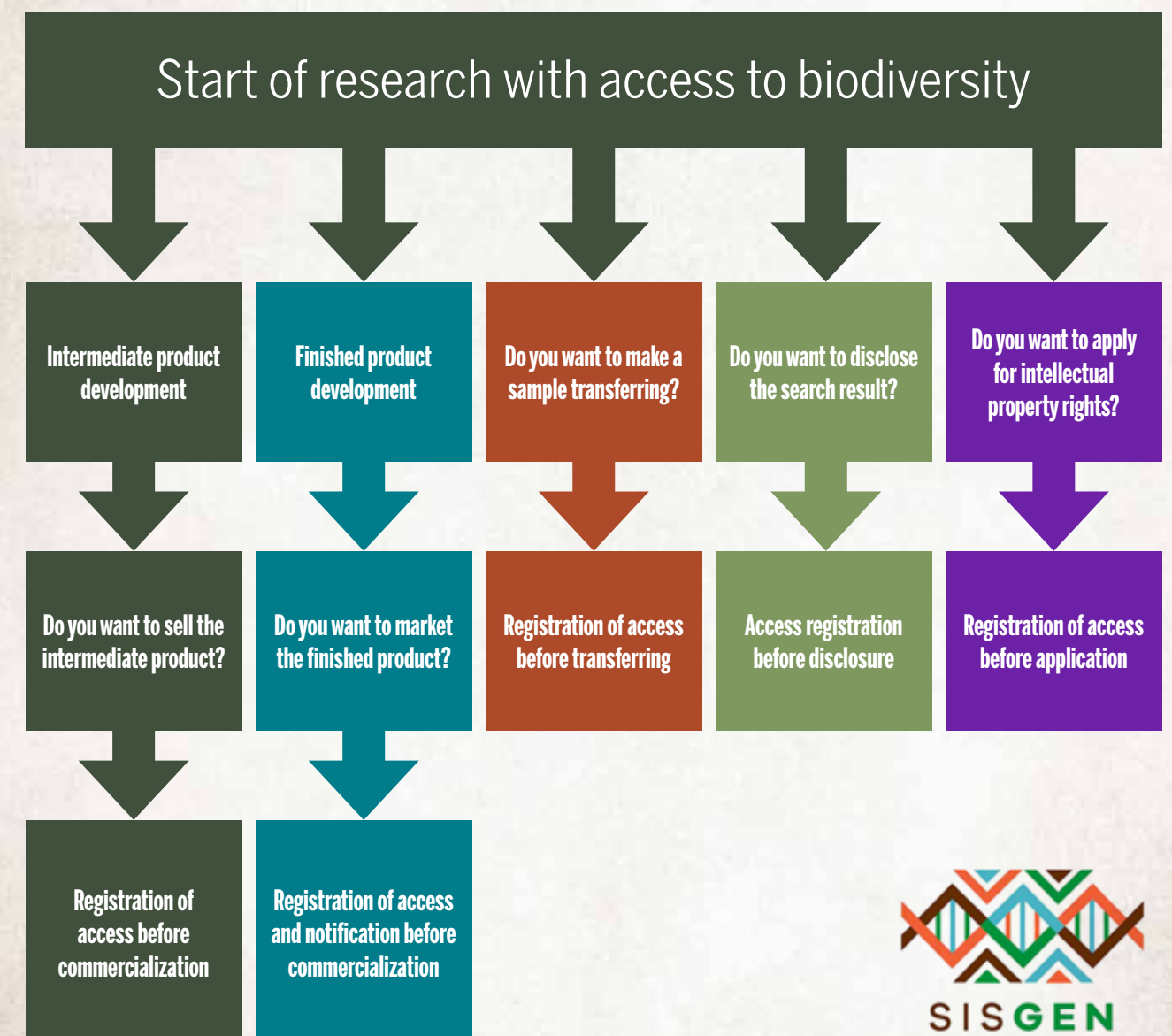


Keep in mind!

Until these moments arrive, there is no need for registration/notification, and research and development can take place normally.

Registration and notification flowchart at SISGen

The flowchart below seeks to demonstrate in a didactic way the moment of registration and notification, simulating different situations involving the research, development, and economic exploitation of the product:



Research with associated traditional knowledge

As previously shown, the general rule is that research and development are free, and the user only needs to be concerned with adopting a specific registration/notification measure when one of the moments indicated in the previous flowchart is reached. However, if the research involves access to associated traditional knowledge of identifiable origin, this logic changes slightly, as there is a need to obtain prior consent from the provider before the start of the research (art.9). Thus, the path to be followed becomes the following:



The provider of associated traditional knowledge can be an indigenous person, a traditional community, or a traditional farmer, and their consent can be obtained by the following means (art. 9, § 1):



- signing a prior consent form;
- audiovisual record of consent;
- opinion from the competent official body; or
- adhesion as provided for in a community protocol.

The system

To access SISGen, the user must access the website **www.sisgen.gov.br** and register as an individual. Further details on the operation of the system can be obtained in the system's own User's Guide, through the following link: https://sisgen.gov.br/download/Manual_SisGen.pdf.

SISGen: user registration x institutional registration



User registration: in order to access the system's functionalities, it is necessary to register access as an individual.

Institution registration: the entity (e.g., a company) that is interested in registering access activity and/or product notification must be linked to the registration of a previously registered individual.



Watch out!

In order to carry out activities to access the national genetic heritage and traditional knowledge, a foreign entity must have a link with a national entity. This link is enabled in the system itself. The registration of activities must be carried out by the national partner entity and not by the foreign counterpart.

Access registration: necessary information

To carry out the access registration, the user must include the following information in SISGen (art. 22 of Federal Decree 8.772 / 2016):

I – user identification;

II – information on research or technological development activities, including:

a) summary of the activity and its respective objectives;

b) application sector, in the case of technological development;

c) expected or obtained results, depending on the moment of registration;

d) responsible team, including partner institutions, if any;

e) period of activities;

f) identification of the genetic heritage at the strictest possible taxonomic level or, as the case may be, associated traditional knowledge, in particular: 1. the origin of the genetic heritage, including georeferenced coordinates, in the form of degree, minute and second, from the place of collection in situ, even if they were obtained from ex situ or in silico sources; and 2. from the indigenous population, traditional community, or traditional farmer who provides the associated traditional knowledge, even if the knowledge has been obtained from secondary sources;

g) statement clarifying whether the genetic heritage is a traditional local or hybrid variety or a locally adapted or hybrid breed, or if the species is on an official list of species threatened with extinction;

h) information from the institution headquartered abroad associated with the national

institution, in the case provided for in **item II of art. 12 of Law No. 13,123, from 2015**;

i) identification of national partner institutions, if any;

III – previous registration or authorization number, in the case of genetic heritage or associated traditional knowledge accessed from research or technological development carried out after June 30, 2000;

IV – proof that prior informed consent was obtained, pursuant to **art. 9 of Law No. 13,123, of 2015**, and of art. 17 of this Decree, when applicable;

V – request for recognition of legal confidentiality (information included in SISGen is, as a rule, accessible to the public. In order to be treated as confidential, the interested party must expressly request);

VI – declaration, as the case may be, of classification in the event of legal exemption or non-incidence of benefit-sharing;

VII – in the case of access to associated traditional knowledge: i - identify the sources from which associated traditional knowledge is obtained; and ii - inform the georeferenced coordinate of the respective community, except in the case of associated traditional knowledge of non-identifiable origin.

Upon completion of the process, the system will automatically issue a proof of access registration (art. 23 of Federal Decree 8.772/2016).

Finished product notification: required information

To obtain the notification of finished product or reproductive material, the user must include the following information in SISGen (art. 34 of Federal Decree 8.772/2016):

- identification of the requesting individual or legal entity;
- commercial identification of the finished product or reproductive material and application sector;
- information on whether the genetic heritage or the associated traditional knowledge used in the finished product is decisive for the development of market appeal;
- information on whether the genetic heritage or the associated traditional knowledge used in the finished product is decisive for the existence of functional characteristics;
- forecasting the local, regional, national, or international scope of the manufacture and marketing of the finished product or reproductive material;
- registration number, or equivalent, of a product or cultivar in a competent organ or entity, such as Anvisa, Ministry of Agriculture, Livestock and Supply, and the Brazilian Institute for the Environment and Renewable Natural Resources - Ibama;
- deposit number for the request for intellectual property rights for a product or cultivar at the Ministry of Agriculture, Livestock and Supply or at the INPI, or at offices abroad, when applicable;
- expected date for the start of commercialization;
- indication of the type of benefit sharing;

- presentation of a benefit sharing agreement, when applicable;
- registration number of the access to genetic heritage or associated traditional knowledge that gave rise to the finished product or reproductive material, subject to the provisions of art. 2 and in Chapter VIII of this Decree;
- registration number of the transfer that gave rise to the finished product or reproductive material, if any;
- request for recognition of legal confidentiality; and
- proof of qualification in the event of legal exemption or non-incidence of benefit sharing.

Upon completion of the process, the system will automatically issue a notification receipt (art. 35 of Federal Decree 8.772/2016).



Beware!

The notification must be made before the commercialization of the finished product or reproductive material begins.

Transferring: required information

In order to register the transfer, the user must include the following information in the SISGen (art. 25 of Federal Decree 8.772/2016).

- Identification: a) of the sender; b) samples of genetic heritage at the strictest possible taxonomic level; and c) the origin of the samples to be transferred;
- Information on: a) the type of sample and the form of packaging; b) the number of containers, the volume or the weight; c) the recipient institution abroad, including indication of legal representative and contact information; and d) access activities abroad, including objectives, intended uses and application sector of the research or technological development project;
- Material Transfer Term (Termo de Transferência de Material - TTM), signed between the individual or legal entity nationally and the legal entity headquartered abroad; and
- Prior informed consent that expressly authorizes the sending in the case of genetic heritage of a local or hybrid traditional variety or locally adapted or hybrid breed for access in non-agricultural activities, when applicable.

Upon completion of the process, the system will automatically issue a notification receipt (art. 35 of Federal Decree 8.772/2016).



Stay tuned!

The Material Transfer Term (TTM) is a typical contract with minimum clauses regulated by art. 25, §1º Federal Decree 8.772/2016.

Sending for provision of services: required information

To carry out the sending registration, the user must include the following information in SISGen (art. 24 of Federal Decree 8.772/2016):

- Information about the recipient institution abroad, including contact information and legal representative;
- Information on the samples to be sent, containing the identification of the genetic heritage in question;
- Legal instrument signed between the national institution responsible for access and the partner or contracted institution.



Stay tuned!

The registration of the sending must be done at the time of registration of the access, but the legal instrument must be signed before the sample is sent abroad and must accompany it. It is important to be aware of the fact that this instrument must follow the standards established in art. 24, §6 of Federal Decree 8.772/2016.



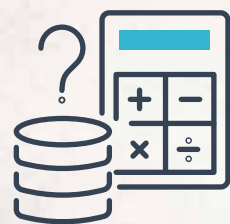
Benefit sharing

Modalities

One of the main obligations foreseen in the Biodiversity Law is to share the benefits resulting from the economic exploitation of a finished product or reproductive material resulting from access to genetic heritage or associated traditional knowledge. This distribution can take place in two ways: monetary and non-monetary (art.19, I and II).

Monetary

Monetary benefit sharing is the transfer in cash of part of the net revenue obtained by the manufacturer of the finished product and by the producer of the reproductive material.



Non-monetary

Non-monetary benefit sharing can take place as follows:

1. projects for the conservation or sustainable use of biodiversity or for the protection and maintenance of knowledge, innovations, or practices of indigenous peoples;
2. technology transfer;
3. availability of a product in the public domain, without protection by intellectual property rights or technological restrictions;
4. licensing of products free of charge;
5. training of human resources on topics related to the conservation and sustainable use of genetic heritage or associated traditional knowledge;
6. free distribution of products through social programs.

Attribution of responsibility for payment

The Biodiversity Law created two benefit-sharing regimes: a general one and a specific one for agricultural activities, which includes food, beverages, planted forests, energy, and fibers (arts. 17 and 18). There are two differences between them: the product on which a percentage is payable as part of the distribution, and the entity responsible for payment.

Two regimes

Agricultural activities

- Foods;
- Drinks;
- Planted forests;
- Energy;
- Fibers

Incidence: benefit sharing is calculated on the net revenue of the reproductive material (e.g., seeds).

Entity responsible for payment: producer of reproductive material in the chain (e.g., seed manufacturer).

Other sectors

Incidence: benefit sharing is calculated on the net revenue of the finished product (e.g., medicine).

Entity responsible for payment: manufacturer of the finished product.

Finished product

In the general benefit sharing regime, identified on the previous page as “other sectors”, only the manufacturer of products in which the component of biodiversity or associated traditional knowledge is one of the main elements of added value is subject to payment. This will occur when this component is decisive for the product’s marketing appeal or for its functional characteristics (art. 2, XVIII).

Marketing appeal:

Reference to genetic heritage or associated traditional knowledge, its origin, or the differentials arising from them, related to a product, product line, or brand, in any visual or auditory media, including marketing campaigns or prominence on the product label; or

Functional characteristics:

Features that determine the main purposes, improve the action of the product, or expand its role.

Keep in mind!

If the biodiversity component is not the main element of adding value to the product, there is no need for payment (art. 17)!



Value and destination

The amount to be paid as benefit sharing and the beneficiary vary according to the chosen modality (whether monetary or non-monetary) and the type of access (whether genetic heritage or traditional knowledge), as shown below.

Monetary

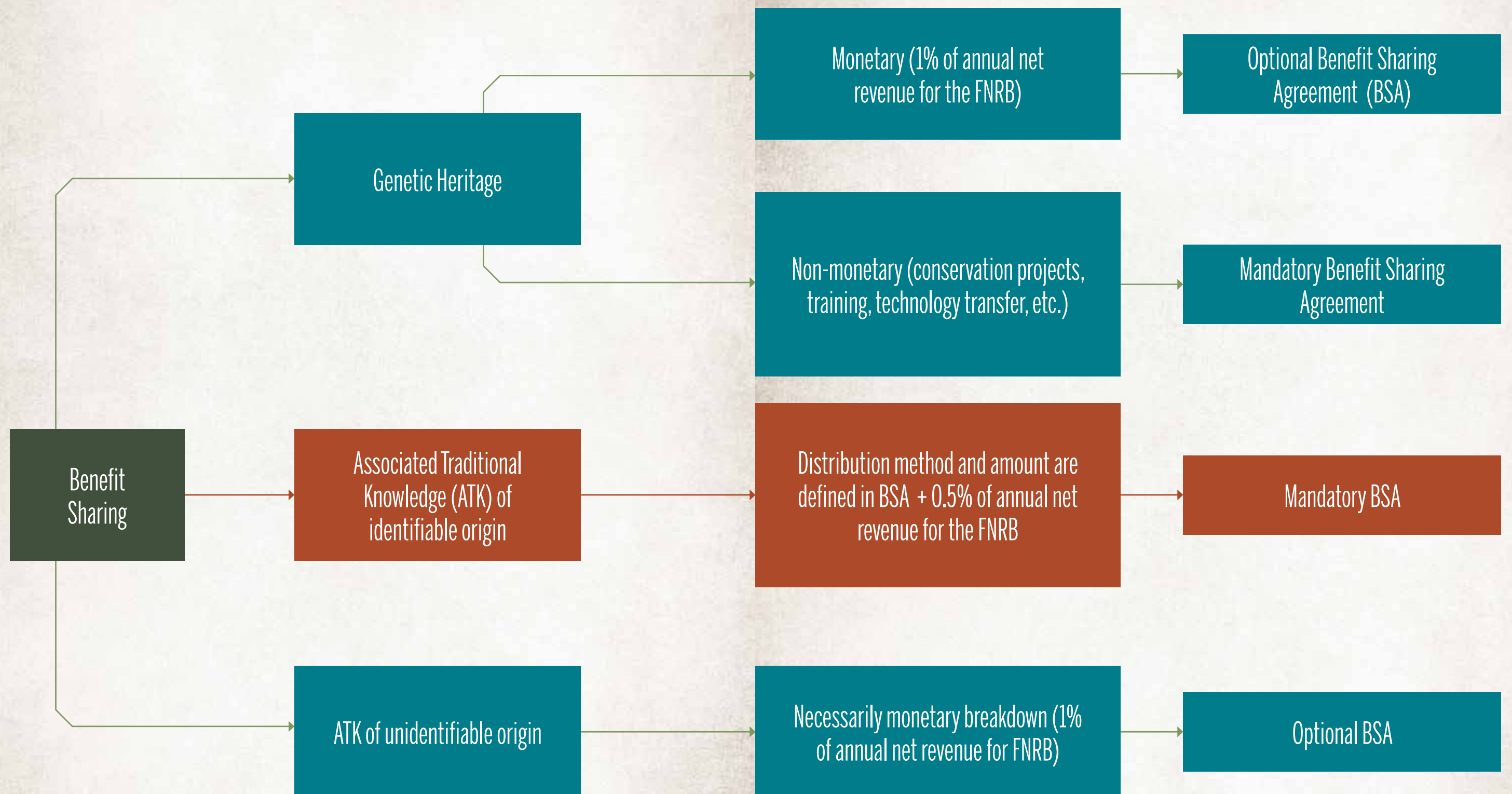
- **Genetic heritage:** 1% of the annual net revenue from the finished product or reproductive material, to be paid to the National Benefit Sharing Fund (Fundo Nacional de Repartição de Benefícios - FNRB).
- **Associated traditional knowledge of identifiable origin:** Compensation freely negotiated between the provider and the user + 0.5% of the annual net revenue of the finished product or reproductive material, to be paid to the FNRB (this final portion must be in monetary form).
- **Non-identifiable associated traditional knowledge:** 1% of the annual net revenue from the finished product or reproductive material, to be paid to the FNRB.

Non-monetary

- **Genetic Heritage:** 0,75% of the annual net revenue of the finished product or reproductive material if the destination occurs in one of the following modalities: (1) Projects for conservation and sustainable use; (2) Training of human resources; (3) Free product distribution. For other forms of allocation, the 1% rate is applied.
- **Associated traditional knowledge of identifiable origin:** Compensation freely negotiated between the provider and the user + 0.5% of the annual net revenue of the finished product or reproductive material, to be paid to the FNRB (the negotiable component can be non-monetary, but in cases of access to traditional knowledge there is always a monetary payment to the FNRB).

Watch out! The choice of the benefit sharing modality in case of access to the genetic heritage will be up to the user; in the case of access to traditional knowledge of identifiable origin, it will be negotiated with the provider; and in the case of access to traditional knowledge of non-identifiable origin, it will always be in monetary form.

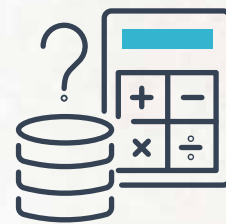




Sectoral agreement

In spite of having set the percentages indicated on the previous pages for sharing benefits as rules, the Biodiversity Law allows them to be reduced in exceptional situations by entering into what are called sectoral agreements. The purpose of these agreements is to guarantee the competitiveness of the relevant sector in the event that the percentage established by Law proves to be inadequate (art.21).

Sectoral agreement - act of a contractual nature signed between the government and users, with a view to the fair and equitable sharing of benefits deriving from economic exploitation arising from access to genetic heritage or associated traditional knowledge of non-identifiable origin (art. 2, XXI)



The signing of the agreement allows the Federal Government to reduce the percentage to be considered for calculating the benefit sharing from 1% to 0.1%, respectively. To date, no such agreement has been drafted.

Benefit Sharing Agreement (BSA): when does it apply?

The Benefit Sharing Agreement (BSA) is the legal instrument entered into by the parties to determine how the benefit sharing will take place (art. 2, XX). This is an authentic contract. The Biodiversity Law requires it in the following cases:

- **Access to genetic heritage:** whenever the user chooses to share benefits in the non-monetary modality (art. 16)
- **Access to associated traditional knowledge of identifiable origin:** (art. 24)



On the other hand, the Biodiversity Law allows - but does not oblige - the celebration of the BSA in the following scenarios. If the user prefers, he/she can only deposit the amounts due as benefit sharing in the FNRB, without closing the agreement.

- **Access to genetic heritage:** whenever the user chooses to share benefits in the monetary modality (art. 25, paragraph 4)
- **Access to associated traditional knowledge of non-identifiable origin** (art. 25, paragraph 4)

Benefit Sharing Agreement (BSA): content

The BSA is a typical contract regulated by the Biodiversity Law, which must have the following clauses (art. 26):

- Products subject to economic exploitation;
- Duration term;
- Benefit sharing modalities;
- Rights and responsibilities of the parties;
- Intellectual property right;
- Termination;
- Penalties; and
- Legal jurisdiction in Brazil.

The parts of the BSA will vary according to the situation as follows (art. 25):

- in the case of economic exploitation of the finished product or reproductive material arising from access to genetic heritage or associated traditional knowledge of unidentifiable origin: a) the Union, represented by the Ministry of the Environment; and b) the user who will explore the finished product or reproductive material;
- in the case of economic exploitation of the finished product or reproductive material arising from access to associated traditional knowledge of identifiable origin: a) the provider of associated traditional knowledge; and b) the user who will explore the finished product or reproductive material.

Exemptions

The Biodiversity Law exempts some products and people from the duty to share benefits (art. 54 of Federal Decree 8.772/2016):

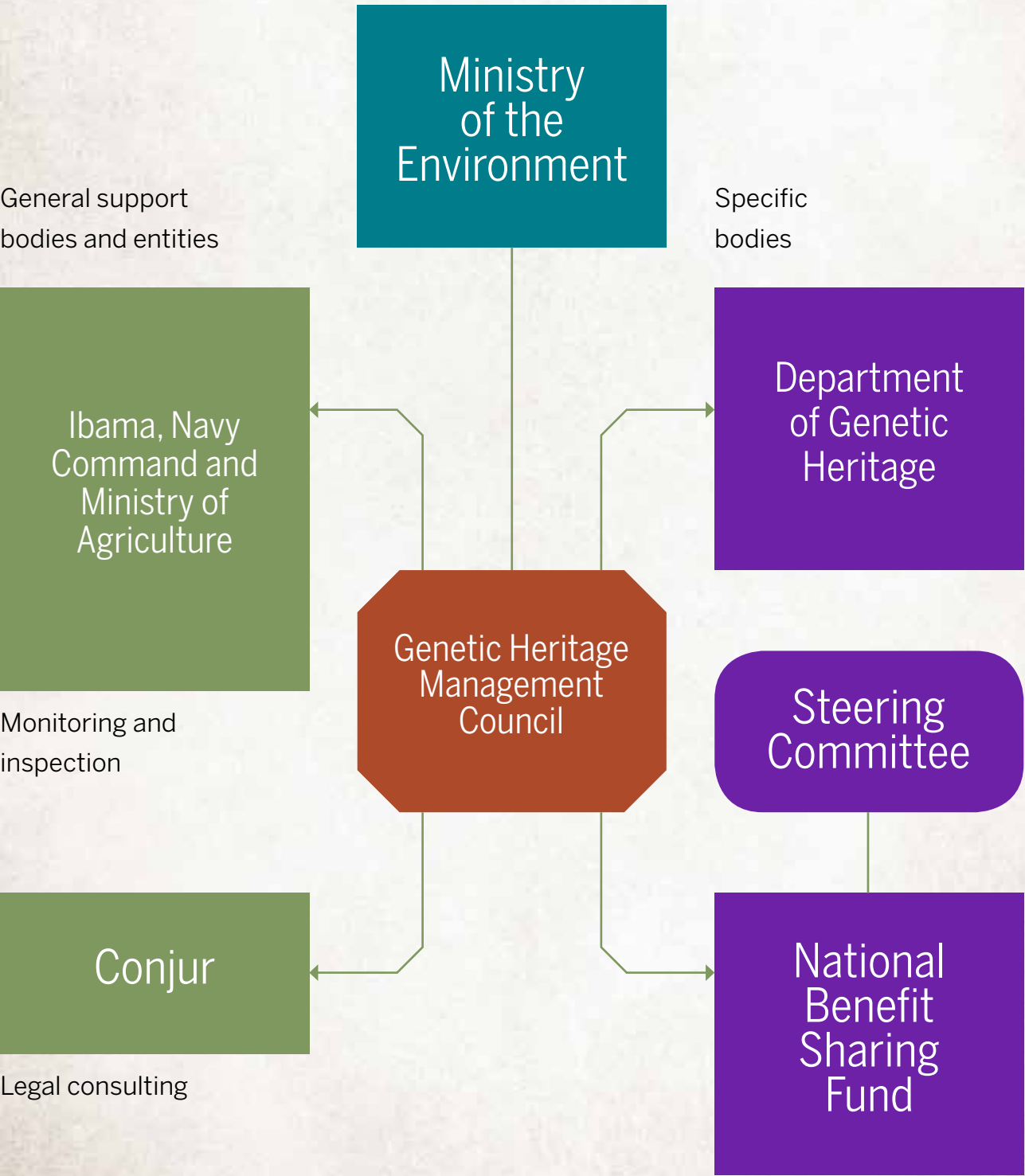
- Final products in which the genetic heritage component and associated traditional knowledge are not major elements of value addition;
- Licensing, transfer, or permission to use any form of intellectual property right in the finished product, process, or reproductive material arising from access to genetic heritage or associated traditional knowledge by third parties;
- Process developers (patents, know-how, etc.) arising from access are exempt from paying benefit sharing;
- Intermediate products along the production chain;
- Reproductive material along the productive chain of reproductive material, except for the economic exploitation carried out by the last link in the productive chain;
- Finished product or reproductive material arising from access to the genetic heritage of species introduced into the national territory by human action, even if domesticated, except for the provisions of items I and II of § 3 of art. 18 of Law No. 13,123, from 2015;
- Reproductive material arising from access to genetic heritage or associated traditional knowledge for the purpose of agricultural activities and intended exclusively for the generation of finished products;
- Finished product or reproductive material developed by traditional farmers and their cooperatives, with annual gross revenue equal to or less than R\$ 3,600,000.00; and
- Finished product or reproductive material developed by micro-enterprises, small businesses and individual micro-entrepreneurs.



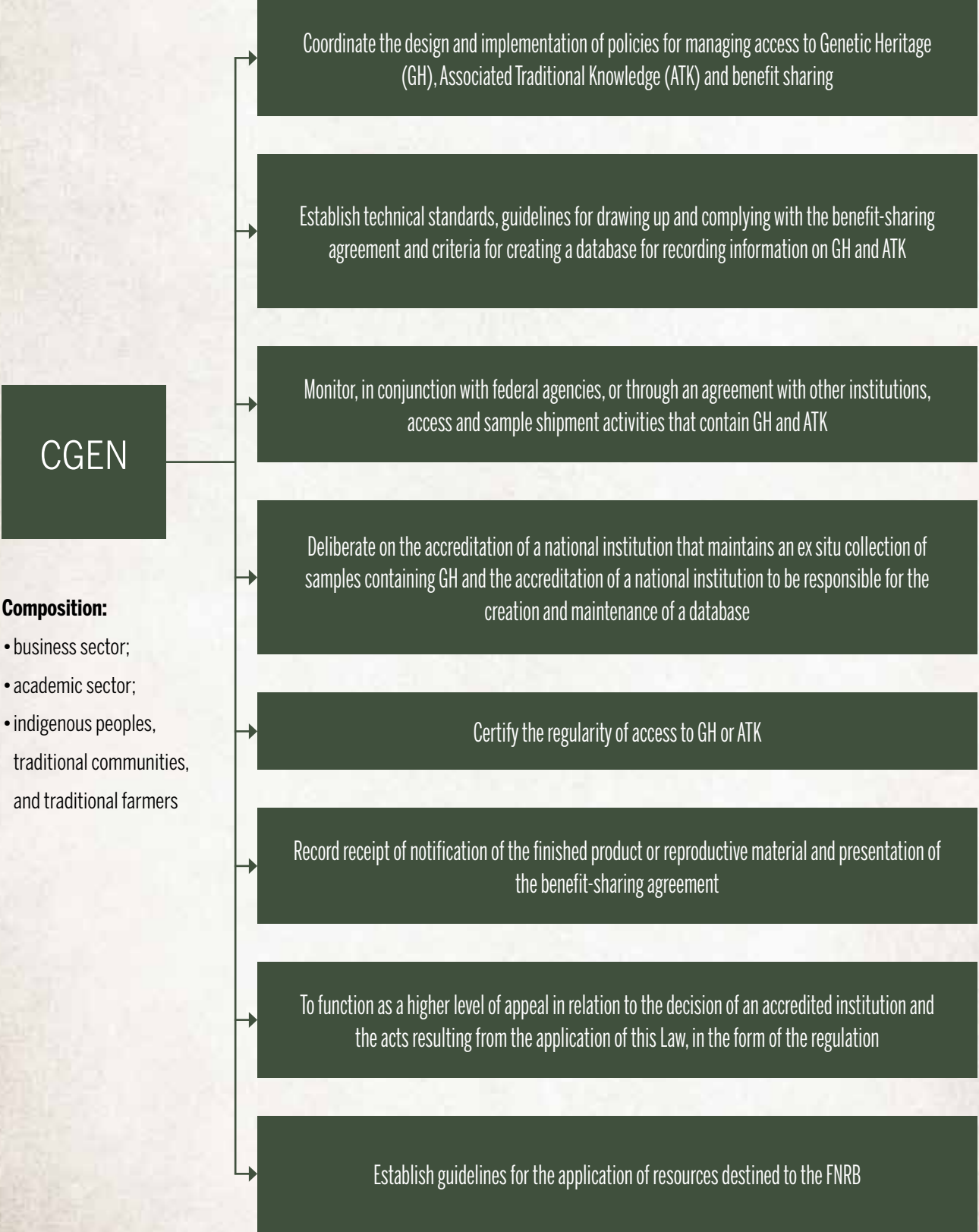
Governance

General structure

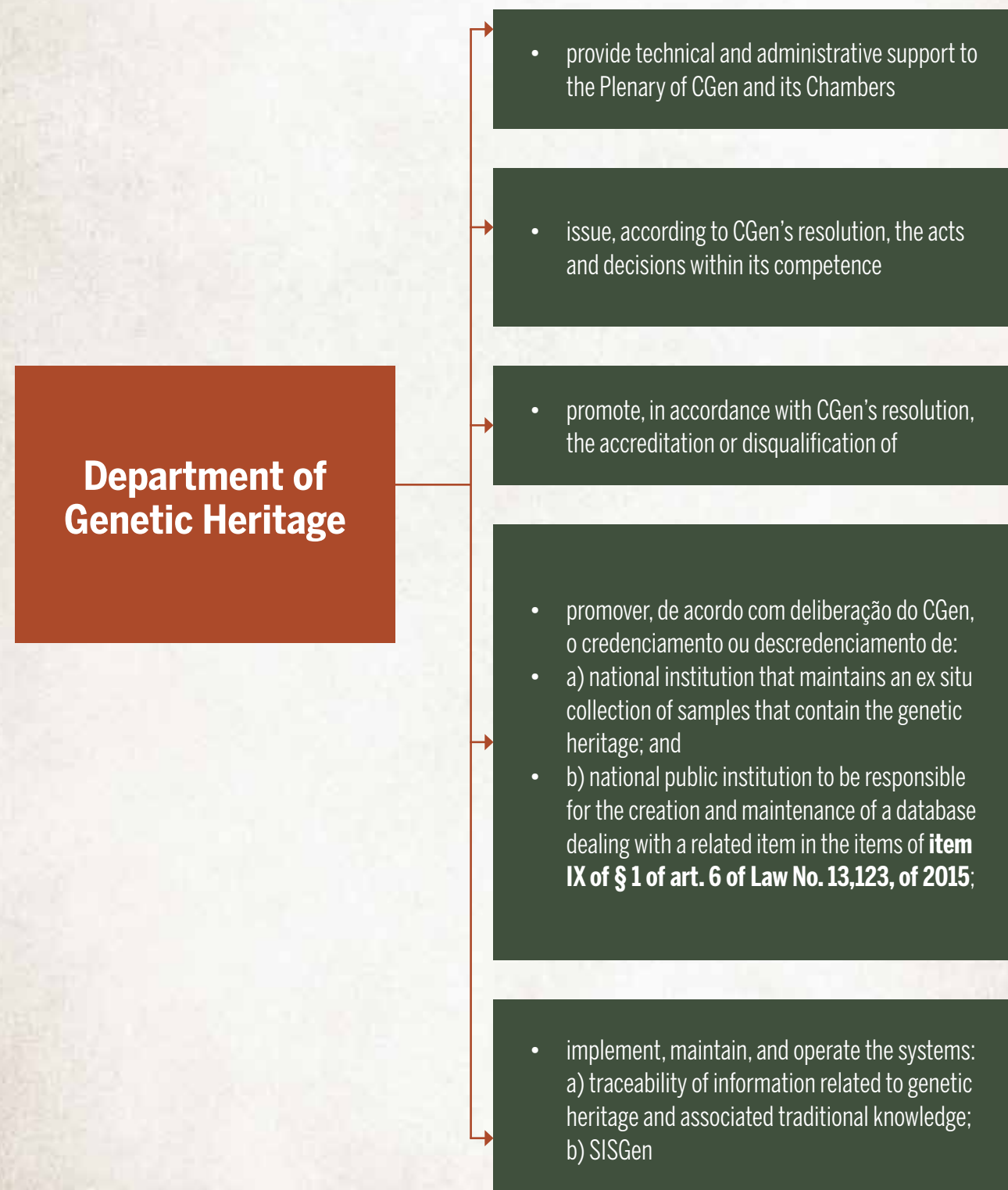
The governance of the Biodiversity Law is carried out through the joint action of the bodies and entities indicated below:



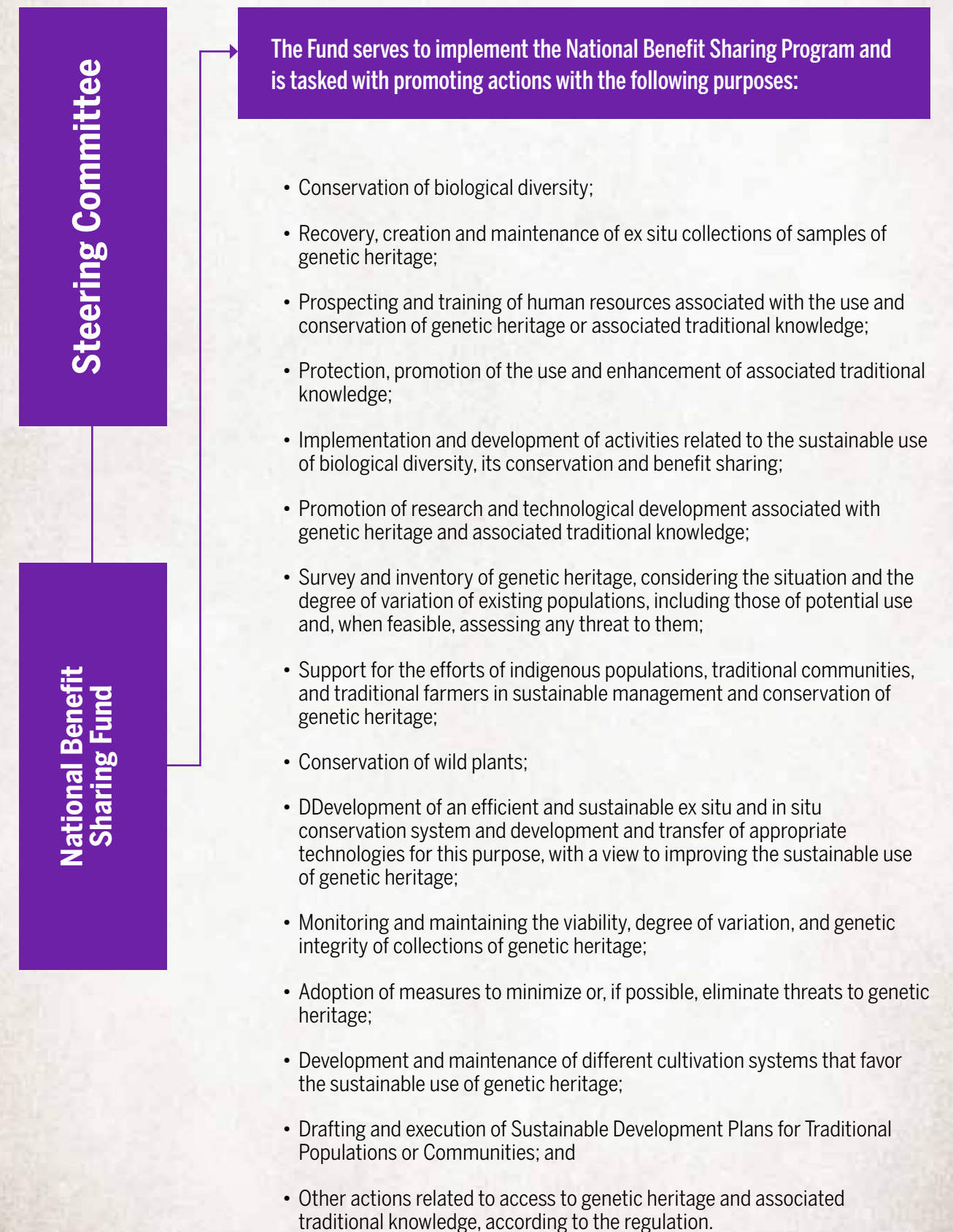
The Genetic Heritage Management Council: composition and duties



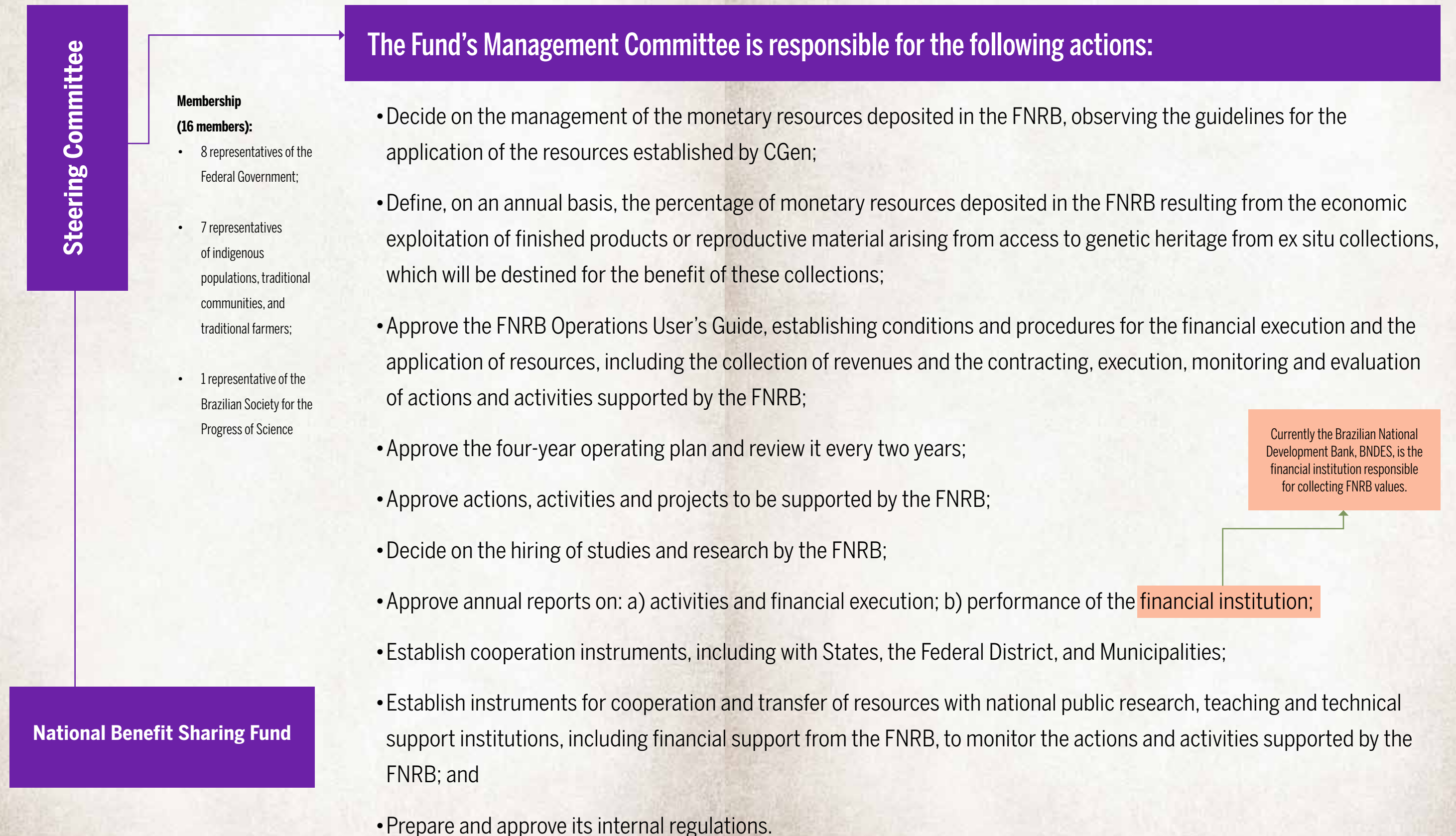
Department of Genetic Heritage: duties



National Benefit Sharing Fund (FNRB)



Managing Committee of the National Fund for Benefit Sharing





Compliance

Administrative infractions and sanctions

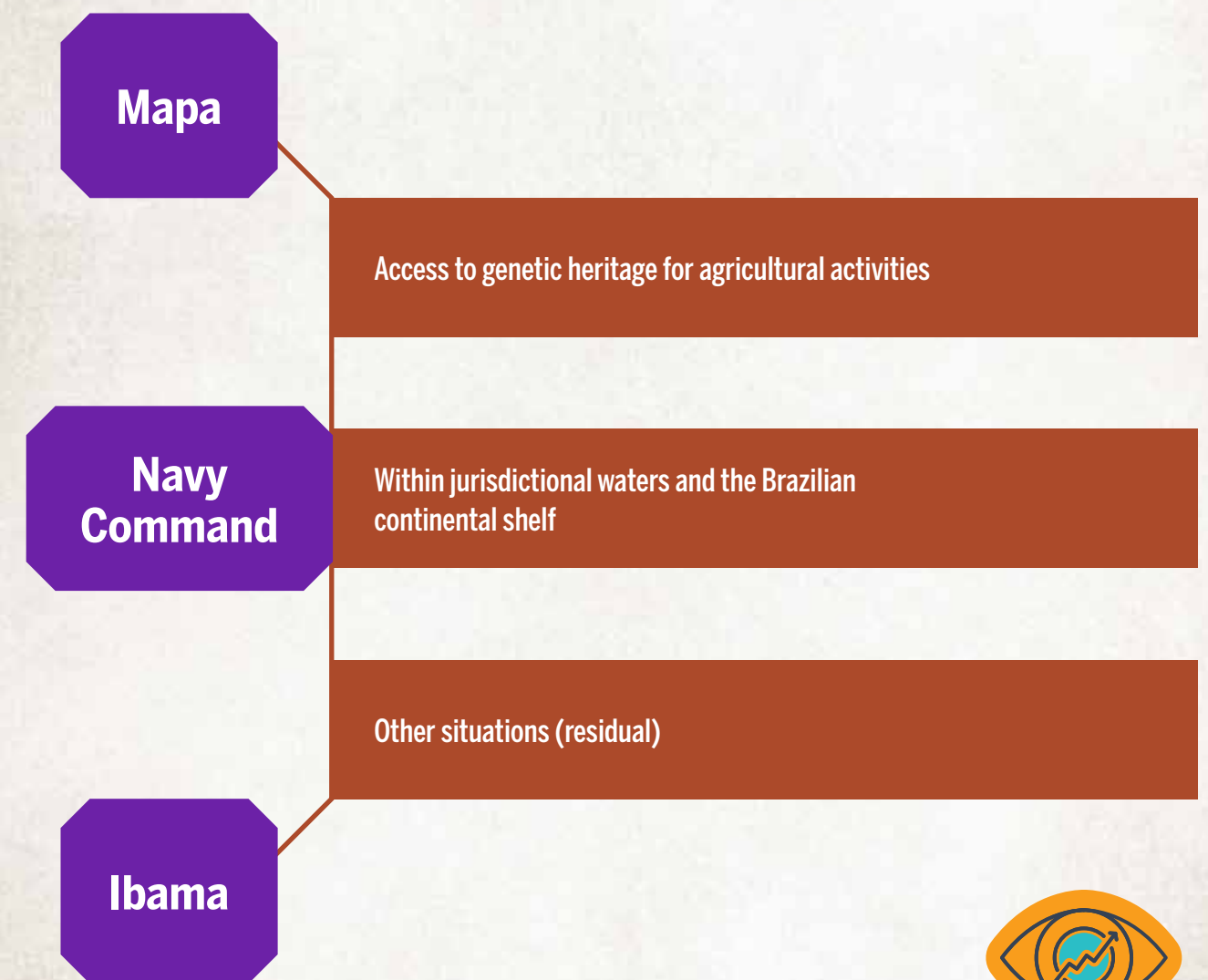
Failure to comply with the Biodiversity Law may constitute an administrative infraction and lead to the imposition of penalties, such as the fine, which can reach 10 million reais. Below we list the main infractions foreseen by Law (art. 27):

- Economically exploit finished product or reproductive material without prior notification
- Send, directly or through an intermediary, a sample of genetic heritage abroad without prior registration or contradicting this
- Failing to register before accessing an intermediate product
- Access associated traditional knowledge of identifiable origin without obtaining prior informed consent or contradicting this
- Failing to adapt or regularize within the legal term
- Request intellectual property right without prior registration
- Disseminate results without prior registration

In addition to imposing a fine, the supervisory body may impose other severe penalties, alternatively or cumulatively, such as the seizure of products derived from access to genetic heritage or associated traditional knowledge; the temporary suspension of the manufacture and sale of the finished product or reproductive material derived from access to genetic heritage or associated traditional knowledge until regularization; an embargo of the specific activity related to the infraction; partial or total prohibition of the establishment, activity or project, among others.

Oversight

The enforcement of compliance with the Biodiversity Law is carried out jointly by the Brazilian Institute of Environment and Renewable Natural Resources (Ibama), the Ministry of Agriculture, Livestock and Supply (Mapa), and the Navy Command. Below we indicate what each agency is responsible for overseeing:



Stay tuned!

A joint act is set to regulate the coordinated action of these supervisory bodies, but it has not yet been published.



Transitional provisions



Adequacy and regularization

The Biodiversity Law created a transitional regime to encourage users to comply with its specifications. This regime applies both to those who had not complied with the previous legislation and those who were in compliance but would need to take measures to adapt to the new law. In the first case, we are talking about the duty of regularization; in the second, about simple adaptation, as shown in the side tables.

Regularization

Regularization (with signature of the Term of Commitment) in accordance with this Law, within 1 (one) year, counting from the date of the availability of the Register by CGEN, the user who, between June 30, 2000 and the date Law No. 13,123/15 entered into force, carried out the following activities in disagreement with the legislation in force at the time: (i) access to genetic heritage or associated traditional knowledge, (ii) access and economic exploitation of a product or process arising access to genetic heritage or associated traditional knowledge, as provided for in MP No. 2,186-16 / 01, (iii) sending of a sample of genetic heritage, or (iv) dissemination, transmission, or retransmission of data or information that are part of or constitute associated traditional knowledge.

Adequacy

The user who carried out, as of June 30, 2000, the following activities in accordance with MP nº 2.186-16 / 01, shall comply with the terms of this Law, within a period of 1 (one) year, counting from the date on which the registration is made available by CGen, (i) access to genetic heritage or associated traditional knowledge or (ii) economic exploitation of finished product or reproductive material arising from access to genetic heritage or associated traditional knowledge.

How to adapt or regularize?

In order to be able to regularize or adapt, the user must adopt the following actions (arts. 37, 38 and 40):

Regularization

- Sign a Term of Commitment to the Union;
- Register access to genetic heritage and/or associated traditional knowledge;
- Issue a notification about the product or process arising from access to genetic heritage or associated traditional knowledge, as provided for in **Provisional Measure No. 2,186-16, from August 23, 2001**; and
- Sharing benefits obtained, within the limit of up to 5 (five) years prior to the signing of the Term of Commitment, subtracting the suspension time of the process in progress at CGen.

Adequacy

- Register access to genetic heritage and/or associated traditional knowledge;
- Issue a notification about the finished product or reproductive material subject to economic exploitation, under the terms of this Law; and
- Share the benefits related to the economic exploration carried out as of 11/17/2015, of the Biodiversity Law, except when it was done under Provisional Measure No. 2,186-16, from August 23, 2001.



Stay tuned!

In many cases, the deadline for regularization and adaptation has already expired, but in others it has not even started due to the non-availability of the necessary functions in SISGen.

Warning

This material **is not** to be construed as legal or other advice. It is exclusively up to each user to properly assess his activities and the current legislation in order to understand and define the rules that apply to him/her and the obligations with which he/she must comply.

Support:

instituto
arapyauú 

Realization:

 **instituto**
Escolhas 