MINISTRY OF THE ENVIRONMENT OF BRAZIL

GENETIC HERITAGE,

ASSOCIATED TRADITIONAL KNOWLEDGE

AND BENEFIT SHARING

LAW 13.123, DATED MAY 20, 2015

DECREE 8,772 DATED MAY 11, 2016

Federative Republic of Brazil

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Summary

Welcome!

Law 13,123 was enacted on May 20, 2015. It provides on access to genetic heritage, protection and access to its associated traditional knowledge, and benefit sharing for the conservation and sustainable use of biodiversity. By entering into force, the current legislation superseded Provisional Measure 2,186-16/2001 and enhanced its system, which was, in itself, a Brazilian pioneering landmark as it regulated the theme in the year 2000. The now called Biodiversity Law established Brazil as a vanguard country, reducing the bureaucratic burden on access to genetic heritage, while conserving the Brazilian biodiversity and protecting the rights of the stewards of biodiversity, in addition to other relevant steps forward to stimulate research and innovation based on the sustainable use of biodiversity. The law enables increased efficiency to its procedures, establishing with greater clarity the criteria on benefit sharing as a result of the economic exploitation of products and materials derived from access to genetic heritage and its associated traditional knowledge, while allowing for increased legal security for companies and facilitating inspection procedures. It also recognizes the distinctive role of Indigenous peoples, traditional peoples and communities, and family farmers through the following guidelines:

participation with voting rights at the Genetic Heritage Management Council - CGEN; guaranteed prior informed consent for access to the traditional knowledge associated to biodiversity; the legal recognition of the Community Protocols proposed by the Nagoya Protocol; the establishment of a National Fund for Benefit Sharing - FNRB with participation of the stewards of biodiversity, of the academia, and of the FNRB Management Committee. This Guidebook, which you now hold in your hands, covers the most relevant aspects under Law 13,123/2015 and Decree 8,772/2016. We, at the Ministry of the Environment, hope that this publication may be useful for the Brazilian society, so that, in better understanding its rights and duties, it may enjoy the full potential enabled by the biodiversity currently found in the national territory.

Secretariat of Biodiversity
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Indigenous Peoples, Traditional Peoples and Communities, and Family Farmers are key holders of the traditional knowledge that comprises a relevant part of the Brazilian cultural heritage, as well as stewards of a part of the Brazilian genetic heritage.

On May 9, Decree 8,750 converted the former CNPCT into the National Council of Traditional Peoples and Communities, a consultive collegiate body within the structure of the Ministry of Social Development (Decree 9,465, dated August 9, 2018, which updates Decree 8,750/2016 and integrates the CNPCT to the Ministry of Human Rights).

Decree 8,772/2016 established detailed rules and instruments so that Law 13,123/2015 may be effective!

Associated Traditional Knowledge is part of the Brazilian cultural heritage. It is essential that Indigenous peoples, traditional peoples and communities, and family farmers be prepared to cope with future situations involving the economic exploitation of the products of biodiversity and of the traditional knowledge associated with it, while ensuring their prominent role in the signing of benefit sharing agreements arising from such exploitation.

After all, what is the objective of producing the present publication?

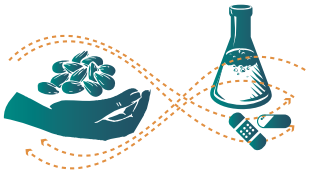
Its principal **objective** is to guide you and your community in regard to the recent legislation on access to the Brazilian genetic heritage and to the knowledge of traditional communities in the use of plants, mushrooms, seeds, animal venoms, roots, animal skins and other products. This publication brings the essential information on the rights of Indigenous peoples, traditional peoples and communities, and family farmers, which regards their traditional knowledge, and how the legislation can have an influence on the daily life of your community.

The Convention on Biological Diversity

The Convention on Biological Diversity or, as it is frequently called, Convention on Biodiversity, is an international commitment signed by 196 countries.

The Convention's principal aim is to preserve the world's biodiversity. To attain this aim, it presents three overarching strategies: conservation of biodiversity; sustainable use; and fair and equitable sharing of the benefits arising from the use of biodiversity.

By recognizing the sustainable use of biodiversity as the way for conserving it, the Convention has encouraged a relevant step forward. And by establishing its benefit-sharing system, it has enabled the possibility that innovation based on biodiversity and traditional knowledge associated to it may generate funds for the conservation of biodiversity.



Benefit sharing is a mechanism by which those who use the components of genetic heritage or traditional knowledge must share their profits with the holders of such heritage and such knowledge.

In the case of **genetic heritage**, we're speaking about living beings such as plants, animals and microorganisms, as well as their parts, such as roots, leaves, seeds, blood and substances as venom and saliva, among others.

In the case of **traditional knowledge**, under the Convention on Biodiversity, we're speaking about knowledge associated to the genetic heritage. It is the knowledge held by Indigenous peoples, traditional peoples and communities, and family farmers on the use and management of a wide diversity of life forms.

Traditional Knowledge
under the Convention on Biodiversity

The Convention also recognizes the importance of Indigenous Peoples and traditional communities for the conservation and use of biodiversity. This is also a step forward. Its Article 8 (j) on this topic is one of the most prominent in the Convention. It states that countries must:

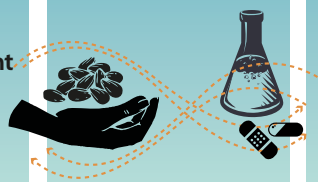
> *Subject to its national legislation,* ***respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities*** *embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity* ***and promote their wider application with the approval and involvement of the holders of such knowledge****, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.*

This means that:

The Convention on Biological Diversity was the first instrument to formally recognize that the knowledge, practices and innovations of Indigenous peoples and local communities are important for the conservation of biodiversity.

It established benefit sharing for all those willing to obtain access to traditional knowledge.

The Convention also established prior informed consent on behalf of the holders of traditional knowledge.



The Law on Access to Genetic Heritage and Associated Traditional Knowledge

(Law No. 13,123 dated May 20, 2015)

Brazilian Law 13,123 regulates the **access to, and use of genetic heritage, as well as the protection and access to its associated traditional knowledge, and benefit sharing for the conservation and sustainable use of biodiversity**. The topic is regulated in Brazil since Provisional Measure No. 2,186-16/2001.

The Law also covers many topics related to these themes, which will be mentioned below, such as prior informed consent, benefit sharing, the Genetic Heritage Management Council, and the National Fund for Benefit Sharing.

This law is in the interest of many sectors of the Brazilian society:

Indigenous peoples, traditional peoples and communities, and family farmers are directly covered by it, since they are the holders of the traditional knowledge associated to the genetic heritage and the stakeholders responsible for the conservation of biodiversity.

Academic researchers are interested in studying and conducting research on the genetic heritage and its associated traditional knowledge, since this knowledge contains a strong potential for the development of products such as medicinal drugs and cosmetics, and of more adequate processes of management and conservation of biodiversity, such as agroecology.

As can be seen, several interests are at play: by the industry, researchers, companies, Indigenous peoples, traditional peoples and communities, family farmers and other actors. Consequently, it is particularly important that all stakeholders pay attention and remain up to date in regard to their rights and the procedures that may be adopted when it comes to access to genetic heritage and its associated traditional knowledge.

The industry and agribusiness are direct users of the genetic heritage and its associated traditional knowledge, due to the potential for developing innovative products for the market, such as cosmetics and seeds.

The **government** is also a stakeholder, since it must regulate and supervise this issue. Finally, the entire **Brazilian people** must be interested in it, since the country's genetic heritage belongs to all Brazilians, and its balanced use can bring benefits to all.

Genetic Heritage

Genetic heritage is the **information on the genetic origin of living beings**. This information is constitutive of all plants, animals and microorganisms.

We cannot see this information with our naked eyes. We only see its results, which are the living beings themselves. For instance, the genetic information of a snake makes it the way it is: without arms or legs, while having its head and particular skin with many colors and patterns. We do not directly see this information, but we do see its end result: the snake itself!

Such genetic heritage often provides **the basis for many products**: medicinal drugs, cosmetics, cleaning substances and many others. They are also used in agriculture: in particular, for the production of seeds.

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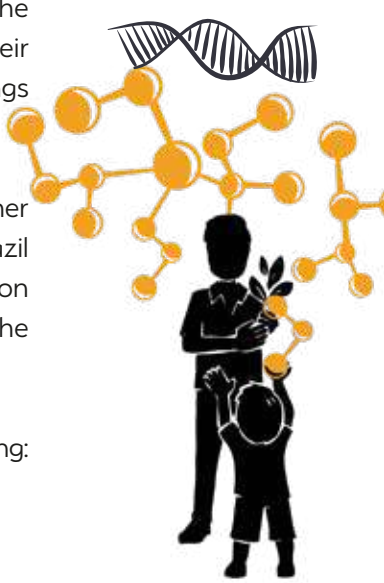
Genetic heritage is only a part of biodiversity. Biodiversity is much more than it; biodiversity is the entire living nature! It includes all living beings, their genetic heritage and the relations among beings throughout distinct ecosystems and biomes.



The genetic heritage of species that are either found or have acquired peculiar features in Brazil is a common good of all Brazilians. The Union (represented by the Federal Government) is the official guardian of this heritage.

It is an important mission, always worth remembering: **the owners of the genetic heritage are all of us!**

The law contains a definition of genetic heritage:

Law 13,123 of 2015 – Article 2, Item I

"I – genetic heritage – genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms".

It only does not include human genetic heritage:

Law 13,123 of 2015 - Article 4

"This Act does not apply to human genetic heritage."

The law **does not include** the genetic heritage that has not developed specific features in Brazil either. For instance, if a plant was brought from China and did not undergo modifications in Brazil, it is not covered by the law.

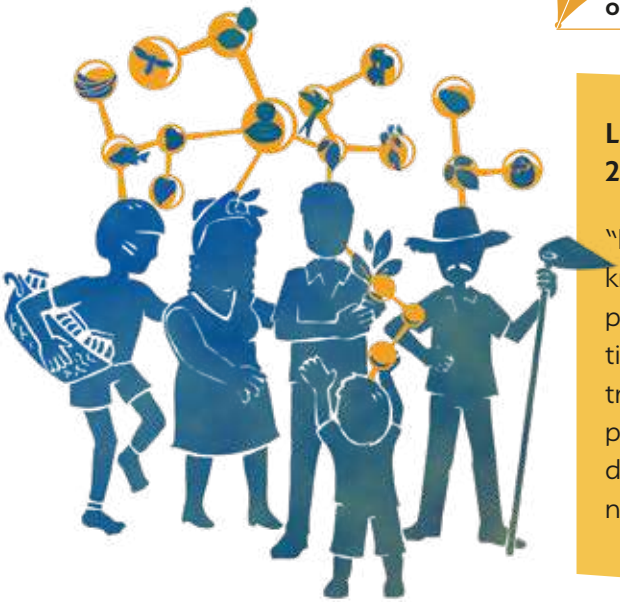
Traditional Knowledge Associated to Genetic Heritage

Indigenous peoples, traditional peoples and communities, and family farmers have lived since long ago in their territories. They hold a huge set of knowledge forms about nature, biodiversity and their local genetic heritage. These traditional forms of knowledge are related to the settings in which they are and to their local animals and plants, as well as to the ways of using and managing them.

These populations know the properties of medicinal plants and food plants used for their survival. They develop and select native and creole seeds for producing their food and other products from family farming.

The traditional knowledge, innovation and practices of traditional peoples and communities, Indigenous peoples and family farmers, which have a direct connection to the living beings, is known as **traditional knowledge associated to genetic heritage**, comprising knowledge forms that serve as a key source of innovation for science, technology and industry.

These knowledge forms are continuously expanding and transforming themselves: new forms are produced, while others are enhanced. Thus, the best way of protecting them is by **guaranteeing the rights** and the good living of those who generate and hold such knowledge. The holders of traditional associated knowledge have particular cultural features that distinguish them from the bulk of the Brazilian society. **The knowledge they hold is part of their own identity**, of their values, meanings and sense of being as peoples. It also ensures their survival and allow their culture to thrive.



The law contains a definition of traditional knowledge:

Law 13,123 of 2015 – Article 2, Item II

"II - associated traditional knowledge – information or practice of indigenous population, traditional community, or traditional farmers about the properties, or the direct or indirect uses associated with genetic heritage."

Associated Traditional Knowledge of Identifiable Origin and Associated Traditional Knowledge of Unidentifiable Origin

Some peoples, communities and family farmers share many traditional knowledge forms. It is not always easy to pinpoint the precise origin of traditional knowledge. Thus, under this law, the traditional knowledge associated to genetic heritage was divided into two categories: traditional knowledge of identifiable origin and of unidentifiable origin.

Associated traditional knowledge of identifiable origin:

When it is possible to identify at least one community that holds the knowledge. Publications, for instance, are also considered as possible sources for identifying the holders of traditional associated knowledge.

Associated traditional knowledge of unidentifiable origin:

When it is not possible to identify at least one people or community to which such knowledge could be linked.

The law has a definition for traditional knowledge of unidentifiable origin:

Law 13,123 of 2015 – Article 2, Item III

"III - associated traditional knowledge from unidentifiable origin – associated traditional knowledge where there is no way to link its origin to at least one indigenous population, traditional community, or traditional farmer."

The Brazilian decree, in turn, covers the origin of a knowledge form:

Decree No. 8,772 of 2016 – Article 12, Paragraph 3

"Any Indigenous population, traditional community or traditional farmer that creates, develops, holds or maintains associated traditional knowledge is considered an identifiable source of this knowledge, except in the **case** of §3 article 9 of Law No. 13,123, 2015."

The special case of Article 9, Paragraph 3

In this case, the same rule of access to associated traditional knowledge of unidentifiable origin applies, that is, access to the genetic heritage of traditionally local or creole seeds does not depend on prior informed consent for agricultural activities.

The law assumes that **all traditional knowledge is shared**. Therefore, in addition to an agreed sharing of benefits with the community that consented to grant access to it, the benefits will be shared with other communities through a fund, named National Fund for Benefit Sharing - FNRB. The FNRB will be described further ahead.

Under the law, agricultural activities comprise the production, processing and commerce of food, beverages, fiber, energy and planted forests.

AGRICULTURAL AND NON-AGRICULTURAL USES

Traditional Variety

Development of Reproductive Material

In this case, there is no need for prior informed consent and the benefits are shared by the producer of the reproductive material.

Agricultural Products

Economic exploitation of agricultural products, that is, activities of production, processing and commercializing food, beverages, fiber, energy and planted forests.

Non-agricultural finished products

Economic exploitation of finished product for cosmetic or pharmaceutical use.

In cases of cosmetic or pharmaceutical use, prior informed consent by the community is mandatory; and the producer of the finished product is the one who must share benefits.

Benefit Sharing

In the chain of agricultural products, it is the producer of the reproductive material.

Furthermore, according to the law, the definition of traditional knowledge of unidentifiable origin has several implications, such as:

For a company or researcher to obtain access to it, prior informed consent is not necessary.

The sharing of benefits as a result of access to this type of knowledge is undertaken by the National Fund for Benefit Sharing (FNRB).

Don't worry, we will still be talking quite a bit about prior informed consent and benefit sharing in the following pages...

Before we continue, let's take a closer look at a few other definitions under Law 13,123 of 2015:

Provider of Associated Traditional Knowledge

Providers are holders of traditional knowledge associated to the genetic heritage: traditional peoples and communities, Indigenous peoples and family farmers. This traditional knowledge attracts researchers and representatives of the industry willing to develop finished products or to exploit creole seed varieties economically. When a people or community (knowledge holders) grants access to researchers or to the industry (users), they become providers.

Holder:

Holders are those who hold knowledge.

Provider:

Providers are those who grant access to their knowledge. A provider **must** be a people or community.

It must be highlighted that traditional knowledge is linked to the lifestyles, cultures, traditions and ancestral relations of Indigenous peoples, traditional peoples and communities, and family farmers.

Definition under Law 13,123 of 2015 - Article 2, Item V (5)

"V – associated traditional knowledge provider – indigenous population, traditional community or traditional farmer who holds and provides associated traditional knowledge."

User

A user is a natural or legal person – frequently, a researcher or member of the Academia or of industries of pharmaceutical, cosmetic or food products, or a representative of the agribusiness or other sectors, who obtains access to the genetic heritage or associated traditional knowledge of Indigenous peoples, traditional peoples and communities, and family farmers, to develop products, commercial varieties, seeds and seedlings to be economically exploited.

Definition under Law 13,123 of 2015 – Article 2, Item XV (15)

"XV – user – a natural or legal person, that accesses genetic heritage or associated traditional knowledge, or economically explores a finished product or reproductive material originated from access to genetic heritage or associated traditional knowledge."

Access to Associated Traditional Knowledge

Access refers to study or research activities undertaken by the users – usually, researchers or representatives of the industry and agribusiness – on the associated traditional knowledge, in such way that this traditional knowledge may help them discover relevant features of the genetic heritage for developing products in the interest of the society, of industry or agribusiness, such as pharmaceuticals, cosmetics and seeds, among others.

However, the users accessing traditional knowledge are often not the ones who develop a product and exploit it economically. It is also worth noting that sometimes, a long period elapses between the moment when access is obtained and the moment when a product is commercialized.

Access to associated traditional knowledge can take place either directly with the Indigenous peoples, traditional peoples and communities, and family farmers; or indirectly, by means of products purchased in fairs, by means of books, publications, inventories, films, scientific articles, registers and other ways of recording distinct types of associated traditional knowledge.

Even in cases when knowledge is obtained in indirect ways, prior informed consent is necessary for obtaining access to it.

Definition under Law 13,123 of 2015 - Article 2, Item IX (9)

"IX – access to associated traditional knowledge – research or technological development conducted on traditional knowledge associated to genetic heritage that makes possible or facilitates access to genetic heritage, even if obtained from secondary sources such as: street markets, publications, inventories, films, scientific articles, registries and other forms of systematization and record of associated traditional knowledge."

Prior Informed Consent

Indigenous peoples, traditional peoples and communities, and family farmers **must be consulted in case of access to their knowledge**. The official procedure to obtain such access is called prior informed consent. This means that these holders must state **whether they agree or not that a particular user (a researcher or a company) should obtain access to their knowledge**. Furthermore, such process must be held **before obtaining access**, and must explicitly describe all its circumstances and likely consequences.

The law has a definition on this procedure:

Definition under Law 13,123 of 2015 - Article 2, Item VI (6)

"VI – prior informed consent – formal consent previously granted by indigenous population or traditional community according to their uses, customs and traditions, or community protocols."

Decree No. 8,772 of 2016 – Article 13

"Indigenous populations, traditional communities or traditional farmers may deny consent to access to their associated traditional knowledge of identifiable source."

The holders of traditional knowledge must decide how will be the process of obtaining prior informed consent. These holders are Indigenous peoples, traditional peoples and communities, and family farmers. They are the ones who must tell the users interested in having access to their knowledge how to proceed.

To obtain prior informed consent, users must, first of all, clarify to the Indigenous people, traditional people or community, or family farmer, the following elements:

- **The social, cultural and environmental impacts** resulting from the activity that will use the associated traditional knowledge.
- **The rights and liabilities** of each party involved in the execution of the planned activity.
- The right of an Indigenous people, traditional people or community, or family farmer to **refuse** access to their traditional knowledge, and to have their decision upheld.
- **The benefit sharing modalities -** monetary or non-monetary - as a result of economic exploitation.

The law also establishes that:

Law 13,123 of 2015 - Article 9, Paragraph 1

"Paragraph 1 – Evidence of prior informed consent can occur at the discretion of the indigenous population, traditional community or traditional farmer, by means of the following documents according to regulations:

I – signed prior consent;
II – registered audiovisual consent;
III – statement from the official governing body; or
IV – adherence to the provisions set forth by community protocol."

Please note!

Persons accessing traditional knowledge **without prior and informed consent, or without respecting it**, can be fined. The prices of fines range between **20 thousand and 10 million reais**. The collected fines go to the National Fund for Benefit Sharing.

Further on, we will be speaking about the Brazilian **registry**, but it is important to know that at the time of obtaining prior informed consent, a community and the user may **establish a deadline for registering** access to the associated traditional knowledge.

During the activities of granting prior informed consent, the Indigenous peoples, traditional peoples and communities, and family farmers may ask to be advised by public bodies such as the National Indian Foundation - FUNAI, the Palmares Cultural Foundation, the Public Prosecutions Office and Public Defender's Office, ICMBio and partnering bodies. Technical assistance may also be requested to the Executive Secretariat of the Genetic Heritage Management Council - CGen.

Community Protocols are norms agreed by Indigenous peoples, traditional peoples and communities, and family farmers that express to the Government, companies, researchers and all other parties interested in accessing their knowledge, their views on how to conduct their consultations in conformity with the norms and rules of their customs, traditions and cultures. They are a way of ensuring that the prior informed consent process will be conducted in a way that the holders of knowledge find adequate. They are also an assurance of protection to their traditional knowledge, innovations and practices, as well as to their ways of living and interacting with the natural resources on their territories.

The law contains a definition of community protocol:

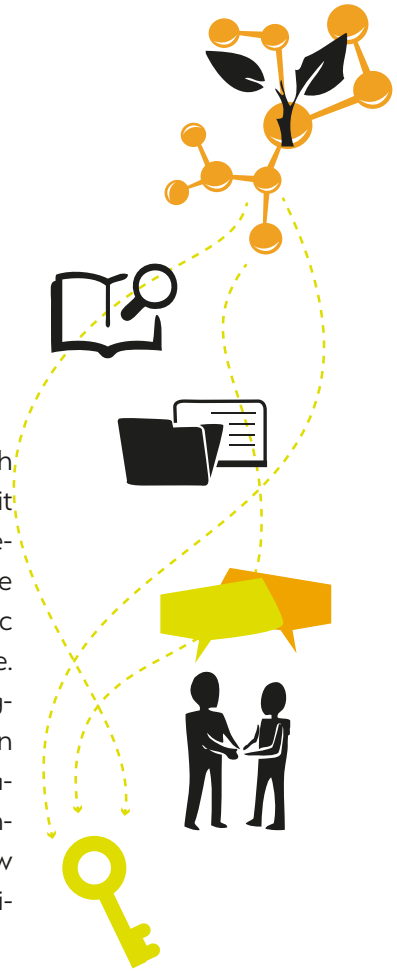
Law 13,123 of 2015 - Article 2, Item VII (7)

"VII – community protocol – indigenous peoples', traditional communities' or traditional farmers' procedural norms which establish, according to their uses, customs and traditions, mechanisms for access to associated traditional knowledge and benefit-sharing in accordance with this Act."

What happens when several peoples and communities share knowledge, and some of them are willing to allow access, while others are not?

A benefit sharing agreement will ONLY be signed with holders who say YES to access to their traditional knowledge! The other holders of the same knowledge will also benefit from the National Fund for Benefit Sharing

Ways of Recognizing Traditional Knowledge



A very important issue regards the way in which traditional knowledge is obtained. For instance, it may be conveyed during a dialogue with someone in a community or village. But it may also be learned by reading a book, undertaking scientific research, or by looking in a registry or data base. Under the law, these are distinct ways of recognizing traditional knowledge. In case of interest in obtaining access to any form of associated traditional knowledge of identifiable origin, prior informed consent must always be granted. The law covers a diversity of forms of recognition of traditional knowledge:

The law recognizes distinct instruments for recognizing traditional knowledge:

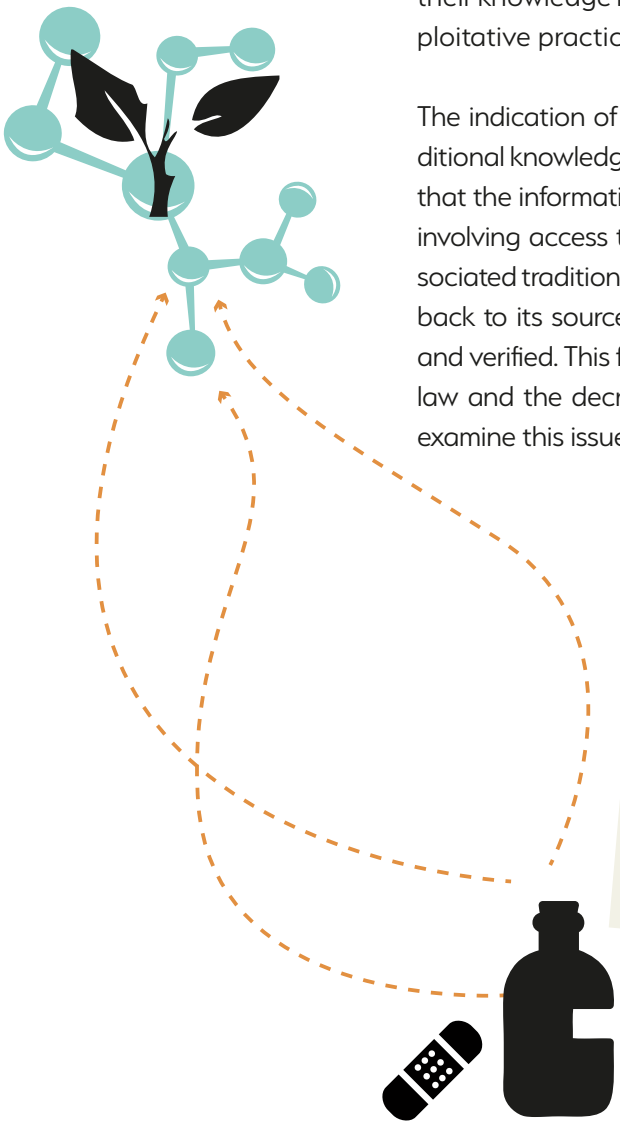
Law 13,123 of 2015 – Article 8, Paragraph 3

"Paragraph 3 – Associated traditional knowledge may be recognized, among others, in the following instruments:

I – scientific publications;
II – registries or databases; or
III – cultural inventories."

Indigenous peoples, traditional peoples and communities, and family farmers have the right to a recognition of the source of their knowledge in all publications, uses, exploitative practices and public disclosures.

The indication of the origin of accessed traditional knowledge is indispensable to ensure that the information of productive processes involving access to genetic heritage and associated traditional knowledge can be traced back to its source and, therefore, monitored and verified. This feature is established by the law and the decree as **traceability**. We will examine this issue in more detail further on.



Please note!

Failing to indicate the origin of ATK can result in fines between **1,000 and 500,000 reais!**

Benefit Sharing

The sharing of benefits from the economic exploitation of a finished product or reproductive material obtained from access to genetic heritage can occur in two ways, which are established by the law as 'modalities':

Monetary: Via payments to the FNRB.

Non-monetary: Via conservation projects, capacity building activities and distribution of products, among other activities.

It is worth remembering that non-monetary benefit sharing may be aimed at territories of Indigenous peoples, traditional peoples and communities, and family farmers, by the following means:

- Projects for conserving or sustainably using the biodiversity.
- Protection and maintenance of traditional knowledge
- Training of human resources, for instance, by 'living drugstore' initiatives, popular herbariums or community seed banks.

Non-monetary benefit sharing by access and ATK will observe the clauses jointly agreed on by the user (company) and the provider of traditional knowledge.

The law provides for three general benefit sharing possibilities:

1

Genetic Heritage

In cases of access only to genetic heritage, the user is the party who decides for the monetary or non-monetary modality.

Under the monetary modality, 1% of the net income resulting from the exploitation of a finished product or reproductive material will be transferred to the National Fund for Benefit Sharing - FNRB.

Under the non-monetary modality, a percentage between 0.75% and 1% of the net annual income obtained from the commercialization of a product or reproductive material can be assigned to Benefit Sharing Agreements - ARB-NM, which may involve protected areas (known as 'Conservation Units' in Brazil), Indigenous lands, Quilombola lands, settlements, traditional territories, research institutions, priority areas for conservation, activities for safeguarding traditional knowledge, *ex situ* collections, conservation projects, training of human resources and distribution of products, among other elements.

2 Traditional knowledge of non-identifiable origin

In this case, benefit sharing will always take place under the monetary modality, by assigning 1% of the net annual income obtained from the commercialization of a finished product or reproductive material. This sum must be directly transferred to the National Fund for Benefit Sharing - FNRB.

3 Traditional knowledge of identifiable origin

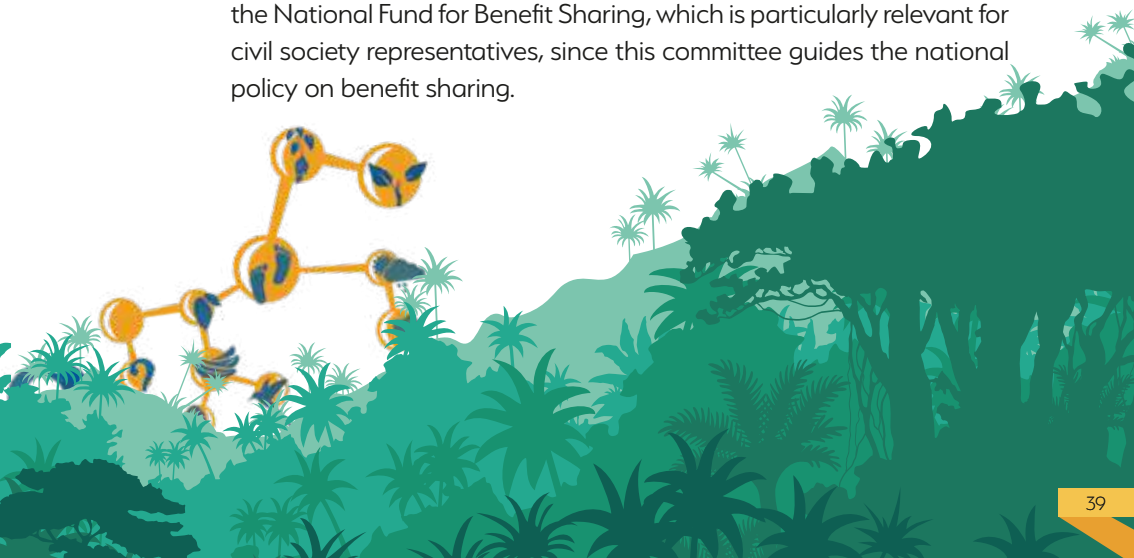
In this case, a Benefit Sharing Agreement - ARB must be signed between the providers of traditional knowledge and those who will undertake the economic exploitation of the finished product developed based on associated traditional knowledge. This agreement will establish how benefit sharing will take place and which will be the sum and form of sharing.

It also worth remembering that the law assumes all knowledge to be shared. That is, associated traditional knowledge may be shared by more than one community. Thus, in addition to the agreement with the providing community, monetary benefit sharing will also be paid to the National Fund for Benefit Sharing - FNRB at a sum established by the law, corresponding to 0.5% of the net annual income obtained through the exploitation of the finished product.

Genetic Heritage access	Monetary BS	1% of net income goes to the FNRB
	Non-monetary BS	ARB-NM with the Union (0.75% - 1% of the net income)
Access to ATK of non-identifiable origin	Monetary BS	1% of the net income goes to the FNRB
Access to ATK of identifiable origin	Monetary or non-monetary with the provider + Monetary portion goes to the FNRB	BS agreement with the provider + 0.5% of the net income goes to the FNRB

Non-monetary Benefit Sharing - ARB-NM on the use of genetic heritage may be reduced to 0.75% of the net annual income if the user accepts to share benefits via conservation projects, capacity-building activities or distribution of products in socially strategic programs.

It is important to monitor the work of the Management Committee of the National Fund for Benefit Sharing, which is particularly relevant for civil society representatives, since this committee guides the national policy on benefit sharing.



According to the law, benefit sharing does not take place in all situations. For non-agricultural activities, benefits are shared on gains from the economic exploitation of a **finished product**, that is, of a product that is ready to be commercialized, and contains genetic heritage or associated traditional knowledge as one of the components that appreciates its value. In this case, the law establishes that this component is **one of the key elements that adds value to the product**.

Law 13,123/2015, Article 2, Item XVI (16) defines "finished product" as "a product originating from access to genetic heritage or associated traditional knowledge that does not need any additional processing, in which the genetic heritage or the traditional knowledge component is a key main element of value adding to the product, being it ready for use by the final consumer, whether a natural or a legal person."

According to **Law 13,123/2015, Article 2, Item XVIII (18)**, the key elements of value adding to a product are those "whose presence in the finished product is determinant to its **functional characteristics** or to its marketing appeal."

These are the characteristics that either determine the principal aims of the product, enhance its action or expand its purposes. This definition can be found in Article 43 of Decree No. 8,772/2015.

This means that when associated traditional knowledge and/or genetic heritage have the effect of adding value to a finished product, benefit sharing must take place. The characterization of the key value adding-elements is decisive, since it defines when a finished product based on genetic heritage or associated traditional knowledge must share benefits.

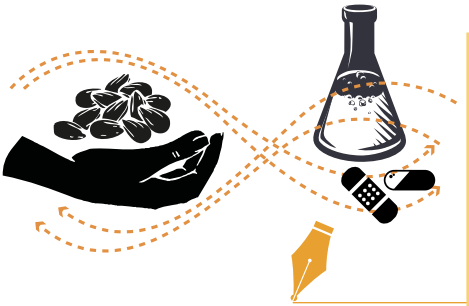
In agricultural activities, benefit sharing will not be made based on the finished product, but, instead, on the reproductive material of the species of variety of that productive chain. Thus, throughout the productive chain of a jaboticaba juice, for instance, the benefits will be shared not by the company that produces and packages the juice, but by the company that produces the jaboticaba parent plants and seedlings that are planted for juice production.

According to **Law 13,123/2015, Article 2, Item XXIV (24)**, agricultural activities are "activities of producing, processing and commercializing food, beverages, fibers, energy and planted forests."

As to the producers of finished products, three large outsourcing segments stand out: a) FULL BUY, which is when a product is fully produced by an outsourced company. For instance, when a brand procures and buys a product without interfering in its production, which is fully conducted and planned by the third party; b) PARTIAL SERVICE: when a given brand choses to delegate a part of the productive process, while maintaining the controls over the final results; c) FULL SERVICE: when the production service itself is outsourced. In this case, the company that developed the formula and now holds the brand's intellectual property rights resorts to third parties to execute the production, while maintaining the controls over the final results of the production.

The taxable person responsible for paying and sharing benefits is the one responsible for the final product, who is holding the controls of the productive process. Thus, the finished product's producer is the brand holder in the second and third cases, and the third party from which the product is outsourced in the first case. They are the ones who must fulfill all duties in connection with the economic exploitation of the finished product obtained by access, as well as the ones responsible for registering the product in the SisGen database and sharing its benefits.

This means that, in the productive chains of agricultural activities, the final product's producer does not share benefits. Benefit sharing is linked to the commercialization of reproductive material, such as seeds and seedlings. Only one link in the productive chain must share benefits (especially, in the seed industry).



Law 13,123/2015, Article 2, Item XXIX (29)

"XXIX – reproductive material – plant propagating material or animal reproductive material from any genus, species or crop, coming from sexual or asexual reproduction."

But check this out:

If the same jaboticabas are used to produce soap, that is, a (non-agricultural) cosmetic product, then the company that makes the finished product is the one that must share benefits.

Law 13,123/2015, Article 17

"Art. 17 – The benefits resulting from economic exploitation of finished product or reproductive material arising from access to genetic heritage of species found in *in situ* conditions or to associated traditional knowledge, even if produced outside the country, will be shared in a fair and equitable way. In the case of a finished product, the genetic heritage or the associated traditional knowledge component must be one of the key elements of value adding to the product, in accordance with this Act."

Benefit Sharing
Exemptions

In addition to the issue of the finished product and the key elements that add value to it, the law provides for a set of situations in which benefit sharing does not apply, or exemptions. These exemptions are designed to encourage the development of some economic sectors that obtain access either to genetic heritage or traditional knowledge. Let's take a look, on the next page, at the excerpt of the law that presents this set of exemptions:

Law 13,123/2015 – Article 17, paragraphs 1 to 5

"**Paragraph 1** – Only the manufacturer of the finished product or the producer of the reproductive material will be obliged to share benefits, regardless of who has previously carried out access activities.

Paragraph 2 – The manufacturers of intermediate products and developers of processes originating from the access to genetic heritage or associated traditional knowledge along the production chain will be exempted from benefit-sharing obligations.

Paragraph 3 – When a single finished product or a reproductive material results from distinct accesses, they will not be considered cumulatively in the calculation of benefit-sharing.

Paragraph 4 – Licensing, transferring or permitting any use of intellectual property rights related to a finished product, process, or reproductive material arising from access to genetic heritage or associated traditional knowledge by third parties are considered economic exploitation exempted from benefit-sharing obligations.

Paragraph 5 – The following are exempt from benefit-sharing obligations, in accordance with the regulation:

I – micro-businesses, small businesses, micro individual entrepreneurs, under provisions of Complementary Law No. 123, dated December 14, 2006;

II – traditional farmers and their cooperatives with annual gross revenue equal to or lower than the upper limit established in Article 3(II) of Complementary Law No 123, dated December 14, 2006."

The State must monitor the exemptions to micro-companies, small companies and individual micro-entrepreneurs, to avoid that the legal provisions of Article 5 of Law 13,123 of 2015 will be unduly applied to cases of access to traditional knowledge and genetic heritage for which a benefit sharing exemption does not apply.

Benefit sharing was conceived under the Convention on Biological Diversity (CBD) as a strategy of conservation. This means that it must generate funds and incentives for the conservation of biodiversity, for maintaining the integrity of natural environments and to help fostering the use and innovation based on biodiversity.

Benefit sharing does not encompass all situations in which genetic heritage and traditional knowledge are used.

These exemptions are neither a waiver from the duty to obtain Prior Informed Consent for accessing associated traditional knowledge, nor from the duty to register in the SisGen data base.

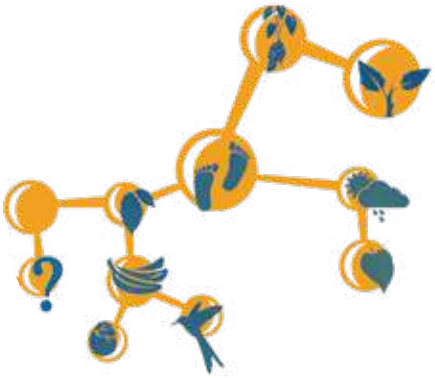
In other words, in regard to these exemptions, we conclude that:

- The producers of finished products share benefits, but intermediaries do not need to share benefits. If the product originated from more than one access (research or technological development) to traditional knowledge or genetic heritage, benefit sharing will take place only once;

- In activities such as transfers or permissions of use of patents, undertaken by other persons, benefit sharing is not necessary;

- Micro-companies, small companies and individual micro-entrepreneurs are exempted from sharing benefits; and

- Traditional farmers and their cooperative groups with a gross annual income below 3.6 million reais do not share benefits.



It must be recalled that it is not only in the benefit sharing agreement that providers and users negotiate rights and duties.

Prior Informed Consent itself is a contract signed between a provider and a user.

In the process of negotiating prior informed consent, each provider will freely negotiate his or her terms and conditions. In other words, the provider may establish conditions of any type, including obligations related to benefit sharing.

Benefit Sharing Agreement

In case of economic exploitation of a finished product or reproductive material deriving from genetic heritage, a Non-Monetary Benefit Sharing Agreement (in Portuguese abbreviation, ARB-NM) can be signed between the Ministry of the Environment, representing the Union, and the companies.

In case of **traditional knowledge of unidentifiable origin**, benefit sharing will always take place through a direct payment to the National Fund for Benefit Sharing.

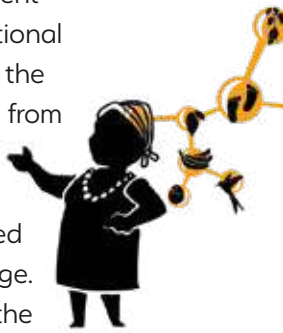
Regarding **genetic heritage**, if the user chooses the **monetary modality** for sharing benefits, a Benefit Sharing Agreement - ARB-NM is not necessary, since the payment can be directly made to the National Fund for Benefit Sharing. However, if a user chooses the **non-monetary modality**, he or she must sign an ARB-NM with the Union.

Another relevant point to be stressed regards deadlines. In cases of access to genetic heritage, the Non-Monetary Benefit Sharing Agreement can be submitted within one year after submitting a notification of finished product or reproductive material - when its economic exploitation may begin. This means that the user may exploit a product economically for up to one year before beginning to share benefits. The period for which benefits will be shared covers the entire period of the economic exploitation. Its calculation basis must be fully disclosed, to avoid fraud and facilitate inspection activities.

Finally, it is worth recalling that under the law, whenever benefits are shared on finished products or reproductive materials deriving from associated traditional knowledge, users are exempted from sharing benefits in connection with the use of genetic heritage.

The rules for submitting an ARB-NM are provided by Ordinance MMA 144 of 2021.

In the case of access and use of **traditional knowledge of identifiable origin**, a Benefit Sharing Agreement - ARB must be signed between the provider of traditional knowledge and those who will economically exploit the finished product or reproductive material deriving from traditional knowledge. It is important to note that this agreement must be signed with the holder of traditional knowledge involved in the prior informed consent that has enabled access to this knowledge. But is also worth recalling that the other party of the agreement, which will exploit the product or reproductive material economically, cannot be the same person or institution previously involved in the prior informed consent process. Finally, it is important to remind that a long period of time may elapse between the prior informed consent process and the signing of a Benefit Sharing Agreement - ARB, that is, between access itself and the commercialization of a product deriving from such access.



In the case of access to associated traditional knowledge of identifiable origin, the Benefit Sharing Agreement - ARB - must be submitted together with the notification of finished product or reproductive material.

It is in the Benefit Sharing Agreement - ARB signed with the providing community that the parties must decide how Benefit Sharing will take place.

In addition to the sum stipulated in the Benefit Sharing Agreement - ARB - with the communities, an additional monetary sum is always paid to the National Fund for Benefit Sharing. The law establishes that this sum is equivalent to **0.5% of the net annual income obtained from the product's exploitation.**

The Law and the Decree describe the indispensable items for a Benefit Sharing Agreement:

Law 13,123/2015 – Article 26

"Article 26 – Without detriment to future clauses that may be established in the regulation, clauses addressing the following are mandatory in the benefit-sharing agreement:

I. products that are object to economic exploitation;
II. time frame;
III. modality for benefit-sharing;
IV. rights and responsibilities of the parts;
V. intellectual property rights;
VI. termination;
VII. penalties; and
VIII. jurisdiction in Brazil."

It is important to remember that the conditions negotiated in the Prior Informed Consent may influence the clauses of Benefit Sharing Agreement - ARB.

Decree No. 8,772/2016 – Article 55

"Article 55. The benefit-sharing agreement between user and provider shall be fairly and equitably negotiated between the parties, given the parameters of clarity, fairness and transparency in contractual clauses, and shall indicate conditions, obligations, types and duration of benefit in the short, medium and long term, without prejudice to other guidelines and criteria to be established by the CGen."

Sectoral Agreement

A Sectoral Agreement is a type of agreement that can be signed to reduce the costs of benefit sharing, with the aim of ensuring the competitivity of an economic sector. This agreement regards only the sharing of benefits from the use of genetic heritage and traditional knowledge of unidentifiable origin.

According to the law:

Law 13,123/2015 – Articles 20 and 21

"**Article 20** – Monetary benefit-sharing should represent 1% (one percent) of the annual net revenue obtained from economic exploitation of finished products or reproductive material arising from access to genetic heritage, except when reduced for up to 0.1% (one tenth percent) by sectoral agreement as defined in Article 21.

Article 21 – In order to foster competitiveness of the beneficiary sector, the Federal Government may, at the request of the interested party and according to regulations, celebrate sectoral agreements to reduce the amount of benefit-sharing for up to 0.1% (one tenth percent) of the annual net revenue obtained from economic exploitation of finished products or reproductive material arising from access to genetic heritage or associated traditional knowledge from an unidentifiable origin.

Sole paragraph. In order to assist in formulation of sectoral agreements, official government offices for indigenous peoples' and traditional communities' rights may be heard in accordance with the regulation."

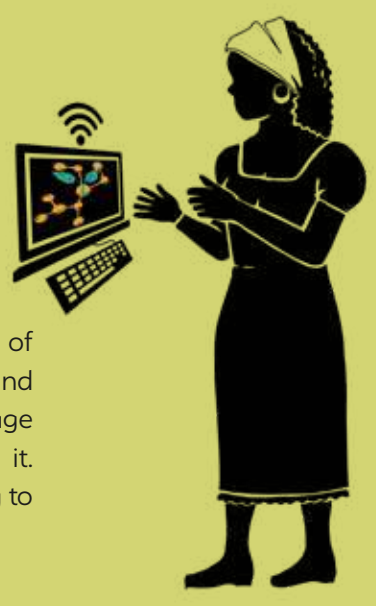
Decree No. 8,772/2016 has regulated all procedures for signing a sectoral agreement. The Decree explains that **a company or group of companies that produce the same product, or similar products**, may request this agreement if they can prove that the payment of Benefit Sharing following the percentages established by the law can impair the production and commercialization of these products – leading, in the words of the decree, to 'material damage' or the 'threat of material damage'.

However, the analysis of this proposal by the government requires compliance with a list of requirements and information as provided by **articles 56-69 of Decree No. 8,772/2016**. In its informed opinion, the Ministry of the Environment must also consider the expressed opinion of bodies in defense of the rights of Indigenous peoples and traditional communities when considering requests of reduced benefit sharing.

It is also worth highlighting that these agreements do not last indefinitely. They are valid for 60 months (5 years). Their extension is possible if the group
of companies can prove that the situation of material damage or threat thereof persists.

A Sectoral Agreement will apply to the entire sector, including the products produced by companies not participating in the request.

Registration



Registration is one of the key elements of this law, since all activities of control and inspection of access to genetic heritage and traditional knowledge depend on it. The activities to be registered, according to the law, are the following:

Law 13, 123/2015 – Article 12

"**I** – access to genetic heritage or associated traditional knowledge carried out within the country by national legal or natural person, public or private;

II - access to genetic heritage or the associated traditional knowledge by a legal person based abroad associated to a national scientific and technological research institution, public or private;

III – access to genetic heritage or associated traditional knowledge carried out abroad by national legal or natural person, public or private;

IV - shipment abroad of genetic heritage sample with the purpose of access, as described in items II and III of this Article; and

V – sending abroad sample containing genetic heritage by national legal person, public or private, for services as part of research or technological development."

This means that every access to genetic heritage or associated traditional knowledge must be registered. Even when access is obtained for non-commercial ends – and benefits, therefore, do not need to be shared -, it must still be registered. Even the activities exempted from sharing benefits must comply with the provisions established by the law.

The activities practiced by Indigenous peoples, traditional peoples and communities, or family farmers among themselves, for their own benefit and based on their usages, customs and traditions, do not need to be registered.

Registration will be made by filling in an online form. This must be done before disclosing any research results or requesting a patent or the protection of a cultivar, as well as before the commercialization of any product, seedling or seed resulting from access.

Please remember that at the occasion of negotiating their Prior Informed Consent, the holders of associated traditional knowledge may choose the moment when the user must register.

The law establishes when the registration must be submitted:

Law 13,123/2015 – Article 12, paragraph 2

"Paragraph 2 – Registration must be carried out prior to shipment, or the application of any intellectual property right, or the commercialization of the intermediate product, or publication of results, partial or final, in scientific or communication media, or the notification of a finished product or reproductive material developed as result of the access."

Shipments must contain a form named "Statement of Transfer of Material - TTM", in Portuguese. You will find this document in Resolution CGen No. 27.

Prior Informed Consent may include, at the parties' agreement, the expected shipments, in case of a traditionally local or creole seed, or in case of locally adapted variations of creole seeds developed by the provider.

It is important to know that in the case of access to traditional knowledge of identifiable origin, in the prior informed consent document, the community can establish a deadline for registration of access to associated traditional knowledge previous to the date established by the law. For instance, by stipulating a number of days after the obtainment of consent for the user to proceed with registration.

For activities of access to genetic heritage or associated traditional knowledge, registration must include at least the following:

- The **objectives** – What is intended with the research;
- The **expected results** (Product or information).
- Information on the **researchers**.
- The (georeferenced by GPS) **location** where the genetic heritage was collected, even if in an herbarium or seed bank (*ex situ* collection).
- Information on the **plant, animal or microorganism** to be studied (identification of genetic heritage), including information on whether it is a traditionally local variety or creole type.
- Whether the traditional knowledge is of identifiable or unidentifiable origin.
- Proof of **prior informed consent**, in case of access to traditional knowledge of identifiable origin.
- The **Indigenous traditional or agricultural community** where access was obtained (even in cases when access was obtained by means of a book, museum, or fair, among other possibilities).
- Information on the partnering institution and researcher(s) in Brazil and internationally, if there is any.
- Timeline of Research or Technological Development Project.
- Statement of no-incidence of benefit sharing, in cases of exemption.

Notification

For the economic exploitation of a finished product in which a component of genetic heritage or traditional knowledge can be characterized as a core value adding-element, it is necessary to submit a notification. A notification is the way for users to inform that they have a finished product and will begin selling it. According to the Law, they must inform at this moment whether the benefit sharing modality is monetary or non-monetary. In cases of genetic heritage use, an ARB-NM may be submitted up to one year after the notification.

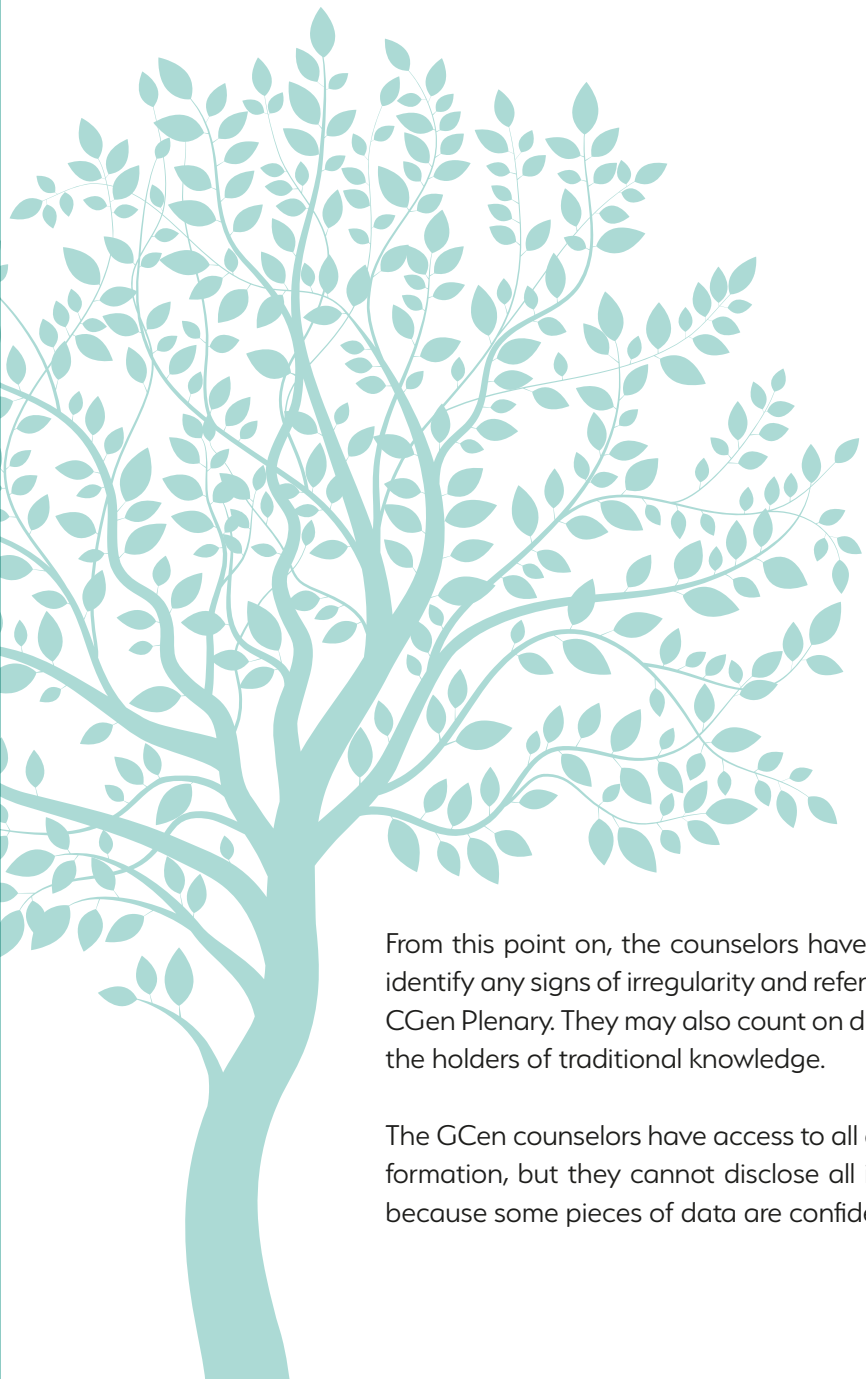
If the user selects the monetary modality, benefit sharing is paid directly to the National Fund for Benefit Sharing - FNRB. In the case of traditional knowledge of identifiable origin, the agreement must be submitted at the moment of the notification. It is important to note that in many cases, the notification and the Benefit Sharing Agreement will be quite distant in time from the moment either of prior informed consent or access. Furthermore, the user responsible for the economic exploitation of the finished product and, consequently, for the notification and Benefit Sharing Agreement, will not always be the same one who requested prior informed consent at the moment of obtaining access to traditional knowledge.

Verification

Verification begins by fully filling in the electronic form of registration and notification. It serves the purpose of checking whether the submitted information is correct and complete.

After the form is completed, CGen's Executive Secretariat has 15 days to:

- Inform the CGen counselors about the registration or notification;
- Refer the data on the accessed species and the municipality where access was obtained to the members of the sectoral committees; and
- Inform the bodies of protection of Indigenous peoples, traditional peoples and communities, and family farmers about the registration of access to associated traditional knowledge.



From this point on, the counselors have 60 days to identify any signs of irregularity and refer them to the CGen Plenary. They may also count on direct help by the holders of traditional knowledge.

The GCen counselors have access to all available information, but they cannot disclose all information, because some pieces of data are confidential.

The Genetic Heritage Management Council (CGen)

Law 13,123 established the Genetic Heritage Management Council - CGen - to coordinate the entire policy of access and use of genetic heritage and associated traditional knowledge. Before this new law, the CGen was already mentioned in a Provisional Measure on the topic, but it had different attributions and composition. According to Law 13,123/2015, the CGen now has the following characteristics:

- It is a **collegiate body**, that is, it comprises a group on individuals who reach the decisions together;
- It has a **deliberative status**, that is, it may decide on the topics under its scope of activities;
- It is **normative**, that is, it establishes the rules and norms on access to the genetic heritage and associated traditional knowledge, as well as on benefit sharing;
- It is **consultive**, that is, in case of doubts, the Council may help improve the necessary understanding;
- It is **appellate**, that is, if a party is not satisfied with a decision on the topic, this party may resort to the CGen and request a new analysis of the situation at stake.
- It is **responsible for coordinating the design and implementation** of policies on the management of access to genetic heritage and associated traditional knowledge, and on benefit sharing;
- It is composed of bodies and entities of the public administration, that is, of representatives of the Federal Government and **representatives of the civil society**, comprising, in the case of this Law, the entrepreneurial sector, the academia and the holders of traditional knowledge.

Participation of good quality by the representatives of Indigenous peoples, traditional peoples and communities, and family farmers is essential for the adequate functioning of the Council.

CGen Composition

The CGen is currently composed of 18 counselors, including:

9 representatives of the Federal Government:

- Ministry of the Environment;
- Ministry of Justice and Public Security;
- Ministry of Health;
- Ministry of Foreign Relations;
- Ministry of Agriculture, Livestock Rearing and Supply;
- Ministry of Citizenship;
- Ministry of Defense;
- Ministry of Development, Industry and Foreign Trade – currently, Ministry of Industry, Foreign Trade and Services;
- Ministry of Science, Technology and Innovation;
- Ministry of Economy.

3 representatives of entities or organizations of the entrepreneurial sector:

- 1 member appointed by the National Confederation of the Industry - CNI;
- 1 member appointed by the National Confederation of Agriculture - CNA – currently, Brazilian Confederation of Agriculture and Livestock Rearing: and
- 1 member appointed alternately and successively by CNI and CNA.

3 representatives of bodies or entities of the Academia:

- 1 member appointed by the Brazilian Society for the Advancement of Science - SBPC;
- 1 member appointed by the Brazilian Association of Anthropology - ABA; and
- 1 member appointed by the Brazilian Academy of Sciences - ABC; and

3 representatives of bodies or organizations on behalf of the Indigenous populations, traditional communities and traditional farmers:

- 1 member appointed by the representatives of traditional peoples and communities and their organizations under the National Council of Traditional Peoples and Communities - CNPCT;
- 1 member appointed by the representatives of family farmers and their organizations under the National Council of Sustainable Rural Development - CONDRAF; and
- 1 member appointed by the representatives of Indigenous peoples and organizations under the National Council of Policies for Indigenous Peoples - CNPI.

Please remember that these 3 appointed members represent their own rights and the rights of the community. They have a seat at the Genetic Heritage Management Council to advocate for the rights of Indigenous peoples, traditional peoples and communities, and family farmers. You may also participate in the CGen by dialoguing and connecting with your representatives, and by participating in your Sectoral Committee!

The law considers the civil society as comprising representatives of the entrepreneurial sector, of the academia and of the holders of traditional knowledge.

How the CGen Works

In addition to its plenary, the Genetic Heritage Management Council - CGen includes Theme Committees, Sectoral Committees and its Executive Secretariat. The Theme and Sectoral Committees provide inputs to the plenary, that is, they gather information, produce analyses and make suggestions for its decision-making process. The committees have the same number of participants representing the public administration and civil society.

The Law also brings an extensive list of the tasks and responsibilities under the CGen's purview (art. 6, paragraph 1). Here is a selection of the most important ones:

Therefore, three Sectoral Committees are available:

- A Sectoral Committee for the entrepreneurial sector;
- A Sectoral Committee for the academia-sector; and
- A Sectoral Committee for representatives of Indigenous peoples, traditional peoples and communities, and family farmers.

The theme committees cover specific themes or fields of knowledge related to access and benefit sharing:

- Establishment of guidelines and criteria for the production of, and compliance with benefit sharing agreements;
- Creation and maintenance of databases;
- Registration of notifications on finished products or reproductive materials, and of their respective benefit sharing agreements;
- Issuance of Certificates of Access Compliance; and
- Establishment of guidelines for the use of resources under the National Fund for Benefit Sharing.

In the following sections, we will examine each one of these activities.

Establishing guidelines and criteria for the production of, and compliance with benefit sharing agreements

For the cases in which the law establishes benefit sharing, a Benefit Sharing Agreement may be signed. In cases of monetary benefit sharing for the commercial use of a product obtained from access to genetic heritage or associated traditional knowledge of unidentifiable origin, sharing may take place through a direct payment to the National Fund for Benefit Sharing - FNRB - without the need for a Benefit Sharing Agreement.

However, **in cases of non-monetary benefit sharing due to the commercial use of a product obtained from genetic heritage**, the signing of a Benefit Sharing Agreement with the Union is necessary. In this case, the CGen must establish the guidelines on how these agreements will work, since the Law mentions several types of activities that may take place under non-monetary benefit sharing. The establishment of mechanisms for verifying the agreement will be essential.

In cases of benefit sharing from the **commercial use of products obtained from traditional knowledge of identifiable origin**, a Benefit Sharing Agreement is necessary between the provider of knowledge, that is, the Indigenous people, traditional people or community, or family farmer who gave access to the associated traditional knowledge, and, on the other hand, the party who will exploit the finished product or reproductive material derived from that knowledge economically.

The clauses of a benefit sharing agreement must be objective, transparent and easily understandable. They must contain the deadlines, sums and all conditions and duties in connection with benefit sharing. They must also point to the type and duration of short-, medium- and long-term benefits.

Creation and maintenance of databases

Databases are **sets of information stored** in a specific place. The CGen shall establish databases on the topics linked to its direct activities, including information, for instance, on access registries, notifications of finished products, Benefit Sharing Agreements and Certificates of Access Compliance.

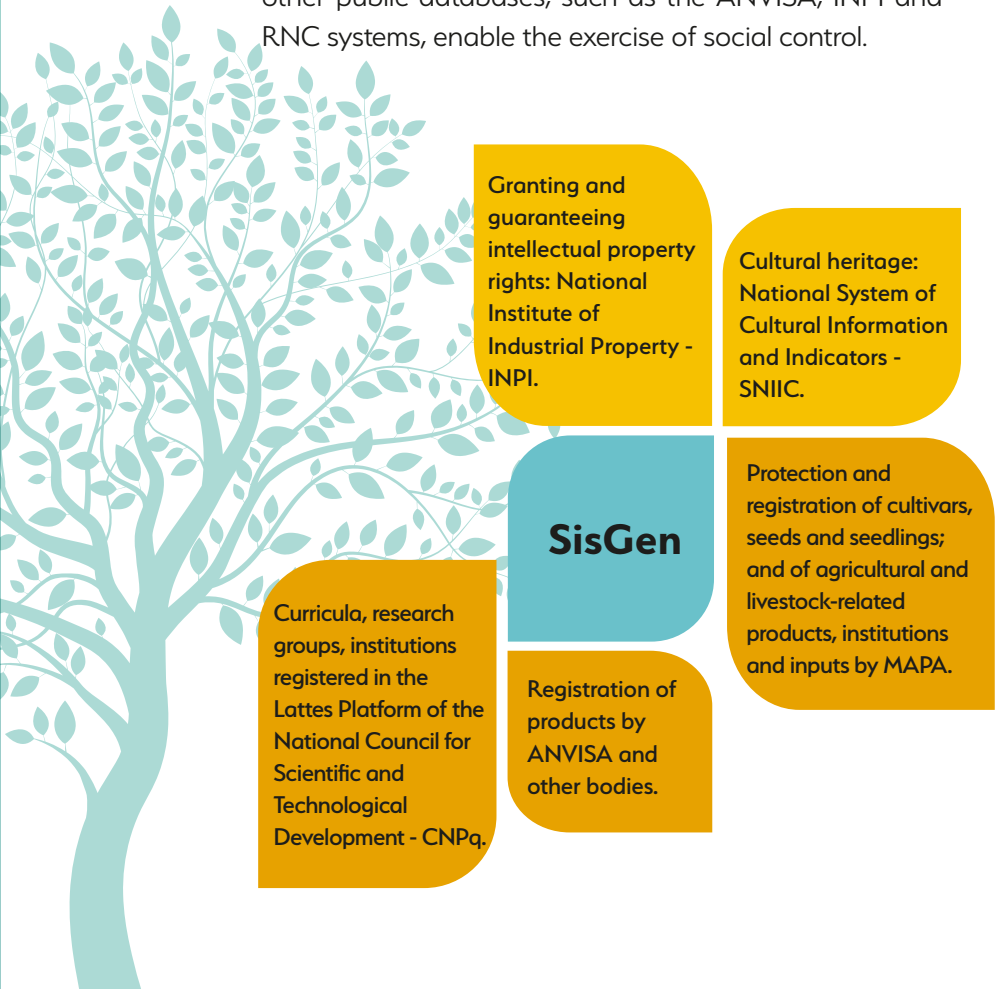
These databases are important, since they **store the history** of a diversity of accesses and usages of the genetic heritage and traditional knowledge, making it possible to know what was used, in which conditions, how benefit sharing took place and other information.

Databases can also be quite useful for distinguishing between associated traditional knowledge of identifiable origin and unidentifiable origin. In cases of access to knowledge that is, in principle, from a unidentifiable origin, databases can be used to help identifying the origin of this knowledge, since, after being registered in the database, such origin can be claimed by its holders.

An important issue in connection with databases is distinguishing between information available for public access and, on the other hand, information protected by confidentiality.

It is important to be capable of using the verification mechanisms and public data to ensure the traceability and the rights of Indigenous peoples, traditional peoples and communities, and family farmers.

In addition to the traceability system (art. 5 of the Decree), other public databases, such as the ANVISA, INPI and RNC systems, enable the exercise of social control.



Notifications on finished products or reproductive materials, and their respective Benefit Sharing Agreements

A notification of finished product or reproductive material is a statement submitted by the user who will economically exploit a finished product or reproductive material deriving from access to the genetic heritage or associated traditional knowledge. It informs that the user has complied with all requisites under the law and indicates the respective benefit sharing modality (as monetary or non-monetary).

The Law has a definition for this notification:

Law 13,123/2015 – Article 2, item XIX (19)

"XIX – product notification – declaration document required prior to economic exploitation of a finished product or reproductive material originating from access to genetic heritage or to associated traditional knowledge in which the user declares compliance with the requirements of this Act and indicates the modality of benefit-sharing, when applicable, to be established in the benefit-sharing agreement."

The CGen must receive and register this notification via electronic form. There may be a period of up to one year between a notification and its Benefit Sharing Agreement, in cases of access to genetic heritage and associated traditional knowledge of unidentifiable origin.

For notifications of products based on access to associated traditional knowledge of identifiable origin, a Benefit Sharing Agreement must also be submitted at the moment of the notification.

Certificate of Access Compliance

The CGen may issue certificates, that is, it may issue a document stating that access has been obtained in conformity with the Law.

The Law defines these certificates as:

Law 13,123/2015 – Article 2, item XXII (22)

"XXII – certificate of access compliance – administrative act by which the responsible agency declares that access to genetic heritage or associated traditional knowledge complied with the requirements of this Law."

The certificates will be issued by SisGen after a CGen plenary deliberation. This document attests to a status of regularity up to the date of its issuance by CGen, preventing eventual fines for an access that has been attested by the Council, except in case of a proven mistake or fraud. For access to associated traditional knowledge of identifiable origin, either the competent body or CGen must produce an assessment of the document's validity, to prove that prior consent was obtained in an adequate way for the issuance of the certificate.

In addition to the Certificate of Access Compliance, upon user request, the CGen may issue an **internationally recognized certificate of compliance**, which will serve as proof that the activities related to genetic heritage or associated traditional knowledge have been conducted in conformity with the provisions of Law 13,123/2015 and other applicable regulations.

The establishment of guidelines for using the resources of the National Fund for Benefit Sharing - FNRB

In which situations will the resources obtained from benefit sharing go to the National Fund for Benefit Sharing?

- Whenever benefits are shared in the monetary modality in connection with the use of genetic heritage;
- In cases of benefit sharing in connection with the commercial use of a product obtained from access to associated traditional knowledge of unidentifiable origin;
- And for that portion of benefit sharing, in case of commercial use of a product obtained from access to associated traditional knowledge of identifiable origin, which must be deposited into the FNRB, since it is always assumed that knowledge is shared, and there may exist other holders of the same knowledge.

The Law also established the National Program for Benefit Sharing (PNRB), which will operate with resources of the Fund. Its text establishes 15 aims. They are:

In addition to these aims, the Management Committee of the FNRB may establish other actions in connection with genetic heritage and associated traditional knowledge to be promoted by the program.

Law 13,123/2015 – Article 33

"Article 33. This Act establishes the National Program for Benefit-Sharing - PNRB, with the purpose to promote:

I - conservation of biological diversity;

II - restoration, creation and maintenance of ex situ collections of genetic heritage sample;

III - prospection and capacity-building of human resources on the use and conservation of genetic heritage or the associated traditional knowledge;

IV - protection, use and strengthening of the associated traditional knowledge;

V - implementation and development of activities for the sustainable use and conservation of biological diversity, and for the benefit-sharing;

VI - support for research and technological development related to the genetic heritage and the associated traditional knowledge;

VII - survey and inventory of genetic heritage, including those with potential uses, considering the current state of and the variance within their existing populations, and, when feasible, assessing any threat to those populations;

VIII - support the efforts of indigenous peoples, traditional communities and traditional farmers for the sustainable management and conservation of genetic heritage;

IX - conservation of wild plants;

X - the development and transfer of appropriate technologies for improving the sustainable use of the genetic heritage and for the development of an efficient and sustainable system of ex situ and in situ conservation.

XI - monitoring and maintenance of the viability, the degree of variation and the genetic integrity of the genetic heritage collections;

XII - adoption of measures to minimize or, if possible, eliminate threats to the genetic heritage;

XIII - development and maintenance of any cropping system that promotes the sustainable use of genetic heritage;

XIV - development and implementation of the Sustainable Development Plans of Indigenous Peoples and Traditional Communities; and

XV - further actions related to access to the genetic heritage and the associated traditional knowledge, according to the regulation."

National Fund for Benefit Sharing

This Fund receives the benefit sharing-sums, both in the monetary modality for the use of genetic heritage and traditional knowledge of unidentifiable origin, and from the portions of sums in connection with benefit sharing for traditional knowledge of identifiable origin.

The Fund's objectives are to appreciate the value of genetic heritage and traditional knowledge, and to promote the sustainable use of biodiversity. Payments to this Fund will come from benefit sharing, as well as from the federal budget, donations, fines collected on non-compliance with the Law, contracts and agreements involving financial resources from abroad assigned to the Fund, contributions by users of the genetic heritage and associated traditional knowledge, and other resources allocated to the Fund.

The sums paid to the Fund for the use of associated traditional knowledge must be exclusively allocated in benefit of the holders of such knowledge. The management of these resources will be conducted by the Management Committee of the Fund with the participation of the holders of associated traditional knowledge.

Management Committee of the National Fund for Benefit Sharing

The management of monetary resources paid to the FNRB will be conducted by the Management Committee, with the participation of the Indigenous peoples, traditional peoples and communities, and family farmers.

Composition of the Committee:

The Management Committee may invite other representatives, without voting rights, to participate in its meetings. The Ministry of the Environment will provide all necessary technical and administrative support so that the Fund and its Management Committee may implement the National Program for Benefit Sharing.

The Decree provides for the work of the Management Committee in these terms:

Decree No. 8,772/2016 – Article 98

"**Article 98.** It is the responsibility of the Managing Committee to:
I - Decide on the management of monetary resources deposited into the FNRB, in compliance with the guidelines for application of resources established by the CGen;
II - Establish, annually, the percentage of monetary resources deposited into the FNRB deriving from economic exploitation of finished product or reproductive material resulting from access to genetic heritage from "*ex situ*" collections, which shall be allocated for the benefit of these collections;
III – Approve the FNRB Operations Manual, establishing conditions and procedures for the financial execution and implementation of resources, including the collection of revenue and the recruitment, implementation, monitoring and evaluation of actions and activities supported by the FNRB;
IV – Approve the quadrennial operating plan and review it biennially;
V - Approve actions, activities and projects to be supported by the FNRB;
VI - Decide on hiring studies and research by the FNRB;
VII – Approve annual reports on:
a) Activities and financial execution;
b) Performance of the financial institution;
VIII - Establish cooperation instruments, including with the States, the Federal District and with Municipalities;
IX - Establish cooperation instruments and transfer of resources with national public institutions for research, education and technical support, including with financial support of the FNRB, to monitor the actions and activities supported by the FNRB; and
X - Develop and approve its internal regulations.
Sole paragraph. The percentage mentioned in item II of the "*caput*" shall not be less than sixty percent nor greater than eighty percent."

Popular herbaria and community seed banks may be accredited by CGen as *ex situ* collections elligible for receiving FNRB resources.

On Infractions against Genetic Heritage and Associated Traditional Knowledge

Section III of Chapter VI of Decree No. 8,772/2016 establishes a set of administrative infractions against genetic heritage or associated traditional knowledge. These infractions include:

> *"Economically exploiting finished product or reproductive material resulting from access to genetic heritage or associated traditional knowledge without prior notification" (Art. 78);*
>
> *"Accessing associated traditional knowledge of identifiable origin without obtaining prior informed consent, or in disagreement with this Decree" (Art. 83); and*
>
> *"Non indication of the origin of the associated traditional knowledge with identifiable source in publications, uses, exploitations and disclosures of results of access"* (Art. 84).

The official bodies in defense of the rights of Indigenous peoples, traditional peoples and communities, and family farmers will provide support to IBAMA's inspection activities in case of infractions involving associated traditional knowledge.

The competent bodies to inspect and investigate violations are IBAMA, the Navy Command and the Ministry of Agriculture, Livestock Rearing and Supply.

Closing Remarks

The topic covered by this publication involves a complex set of situations and tools, which cannot be exhausted in these lines. It has been a great challenge to make the content of the legislation accessible – a content, which, as well as in other laws, builds on a more formal language that is often difficult to understand and read.

After examining this publication, we invite you to look for additional information sources that may further enrich your understanding of this legislation and of your rights.

You may learn more about this topic by accessing the website of the Genetic Heritage Management Council at the Ministry of the Environment's web portal: https://www.gov.br/mma/pt-br/assuntos/biodiversidade/patrimonio-genetico. In case of any doubts or questions, you may both seek guidance by a supporting institution near your community, and contact the Secretariat of Biodiversity at the Ministry of the Environment:

Phone #:
+55 (61) 2028-2325
Address:
Secretaria de Biodiversidade - SBio
Ministério do Meio Ambiente - MMA
Esplanada dos Ministérios, Bloco B,
8º Andar, CEP 70.068-900
Brasilia, DF, Brazil
E-mail addresses:
dpg@mma.gov.br and
cgen@mma.gov.br

In the following pages, you will find a set of illustrations that summarize the three possible cases of benefit sharing: as a result of access to genetic heritage; in connection with access to associated traditional knowledge of identifiable origin; and in connection with access to associated traditional knowledge of unidentifiable origin.

We hope that these illustrations can be instructive and serve as an additional resource for the communities who seek to increase their understanding in regard to the entire process that involves benefit sharing.

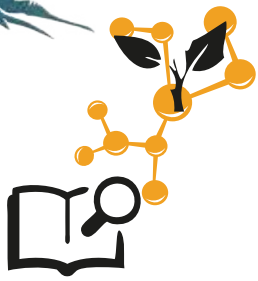
Access to Genetic Heritage

FNRB FUND

Non-monetary Benefit Sharing is made by signing a Non-Monetary Benefit Sharing Agreement - ARB-NM with the Union and paying a sum equivalent to 0.75% to 1% of the net income.

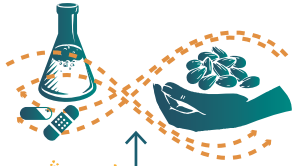
Monetary benefit sharing is directly deposited into the FNRB Fund by paying a sum equivalent to 1% of the net income.

Benefit Sharing is made with the Union and may be either monetary or non-monetary, at the choice of the user.



Beginning and conduction of RESEARCH activities with access to Genetic Heritage.

BENEFIT SHARING



365 days for submitting the ARB-NM, or 120 days after the closing of the fiscal year for paying the benefit sharing sum to the FNRB.

Reproductive Material

Finished Product

SisGen **REGISTRATION**

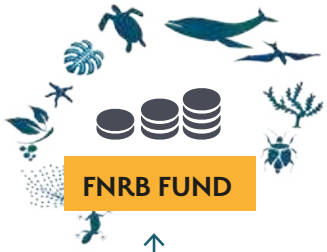
Registration must be made before ANY disclosure of research results and patent or cultivar protection request, as well as before any shipment of materials abroad.

NOTIFICATION

Notifications must be submitted before the commercialization of the final product or reproductive material.

Access to traditional knowledge of unidentifiable origin

Traditional knowledge of unidentifiable origin is the knowledge for which there is not even one identified community that creates, develops, holds or conserves it.

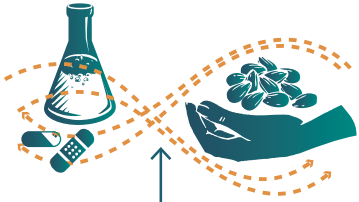


FNRB FUND

Benefit Sharing is directly deposited into the Fund.

1% of the net income.

BENEFIT SHARING

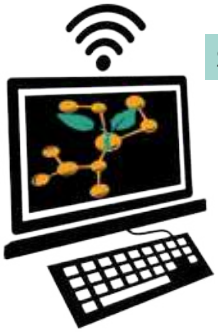


Beginning and conduction of RESEARCH activities with access to associated traditional knowledge of unidentifiable origin.

Reproductive material

Finished product

SisGen NOTIFICATION



SisGen REGISTRATION

Registration must be made before ANY disclosure of research results and patent or cultivar protection request, as well as before any shipment of materials abroad.

Notifications must be submitted before the commercialization of the final product or reproductive material.

Access to traditional knowledge of identifiable origin

Information on research activities with the community

Prior Informed Consent

Denied

The community may officially inform its denied consent to the CGen. This does not prevent the user from looking for another community that holds the same knowledge.

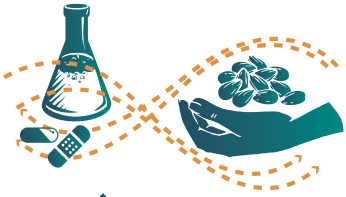
Granted

Beginning and conduction of research activities with access to associated traditional knowledge.

+ 0.5% of the net income goes to the **FNRB FUND**

BENEFIT SHARING

Benefit Sharing with the community may be made either by paying to the community or through a cooperation project, depending on the terms agreed with the community. There must also be a **Monetary Benefit Sharing** deposit into the FNRB.



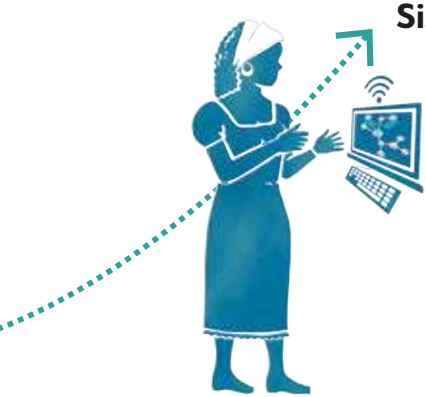
Reproductive material

Finished product

NOTIFICATION to SisGen and ARB submission

Upon reaching the results of a research, the user (may be the same user who negoatiated the Prior Informed Consent, or another one) must present the results to the community and negotiate a Benefit Sharing Agreement (ARB).

SisGen REGISTRATION



Registration must be made before ANY disclosure of research results and patent or cultivar protection request, as well as before the commercialization of the product or shipment of materials abroad. Or BEFORE THIS, as agreed in the prior informed consent.

LEGISLATION

Law 13,123, dated May 20, 2015

Provides for access to genetic heritage, for protection and access to associated traditional knowledge, and for benefit sharing for conservation and sustainable use of biodiversity.

Decree No. 8,772, dated May 11, 2016

Regulates Law 13,123, dated May 20, 2015, which makes provisions regarding access to genetic heritage, protection and access to associated traditional knowledge, and benefit sharing for consertation and sustainable use of biodiversity.

Presidency of the Republic of Brazil
Civilian Staff Office of the Presidency
Subdivision of Legal Affairs

LAW No 13,123, dated May 20, 2015

An Act

To regulate paragraph 1, item II and paragraph 4 of Article 225 of the Federal Constitution; Article 1, Article 8(j), Article 10(c), Article 15, and Article 16, items 3 and 4 of the Convention on Biological Diversity, enacted by Decree no 2,519, dated March 16, 1998; to provide for access to genetic heritage, for protection and access to associated traditional knowledge, and for benefit-sharing for conservation and sustainable use of biodiversity; to revoke Provisional Act no. 2,186-16, dated August 23, 2001; and for other purposes.

THE PRESIDENT OF THE REPUBLIC

Let it be known that the National Congress enacted the following bill and I sign it into Law:

CHAPTER I
GENERAL PROVISIONS

Article 1 . This Act provides for the assets, rights, and obligations relating to:

I – access to the country's genetic heritage, asset of common use by the people, found in *in situ* conditions, including domesticated species and spontaneous populations, or kept in *ex situ* conditions, as long as found in *in situ* conditions within the national territory, on the continental shelf, on territorial waters, or in the exclusive economic zone;

II – traditional knowledge associated to genetic heritage relevant to the conservation of biological diversity, to the integrity of the country's genetic heritage and to the utilization of its components;

III – access to technology and to the transfer of technology for conservation and use of biological diversity;

IV – economic exploitation of finished product or reproductive material originating from access to genetic heritage or associated traditional knowledge;

V – fair and equitable sharing of the benefits arising from economic exploitation of finished products or reproductive material originating from access to genetic heritage or associated traditional knowledge, for conservation and sustainable use of biodiversity;

VI – shipping abroad live or dead animals, plants, microbial species, or any other species, be it as whole organisms or their parts, intended for access to genetic heritage; and

VII – the implementation of international treaties, approved by congress and promulgated, concerning genetic heritage or associated traditional knowledge.

Paragraph 1 – Access to genetic heritage or associated traditional knowledge will occur without infringing upon material or immaterial property rights related to genetic heritage or to the associated traditional knowledge accessed or to the site that it occurs.

Paragraph 2 – Access to genetic heritage in the continental shelf shall comply with Law no 8,616, dated January 4, 1993.

Article 2. In addition to concepts and definitions set forth by the Convention on Biological Diversity (CBD) promulgated by Decree no 2,519, dated March 16, 1998, the following terms are defined for the purposes of this Act:

I – genetic heritage – genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms;

II – associated traditional knowledge – information or practice of indigenous population, traditional community, or traditional farmers about the properties, or the direct or indirect uses associated with genetic heritage;

III – associated traditional knowledge from unidentifiable origin – associated traditional knowledge where there is no way to link its origin to at least one indigenous population, traditional community, or traditional farmer;

IV – traditional community – a culturally differentiated group, which recognizes itself as such, has its own social organization and occupies and uses territories and natural resources as a condition for its cultural, social, religious, ancestral and economic perpetuation, using knowledge, innovations and practices generated from and passed on by tradition;

V – associated traditional knowledge provider – indigenous population, traditional community or traditional farmer who holds and provides associated traditional knowledge;

VI – prior informed consent – formal consent previously granted by indigenous population or traditional community according to their uses, customs and traditions, or community protocols;

VII – community protocol – indigenous peoples', traditional communities' or traditional farmers' procedural norms which establish, according to their uses, customs and traditions, mechanisms for access to associated traditional knowledge and benefit-sharing in accordance with this Act;

VIII – access to genetic heritage – research or technological development carried out on genetic heritage samples;

IX – access to associated traditional knowledge – research or technological development carried out on traditional knowledge associated to genetic heritage that makes possible or facilitates access to genetic heritage, even if obtained from secondary sources such as: street markets, publications, inventories, films, scientific articles, registries and other forms of systematization and record of associated traditional knowledge;

X – research – experimental or theoretical activity carried out on genetic heritage or associated traditional knowledge with the objective of building new knowledge by means of a systematic process that creates and tests hypothesis, describes and interprets fundamentals of observed phenomena and facts;

XI – technological development – systematic work on genetic heritage or associated traditional knowledge based on existing procedures resulting from research or from practical experience carried out with the objectives of developing new materials, products or devices, or improving or developing new processes, for economic exploitation;

XII – registry of access or shipment of genetic heritage or associated traditional knowledge – mandatory declaration document of access or shipment of genetic heritage or associated traditional knowledge activities;

XIII – shipment – transfer of a sample of genetic heritage, intended for access, to an institution located abroad, in which responsibility for the sample is transferred to the recipient institution;

XIV – authorization for access or shipment – administrative act which allows, under specific conditions, access to genetic heritage or associated traditional knowledge and shipment of genetic heritage;

XV – user – a natural or legal person, that accesses genetic heritage or associated traditional knowledge, or economically explores a finished product or reproductive material originated from access to genetic heritage or associated traditional knowledge;

XVI – finished product – a product originating from access to genetic heritage or associated traditional knowledge that does not need any additional processing, in which the genetic heritage or the traditional knowledge component is a key main element of value adding to the product, being it ready for use by the final consumer, whether a natural or a legal person;

XVII – intermediate product – a product used in the production chain as input, excipient and raw material, for developing another intermediate or finished product;

XVIII – key elements of value adding to the product – elements whose presence in the finished product is determinant to its functional characteristics or to its marketing appeal;

XIX – product notification – declaration document required prior to economic exploitation of a finished product or reproductive material originating from access to genetic heritage or to associated traditional knowledge in which the user declares compliance with the requirements of this Act and indicates the modality of benefit-sharing, when applicable, to be established in the benefit-sharing agreement;

XX – benefit-sharing agreement – a legal document that identifies the parts, object; and terms for benefit-sharing;

XXI – sectoral agreement – contracts signed by public authority and users, considering the fair and equitable sharing of the benefits derived from economic exploitation arising from access to genetic heritage or associated traditional knowledge of unidentifiable origin.

XXII – certificate of access compliance – administrative act by which the responsible agency declares that access to genetic heritage or associated traditional knowledge complied with the requirements of this Law;

XXIII –material transfer agreement – a document signed by sender and recipient for shipping abroad samples containing genetic heritage accessed or available for access, which indicates if access to associated traditional knowledge was carried out and establishes the commitment of benefit-sharing according to the provisions in this Act;

XXIV – agricultural activities – activities of producing, processing and commercializing food, beverages, fibers, energy and planted forests;

XXV – *in situ* conditions – conditions in which genetic heritage exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, including those forming spontaneous populations, in the surroundings where they have naturally developed their distinctive properties;

XXVI – domesticated or cultivated species – species in which evolutionary process has been influenced by humans to meet their needs;

XXVII – *ex situ* conditions - conditions in which genetic heritage is kept outside its natural habitat;

XXVIII – spontaneous population – populations of species introduced into the national territory, including domesticated species, capable of naturally self-perpetuating in Brazilian ecosystems and habitats;

XXIX – reproductive material – plant propagating material or animal reproductive material from any genus, species or crop, coming from sexual or asexual reproduction;

XXX – sending of samples – sending samples containing genetic heritage for services abroad as part of research or technological development, in which the responsibility for the sample is kept by the Brazilian user;

XXXI – traditional farmer – natural person, including family farmer, who uses local traditional varieties or landraces, or locally adapted races or land breeds, and maintains and preserves its genetic diversity;

XXXII – local traditional variety or landrace – variety originating from species occurring in *in situ* condition or kept in *ex situ* condition, comprising a group of plants within the lowest known taxon level, with genetic diversity developed or adapted by indigenous population, traditional community, or traditional farmer, including natural selection coupled with human selection in the local environment, that is not substantially similar to a registered commercial variety; and

XXXIII – locally adapted breed or creole breed – breed originated from species occurring in *in situ* condition or kept in *ex situ* condition, comprising a group of animal with genetic diversity developed or adapted to a defined ecological niche and generated by natural selection or selection performed by indigenous population, traditional community, or traditional farmer;

Sole paragraph. For the purposes of this Act, a microorganism isolated from national territory, national waters, exclusive economic zone, or from the continental shelf substrates is considered part of genetic heritage existing in the national territory.

Article 3. Access to genetic heritage existent in the country or to associated traditional knowledge with the purpose of research or technological development or economic exploitation of finished product or reproductive material arising as a result of this access will only be carried out upon registration, authorization or notification, and will be subject to monitoring, restrictions and benefit-sharing according to the provisions and terms established by this Act and by its regulations.

Sole paragraph. It is the Federal Government's responsibility to manage, control and inspect activities described in the *caput*, according to the provisions in item XXIII of the *caput* in Article 7 of Complementary Law nº 140, dated December 8, 2011.

Article 4. This Act does not apply to human genetic heritage.

Article 5. Access to genetic heritage and to associated traditional knowledge is prohibited for practices that are harmful to the environment, to cultural reproduction and to human health, and for the development of biological and chemical weapons.

CHAPTER II
COMPETENCE AND INSTITUTIONAL ATTRIBUTIONS

Article 6. The Genetic Heritage Management Council (CGen), created within the Ministry of the Environment, is a deliberative, normative, advisory and appellate Council, responsible for coordinating the development and implementation of policies for managing the access to genetic heritage and associated traditional knowledge and benefit-sharing, composed by representatives from different entities and bodies of the federal public administration with jurisdiction over the different actions specified in this Act, in a maximum of 60% (sixty percent), and by representatives from members of society, in no less than 40% (forty percent), ensuring parity of:

I – business sector;

II – academic sector; and

III – indigenous peoples, traditional communities and traditional farmers.

Paragraph 1 – It is also the responsibility of the CGen to:

I – establish:

a) technical rules;

b) guidelines and criteria for elaboration of and compliance with the benefit-sharing agreement;

c) criteria for developing a database to store information on genetic heritage and associated traditional knowledge;

II – monitor, in collaboration with federal bodies, or by agreement with other institutions, activities of:

a) access and shipment of samples containing genetic heritage; and

b) access to associated traditional knowledge;

III – deliberate on:

a) authorizations referred to in Article 13, paragraph 3, item II;

b) accreditation of national institution that keep an *ex situ* collection of samples containing genetic heritage; and

c) accreditation of national institution to be responsible for the creation and maintenance of the database referred to in item IX;

IV – attest compliance of access to genetic heritage or associated traditional knowledge, referred in Chapter IV of this Act;

V – record receipt of notification of a finished product or reproductive material and the presentation of the benefit-sharing agreement, in the terms of Article 16;

VI – promote debates and public consultation on the themes addressed in this Act;

VII – function as the higher instance of appeal to decisions of accredited institutions and to acts resulting from enforcing this Act, in the form of regulation;

VIII – establish guidelines for the allocation of funds destined to the National Fund for Benefit-Sharing – FNRB, provided for in Article 30, for the purpose of benefit-sharing;

IX – create and maintain databases related to;

a) registries of access to genetic heritage or associated traditional knowledge and registry of shipment;

b) authorizations to access genetic heritage or associated traditional knowledge and authorization for shipment;

c) material transfer agreements and legal documents;

d) *ex situ* collections of genetic heritage samples kept by accredited institutions;

e) notifications of finished products or reproductive material;

f) benefit-sharing agreements;

g) certificates of access compliance;

X – notify federal government bodies responsible for the protection of rights of indigenous peoples and traditional communities of the registry of access to associated traditional knowledge;

XI – (VETOED); and

XII – approve its bylaws;

Paragraph 2 – Regulation will determine the composition and operation of the CGen.

Paragraph 3 – The CGen will create Thematic and Sectoral Chambers, with equal participation of the government and members of civil society, represented by business and academic sectors, and representatives of the indigenous population, traditional communities and traditional farmers, to provide support for plenary decisions;

Article 7. The federal public administration will make available to the CGen, in the form of regulation, the necessary information to track activities resulting from access to genetic heritage or to associated traditional knowledge, including information regarding economic exploitation.

CHAPTER III
ASSOCIATED TRADITIONAL KNOWLEDGE

Article 8. This Act protects the associated traditional knowledge of indigenous peoples, traditional communities or traditional farmers against illegal use and exploitation.

Paragraph 1 – The Government recognizes the rights of indigenous peoples, traditional communities and traditional farmers to take part in the decision-making process, at national levels, on matters related to the conservation and sustainable use of their traditional knowledge associated to the country's genetic heritage, according to the provisions and terms established by this Act and its regulations.

Paragraph 2 – Traditional knowledge associated to genetic heritage referred to in this Act is part of the Brazilian cultural heritage and can be stored in databases, according to the provisions of the CGen or specific legislation.

Paragraph 3 – Associated traditional knowledge may be recognized, among others, in the following instruments:

I – scientific publications;

II – registries or databases; or

III – cultural inventories.

Paragraph 4 – The exchange and dissemination of genetic heritage and associated traditional knowledge practiced among indigenous peoples, traditional communities or traditional farmers for their own benefit and based on their use, customs and traditions are exempted from the obligations in this Act.

Article 9. Access to associated traditional knowledge from an identifiable origin is dependent on obtaining prior informed consent.

Paragraph 1 – Evidence of prior informed consent can occur at the discretion of the indigenous population, traditional community or traditional farmer, by means of the following documents according to regulations:

I – signed prior consent;

II – registered audiovisual consent;

III – statement from the official governing body; or

IV – adherence to the provisions set forth by community protocol.

Paragraph 2 – Access to associated traditional knowledge from unidentifiable origin does not require prior informed consent.

Paragraph 3 – Access to the genetic heritage of local traditional variety or landrace, or to locally adapted breed or creole breed for agricultural activities, encompasses access to associated traditional knowledge from unidentifiable origin that originated the variety or breed and does not require prior consent from indigenous people, traditional community, or traditional farmer who creates, develops, holds or preserves the variety or breed.

Article 10. The following rights are guaranteed to the indigenous peoples, the traditional communities and the traditional farmers, who create, develop, hold or retain associated traditional knowledge:

I – recognition, in any form of publication, use, exploitation, and dissemination, for their contributions to the development and conservation of genetic heritage;

II – identification of the origin of access to associated traditional knowledge in all publications, uses, exploitations and disclosures;

III – to benefit, directly or indirectly, from economic exploitation of the associated traditional knowledge by third parties, in accordance with this Act;

IV – to participate in the decision-making process on issues related to access to associated traditional knowledge and benefit-sharing resulting from such access, in the form of regulation;

V – to freely use or sell products containing genetic heritage or associated traditional knowledge, in accordance with Law nº. 9.456, dated April 25th, 1997 and Law nº. 10.711, dated August 5th, 2003; and

VI – to conserve, manage, store, produce, exchange, develop, and improve reproductive material containing genetic heritage or associated traditional knowledge;

Paragraph 1 – For the purpose of this Act, any traditional knowledge associated to genetic heritage will be regarded collective, even if only one individual of the indigenous people or traditional community possesses it;

Paragraph 2 – The Genetic heritage kept in *ex situ* collections in publicly funded national institutions and the information associated with it may be accessed by indigenous peoples, by traditional communities and by traditional farmers, in the form of the regulation.

CHAPTER IV
ACCESS, SHIPMENT AND ECONOMIC USE

Article 11. The following activities are subject to the requirements of this Act:

I – access to genetic heritage or associated traditional knowledge;

II – shipment abroad of genetic heritage samples; and

III – economic exploitation of finished product or reproductive material arising from the access to genetic heritage or associated traditional knowledge carried out after this Act has entered into force.

Paragraph 1 – Foreign natural persons are not allowed to carry out access to genetic heritage or the associated traditional knowledge;

Paragraph 2 – Shipment abroad of genetic heritage sample depends on signing the material transfer agreement, according to provisions set forth by CGen;

Article 12. The following activities must be registered:

I – access to genetic heritage or associated traditional knowledge carried out within the country by national legal or natural person, public or private;

II - access to genetic heritage or the associated traditional knowledge by a legal person based abroad associated to a national scientific and technological research institution, public or private;

III – access to genetic heritage or associated traditional knowledge carried out abroad by national legal or natural person, public or private;

IV - shipment abroad of genetic heritage sample with the purpose of access, as described in items II and III of this Article; and

V – sending abroad sample containing genetic heritage by national legal person, public or private, for services as part of research or technological development.

Paragraph 1 – The operation of the registry described in this Article will be defined in regulation.

Paragraph 2 – Registration must be carried out prior to shipment, or the application of any intellectual property right, or the commercialization of the intermediate product, or publication of results, partial or final, in scientific or communication media, or the notification of a finished product or reproductive material developed as result of the access.

Paragraph 3 – Information contained in the database referred to in Article (6)(1)(IX) are public, except for those that may jeopardize research, or technological or scientific

development activities, or the commercial activities of third parties. In these cases, the information can be made available with the permission of the user.

Article 13. The following activities may require, at the discretion of the Federal Government, prior authorization, in the form of the regulation:

I – access to genetic heritage or associated traditional knowledge in a crucial national security area may only occur after formal consent granted by the National Defense Council;

II - access to genetic heritage or associated traditional knowledge in national waters, on the continental shelf, and in the exclusive economic zone may only occur after formal consent granted by the maritime authority.

Paragraph 1 – Access or shipment authorizations may be requested jointly or separately.

Paragraph 2 – Authorization for shipment of a genetic heritage sample abroad transfers the responsibility for the shipped sample or material to the recipient.

Paragraph 3 – (VETOED)

Paragraph 4 – (VETOED)

Article 14. *Ex situ* conservation of samples of genetic heritage found in *in situ* condition will be preferably carried out in national territory.

Article 15. The authorization or registry for shipment abroad of a genetic heritage sample is dependent upon the information of its intended use, according to regulation requirements.

Article 16. The requirements for economic exploitation of a finished product or reproductive material resulting from the access to genetic heritage or to associated traditional knowledge are:

I - notify the finished product or reproductive material to CGen; and

II – present the benefit-sharing agreement, except for the provision set forth in Article 17 (5) and Article 25(4).

Paragraph 1 – The modality of benefit-sharing, be it monetary or non-monetary, should be indicated at the time of notification of the finished product or reproductive material arising from the access to genetic heritage or associated traditional knowledge.

Paragraph 2 – The benefit-sharing agreement should be presented in 365 (three hundred and sixty-five) days from the moment of notification of finished product or reproductive material, as set forth in Chapter V of this Act, except in cases involving access to the associated traditional knowledge of identifiable origin.

CHAPTER V
BENEFIT-SHARING

Article 17. The benefits resulting from economic exploitation of finished product or reproductive material arising from access to genetic heritage of species found in *in situ* conditions or to associated traditional knowledge, even if produced outside the country, will be shared in a fair and equitable way. In the case of a finished product, the genetic heritage or the associated traditional knowledge component must be one of the key elements of value adding to the product, in accordance with this Act.

Paragraph 1 – Only the manufacturer of the finished product or the producer of the reproductive material will be obliged to share benefits, regardless of who has previously carried out access activities.

Paragraph 2 – The manufacturers of intermediate products and developers of processes originating from the access to genetic heritage or associated traditional knowledge along the production chain will be exempted from benefit-sharing obligations.

Paragraph 3 – When a single finished product or a reproductive material results from distinct accesses, they will not be considered cumulatively in the calculation of benefit-sharing.

Paragraph 4 – Licensing, transferring or permitting any use of intellectual property rights related to a finished product, process, or reproductive material arising from access to genetic heritage or associated traditional knowledge by third parties are considered economic exploitation exempted from benefit-sharing obligations.

Paragraph 5 – The following are exempt from benefit-sharing obligations, in accordance with the regulation:

I – micro-businesses, small businesses, micro individual entrepreneurs, under provisions of Complementary Law No. 123, dated December 14, 2006;

II – traditional farmers and their cooperatives with annual gross revenue equal to or lower than the upper limit established in Article 3(II) of Complementary Law No 123, dated December 14, 2006;

Paragraph 6 – In the case of access to associated traditional knowledge by those provided for in paragraph 5, the holders of this knowledge will perceive benefits in the terms of Article 33.

Paragraph 7 – In the case the finished product or reproductive material has not been produced in Brazil, the importer, subsidiary, associate, affiliate, partner, or commercial representative of a foreign producer in national territory or in the territory of a country that Brazil has an agreement with for this purpose, will be jointly liable with the manufacturer of the finished

product or the reproductive material for benefit-sharing.

Paragraph 8 – In the absence of essential information to determine, in due time, the base of calculation for the benefit-sharing, as referred to in paragraph 7, the Federal Government will arbitrate it according to the best available information, considering the percentage fixed in this Act or in a sectoral agreement, ensured the right to fair hearing.

Paragraph 9 – The Federal Government will establish, by Decree, the Benefit-Sharing Classification List, based on the MERCOSUL Common Nomenclature - MCN.

Paragraph 10 – (VETOED)

Article 18. The benefits resulting from economic exploitation of a product arising from access to genetic heritage or associated traditional knowledge for agricultural activities will be shared based upon the commercialization of the reproductive material, even if the access or economic exploitation was carried out by an individual or a legal subsidiary, associate, affiliate, contracted, outsourced parties or partner entity, in accordance with paragraph 7 or Article 17.

Paragraph 1 – The benefit-sharing specified at the *caput* of this Article must be carried out by the ones located at the final point in the production chain of reproductive materials. Intermediate points in these production chains are exempt from benefit-sharing.

Paragraph 2 – In the case of economic exploitation of reproductive material arising from the access to genetic heritage or associated traditional knowledge for agricultural activities and destined exclusively to produce finished products that do not involve agricultural activities, only the economic exploitation of the finished product will require benefit-sharing.

Paragraph 3 – Economic exploitation of finished products or reproductive material arising from access to genetic heritage of species introduced to the national territory by human action, even if domesticated, are exempt from benefit-sharing except:

I – those that develop spontaneous populations with distinctive properties acquired in the country; and

II – local traditional variety or landrace, or locally adapted breed or creole breed.

Article 19. The benefit-sharing resulting from the economic exploitation of a finished product or reproductive material arising from access to genetic heritage or associated traditional knowledge may occur in the following modalities:

I – monetary; or

II – non-monetary, including, inter alia:

a) projects for conservation or sustainable use of biodiversity, or for protection and maintenance of knowledge, innovations, or practices of indigenous peoples, traditional communities

or traditional farmers, preferable at the site where the species occurs in *in situ* conditions or where the sample was obtained, when the original location cannot be specified;

b) technology transfer;

c) making the product available in public domain, unprotected by intellectual property rights or technological restrictions;

d) licensing products free of charge;

e) capacity building of human resources in topics related to the conservation and sustainable use of genetic heritage or associated traditional knowledge; and

f) distribution of products free of charge in social programs.

Paragraph 1 – In case of access to genetic heritage, the user may choose, at his own discretion, one of the modalities of benefit-sharing provided for in the *caput* of this Article.

Paragraph 2 – An Act by the Executive Branch will regulate the form of non-monetary benefit-sharing in the case of access to genetic heritage.

Paragraph 3 – The non-monetary benefits related to transfer of technology can be shared, inter alia, by:

I – participation in research and technological development;

II – information exchange;

III – exchange of human resources, materials or technologies between national scientific and technological research institutions, private or public, and research institutions based abroad;

IV – infrastructure consolidation for research and development of technology; and

V – establishment of technology-based joint venture.

Paragraph 4 – (VETOED).

Article 20. Monetary benefit-sharing should represent 1% (one percent) of the annual net revenue obtained from economic exploitation of finished products or reproductive material arising from access to genetic heritage, except when reduced for up to 0.1% (one tenth percent) by sectoral agreement as defined in Article 21.

Article 21. In order to foster competitiveness of the beneficiary sector, the Federal Government may, at the request of the interested party and according to regulations, celebrate sectoral agreements to reduce the amount of benefit-sharing for up to 0.1% (one tenth percent) of the annual net revenue obtained from economic exploitation of finished products or reproductive material arising from access to genetic heritage or associated traditional knowledge from an unidentifiable origin.

Sole paragraph. In order to assist in formulation of sectoral agreements, official government offices for indigenous peoples' and traditional communities' rights may be heard in accordance with the regulation.

Article 22. Non-monetary benefit-sharing outlined at the Article 19(II)(a)(e)(f), should be equivalent to 75% (seventy five percent) of the monetary benefit-sharing amount, in accordance with criteria set by CGen.

Sole paragraph. CGen may define result or effectiveness criteria or parameters that users must meet, in replacement to the cost parameter for non-monetary benefit-sharing determined at the *caput* of this Article.

Article 23. When the finished product or reproductive material results from access to the associated traditional knowledge of unidentifiable origin, the benefits arising from using such knowledge should be shared in the modality determined at the Article 19 (I), in a corresponding amount as described in Articles 20 and 21 of this Act.

Article 24. Benefits arising from economic exploitation of finished products or reproductive materials originated from access to associated traditional knowledge from an identifiable origin shall be shared with the provider of the associated traditional knowledge through a benefit-sharing agreement.

Paragraph 1 – Benefit-sharing shall be negotiated, in a fair and equitable way, between the parties, meeting clarity, loyalty and transparency parameters agreed to in contractual clauses indicating conditions, obligations, types and duration of benefits in short, medium, and long term.

Paragraph 2 – Benefit-sharing with co-holders of the same associated traditional knowledge will be carried out in the monetary modality through the National Fund for the Benefit-Sharing – FNRB.

Paragraph 3 – The amount to be deposited by the user in the National Fund for Benefit-Sharing – FNRB, as the benefit-sharing determined in paragraph 2, will correspond to half of what is described in Article 20 of this Act or half of what is established by sectoral agreement.

Paragraph 4 – Benefit-sharing described in paragraph 3 is independent from the number co-holders of the same associated traditional knowledge accessed.

Paragraph 5 – In all cases, the existence of other co-holders of the same associated traditional knowledge is presumed.

Article 25. The benefit-sharing agreement must clearly indicate and specify the parts, which shall be:

I – in the case of economic exploitation of finished products or reproductive material

originating from access to genetic heritage or associated traditional knowledge of unidentifiable origin:

a) the Federal Government, represented by the Ministry of the Environment; and

b) those who economically explore finished products or reproductive material originating from access to genetic heritage or associated traditional knowledge of unidentifiable origin; and

II – in the case of economic exploitation of finished products or reproductive material arising from access to associated traditional knowledge of identifiable origin:

a) the provider of the associated traditional knowledge; and

b) those who economically explore finished products or reproductive material originating from access to associated traditional knowledge.

Paragraph 1 – In addition to the Benefit-Sharing Agreement, the user must deposit, in the National Fund for Benefit-Sharing – FNRB, the amount stipulated in Article 24 (3) when economically exploiting finished products or reproductive material originating from the access to associated traditional knowledge of identifiable origin.

Paragraph 2 - In the case of economic exploitation of finished products or reproductive material originating from access to genetic heritage or associated traditional knowledge of unidentifiable origin, sectoral agreements can be signed with the Federal Government with the goal of benefit-sharing, according to regulation.

Paragraph 3 – Sharing the benefits resulting from exploiting finished products or reproductive material arising from access to associated traditional knowledge exempts the user from sharing benefits related to genetic heritage.

Paragraph 4 – Monetary benefit- sharing referred to in insert I at the *caput* of this Article may, at the user's discretion and in the form of the regulation, be deposited directly in the National Fund for the Benefit-Sharing – FNRB without the need of a benefit-sharing agreement.

Article 26. Without detriment to future clauses that may be established in the regulation, clauses addressing the following are mandatory in the benefit-sharing agreement:

I – products that are object to economic exploitation;

II – time frame;

III – modality for benefit-sharing;

IV – rights and responsibilities of the parts;

V – intellectual property rights;

VI – termination;

VII – penalties; and

VIII – jurisdiction in Brazil.

CHAPTER VI
ADMINISTRATIVE PENALTIES

Article 27. Any action or omission that violates the rules of this Act is considered, in the form of the regulation, an administrative infraction against the genetic heritage or the associated traditional knowledge.

Paragraph 1 - Without prejudice to the criminal and civil penalties, the administrative infractions will be punished by the following penalties:

I - warning;

II - fine;

III - seizure of:

a) the samples containing the genetic heritage accessed;

b) the instruments used in obtaining or processing the genetic heritage or the associated traditional knowledge accessed;

c) the products arising from access to the genetic heritage or the associated traditional knowledge; or

d) the products developed from information on associated traditional knowledge;

IV - temporary suspension of the manufacture and sale of the finished product or the reproductive material arising from access to the genetic heritage or the associated traditional knowledge until the offender completes the regularization process referred to in Article 38 of this Act;

V - suspension of the specific activity related to the infraction;

VI - banning, partially or totally, the establishment, activity or enterprise;

VII - suspension of the certificate or the authorization referred to in this Act; or

VIII - cancellation of the certificate or the authorization referred to in this Act.

Paragraph 2 - The competent authority shall establish the administrative penalties considering the following criteria:

I - the seriousness of the infraction;

II - the infraction records of the offender regarding the legislation of genetic heritage and the associated traditional knowledge;

III - recurrence; and

IV - the wealth of the offender, in case of applying a fine.

Paragraph 3 - The penalties provided for in Paragraph 1 may be applied cumulatively.

Paragraph 4 - CGen will set the destination of the samples, products and instruments listed in Paragraph 1 (III).

Paragraph 5 - The fine described in Paragraph 1(II) will be arbitrated, for each infraction, by the competent authority, and may vary:

I - from R$ 1,000.00 (one thousand Brazilian reais) to $100,000.00 (one hundred thousand Brazilian reais), whenever the infraction is committed by a natural person; or

II - from $10,000.00 (ten thousand Brazilian reais) to R$ 10,000,000,00 (ten million Brazilian reais), whenever the infraction is committed by a legal person, or with its aid.

Paragraph 6 - Recurrence occurs when an agent commits a second infraction within up to 5 (five) years from the final administrative decision by which the agent has been condemned for a previous infraction.

Paragraph 7 - The regulation shall provide for the administrative procedure for application of the penalties mentioned in this Act, guaranteed the right to the due process of law.

Article 28. The competent federal agencies shall supervise, intercept and seize samples containing accessed genetic heritage, and products or reproductive material arising from access to the genetic heritage or the associated traditional knowledge, when access or the economic exploitation has been carried out in disagreement with the provisions of this Act and its regulation.

Article 29. (VETOED).

CHAPTER VII

THE NATIONAL FUND FOR THE BENEFIT-SHARING AND THE NATIONAL PROGRAM FOR BENEFIT-SHARING

Article 30. This Act establishes, under the Ministry of the Environment, the National Fund for the Benefit-Sharing - FNRB, with the purpose of strengthening the genetic heritage and the associated traditional knowledge and promoting their sustainable uses.

Article 31. The Executive Branch shall define, by the regulation, the composition, organization and operation of the FNRB Management Committee.

Sole paragraph. The monetary resources deposited in the FNRB and intended to the indigenous peoples, the traditional communities and the traditional farmers will be managed with their participation, in the form of the regulation.

Article 32. FNRB resources are composed by, inter alia:

I - appropriations set out in the annual budget Act and its additional credits;

II - donations;

III - funds collected as the administrative fines provided for in this Act;

IV - external financial resources arising from contracts, agreements or covenants particularly designed for the purposes of the Fund;

V - contributions from the users of genetic heritage or associated traditional knowledge for the National Program for Benefit-Sharing;

VI - funds arising from the benefit-sharing; and

VII - other resources.

Paragraph 1 - The monetary resources deposited in FNRB resulting from the economic exploitation of a finished product or reproductive material arising from access to associated traditional knowledge will be exclusively allocated for the holders of traditional knowledge.

Paragraph 2 - The monetary resources deposited in FNRB resulting from the economic exploitation of a finished product or reproductive material arising from access to genetic heritage obtained from *ex situ* collections will be partially allocated to these collections, in the form of the regulation.

Paragraph 3 - The FNRB may establish cooperation instruments with, inter alia, states, municipalities and the Federal District.

Article 33. This Act establishes the National Program for Benefit-Sharing - PNRB, with the purpose to promote:

I - conservation of biological diversity;

II - restoration, creation and maintenance of *ex situ* collections of genetic heritage sample;

III - prospection and capacity-building of human resources on the use and conservation of genetic heritage or the associated traditional knowledge;

IV - protection, use and strengthening of the associated traditional knowledge;

V - implementation and development of activities for the sustainable use and conservation of biological diversity, and for the benefit-sharing;

VI - support for research and technological development related to the genetic heritage and the associated traditional knowledge;

VII - survey and inventory of genetic heritage, including those with potential uses, considering the current state of and the variance within their existing populations, and, when feasible, assessing any threat to those populations;

VIII - support the efforts of indigenous peoples, traditional communities and traditional

farmers for the sustainable management and conservation of genetic heritage;

IX - conservation of wild plants;

X - the development and transfer of appropriate technologies for improving the sustainable use of the genetic heritage and for the development of an efficient and sustainable system of *ex situ* and *in situ* conservation.

XI - monitoring and maintenance of the viability, the degree of variation and the genetic integrity of the genetic heritage collections;

XII - adoption of measures to minimize or, if possible, eliminate threats to the genetic heritage;

XIII - development and maintenance of any cropping system that promotes the sustainable use of genetic heritage;

XIV - development and implementation of the Sustainable Development Plans of Indigenous Peoples and Traditional Communities; and

XV - further actions related to access to the genetic heritage and the associated traditional knowledge, according to the regulation.

Article 34. The PNRB will be implemented by the FNRB.

CHAPTER VIII

TRANSITIONAL PROVISIONS ON ADJUSTMENT AND REGULARIZATION PROCEDURES

Article 35. The application for authorization or for regularization of access to and shipment of genetic heritage or associated traditional knowledge currently pending on the date this Act enters into force should be reformulated by the user in the form of a registry or an authorization of access or shipment, as applicable.

Article 36. The user shall reformulate the applications for authorization or regularization described in Article 35 within 1 (one) year of the date CGen makes the registry system available.

Article 37. The user shall adjust his activities to the terms of this Act within 1 (one) year of the date the CGen makes the registry system available, when he has carried out, after June 30, 2000 and in accordance with the Provisional Measure No. 2.186-16, the following activities:

I - access to the genetic heritage or the associated traditional knowledge;

II - economic exploitation of a finished product or reproductive material arising from

access to genetic heritage or the associated traditional knowledge.

Sole paragraph. For the purposes of the *caput* of this Article, observed the Article 44, the user should adopt one or more of the following measures, as applicable:

I - register access to the genetic heritage or the associated traditional knowledge;

II - notify the finished product or the reproductive material object of economic exploitation, in accordance with this Act; and

III – share, in accordance with Chapter V, the benefits resulting from the economic exploitation performed by the date this Act enters into force, except when they have already been shared in the form of the Provisional Measure No. 2.186-16[1].

Article 38. The user shall regularize his activities in accordance with this Act within 1 (one) year of the date the CGen makes the registry system available, when he has carried out, in disagreement with the Provisional Measure No. 2.186-16 and between June 30, 2000 and the date this Act enters into force, the following activities:

I - access to the genetic heritage or the associated traditional knowledge;

II - access and economic exploitation of a product or process arising from access to genetic heritage or associated traditional knowledge referred to in the Provisional Measure No. 2.186-16, dated August 23, 2001;

III - shipment abroad of genetic heritage sample; or

IV - disclosure, transmission or retransmission of data or information that are part of or constitute associated traditional knowledge.

Paragraph 1 - The regularization process referred to in the *caput* of this Article depends on signing of a Term of Commitment.

Paragraph 2 - In case of access to the genetic heritage or the associated traditional knowledge with the only purpose of scientific research, the user will be exempted from the obligation of signing the Term of Commitment, and may regularize his activities by registering them or applying for an authorization, as the case may be.

Paragraph 3 - The registry and the previous authorization described in Paragraph 2 extinguish the enforceability of the administrative penalties provided for in the Provisional Measure No. 2.186-16, dated August 23, 2001, and specified in Articles 15 and 20 of the Decree No. 5.459, dated June 7, 2005, provided that the infraction has been committed until the day before the date this Act enters into force.

1 From August 30, 2007, to the publication of CGEN Resolution no 35, in April 27, 2011, the CGen suspended the process of regularizing access and shipment activities carried out in disagreement with the Provisional Measure No. 2.186-16 due to lack of administrative procedures.

Paragraph 4 - For purpose of regularization of the patent applications requested for the National Institute of Industrial Property - INPI - during the period when the Provisional Measure No. 2.186-16 was effective, the applicant should submit the receipt of registry or authorization referred to in this Article.

Article 39. The Term of Commitment will be signed by the user and the Federal Government, represented by the Minister of the Environment.

Sole paragraph. The Minister of the Environment may delegate the powers provided for in the *caput*.

Article 40. The Term of Commitment shall provide, as applicable:

I - the registry or the authorization of access or shipment of genetic heritage or associated traditional knowledge;

II - notification of product or process arising from access to genetic heritage or associated traditional knowledge referred to in the Provisional Measure No. 2.186-16, dated August 23, 2001; and

III – sharing, in the form of Chapter V of this Act, the benefits obtained during the period of time of marketing of the product arising from access to genetic heritage or associated traditional knowledge developed after June 30, 2000, in the limit of up to 5 (five) years prior to signing the Term of Commitment, subtracted the period of time in which CGen has suspended the process of regularizing access and shipment activities carried out in disagreement with the Provisional Measure No. 2.186-16 .

Article 41. Signing the Term of Commitment shall suspend, in all cases:

I - the application of the administrative penalties provided for in the Provisional Measure No. 2.186-16, dated August 23, 2001, and specified in Articles 16 to 19 and 21 to 24 of Decree No. 5.459, dated June 7, 2005, provided that the infraction has been committed until the day before this Act enters into force; and

II - the enforceability of the penalties applied based on the Provisional Measure No. 2.186-16, dated August 23, 2001, and on Articles 16 to 19 and 21 to 24 of Decree No. 5.459, dated June 7, 2005.

Paragraph 1 - The Term of Commitment mentioned in this Article is an extrajudicial enforcement instrument.

Paragraph 2 - The prescription time is suspended during the Term of Commitment.

Paragraph 3 - Provided that the obligations undertaken in the Term of Commitment are fully met, as demonstrated by technical advice issued by the Ministry of the Environment:

I - the administrative penalties referred to in the Articles 16, 17, 18, 21, 22, 23 and 24 of Decree No. 5.459, dated June 7, 2005, shall not apply;

II - the administrative penalties applied based on Articles 16 and 18 of Decree No. 5.459, dated June 7, 2005 will have their enforceability extinguished; and

III - the values of the fines applied based on Articles 19, 21, 22, 23 and 24 of Decree No 5.459, dated June 7, 2005, adjusted for inflation, will be reduced by 90%(ninety percent) of its value.

Paragraph 4 - The user who has initiated the process of regularization before this Act enters into force, may, at his discretion, share the benefits in accordance with the terms of the Provisional Measure No. 2.186-16, dated August 23, 2001.

Paragraph 5 - The remaining balance of the funds described in Article 41(3)(III), will be converted, by the supervisory authority and at the request of the user, into the obligation to share the benefits in one of the non-monetary forms provided for in Article 19(II) of this Act.

Paragraph 6 - The penalties provided for in the *caput* will have immediate enforceability in the cases of:

I - breach of the obligations provided for in the Term of Commitment by the offender; or

II - committing an additional infraction provided for in this Act, during the Term of Commitment.

Paragraph 7 - For characterizing recurrence, extinction of the enforceability of the fine does not extinguish the infraction committed.

Article 42. In order to solve administrative or judicial disputes, the adjustment and regularization rules provided for in this Act may, at the discretion of the parties, be applied in cases of access activities carried out before June 29, 2000.

Sole paragraph. In case of litigation, provided that the rules of regularization and adjustment provided for in this Act are respected, the Federal Government is authorized to:

I - sign agreement or court settlement; or

II - give up the lawsuit.

Article 43. Remain valid the acts and decisions of CGen relating to activities of access to or shipment of genetic heritage or associated traditional knowledge which generated marketed products or processes already subject to the regularization process before this Act enters into force.

Paragraph 1 - The CGen shall register, in accordance to the provisions of this Act, the authorizations already issued under the Provisional Measure No. 2.186-16.

Paragraph 2 - The benefit-sharing agreements validated by CGen before this Act enters into force shall be valid for the period laid down therein.

Article 44. The civil indemnities related to genetic heritage or the associated traditional knowledge of which the Federal Government is creditor are remitted.

Article 45. The application for the regularization process provided for in this Chapter allows the competent agency to resume the examination of pending application of industrial property rights arising from access and shipment activities.

CHAPTER IX
FINAL PROVISIONS

Article 46. The activities related to the genetic heritage or the associated traditional knowledge described in international agreements approved by the National Congress and enacted by the Federal Senate, when performed under such international agreements, must comply with the conditions set therein.

Sole paragraph. The benefit-sharing provided for in the Nagoya Protocol does not apply to the economic exploitation, for agricultural activities, of reproductive material of species introduced in the country by the human until this Treaty enters into force.

Article 47. Granting of intellectual property rights by the competent agency related to a finished product or a reproductive material arising from access to genetic heritage or associated traditional knowledge depends on the completion of the registration or authorization processes provided for in this Act.

Article 48. The Commissioned Technical Functions created under the Executive Branch by the Article 58 of the Provisional Measure No. 2.229-43, dated September 6, 2001, are extinguished in the following quantitative per level:

I - 33 (thirty-three) FCT-12; and

II - 53 (fifty-three) FCT-11.

Sole paragraph. The following commissioned functions of Superior Advisory and Management are created and allocated to the unit that will function as the Executive Secretary of CGen:

I - 1 (one) DAS-5;

II - 3 (three) DAS-4; and

III - 6 (six) DAS-3.

Article 49. This Act shall enter into force after 180 (one hundred and eighty) days of the date of its official publication.

Article 50. The Provisional Measure No. 2.186-16, dated August 23, 2001 is revoked.

Brasilia, May 20, 2015; 194th Year of the Independence and 127th of the Republic.

DILMA ROUSSEFF

Jose Eduardo Cardozo

Joaquim Vieira Ferreira Levy

Kátia Abreu

Armando Monteiro

Nelson Barbosa

Tereza Campello

João Luiz Silva Ferreira

Aldo Rebelo

Francisco Gaetani

Patrus Ananias

Miguel Rossetto

Nilma Lino Gomes

This text does not replace the text published on May 15, 2015 in the Official Journal of the Federal Government of Brazil.

Presidency of the Republic
Civil Office
Deputy Head for Judicial Affairs

Decree No. 8,772, 11TH May 2016*

Regulates Law No.13,123, 20th May 2015, which makes provisions regarding access to genetic heritage, protection and access to associated traditional knowledge and benefit-sharing for conservation and sustainable biodiversity uses.

THE PRESIDENT OF THE REPUBLIC using the powers delegated o by article 84, "*caput*", item IV and item VI, Line "a", of the Constitution, and regarding the provisions made by Law No. 13,123, 20th May 2015,

DECREES:

CHAPTER I
PRELIMINARY PROVISIONS

Article 1. This Decree regulates Law No. 13,123, 20th May 2015, which makes provisions regarding access to genetic heritage, protection and access to associated traditional knowledge and benefit-sharing for conservation and sustainable biodiversity uses.

§ 1 Is considered part of the existing genetic heritage in the national territory, for the purposes of this Decree, micro-organisms that have been isolated from substrates of the national territory, the territorial sea, the exclusive economic zone or the continental shelf.

§ 2 The micro-organism shall not be considered national genetic heritage when the user, urged by the competent authority, provides proof:

I - That it was isolated from substrates that are not from the national territory, the territorial sea, the exclusive economic zone or the continental shelf; and

II - The lawfulness of its importation.

§ 3 The vegetable and animal species introduced into the country shall only be considered genetic heritage found in "*in situ*" conditions in national territory when they form spontaneous populations that have acquired their own distinctive characteristics in the country.

*Unofficial translation

§ 4 It shall also be considered genetic heritage found in "*in situ*" conditions the varieties descendant of species introduced into the national territory with genetic diversity developed or adapted by indigenous peoples, traditional communities or traditional farmers, including natural selection combined with human selection in the local environment, that is not substantially similar to commercial cultivars.

Article 2. Subject below are requirements of law No. 13,123 of 2015 and of this Decree, as follows: The following activities shall be subject to the requirements provided for in Law No. 13,123, 2015, and in this Decree:

I - Access to genetic heritage or associated traditional knowledge;

II – Shipment abroad of genetic heritage samples; and

III - Economic exploitation of finished product or reproductive material originated from access to genetic heritage or associated traditional knowledge held after the entry into force of Law No. 13,123, 2015.

§ 1 For the purposes of the provisions made in item II of the "*caput*", the practice of any research or technology development activity performed after 17th November 2015, shall be, regardless of the date of its inception, considered as access held after the entry into force of Law No. 13,123, 2015.

§ 2 The activities carried out between the 30th June 2000 and 17th November 2015 shall abide the provisions made in Chapter VIII of this Decree.

Article 3. Access to genetic heritage or associated traditional knowledge concluded before the 30th June 2000, as well as the economic exploitation of resulting finished product or its reproductive material are not subject to the requirements provided for Law No. 13,123, of 2015, and in this Decree.

§ 1 For the purposes referred to in the "*caput*", and when urged by the competent authority, the user must provide receipt that all steps of access were performed prior to 30th June 2000.

§ 2 The receipt referred to in §1 must occur by means of:

I - In case of research:

a) publication of an article in a scientific journal;

b) communication in scientific event;

c) deposit of the patent application;

d) research conclusion report at the agency or public fomentation body; or

e) publication of conclusion papers for course, master's thesis, doctoral theses; and

II - In case of technological development:

a) deposit of patent application;

b) cultivar registry;

c) product registration at public agencies; or

d) receipt of product commercialization.

§ 3 In case of economic exploitation of finished product or reproductive material, in addition to the provisions made in items I and II of §2, the user shall provide proof that the concluded access was sufficient to obtain the finished product or reproductive material object of the economic exploitation.

§ 4 For the purposes of §3, it is considered that the concluded access was sufficient to obtain the finished product or reproductive material object of the economic exploitation when there was no research activity or technological development held after the 30th of June of 2000.

§ 5 The Genetic Heritage Management Council may:

I - Establish other means of evidencing than those provided for in items I and II of §2; and

II - Issue, upon request and attestation, a document attesting the placement of the user under the situations provided for in this article..

CHAPTER II
ON THE GENETIC HERITAGE MANAGEMENT COUNCIL - CGEN

SECTION I
General provisions

Article 4. The Genetic Heritage Management Council - CGen, collegiate body of deliberative, normative, advisory and appellate nature, has the following competencies:

I - Coordinate the elaboration and implementation of policies for managing access to genetic heritage and associated traditional knowledge and benefit-sharing;

II - Establish:

a) Technical rules;

b) guidelines and criteria for elaboration of and compliance with the benefit-sharing agreement;; and

c) criteria for developing a database to store information on genetic heritage and associated traditional knowledge;

III - Monitor, in collaboration with federal bodies, or by agreement with other institutions, activities of:

a) access and shipment of samples containing genetic heritage; and

b) Access to associated traditional knowledge;

IV - Deliberate on:

a) Accreditation of national institution that keep an *ex situ* collection of samples containing genetic heritage; and; whether:

1. Public; or

2. Non-profit private that maintains a popular herbaria or community seed banks; and

b) Accreditation of national institution to be responsible for the creation and maintenance of the database referred to in item IX;

V – Attest compliance of access to genetic heritage or associated traditional knowledge, referred in Chapter IV of Law No. 13,123, 2015;

VI - Record receipt of notification of a finished product or reproductive material and the presentation of the benefit-sharing agreement, in the terms of Article 16;of Law No. 13,123, 2015;

VII - Promote debates and public consultation on the themes addressed in Law No. 13,123, 2015;

VIII - Function as the higher instance of appeal to decisions of accredited institutions and to acts resulting from enforcing Law No. 13,123, 2015;

IX - Establish guidelines for the allocation of funds destined to the National Fund for Benefit-Sharing – FNRB, for the purpose of benefit-sharing;

X - Create and maintain databases related to; a) registries of access to genetic heritage or associated traditional knowledge and registry of shipment;

b) authorizations to access genetic heritage or associated traditional knowledge and authorization for shipment;

c) Instruments and terms for transfer of material for sample sending and shipment;

d) "*ex situ*" collections of accredited institutions that contain genetic heritage samples;

e) Finished product or reproductive material notifications;

f) Benefit-sharing agreements; and

g) Lawfulness of access certificates;

XI - Advise federal agencies on protection of indigenous peoples, traditional communities and traditional farmers rights regarding registration, in a registry for access to associated traditional knowledge; and

XII - Approve its internal regulations, which shall provide, at least, for the:

a) Organization and operation of its meetings;

b) Functioning of the Executive Secretariat;

c) Procedure for appointment of its Counsellors;

d) Removal, impediment, suspicion and hypotheses of conflict of interests between its Counsellors;

e) Advertising of its technical standards and deliberations; and

f) Composition and operation of Thematic and Sectorial Chambers.

Sole paragraph. The CGen may, as per request of the user, issue a certificate of compliance recognized internationally which shall serve as receipt that the activities on genetic heritage or associated traditional knowledge were carried out in accordance with the provisions made in Law No. 13,123, 2015, and in this Decree.

Article 5. Without prejudice to the System laid down in Chapter IV of this Decree, the CGen may maintain its own traceability system of the activities arising from access to genetic heritage or associated traditional knowledge, including those related to economic exploitation.

§ 1 In the terms determined by Article 7 of Law No. 13,123, 2015, the system provided for in the "*caput*" shall be managed by the CGen Executive Secretariat and shall contain the information necessary for the traceability of activities resulting from access to genetic heritage or associated traditional knowledge contained in the systems' databases:

I – On protection and registration of cultivars, seeds and seedlings, of products, establishments and agricultural inputs, information on the international transit of goods and agricultural inputs from the Ministry of Agriculture, Livestock and Supplies;

II – On import and export registration under the "Sistema Integrado de Comercio Exterior" (Integrated Foreign Trade System) - Siscomex, established by Decree No. 660, 25th September 1992;

III – On information about curricula, research groups, institutions registered in the Lattes Platform of the "Conselho Nacional de Desenvolvimento Cientifico e Tecnologico" (National Council for Scientific and Technological Development) - CNPq;

IV – On information about research on and commercial release of genetically modified organisms and their derivatives, of the "Comissao Tecnica Nacional de Biosseguranca" (National Technical Commission for Biosafety) – CTNBio of the Ministry of Science, Technology and Innovation;

V – On product registration of the "Agencia Nacional de Vigilancia Sanitária" (National Agency for Sanitary Surveillance) - Anvisa;

VI - For granting and guaranteeing the "Instituto Nacional da Propriedade Industrial" (National Institute for Industrial Property) – INPI intellectual property rights;

VII – On the "Ministerio do Desenvolvimento Social e Combate a Fome" (Ministry of Social Development and Combating Hunger)'s national registry for social information; and

VIII – On information about cultural heritage provided by the "Sistema Nacional de Informacoes e Indicadores Culturais" (National System for Information and Cultural Indicators) - SNIIC, of the Ministry of Culture.

§ 2 The agencies and bodies mentioned in this article shall adopt the measures necessary to ensure access to information by the traceability system and the Ministry of Environment shall adopt the necessary measures for integrating the information contained in the databases referred to in §1.

§ 3 In case of impossibility of adoption of the measures provided for in §2, the information shall be submitted to the CGen within thirty days of the request.

§ 4 The CGen may also:

I - Request complementary information to the agencies and bodies referred to in §1;

II – Request from other agencies and bodies of the Federal public administration information it understands as being necessary for the traceability of activities resulting from access to genetic heritage or associated traditional knowledge; and

III - Adopt measures to ensure access to information by the traceability system and the integration of databases with several agencies and bodies other than those referred to in items I to VIII of §1 of the "*caput*".

§ 5 The agencies and bodies of the Federal public administration providing sensitive information to the CGen shall explicitly indicate this, specifying, when applicable, the classification of the information as to the extent and term of secrecy, in accordance with the provisions of Law No 12,527, 18th November 2011, or specific legislation.

§ 6 The CGen Executive Secretariat shall ensure the legal confidentiality of information, in accordance with the classification of the information as to the extent and term of secrecy, when applicable.

§ 7 For the purposes of the provisions made in "*caput*", the CGen may have access to the data contained in the "Secretaria da Receita Federal do Brasil" (Secretariat for Federal Internal Revenue of Brazil) systems listed in public domain registry which do not inform the economic or financial situation of taxpayers.

Article 6. The CGen shall function by means of:

I - Plenary;

II - Thematic Chambers;

III - Sectorial Chambers; and

IV - Executive Secretariat.

SECTION II

The plenary

Article. 7. The CGen plenary shall be comprised of twenty-one Counsellors, being twelve representatives of agencies of the Federal public administration and nine civil society representatives, distributed as follows:

I - One representative from each of the following Ministries:

a) Ministry of Environment;

b) Ministry of Justice;

c) Ministry of Health;

d) Ministry of Foreign Affairs;

e) Ministry of Agriculture, Livestock and Supplies;

f) Ministry of Culture;

g) Ministry of Social Development and Combating Hunger;

h) Ministry of Defence;

I) Ministry of Development, Industry and Foreign Trade;

j) Ministry of Science, Technology and Innovation; and

k) Ministry of Agrarian Development;

II - Three representatives of business sector bodies or organizations, of which:

a) One shall be indicated by the "*Confederacao Nacional da Industria*" (National Confederation of the Industry) - CNI;

b) One indicated by the "*Confederacao Nacional da Agricultura*" (National Confederation of Agriculture) - CNA; and

c) One alternate and successively by the CNI and the CNA;

III - Three representatives of academic sector bodies or organizations, of which:

a) One indicated by the "*Sociedade Brasileira para o Progresso da Ciencia*" (Brazilian Society for the Progress of Science) - SBPC;

b) One indicated by the "*Associacao Brasileira de Antropologia*" (Brazilian Anthropology Association) - ABA; and

c) One indicated by the "*Academia Brasileira de Ciencias*" (Brazilian Science Academy) - ABC; and

IV - Three representatives of bodies or organisations representing indigenous peoples, traditional communities and traditional farmers, being:

a) One indicated by representatives of the traditional peoples and communities and their organizations of the "*Conselho Nacional dos Povos e Comunidades Tradicionais*" (National Council of Traditional Peoples and Communities) - CNPCT;

b) One indicated by representatives of traditional farmers and their organizations of the "*Conselho Nacional de Desenvolvimento Rural Sustentavel*" (National Council for Sustainable Rural Development) - Condraf; and

c) One indicated by representatives of indigenous peoples and organizations members of the "*Conselho Nacional de Politica Indigenista*" (National Council for Indigenous Policy) -CNPI.

§ 1 The CGen shall be chaired by the holding Counsellor of the Ministry of Environment and in the impediment or removal of such a member, by the respective substitute.

§ 2 The representations referred to in this article shall be comprised of a holder and two substitutes each, which shall be indicated by the holder of the Federal public administration agencies and by the respective legal representatives of civil society bodies or organizations.

§ 3 The members of CGen, holders and substitutes, shall be designated by Act of the Minister of Environment, within thirty days in of receiving the indications.

§ 4 The CGen plenary shall meet with the presence of, at least, eleven Counsellors, and its deliberations shall be taken by simple majority.

§ 5 The functions of the Counsellors shall not be remunerated and their exercise is considered relevant public service, being the responsibility of the public bodies and bodies representing civil society to cover the travel expenses and accommodations of their respective representatives.

§ 6 It shall be the responsibility of the Union to cover the expenses and accommodations of the Counsellors referred to in item IV of the "*caput*".

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SECTION III

The thematic chambers and sectorial chambers

Article 8. The Thematic Chambers shall be established by the CGen to support the decisions of the Plenary as from technical discussions and submission of proposals on topics or specific knowledge areas related to the access and benefit-sharing.

§ 1 The Act for establishment of the Thematic Chambers shall make provisions for its competencies, duration and composition, which shall observe the ratio of:

I – Fifty percent of representatives of Federal public administration agencies and bodies with competencies related to the theme of the respective Chamber;

II – Twenty-five percent of organizations representing the user sector; and

III – Twenty-five percent of organizations representing associated traditional knowledge providers.

§ 2 The CGen may establish a special Thematic Chamber to analyse and subsidize the Plenary judgment of last instance interposed appeals.

Article 9. The Sectorial Chambers shall be established by the CGen in order to support the Plenary decisions as from technical discussions and submission of proposals of interest to the business and academic sectors, as well as of indigenous peoples, traditional communities and traditional farmers.

Sole paragraph. The Act of creation of Sectorial Chambers shall make provisions for their competencies, duration and composition, which shall observe parity between the representation of the agencies and bodies of the Federal public administration with competencies related to its Chamber and the respective civil society sector.

Article 10. The members of the Thematic Chambers and Sectorial Chambers shall be appointed by the CGen Plenary Counsellors, considering training, expertise or notorious knowledge in the area related to the Chamber's competency.

SECTION IV

The Executive Secretariat

Article 11. The CGen Executive Secretariat is responsible for:

I - Providing technical and administrative support to the CGen Plenary and its Chambers;

II - Promoting instructions and the processing of the dossiers to be submitted for the CGen deliberation;

III - Issuing, according to the CGen deliberation, of the acts and decisions under its competence;

IV - Promote, according to the CGen deliberation, the accreditation or suspend the accreditation of:

a) A national institution that maintains an "*ex situ*" collection of genetic heritage samples; and

b) A national public institution to be responsible for creating and maintaining a database as mentioned in Item IX of §1 article 6 of Law No. 13,123, 2015; and

V - Implement, maintain and operate the systems:

a) For traceability of information relating to genetic heritage and associated traditional knowledge as provided for in article 5; and

b) Referred to in Chapter IV of this Decree.

CHAPTER III
ASSOCIATED TRADITIONAL KNOWLEDGE

Article 12. Guarantees that indigenous peoples, traditional communities and traditional farmers who create, develop, hold or maintain associated traditional knowledge have a right to participate on issues related to the access to associated traditional knowledge as well as a right to share the benefits resulting from that access.

§ 1 Access to associated traditional knowledge of identifiable origin is conditioned to obtaining prior informed consent.

§ 2 Access to associated traditional knowledge of unidentifiable origin is independent of prior informed consent.

§ 3 Any indigenous population, traditional community or traditional farmer that creates, develops, holds or maintains associated traditional knowledge is considered an identifiable source of this knowledge, except in the case of §3 article 9 of Law No. 13,123, 2015.

Article 13. Indigenous populations, traditional communities or traditional farmers may deny consent to access their associated traditional knowledge of identifiable source.

Article 14. The associated traditional knowledge provider of identifiable source shall choose the form for confirmation of their prior informed consent; freely negotiate their terms and conditions, as well as the terms of benefit-sharing, including modality, guaranteeing the right to refuse them.

§ 1 The parties may establish a deadline for the completion of registration to access the

associated traditional knowledge, object of consent, which shall not exceed the time limit provided for in §2 article 12 of Law No. 13,123, 2015.

§ 2 The Federal agencies and bodies responsible for protection of rights, assistance or for promoting activities for indigenous peoples, traditional communities and traditional farmers must, as per request of the holders, assist in the activities related to obtaining prior informed consent and in the negotiation of benefit-sharing agreements.

§ 3 For the purposes of the provisions made in §2 the Federal agencies and bodies may request technical support from the CGen Executive Secretariat.

Article 15. The obtaining of prior informed consent from an associated traditional knowledge provider must respect the traditional forms of organization and representation of the indigenous population, traditional community or traditional farmer and the respective community protocol, if any.

Article 16. The user shall observe the following guidelines for obtaining prior informed consent:

I - Clarifications to the indigenous population, traditional community or traditional farmer about:

a) The social, cultural and environmental impacts resulting from the implementation of the activity involving access to associated traditional knowledge;

b) The rights and responsibilities of each of the parties in the implementation of the activity and its results; and

c) The indigenous population, traditional community and traditional farmer's right to refuse access to associated traditional knowledge;

II - Establishment, together with the indigenous population, traditional community or traditional farmer, of the monetary or non-monetary benefit-sharing modalities, resulting from the economic exploitation; and

III – Respect to the indigenous population, traditional community and traditional farmer's right to refuse access to associated traditional knowledge during the prior consent process.

Article 17. Having observed the guidelines mentioned in article 16, the instrument for receipt of prior informed consent shall be formalized in a language accessible to the indigenous population, traditional community and traditional farmer and shall contain:

I - Historical description of the process for obtaining prior informed consent**;**

II - Description of the indigenous population, traditional community or traditional farmer's traditional forms of organization and representation;

III - The objective of the research, as well as its methodology, duration, budget, possible

benefits and sources for project financing;

IV - The intended use for the associated traditional knowledge to be accessed; and

V - The geographical area covered by the project and the indigenous people, traditional communities or traditional farmers involved.

Sole paragraph. The instrument referred to in the "*caput*" must also expressly mention whether the indigenous population, traditional community or traditional farmer have received legal or technical advice during the process of obtaining prior informed consent.

Article 18. Access to genetic heritage of traditional local or creole variety or locally adapted or creole breed for agricultural activities includes access to associated traditional knowledge of unidentifiable source that originated the variety or the breed and does not depend on prior consent from the indigenous population, traditional community or traditional farmer that creates, develops, holds or maintains the variety or the breed.

§ 1 As provided for in Item XXIV of article 2 of Law No. 13,123, 2015, the activities for production, processing and commercialization of food, beverages, fibres, energy and planted forests are considered agricultural activities.

§ 2 Included in the concept of energy provided for in §1 are biofuels, such as ethanol, biodiesel, biogas and cogeneration of electricity from biomass processing.

§ 3 For activities that do not fit into the concept of agricultural activity, access to genetic heritage of traditional local or creole variety or locally adapted creole breed comprises the associated traditional knowledge that originated the variety or breed, and shall follow the rules for access to associated traditional knowledge provided for in Law No. 13,123, 2015 and in this Decree.

§ 4 In case of access to genetic heritage of traditional local or creole variety such as the referred to in the "*caput*", the user shall deposit reproductive material of the variety object of the access in an "*ex situ*" collection maintained by a public institution, except when the variety has been obtained from the collection itself.

Article 19. The indigenous peoples, traditional communities and traditional farmers who create, develop, hold or maintain associated traditional knowledge are guaranteed the right to freely use or sell products containing genetic heritage or associated traditional knowledge, subject to the provisions of Law No. 9,456, 25th April 1997, and Law No. 10,711, 5th August 2003.

§ 1 Anvisa, within the competence laid out in Law No 9,782, 26th January 1999, shall regulate the production and marketing of the products referred to in the "*caput*".

§ 2 The regulations provided for in §1 should establish simplified procedures with the participation of indigenous peoples, traditional communities and traditional farmers, considering their uses, customs, and traditions.

CHAPTER IV
NATIONAL SYSTEM FOR GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE MANAGEMENT - SISGEN

SECTION I
General provisions

Article 20. Creates the National System for Genetic Heritage and Associated Traditional Knowledge Management - SisGen, an electronic system to be implemented, maintained and operated by the CGen Executive Secretariat, it shall manage:

I –The registry of access to genetic heritage or associated traditional knowledge, as well as the registry of sending of samples containing genetic heritage for the provision of foreign services;

II – The registry of shipment of genetic heritage samples and the Term for Transfer of Material;

III – Authorizations for access to genetic heritage or associated traditional knowledge and shipment abroad, for the cases referred to in Article 13 of Law No. 13,123, 2015;

I**V** – The accreditation of institutions maintaining "*ex situ*" collections containing genetic heritage samples;

V – Notifications of finished product or reproductive material and benefit-sharing agreements; and

VI - Certificates of lawful access.

§ 1 The registration must be carried out previously:

I – On the consignment;

II – On the application for any intellectual property rights;

III – On the commercialization of the intermediate product;

IV – On the disclosure of final or partial results in scientific or communication circles; or

V – On the notification of finished product or reproductive material developed as a result of the access.

§ 2 Should there be any "de facto" or "de jure" modifications in the information provided to the SisGen, the user should update its registry or notification at least once a year.

§ 3 The update referred to in §2 shall also be carried out to include information relating to the application of any intellectual property right or patent licensing.

Article 21. The information in SisGen is public, except for those that, upon request of the user, are considered sensitive.

Sole paragraph. The request referred to in the "*caput*" must indicate the relevant legal grounds and be accompanied by a non-confidential summary.

SECTION II

Registry of access to genetic heritage or associated traditional knowledge and registry of sending of samples containing genetic heritage for the provision of foreign services

Article 22. For the registration of access to genetic heritage or associated traditional knowledge, the national individual or legal person shall fill in the SisGen electronic form which will require:

I – User identification;

II - Information on the research or technological development activities, including:

a) Summary of the activity and its respective objectives;

b) Application sector, in case of technological development;

c) Results expected or obtained, depending on the period of registry;

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

e) Period of activities;

f) Identification of genetic heritage - in the strictest possible taxonomic level - or associated traditional knowledge, as the case may be, in particular:

1. Source of genetic heritage, including georeferenced coordinates in the degree, minutes and seconds format, "*in situ*" locality (even if they were obtained in "*ex situ*" or "in silico" sources); and

2. Indigenous population, traditional community or traditional farmer providers of the associated traditional knowledge, even if the knowledge was obtained through secondary sources;

g) Declaration on if the genetic heritage is a traditional local or creole variety or locally adapted or creole breed or if the species is listed in the official list of endangered species;

h) Information about the foreign based institution associated with the national institution, in the case provided for in Item II of article 12 of Law No. 13,123, 2015; and

I) Identification of national partner institutions, if any;

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

IV - Prior informed consent receipt as per Article 9 of Law No. 13,123, 2015, and article 17 of this Decree, if applicable;

V - Application for recognition of the lawful secrecy hypothesis; and

VI - Declaration, if applicable, of legal exemption framework hypothesis or of non-incidence of benefit-sharing.

§ 1 Should it not be possible to identify the georeferenced coordinate of the "*in situ*" acquisition site as mentioned in line 1 sub-item "f" of item II of the "*caput*", and only in cases where the acquisition date of the genetic heritage is prior to the entry into force of Law No. 13,123, 2015 the source may be reported based on the most specific geographic location possible, through one of the following means:

I - Identification of the "*ex situ*" genetic heritage acquisition source, with the information contained in the deposit registry when originally from an "*ex situ*" collection; or

II - Identification of the source genetic heritage database with the information contained in the deposit registry, when originally from an "in silico" database.

§ 2 The registration for access to associated traditional knowledge shall:

I - Identify the production sources of the associated traditional knowledge; and

II - Inform the georeferenced coordinates of the community, except in case of associated traditional knowledge of unidentifiable origin.

§ 3 Should it not be possible to inform the georeferenced coordinates referred to in item II of §2, the user must inform the most specific geographic location possible.

§ 4 The CGen shall establish in technical standards:

I - The strictest taxonomic level to be informed, in case of research, to evaluate or elucidate genetic diversity or evolutionary history of a species or taxonomic group;

II - How to indicate the most specific possible geographic location, in cases where access is exclusively for research purposes which requires more than 100 records of origin for registration; and

III - How to indicate genetic heritage in cases of access as from samples of substrates containing non-isolated microorganisms.

§ 5 The user must fill out a new record when there is a change in the genetic heritage or associated traditional knowledge accessed or in the access purpose.

Article 23. Once the form is finalized - as referred to in article 22 - SisGen shall automatically issue the receipt of access registration.

§ 1 The receipt of access registration constitutes a proper document to demonstrate that the user provided the information required, and has the following effects:

I – Allows for, pursuant to §2 of article 12 of Law No. 13,123, 2015:

a) The application for any intellectual property right;

b) The commercialization of an intermediate product;

c) The disclosure of results, final or partial, of the research or technological development in scientific or media circles; and

d) The notification of a finished product or reproductive material developed as a result of access; and

II - Establishes the beginning of the verification procedure as provided for in Section VII of this Chapter.

§ 2 The user will not need to wait for the verification procedure to perform the activities mentioned in item I of §1.

Article 24. The Sisgen shall provide an electronic access registration form for the national legal person, whether public or private, to register the sending of a genetic heritage sample for the provision of foreign services as part of a research or technological development.

§ 1 The national legal person, whether public or private, may authorize the individual responsible for the research or technological development to complete the sending registration.

§ 2 The sending registration mentioned in the "*caput*" shall require:

I - Information about the foreign receiving institution, including contact information and indication of a legal representative; and

II - Information on the samples to be sent, containing identification of genetic heritage to be sent.

§ 3 The sending of a sample containing genetic heritage for the provision of foreign services, pursuant to Item XXX article 2 of Law No. 13,123, of 2015, does not transfer responsibility for the sample from the sending institution responsible to the receiving institution.

§ 4 For the purposes laid out in §3, it is considered the provision of foreign services running tests or specialized technical activities carried out by the partner institution of the national institution responsible for access or by her hired by retribution or counterpart.

§ 5 The retribution or counterpart referred to in §4 may be waived when the partner institution integrates the research as co-author, subject to the provisions of §6.

§ 6 The legal instrument signed by the national institution responsible for access and the partner institution or contractor shall contain:

I - Genetic heritage identification in the strictest possible taxonomic level, subject to the provisions made in §4 of article 22;

II - Information about:

a) The sample type and form of packaging; and

b) The quantity of containers, volume or weight;

III - Description of the specialized technical service object of the provision;

IV - Obligation to return or destroy the samples submitted;

V - Discrimination of the deadline for service provision, detailing each activity to be performed, when applicable; and

VI - Clauses prohibiting the partner or contracted institution from:

a) Handing over the genetic heritage sample or information about genetic origin of the species object of sending - including substances originating from the metabolism of these beings - to third parties;

b) Using the sample of the genetic heritage or information of genetic origin of the species object of sending for any purposes other than those provided for;

c) Exploring intermediate or finished product or reproductive material resulting from the access economically; and

d) Requiring any type of intellectual property right.

§ 7 The legal instrument referred to in §6 shall not be required in cases of sending samples for genetic sequencing.

§ 8 In the hypothesis of §7, the user shall formally communicate to the partner or hired institution the obligations laid down in items IV and VI of §6.

§ 9 The sending registration of the sample shall be conducted within the time limits set out in the access registration.

§ 10 The samples object of the shipment must be accompanied by:

I – The legal instrument referred to in §6; and

II – The prior informed consent, in the case of sending of a genetic heritage sample of traditional local or creole variety or locally adapted or creole breed for access in non-agricultural activities, when applicable.

SECTION III

Sample shipment registration of genetic heritage and Material Transfer Agreement

Article 25. To carry out the sample shipment registration of a genetic heritage sample, the national individual or legal person must fill in the SisGen electronic form which shall require:

I - Identification:

a) Of the sender;

b) Of the genetic heritage samples in the strictest possible taxonomic level; and

c) Of the source of the samples to be sent, subject to the provisions made in line 1 sub-item "f" of item II in §1 and in item II of §4 of article 22;

II - Information about:

a) The sample type and form of packaging;

b) The quantity of containers, the volume or weight;

c) The foreign receiving institution, including the indication of a legal representative and contact information; and

d) The foreign access activities, including objectives, intended uses and application sector of the research or technological development;

III – Material Transfer Agreement - TTM, signed between the national individual or legal person and the foreign legal person; and

IV - Prior informed consent expressly authorizing the consignment in case of genetic heritage of traditional local or creole variety or locally adapted or creole breed for access in non-agricultural activities, when applicable.

§ 1 The TTM referred to in item III of the "*caput*" shall contain:

I - The information referred to in items I and II of the "*caput*" of this article;

II - The obligation of compliance with the requirements of Law No. 13,123, 2015;

III - The following provisions:

a) The TTM must be interpreted in accordance with Brazilian law, and, in case of dispute, the competent court is that of Brazil, accepting agreed arbitration between the parties.

b) The institution receiving genetic heritage shall not be regarded as a provider of genetic heritage; and

c) The institution receiving shall require that third parties sign a TTM obligating them to comply with the requirements of Law No. 13,123, 2015, including the provisions made in line "a" of this item;

IV - A clause that authorizes or prevents the transfer of the sample to a third party; and

V - Information about access to associated traditional knowledge, when appropriate.

§ 2 In the hypothesis of the authorization referred to in item IV of §1, the transfer of the sample to a third party shall depend upon the signature of a TTM containing the clauses provided for in §1.

§ 3 The provisions of §2 shall apply to all subsequent transfers.

Article 26. Finalizing the form mentioned in article 25 the SisGen shall automatically issue a receipt of shipment registry.

§ 1 The receipt of shipment registry constitutes a proper document to demonstrate that the user provided the information required and has the following effects:

I - Allows the effective shipment pursuant to the §2 of article 12, Law No. 13,123, 2015; and

II - Establishes the beginning of the verification procedure as provided for in Section VII of this Chapter.

§ 2 For the purposes of the item I §1, in addition to the receipt of shipment registry, the samples must be accompanied by the respective TTM to be legally forwarded.

§ 3 The user need not await the completion of the verification procedure mentioned in item II §1 to carry out the shipment.

SECTION IV

Authorizations for access to genetic heritage and associated traditional knowledge and the foreign shipment, in the cases referred to in Article 13 of Law No. 13,123, 2015

Article 27. In case of access to genetic heritage or associated traditional knowledge in areas essential to national security in Brazilian jurisdictional waters, the continental shelf and in the exclusive economic zone, the access to or the shipment shall be subject to prior authorization pursuant to Article 13 of Law No. 13,123, 2015, when the user is:

I – A national legal person, whose controlling shareholders or partners are foreign individuals or legal persons;

II – A national scientific and technological research institution, public or private, when the access is carried out in association with a foreign legal person based abroad; or

III – A Brazilian individual associated to, funded by or hired by a foreign legal person based abroad.

§ 1 For the purposes of the "*caput*" it shall be deemed as essential to national security areas, the borderland strip and the oceanic islands.

§ 2 The user must, prior to accessing genetic heritage or associated traditional knowledge, fill in all the information for the access or shipment registry provided for in articles 22 and 25, as well as identify the corporate board of the company and the associated legal person, as the case may be.

§ 3 In the hypothesis that the corporate board is comprised of other legal persons, the user must identify the respective corporate boards until the individuals bearing the membership or controllership can be identified.

§ 4 The access and shipment authorizations can be claimed jointly or separately.

§ 5 The filling out of the information for access and shipment registry comprises the automatic request of prior authorization and consent of the National Defence Council or the Naval Command, as appropriate.

§ 6 The national institution referred to in item II of the "*caput*" that carries out several accesses in association with the same foreign legal person may receive a single authorization for all accesses.

§ 7 The access and shipment registration shall not be concluded until the consent of the National Defence Council or the Naval Command is obtained.

Article 28. Given the information, the SisGen shall, within five days, notify the Executive Secretariat of the National Defence Council or the Naval Command, which shall manifest itself within sixty days, considering the national interest.

§ 1 The requirement for additional information or documents by the National Defence Council or Naval Command suspends the deadline for their manifestation until the effective delivery of what was requested.

§ 2 The provisions made in this Section do not suspend the time limits of the administrative verification procedure mentioned in Section VII of this Chapter.

Article 29. The access or consignment is automatically authorized through consent of the National Defence Council or the Naval Command.

§ 1 Changes to the corporate or shareholder control board that occur after obtaining consent should be reported to SisGen within thirty days.

§ 2 The National Defence Council or the Naval Command may, on a reasoned decision, withdraw the previously granted consent.

§ 3 In the hypothesis provided for in §2 the user shall have thirty days to submit its defence.

§ 4 If the user's arguments are not accepted, the National Defence Council or the Naval Command shall withdraw the consent and notify CGen such as to cancel the access or shipment registration.

SECTION V

Accreditation of national institutions that maintain "*ex situ*" collections of samples containing genetic heritage

Article 30. The accreditation of a national institutions that maintain "*ex situ*" collections of samples containing genetic heritage aims to gather the information necessary for the creation of the database mentioned in line "d" item IX §1 of article 6 of law No. 13,123, 2015, so as to ensure access to strategic information on "*ex situ*" conservation of genetic heritage in the national territory.

§ 1 In accordance with the provisions laid down in §2 of article 32 of law No. 13,123, 2015, FNRB resources can only be received by the national institution that upholds "*ex situ*" collections and is accredited in accordance with this Section.

§ 2 Private non-profit institutions that maintain popular herbaria or community seed banks may be accredited as national institutions that maintain "*ex situ*" collections once they observe the provisions made in this Section.

§ 3 The criteria for receiving the resources mentioned in the present article shall be defined by the FNRB Managing Committee.

Article 31. For the accreditation of a national institution that maintains an "*ex situ*" collection of samples containing genetic heritage, the legal person must fill in a SisGen electronic form, which shall require:

I - Identification of the institution; and

II - Information about each of the "*ex situ*" collections including:

a) Identification of the curators or guardians;

b) Types of preserved samples;

c) Taxonomic groups collected; and

d) Storage and conservation method.

§ 1 After the legal person completes the form, the CGen, pursuant to article 6, §1, item III, line "b", of law No. 13,123, 2015, shall decide upon the accreditation as mentioned in the "*caput*".

§ 2 The national institution shall maintain the information updated as mentioned in items I and II of the "*caput*".

Article 32. The samples of genetic heritage kept in "*ex situ*" collections in national institutions managed with public resources and the associated information can be accessed by indigenous peoples, traditional communities and traditional farmers.

§ 1 The institution receiving the request shall, within no more than twenty days:

I - Notify the date, place and manner of provision of the genetic heritage;

II - Indicate the reasons for total or partial impossibility of answering the request; or

III - Report that it does not hold the genetic heritage.

§ 2 The period referred to in §1 may be extended for another ten days, upon expressed justification, of which the applicant shall be notified.

§ 3 The institution may charge only the amount needed for the reimbursement of costs for regeneration or multiplication of samples or provision of information on the genetic heritage.

§ 4 The provision of samples shall be free of charge should it be done by a national institution maintaining an "*ex situ*" collection receiving funds from the FNRB.

SECTION VI
Notifications of finished product or reproductive material and benefit-sharing agreements

Article 33. The user must notify the finished product or reproductive material resulting from access to genetic heritage or associated traditional knowledge carried out after the enforcement of Law No. 13,123, 2015.

§ 1 The notification mentioned in the "*caput*" shall be made prior to economic exploitation.

§ 2 For the purposes of §1, it is considered economic exploitation issuing the first sales invoice of the finished product or reproductive material.

Article 34. To carry out the notification of the finished product or reproductive material resulting from access to genetic heritage or associated traditional knowledge, the user must fill in the SisGen electronic form, which shall require:

I - Identification of the individual or legal person applicant;

II – Commercial identification of the finished product or reproductive material and application sector;

III - Information on if the genetic heritage or associated traditional knowledge used in the finished product is crucial to the product's market appeal;

IV - Information on if the genetic heritage or associated traditional knowledge used in the finished product is crucial to the existence of functional features;

V – Estimate of the local, regional, national or international scope of manufacturing and commercialization of the finished product or reproductive material;

VI - Registration number or equivalent, of the product or cultivar in a competent agency

or body such as Anvisa, Ministry of Agriculture, Livestock and Supplies and the "*Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renovaveis*" (Brazilian Institute for the Environment and Renewable Natural Resources) - Ibama;

VII – Deposit number of the intellectual property product or cultivar rights request at the Ministry of Agriculture, Livestock and Supplies or at the INPI, or in foreign offices, when applicable;

VIII – Estimated date for the beginning of commercialization;

IX - Indication of the benefit-sharing modality;

X – Submission of the benefit-sharing agreement, when applicable;

XI - Numbers of the registries for access to genetic heritage or associated traditional knowledge that resulted in the finished product or reproductive material subject to the provisions of article 2 and Chapter VIII of this Decree;

XII – Numbers of the shipment registries that resulted in the finished product or reproductive material, if any;

XIII - Application for recognition of a legal secrecy hypothesis; and

XIV - Receipt of legal exemption hypothesis framework or of non-incidence of benefit-sharing.

Sole paragraph. The benefit-sharing agreement must be submitted:

I - At the time of notification, in case of access to associated traditional knowledge of identifiable origin; or

II – In up to three hundred and sixty-five days as from the date of notification of the finished product or reproductive material.

Article 35. After completing the form mentioned in article 34 the SisGen shall automatically issue a receipt of notification.

§ 1 The receipt of notification constitutes a proper document to demonstrate that the user has provided the required information and has the following effects:

I - Allows the economic exploitation of the finished product or reproductive material, subject to the provisions of Article 16 of Law No. 13,123, 2015; and

II - Establishes the beginning of the verification procedure as provided for in Section VII of this Chapter.

§ 2 The user need not await the completion of the verification procedure mentioned in item II §1 to begin economic exploitation.

SECTION VII

The administrative verification procedure

Article 36. The administrative verification procedure provided for in this section shall be applied in the cases of:

I – Registry for access to genetic heritage or associated traditional knowledge referred to in Section II of this Chapter;

II - Registry for shipment of genetic heritage sample referred to in Section III of this Chapter; and

III - Notification of finished product or reproductive material referred to in Section VI of this Chapter.

Article 37. During the verification period, the CGen Executive Secretariat:

I – Shall advise the CGen Counsellors on the registries or the notifications;

II – Shall forward to the members of the competent sectorial chambers information relating to the species that is the object of access and the municipality of its location, dissociated from the registries and other information therein;

III – Shall advise, in accordance with Item X of article 6 of Law No. 13,123, 2015, Federal agencies for the protection of indigenous peoples and traditional communities' rights on the registration of access registry to associated traditional knowledge; and

IV - May identify, ex officio, eventual irregularities in the conduct of registries or notifications, whereas it shall request the ratification of information or proceed with the rectification of formal errors.

§ 1 The provisions made in the "*caput*" shall be effected by the CGen Executive Secretariat within:

I – Fifteen days, in relation to items I, II and III; and

II - Sixty days, in relation to item IV.

§ 2 The CGen Counsellors shall have access to all information available, including information considered sensitive, and cannot disclose it, under penalty of accountability under the law.

§ 3 In cases of fraud manifest, the CGen Chairman may cautionally suspend the registries and the Plenary "*ad referendum*" notification.

§ 4 In the hypothesis of §3, the cautionary decision shall be forwarded for deliberation in the following plenary.

Article 38. The CGen Counsellors may identify evidence of irregularity in the information contained in the registers and the notification within sixty days of the date of advice referred to in item I of the "*caput*" of article 37.

§ 1 The Counsellors can, within the period referred to in the "*caput*", receive subsidies:

I – From the sectorial chambers;

II – From the agencies referred to in item III of the "*caput*" of article 37;

III – From the CGen Executive Secretariat; and

IV - Directly from associated traditional knowledge holders or their representatives.

§ 2 In the hypothesis of the "*caput*", the Counsellor shall submit an application for verification of irregularity evidence duly substantiated for deliberation of the CGen plenary.

§ 3 In agricultural activities, the fact that the species is domesticated cannot be regarded in itself as the basis of evidence of irregularity in registration of access to genetic heritage under the claim of access to associated traditional knowledge.

Article 39. The CGen plenary shall hold an admissibility judgment for the application mentioned in article 38, which shall determine:

I – Notification of the user, should it rule that there is evidence of irregularity; or

II - The filing of the application, should it not rule that there is evidence of irregularity.

§ 1 In case of item I of the "*caput*", the user will have fifteen days to submit its manifestation.

§ 2 Manifestations shall not be received if submitted after the deadline laid down in §1.

Article 40. Exhausted the deadline for submission of manifestation, the Executive Secretariat shall forward the process for deliberation of the CGen plenary, which can:

I – Deny the application's merits;

II - Accept the application, and therefore:

a) Determine that the user rectify the registry for access or of shipment or the notification - should the irregularity be rectifiable - under penalty of cancellation of the respective registries or notification; or

b) Cancel the registries for access or shipment or the notification, should the irregularity be insoluble, and notify:

1. The agencies and bodies referred to in articles 93 and 109; and

2. The user, in order to make new registries or notification.

§ 1 Are considered insoluble irregularities:

I - The existence of associated traditional knowledge of identifiable source when the registry or the notification indicates only genetic heritage;

II - The existence of associated traditional knowledge of identifiable source, when the registry or the notification indicates only associated traditional knowledge of unidentifiable source; and

III - The obtaining of prior informed consent in disagreement with the provisions made in Law No. 13,123, 2015 and in this Decree.

§ 2 If the irregularity findings referred to in items I, II and III §1 occur when the economic exploitation of the finished product or reproductive material has already been initiated, the CGen - exceptionally, and as long as it does not configure an act of ill repute - may determine that the user rectifies the registry or notification, and submit, within ninety days, the benefit-sharing agreement with the provider of associated traditional knowledge.

§ 3 In the hypothesis provided for in §2, the benefit-sharing relating to the full corresponding period of ascertainment shall be calculated and collected in favour of the beneficiaries and on the values laid down in the benefit-sharing agreement in force on the date of payment.

Article 41. The user may request the issuance of a certificate stating that in the respective registries for access and shipment as well as the notification:

I - No applications for evidence of irregularity verification were admitted during the verification process; or

II – That y were the object of a verification application that was not accepted.

Sole paragraph. The certificate referred to in the "*caput*" enables the user to be initially warned by the supervising agency or body before receiving any other administrative penalty should the infraction occur on facts reported in the respective registries for access and shipment as well as in the notification.

SECTION VIII
The lawful access certificate

Article 42. The CGen may issue a lawful access certificate mentioned in section XXII of article 2 of law No. 13,123, 2015, per user's request.

§ 1 The certified statement referred to in the "*caput*" declares that the registry has fulfilled the access requirements of Law No. 13,123, 2015.

§ 2 In the terms determined by item IV §1 article 6 of Law No. 13,123, 2015, the granting of a lawful access certificate shall be subject of prior deliberation by the CGen, according to procedures to be laid down in its rules of procedure.

§ 3 Once granted, the lawful access certificate:

I - Declares as lawful access to the date of its issue by the CGen; and

II – Prevents the application of administrative sanctions by the competent agency or body

specifically in relation to access activities carried out to the date of issue of the certificate.

§ 4 In the situation described in item II §3, if errors or fraud is detected in the access already certified by the CGen, the supervising agency or body should adopt administrative measures within the CGen to disestablish the previously awarded certificate.

CHAPTER V
BENEFIT-SHARING

SECTION I
General provisions

Article 43. The benefit-sharing provided for in Law No. 13,123, 2015, shall be due as long as there is economic exploitation of:

I - Finished product resulting from access to genetic heritage or associated traditional knowledge carried out after the enforcement of Law No. 13,123, 2015, or

II - Reproductive material resulting from access to genetic heritage or associated traditional knowledge for purposes of agricultural activities carried out after the enforcement of Law No. 13,123, 2015.

§ 1 In case of finished product as referred to in item I of the "*caput*", the genetic heritage component or associated traditional knowledge must be one of the main elements of aggregation of value.

§ 2 In the terms provided for in item XVIII, article 2 of law No. 13,123, 2015, are considered as main elements of value aggregation those whose presence in the finished product are crucial to the existence of its functional features or its commercialization appeal.

§ 3 For the purposes of this Decree, it is considered to be:

I - Commercialization appeal: reference to genetic heritage or associated traditional knowledge, their origin or their resulting differentials, related to a product, line of product or brand in any visual or audible means of communication, including marketing campaigns or highlight on the product label; and

II - Functional features: characteristics that determine the main purposes, improve the product or extend its list of purposes.

§ 4 It is not considered to be decisive for the existence of functional features the use of genetic heritage exclusively as excipients, vehicles or other inert substances, which do not provide functionality.

§ 5 The substance resulting from the metabolism of a microorganism shall not be considered decisive for the existence of its functional features when it is identical to the existing fossil substance and used to replace this one.

§ 6 The SisGen shall provide a specific field in the registry of access referred to in article 22 so that the user, should there be interest, can indicate and verify the framework as in the situation described in §5.

Article 44. Are considered to be subject to benefit-sharing the manufacturer of the finished product or the producer of the reproductive material, exclusively, regardless of who carried out previous access.

§ 1 In case of agricultural activity, the benefit-sharing shall be payable by the producer responsible for the last link in the production chain of the reproductive material.

§ 2 For the purposes of the provisions of §1, is considered to be the last link in the production chain the producer responsible for sale of reproductive material, for production, processing and sale of food, beverages, fibres, energy and planted forests.

§ 3 In case of economic exploitation of reproductive material resulting from access to genetic heritage or associated traditional knowledge for purposes of agricultural activities and intended solely for generating finished products into productive chains that do not involve agricultural activity, the benefit-sharing shall occur only on the economic exploitation of the finished product.

Article 45. The calculation of the net income provided for in articles. 20, 21 and 22 of Law No. 13,123, 2015, shall be done as determines §1 of article 12 of Decree-Law No. 1,598, 26th December 1977.

§ 1 For the purposes of the provisions made in the "*caput*" the manufacturer of the finished product or producer of reproductive material shall declare the annual net income of each fiscal year, obtained with the economic exploitation of each finished product or reproductive material and present a document able to prove it.

§ 2 The information referred to in the "*caput*" shall be submitted to the Ministry of Environment, in a format specified, within ninety days after the closing of the fiscal year.

§ 3 The Ministry of Finance and the Ibama shall provide the information and technical support required for the fulfilment of the provisions of this article.

§ 4 For the purposes of §3, the Ministry of Finance shall observe the provisions made in §2 of article 198 of Law No. 5,172, 25th October 1966 – *Codigo Tributario Nacional* (National Tax Revenue Code).

Article 46. In case of finished product or reproductive material produced outside of Brazil,

and for the purpose of determining the calculation basis referred to in §8 article 17 of Law No. 13,123, 2015, the Ministry of Environment may request from the manufacturer of the finished product or producer of reproductive material or the jointly responsible as laid down in §7 of article 17 of Law No. 13,123, 2015, data and information, duly accompanied by the relevant receipts.

§ 1 The data and information requested should be submitted in a format compatible with the systems used by the Ministry of Environment or in media thus specified.

§ 2 It is the duty of the notified party to provide all data and information requested, being responsible for the veracity of its contents or for its omission.

§ 3 The Ministry of Finance shall provide the information and technical support necessary for compliance with the provisions of the "*caput*".

§ 4 For the purposes of §3, the Ministry of Finance shall observe the provisions made in §2 of article 198 of Law No. 5,172, 25th October 1966 - *Codigo Tributario Nacional*.

Article 47. The benefit-sharing can be made in monetary and non-monetary arrangements.

§ 1 In case of economic exploitation of finished product or reproductive material resulting from access to genetic heritage, it is up to the user to choose one of the methods of benefit-sharing provided for in the "*caput*".

§ 2 In case of economic exploitation of finished product or reproductive material resulting from access to associated traditional knowledge of unidentifiable origin, the allocation shall be in the monetary modality and shall be payable to the FNRB.

§ 3 In case of economic exploitation of finished product or reproductive material resulting from access to associated traditional knowledge of identifiable source, the benefit-sharing:

I - Shall be freely negotiated between user and indigenous population, traditional community or traditional farmer provider of the knowledge; and

II - The portion due by the user to the FNRB shall correspond to 0.5% (five tenths per hundred) of the annual net income gained from economic exploitation or the half of that provided for in sectorial agreement.

SECTION II

Monetary benefit-sharing

Article 48. The monetary benefit-sharing shall be allocated:

I - To indigenous peoples, traditional communities and traditional farmers in cases of associated traditional knowledge of identifiable origin, as to agreement fairly and equitably negotiated between the parties, in accordance with article 24 of Law No. 13,123, 2015; and

II - The FNRB, in cases of economic exploitation of finished product or reproductive material resulting from access:

a) To genetic heritage, to the amount of 1% of the net income of the finished product or reproductive material, except in the event of the signing of a sectorial agreement as referred to in article 21 of Law No. 13,123, 2015;

b) To associated traditional knowledge of unidentifiable origin, to the amount of 1% of the net income of the finished product or reproductive material, except in the event of the signing of a sectorial agreement as referred to in article 21 of Law No. 13,123, 2015;

c) To associated traditional knowledge of identifiable origin regarding the quota provided for in §3 of article 24 of Law No. 13,123, 2015.

Article 49. The monetary benefit-sharing allocated to the FNRB shall be collected regardless of benefit-sharing agreement and shall be calculated after the close of each fiscal year, considering:

I - Notification information on finished product or reproductive material;

II - Annual net income resulting from the economic exploitation of finished product or reproductive material; and

III - Sectorial agreement in force applicable to the finished product or reproductive material.

§ 1 The value pertaining to benefit-sharing shall be collected in up to thirty days after provision of the information referred to in §2 of article 45 as far as there is economic exploitation of finished product or reproductive material

§ 2 The first collecting of the value pertaining to benefit-sharing shall include the benefit accrued from the beginning of the economic exploitation to the end of the fiscal year in which there is:

I - Submission of the benefit-sharing agreement; or

II - Notification of finished product or reproductive material in cases where the benefit-sharing is deposited directly into the FNRB, including previous years, if any.

§ 3 In the case of signing of a sectorial agreement, the benefit-sharing value due from the year of its entry into force shall be calculated for the entire fiscal year, based on the rate set.

§ 4 For the purposes of §8 article 17 of Law No. 13,123, 2015 should there be no access to information on the net income of the manufacturer of the finished product or reproductive material produced outside of Brazil, the calculating basis of the benefit-sharing shall be the net income of the importer, subsidiary, controlled undertaking, affiliate, associate or commercial representative linked to the foreign producer in the national territory or abroad.

SECTION III

Non-monetary benefit-sharing

Article 50. The non-monetary benefit-sharing shall be made through agreement signed:

I - With indigenous peoples, traditional communities or traditional farmer provider of associated traditional knowledge of identifiable source, in the cases of economic exploitation of finished product or reproductive material resulting from this knowledge fairly and equitably negotiated between the parties, in accordance with article 24 of Law No. 13,123, 2015; or

II - With the Union, in the cases of economic exploitation of finished product or reproductive material resulting from access to genetic heritage.

§ 1 For the benefit-sharing arrangements established by means of the instruments referred to in Lines "a", "e" and "f" of item II article 19 of Law No. 13,123, 2015, the allocation shall be equivalent to seventy-five percent of the predicted value for the monetary modality.

§ 2 In case of benefit-sharing arrangements established by means of instruments other than those referred to in §1, the allocation shall be equivalent to the predicted value for the monetary modality.

§ 3 The costs of project management, including planning, and accountability cannot be computed to achieve the percentage provided for in §§1 and 2.

§ 4 For the purposes of attesting the equivalence as provided for in §§1 and 2, the user must present an estimate, based on commercialization values.

§ 5 The benefit-sharing agreements signed by the Union shall be implemented preferably through the instrument referred to in Line "a" of item II article 19 of Law No. 13,123, 2015.

§ 6 The user shall not be able to use resources of the non-monetary benefit-sharing in marketing campaigns or any other form of advertising for their products, product lines or brands.

Article 51. In case of item II of article 50, the non-monetary benefit-sharing referred to in Lines "a" and "e" of item II article 19 of Law No. 13,123, 2015, shall be allocated for:

I - Conservation Units;

II - Indigenous lands;

III - Remaining quilombo territories;

IV - Rural settlement of traditional farmers;

V - Traditional territories pursuant to Decree No. 6,040, 7th February 2007;

VI - National public institutions for research and development;

VII - Priority areas for conservation, sustainable use and benefit-sharing of Brazilian biodiversity, as per Act sanctioned by the Minister of Environment;

VIII - Activities related to the safeguard of associated traditional knowledge;

IX - "*ex situ*" collections held by institutions accredited pursuant to Section V of Chapter IV; and

X - Indigenous populations, traditional communities and traditional farmers.

Article 52. In case of item II of article 50 the non-monetary benefit-sharing referred to in Lines "a", "b" , "c", "d" and "f" of item II article 19 of Law No. 13,123, 2015, shall be allocated to agencies and national public institutions running social interest programmes.

Article 53. The Ministry of Environment shall create and maintain a database of non-monetary benefit-sharing proposals, to which extensive publicity shall be given, including through its electronic website, to meet the requirements of item II article 19 of Law No. 13,123 2015.

Sole paragraph. The proposals referred to in the "*caput*" shall be aimed at the conservation and sustainable use of biodiversity, the valuing and protection of associated traditional knowledge, and at serving the public interest.

SECTION IV
Exemptions from benefit-sharing

Article 54. Is to be considered exempt from the benefit-sharing obligations the economic exploitation of:

I - Finished product or reproductive material developed by traditional farmers and their cooperatives, with annual gross income equal to or less than the maximum limit set out in item II of article 3 of Supplementary Law No. 123, 14th December 2006;

II - Finished product or reproductive material developed by micro-enterprises, by small firms and individual micro-enterprises as provided for in Supplementary Law No. 123, 2006;

III - Licensing operations, transfer or permission for the use of any form of intellectual property right on finished product, process, or reproductive material resulting from the access to genetic heritage or associated traditional knowledge by third parties;

IV - Intermediate products along the productive chain;

V - Reproductive material along the production chain of reproductive material, except the economic exploitation carried out by the last link of the production chain;

VI - Reproductive material resulting from access to genetic heritage or associated traditional

knowledge for the purpose of agricultural activities and intended solely for generating finished products; and

VII - Finished product or reproductive material resulting from access to genetic heritage of species introduced into the national territory by human action, even though domesticated, except as provided for in items I and II of §3 article 18 of Law No. 13,123, 2015.

§ 1 Are also exempt from the obligation of benefit-sharing, the exchange and dissemination of genetic heritage and associated traditional knowledge practiced by indigenous peoples, traditional community or traditional farmer for their own benefit and based on their usages, customs and traditions;

§ 2 The exemption from benefit-sharing referred to in the "*caput*" does not exempt the user from the obligation to notify the finished product or reproductive material as well as the fulfilment of the other obligations under the Law No.13,123, 2015.

§ 3 The provisions of §2 does not apply to the cases referred to in § 4 article 8 of Law No. 13,123, 2015.

§ 4 The user who no longer meets the requirements for exemption provided for in Law No. 13,123, 2015, shall apportion benefit in the following fiscal year.

§ 5 In the cases projected in items IV, V and VI of the "*caput*", the user must declare that the product or reproductive material meets the requirement of intermediate product and is intended only for activities and processes along the reproductive chain.

SECTION V
Benefit-sharing agreement

Article 55. The benefit-sharing agreement between user and provider shall be fairly and equitably negotiated between the parties, given the parameters of clarity, fairness and transparency in contractual clauses, and shall indicate conditions, obligations, types and duration of benefit in the short, medium and long term, without prejudice to other guidelines and criteria to be established by the CGen.

SECTION VI
Sectorial agreements

Article 56. The sectorial agreements are intended to ensure the competitiveness of the productive sector in cases where the application of the 1% (one percent) share of the annual net

income resulting from the economic exploitation of finished product or reproductive material resulting from access to genetic heritage or associated traditional knowledge of unidentifiable origin features material damage or threat of material damage.

§ 1 For the purposes of this Decree, it is considered a productive sector the company or group of companies that produce a particular product or similar characterized in the reduction application.

§ 2 In the case referred to in the "*caput*", the percentage of payment of monetary benefit-sharing can be reduced to up to 0.1% (one tenth percent) of the annual net income gained from economic exploitation.

Article 57. The application for reduction of the amount of monetary benefit-sharing shall be directed to the Ministry of Environment and will depend on the demonstration that the payment of that percentage resulted or would result in material damage.

§ 1 Shall be treated as sensitive information contained in the request referred to in the "*caput*", the information identified as such by the person concerned, provided that the request is duly justified, and cannot, in this case be disclosed without express authorization of the person concerned.

§ 2 The person that supplied sensitive information should submit an abstract to be published, with details that allows its understanding, under penalty of being considered non-confidential.

§ 3 If the Ministry of Environment considers as unjustified the request for confidential treatment and the interested party refuses to adapt it for annexation to non-sensitive documents, the information shall not be known.

Article 58. The application for reduction of benefit-sharing shall only be known when the signatory companies hold more than:

I – Fifty percent of the value of the sectorial production, in case the production is concentrated in up to twenty companies; and

II – Twenty-five percent of the value of the sectorial production, in case the production is concentrated in more than twenty companies.

§ 1 For the purposes of this article, it is considered as sectorial production value, the estimated value of the domestic production of the finished product or reproductive material resulting from access to genetic heritage or associated traditional knowledge of unidentifiable origin as described in the application.

§ 2 The request should be signed by the legal representatives of each of the signatories and shall contain:

I - Documents proving the causal link between the material damage or its threat, and the

payment of the monetary benefit-sharing corresponding to the portion of 1% (one percent) of the annual net income; and

II - Characterization of the finished product or reproductive material for which is required the reduction in the apportion of 1% (one percent) provided for in article 56.

§ 3 The characterization indicated in item II of §2 shall contain the following information:

I - Genetic heritage accessed;

II - Associated traditional knowledge accessed;

III - Raw materials;

IV - Chemical composition;

V - Physical characteristics;

VI - Technical standards and specifications;

VII - Production process;

VIII - Uses and applications;

IX – Exchangeability rate; and

X - Distribution channels.

§ 4 The request shall not be known if there is ongoing verification covering the same or similar products.

Article 59. Once demonstrated the conditions of article 58, the Ministry of Environment:

I – Shall publish an Act initiating the verification of the material damage or threat; and

II - Shall notify:

a) The companies concerned;

b) The Ministry of Development, Industry and Foreign Trade; and

c) The agencies mentioned in the sole paragraph of article 21 Law No. 13,123, 2015.

§ 1 The Act referred to in item I of the "*caput*" shall specify the finished product or the reproductive material object of verification and the signatory companies of the application.

§ 2 The manifestation of the Ministry of Development, Industry and Foreign Trade is a condition for the analysis of article 62 and shall be submitted within sixty days.

§ 3 The agencies referred to in line "c" of item II of the "*caput*" may manifest themselves within sixty days as from the date of notification.

§ 4 There shall be granted a period of twenty days as from the date of publication of the Act referred to in item I of the "*caput*", for the submission of license applications by other parties who consider themselves interested.

Article 60. The finding of material damage or threat shall be evidence-based and shall include the objective examination of the benefit-sharing effect on the price of the product and the consequent impact on the productive sector.

§ 1 The examination referred to in the "*caput*" shall include, among others, the assessment of the following factors and economic indices:

I - Actual or potential loss:

a) In sales;

b) Of profits;

c) In production;

d) In market shares;

e) Of productivity; and

f) The utilization rate of the established capacity;

II - Actual or potential negative effects on:

a) Stocks;

b) Employment;

c) Wages; and

d) Growth of the productive sector;

III - The contraction in demand or changes in the consumption patterns;

IV - The competition between domestic and foreign producers; and

V - The export performance.

§ 2 For the purposes of the provisions made in this article it is to be segregated the effect of monetary benefit-sharing payment corresponding to the apportion of 1% (one percent) of the annual net income of the effects resulting from other causes that may cause material damage or threat.

§ 3 For the examination of the impact referred to in the "*caput*" it shall be considered if the value of benefit-sharing represented a significant decrease in sales.

Article 61. The Ministry of Development, Industry and Foreign Trade shall carry out the analysis referred to in article 60 and forward technical advice on the request for reducing the value of benefit-sharing to the Ministry of Environment, within the time limit referred to in §2 article 59.

Article 62. Once received the advice referred to in article 61, the Ministry of Environment shall issue technical advice which must consider the contents of the manifestations:

I – Of the Ministry of Development, Industry and Foreign Trade; and

II – Of the official agencies for defence of indigenous peoples, traditional communities or traditional farmers' rights when submitted.

§ 1 The companies concerned shall be notified to, within thirty days, issue manifestation regarding the advice referred to in the "*caput*".

§ 2 The Ministry of Environment may accept the manifestations of the companies concerned, and thus issue new advice.

Article 63. The advice shall be submitted to the Minister of Environment which shall decide, so as motivated, on the implementation or not of the sectorial agreement.

Article 64. The terms of the sectorial agreement in force shall apply to all products produced in the national territory that are within the terms of the decision, even if produced by companies that have not signed the reduction request.

Article 65. The sectorial agreement shall remain in force for sixty months as from the publication of the decision referred to in article 63.

§ 1 In case there is a sectorial agreement in force at the time of benefit-sharing payment for a particular finished product or reproductive material, the quota to be paid shall be that established in the sectorial agreement.

§ 2 Elapsing the timeframe referred to in the "*caput*", and not existing a request for an extension, the sectorial agreement shall be extinct.

§ 3 The sectorial agreement may be extended if the conditions upon its signature remain.

§ 4 The request for extension should be made by the person concerned, at least four months before its extinction.

§ 5 During the examination of the extension application, the sectorial agreement remains in effect.

Article 66. During the period covered by the sectorial agreement, the applicant contemplated may apply for review of the quota, considering that at least thirty months have elapsed as from the beginning of the agreement.

§ 1 The application referred to in the "*caput*" must be instructed with receipt that the circumstances which justified the application for reduction of the quota granted at that time have changed.

§ 2 The examination of the review application shall follow the provisions made in this Section and shall consider only new facts justifying the request.

Article 67. The final decision on the application for review shall be the responsibility of the

Minister of Environment and shall be limited to reducing or not the quota.

Article 68. Should the application for review be accepted, an additive term to the sectorial agreement in force shall be formalized.

Article 69. An Act sanctioned by the Minister of Environment shall establish supplementary rules to the provisions made in this Section.

CHAPTER VI
INFRACTIONS AND ADMINISTRATIVE SANCTIONS

SECTION I
General provisions

Article 70. It is considered to be an administrative violation against genetic heritage or associated traditional knowledge the referrals of articles 78 to 91 of this Decree.

Article 71. Without prejudice to the appropriate criminal and civil responsibilities, administrative infractions shall be punished with the following penalties:

I - Warning;

II - Fine;

III - Seizure:

a) Of the samples containing genetic heritage accessed;

b) Of the instruments used in obtaining or processing genetic heritage or associated traditional knowledge accessed;

c) Of the products resulting from access to genetic heritage or associated traditional knowledge; or

d) Of the products obtained from information on associated traditional knowledge;

IV - Temporary suspension of the manufacture and sale of the finished product or the reproductive material resulting from access to genetic heritage or associated traditional knowledge until the settlement;

V – Suspension of the specific activity related to the violation;

VI - Partial or total interdiction of the establishment, activity or undertaking;

VII - Suspension of certificate or authorization; or

VIII - Cancellation of certificate or authorization.

Sole paragraph. The penalties laid down in items I to VIII of the "*caput*" may be applied cumulatively.

Article 72. The assessing agent, when issuing the infraction notice, should indicate the penalties established in this Decree, observing:

I - The seriousness of the fact;

II - The background of the offender, as to the enforcement of legislation concerning genetic heritage and associated traditional knowledge;

III - Recurrence; and

IV - Economic situation of the offender, in case of fine.

Sole paragraph. For application of the provisions made in this article, the competent agency or authority may establish, by means of technical standard, additional criteria for aggravation and mitigation of the administrative sanctions.

Article 73. The fine shall be arbitrated by the competent authority, for each infraction, and can vary:

I – From R$1,000.00 (one thousand reais) to R$100,000.00 (one hundred thousand reais), should the infraction be committed by an individual; or

II – From R$10,000.00 (ten thousand reais) to R$10,000,000.00 (ten million reais), should the infraction be committed by a legal person, or with their concurrence.

Article 74. The commitment of new infringements by the same offender, within the period of five years as from the final judgement of the administrative decision that convicted them on the previous infringement, implies:

I – On application of triple penalty, in case of commitment of the same violation; or

II – On application of double penalty, in the case of commitment of a distinct violation.

§ 1 The aggravation shall be determined in the procedure of the new violation, which shall hold on record, per copy, the previous infraction notice and the judgement that confirmed it.

§ 2 Before the trial of the new violation, the environmental authority shall verify the existence of a previous violation judged and confirmed, for purposes of application of aggravation to the new penalty.

§ 3 Once confirmed the existence of a previous infraction notice - confirmed in judgment -, the environmental authority must:

I - Aggravate the penalty as provided for in the "*caput*";

II - Notify the offender to manifest on the aggravation of the penalty within ten days; and

III - Judge the new violation considering the aggravation of the penalty.

Article 75. Upon the penalties provided for in items III to VI article 71, applies, when applicable, the provisions made in Decree No. 6,514, 22nd July 2008.

SECTION II

Prescription deadlines

Article 76. Pursuant to Law No. 9,873, 23rd November 1999, which prescribes within five years the action of the public administration in order to establish the practice of administrative infractions against genetic heritage and associated traditional knowledge, counted as from the date of practice of the act, or, in the case of a permanent or continuous infringement, the day in which it ceased.

§ 1 It is considered as instituted the verification of infringement against genetic heritage and associated traditional knowledge, the drawing up of the infraction notice by the competent authority or administrative notification.

§ 2 The intercurrent prescription falls upon the procedure for determining the infraction notice paralyzed for more than three years, pending a judgement or order, whose records shall be filed "*ex officio*" or upon request of the interested party, without prejudice to determining the functional responsibility resulting from the downtime.

Article 77. The prescription is interrupted:

I - By notification of the offender by any means, including public notice;

II - By any unambiguous public administration act determining the fact; and

III – By the judgment decision open to challenge.

Sole paragraph. Is to be considered an unambiguous act of public administration, for the purpose of item II, that involving procedural instruction.

SECTION III

Infractions against genetic heritage and associated traditional knowledge

Article 78. Economically exploiting finished product or reproductive material resulting from access to genetic heritage or associated traditional knowledge without prior notification.

Minimum fine of R$3,000.00 (three thousand reais) and a maximum of R$30,000.00 (thirty thousand reais), in case of individuals.

Minimum fine of R$10,000.00 (ten thousand reais) and a maximum of R$200,000.00 (two hundred thousand reais), in case of legal body ranked as a micro-enterprise, small business or traditional farmer cooperative with an annual gross income equal to or less than the maximum limit set out in item II article 3 of Supplementary Law No. 123, 14th December 2006.

Minimum fine of R$30,000.00 (thirty thousand reais) and a maximum of R$10,000,000.00 (ten million reais), for other legal persons.

§ 1 The penalties provided for in the "*caput*" shall be applied for each finished product or reproductive material, regardless of the number of species accessed for the preparation of finished product or reproductive material.

§ 2 The fine penalty is applied in double should there be foreign commercialization of finished product or reproductive material developed as a result of access.

§ 3 The same penalties provided for in this article incur on whoever presents a benefit-sharing agreement disagreeing with the deadlines laid down in items I and II §1 article 34.

Article 79. Shipment abroad – be it direct or through an intermediary - of a genetic heritage sample without prior registration or in disagreement with this.

Minimum fine of R$20,000.00 (twenty thousand reais) and maximum fine of R$100,000.00 (one hundred thousand), in case of individuals.

Minimum fine of R$50,000.00 (fifty thousand reais) and maximum fine of R$500,000.00 (five hundred thousand reais), in case of legal person ranked as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the Supplementary Law No. 123, 2006.

Minimum fine of R$100,000.00 (one hundred thousand) and maximum fine of R$10,000,000.00 (ten million reais), for other legal persons.

§ 1 The sanction provided for in the "*caput*" shall be applied:

I - By species;

II – In triple should the sample be obtained from a species listed in official lists of Brazilian species threatened with extinction or Annex I of the Convention on International Trade of Endangered Species of Wild Fauna and Flora – CITES, enacted by Decree No. 76,623, 17th November 1975; and

III – In double should the sample be obtained from a species listed only in annex II of the CITES, enacted by Decree No. 76,623, 1975.

§ 2 Should the consignment be carried out for the development of biological or chemical weapons, the penalty provided for in the "*caput*" shall be quadrupled and sanctions for embargo, suspension or partial or total interdiction of the establishment, activity or enterprise of the responsible for the consignment shall be applied.

Article 80. Requesting intellectual property right resulting from access to genetic heritage or associated traditional knowledge, in Brazil or abroad, without carrying out prior registration.

Minimum fine of R$3,000.00 (three thousand reais) and maximum fine of R$30,000.00 (thirty thousand reais), in case of individuals.

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$200,000.00 (two hundred thousand reais), in case of legal person ranked as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the Supplementary Law No. 123, 2006.

Minimum fine of R$20,000.00 (twenty thousand reais) and maximum fine of R$10,000,000.00 (ten million reais), for other legal persons.

Article 81. Disclosing results - final or partial - in scientific or communication circles without prior registration:

Minimum fine of R$1,000.00 (one thousand reais) and maximum fine of R$20,000.00 (twenty thousand reais), in case of individuals.

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$200,000.00 (two hundred thousand reais), in case of legal person ranked as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the Supplementary Law No. 123, 2006.

Minimum fine of R$50,000.00 (fifty thousand reais) and maximum fine of R$500,000.00 (five hundred thousand reais), for other legal persons.

§ 1 The sanction of fines may be replaced by warning, when favourable to the circumstances provided for in article 72.

§ 2 The provisions made in §1 shall not apply where the offensive conduct involves access to associated traditional knowledge or when the offender is a repeat offender under this Decree.

Article 82. Non carry out registration of access before commercialization of intermediate product:

Minimum fine of R$1,000.00 (one thousand reais) and maximum fine of R$20,000.00 (twenty thousand reais), in case of individuals.

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$200,000.00 (two hundred thousand reais), in case of legal person ranked as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the Supplementary Law No. 123, 2006.

Minimum fine of R$50,000.00 (fifty thousand reais) and maximum fine of R$500,000.00 (five hundred thousand reais), for other legal persons.

§ 1 The sanction of fines may be replaced by warning, when favourable to the circumstances provided for in article 72.

§ 2 The provisions made in §1 shall not apply where the offensive conduct involves access to associated traditional knowledge or when the offender is a repeat offender under this Decree.

Article 83. Accessing associated traditional knowledge of identifiable origin without obtaining prior informed consent, or in disagreement with this.

Minimum fine of R$20,000.00 (twenty thousand reais) and maximum fine of R$100,000.00 (one hundred thousand reais), in case of individuals.

Minimum fine of R$50,000.00 (fifty thousand reais) and maximum fine of R$500,000.00 (five hundred thousand reais), in case of legal person ranked as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the Supplementary Law No. 123, 14th December 2006.

Minimum fine R$100,000.00 (one hundred thousand reais) and maximum fine of R$10,000,000.00 (ten million reais), for other legal persons.

Sole paragraph. The same penalties incur on whoever obtains prior informed consent permeated with flaws to the will of the associated traditional knowledge provider under the Civil Code.

Article 84. Non indication of the origin of the associated traditional knowledge with identifiable source in publications, uses, exploitations and disclosures of results of access.

Minimum fine of R$1,000.00 (one thousand reais) and maximum fine of R$10,000.00 (ten thousand reais) in case of individuals.

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$50,000.00 (fifty thousand reais), in case of legal person ranked as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the Supplementary Law No. 123, 14th December 2006.

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$500,000.00 (five hundred thousand reais), for other legal persons.

Article 85. Non-payment of the annually due instalment to the FNRB, resulting from economic exploitation of finished product or reproductive material developed as a result of access to genetic heritage or associated traditional knowledge.

Minimum fine of R$1,000.00 (one thousand reais) and maximum fine of R$100,000.00 (one hundred thousand reais) in case of individuals.

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$10,000,000.00 (ten million reais), for legal persons.

§ 1 The same penalties incur on whoever interrupts or partially fulfils the agreed upon benefit-sharing, be it monetary or non-monetary.

§ 2 In compliance with the limits laid down in the "*caput*", the fine shall not be less than 10% (ten percent) nor more than 30% (thirty percent) of the due annual value.

Article 86. Drawing up or submitting information, document, study or technical report fully or partly false or misleading, whether in official systems or any other administrative procedure related to genetic heritage or associated traditional knowledge:

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$50,000.00 (fifty thousand reais), in case of individuals.

Minimum fine of R$30,000.00 (thirty thousand reais) and maximum fine of R$300,000.00 (three hundred thousand reais), in case of legal person ranked as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the Supplementary Law No. 123, 2006.

Minimum fine of R$100,000.00 (one hundred thousand reais) and maximum fine of R$5,000,000.00 (five million reais), for other legal persons.

Sole paragraph. The sanction provided for in the "*caput*" shall be applied in double if the information, document, study, technical report or total or partially false or misleading report is referring to the shipment or to the sending of a sample for provision of foreign services.

Article 87. Breaching suspension, embargo or interdiction resulting from an administrative infraction against genetic heritage or associated traditional knowledge:

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$100,000.00 (one hundred thousand reais), in case of individuals.

Minimum fine of R$50,000.00 (fifty thousand reais) and maximum fine of R$500,000.00 (five hundred thousand reais), in case of legal person rated as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the supplementary Law No. 123, 2006.

Minimum fine of R$200,000.00 (two hundred thousand reais) and maximum fine of R$10,000,000.00 (ten million reais), for other legal persons.

Article. 88. Obstruct or hinder supervision of the obligations laid down in Law No. 13,123, 2015:

Minimum fine of R$5,000.00 (five thousand reais) and maximum fine of R$50,000.00 (fifty thousand reais), in case of individuals.

Minimum fine of R$30,000.00 (thirty thousand reais) and maximum fine of R$300,000.00 (three hundred thousand reais), in case of legal person rated as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the supplementary Law No. 123, 2006.

Minimum fine of R$100,000.00 (one hundred thousand reais) and maximum fine of R$5,000,000.00 (five million reais), for other legal persons.

Article 89. Failing on make adjustments within the time limit laid down in article 37 of Law No. 13,123, 2015:

Minimum fine of R$1,000.00 (one thousand reais) and maximum fine of R$10,000.00 (ten thousand reais) in case of individuals.

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$50,000.00 (fifty thousand reais), in case of legal person rated as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the supplementary Law No. 123, 2006.

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$300,000.00 (three hundred thousand reais), for other legal persons.

§ 1 The sanction provided for in the "*caput*" shall be applied for each finished product or reproductive material or for each access activity, singly, that fails to promote its suitability regardless of the number of species accessed.

§ 2 The penalties of fine may be replaced by warning, when favourable to the circumstances provided for in article 72.

§ 3 In the case of access to genetic heritage or associated traditional knowledge conducted solely for purposes of scientific research, the warning sanction on facts related to its registration for the purpose of adjustment should precede the application of any other administrative penalty.

Article 90. Failing on make adjustments within the time limit laid down in article 38 of Law No. 13,123, 2015:

Minimum fine of R$1,000.00 (one thousand reais) and maximum fine of R$10,000.00 (ten thousand reais) in case of individuals.

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$50,000.00 (fifty thousand reais), in case of legal person rated as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the supplementary Law No. 123, 2006.

Minimum fine of R$10,000.00 (ten thousand reais) and maximum fine of R$10,000,000.00 (ten million reais), for other legal persons.

§ 1 The sanction provided for in the "*caput*" shall be applied for each finished product or reproductive material or for each access activity, singly, that fails to promote its suitability regardless of the number of species accessed.

§ 2 The penalties of fine may be replaced by warning, when favourable to the circumstances provided for in article 72, and in the case of:

I - Individual; or

II - Legal person that carried out access to genetic heritage or associated traditional knowledge solely for the purpose of scientific research.

Article 91. Non attending legal or regulatory requirements, when notified by the competent authority within the timeframe granted:

Minimum fine of R$1,000.00 (one thousand reais) and maximum fine of R$30,000.00 (thirty thousand reais), in case of individuals.

Minimum fine of R$10,000.00 (ten thousand reais) and a maximum of R$200,000.00 (two hundred thousand reais), in case of legal person ranked as a micro-enterprise, small business or traditional farmer cooperative with annual gross income equal to or less than the maximum limit set out in item II article 3 of the supplementary Law No. 123, 2006.

Minimum fine of R$15,000.00 (fifteen thousand reais) and maximum fine of R$5,000,000.00 (five million reais), for other legal persons.

Sole paragraph. The penalty of fine may be replaced by warning, when favourable to the circumstances provided for in article 72.

SECTION IV

The administrative process for verification of infractions

Article 92. The infractions against genetic heritage or associated traditional knowledge shall be verified in a proper administrative process by the drawing up of a notice of infraction and its terms, ensuring the right to ample defence and contradictory.

Sole paragraph. The administrative proceedings referred to in the "*caput*" shall be governed by the provisions made in Decree No. 6,514, 2008, except when there are diverse provisions in this Chapter.

Article 93. Are considered competent to supervise and verify the committing of the administrative offences provided for in this Decree:

I - Ibama;

II - The Naval Command, in the scope of the Brazilian jurisdictional waters and continental shelf; and

III - The Ministry of Agriculture, Livestock and Supplies, in the scope of the access to genetic

heritage for agricultural activities, in the terms referred to in article 3 of the Law No. 10,883, 16th June 2004.

§ 1 When the infraction involves associated traditional knowledge, the official agencies for the defence indigenous peoples, traditional communities and traditional farmers' rights shall provide support to the Ibama surveillance actions.

§ 2 A joint Act sanctioned by the Ministers of Environment, Agriculture, Livestock and Supplies and of Defence shall dictate the coordinated performance of the supervisory agencies.

Article 94. Appeals concerning the final decision made by the agencies provided for in article 93 can be made to the CGen within twenty days.

Article 95. A CGen Act shall establish the criteria for allocation of samples, products and instruments seized, referred to in §4 article 27 of Law No. 13,123, 2015.

Sole paragraph. Whilst the Act mentioned in the "*caput*" is not edited, the supervisory authority shall make the allocation, in accordance with the provisions made in Decree No. 6,514, 2008.

CHAPTER VII
NATIONAL FUND FOR BENEFIT-SHARING AND NATIONAL BENEFIT-SHARING PROGRAMME

Article. 96. The National Fund for Benefit-Sharing - FNRB, established by Law No. 13,123, 2015, linked to the Ministry of Environment, financial in nature and intended to support actions and activities designed to enhance the genetic heritage and associated traditional knowledge and promote its sustainable use.

§ 1 Constitutes FNRB income:

I - Allocations contained in the annual budget law and its additional credits;

II - Donations;

III - Values collected with the payment of administrative fines applied due to the breach of Law No. 13,123, 2015;

IV – External financial resources resulting from contracts, agreements or covenants especially reserved for the purposes of the Fund;

V - Contributions made by users of genetic heritage or associated traditional knowledge to the National Benefit-Sharing Programme;

VI - Values deriving from benefit-sharing; and

VII - Other funds allocated.

§ 2 Monetary resources deposited in the FNRB deriving from economic exploitation of finished product or reproductive material resulting from access to associated traditional knowledge shall be used exclusively in actions, activities and projects for the benefit of the holders of the associated traditional knowledge.

§ 3 The funds allocated to the FNRB and eventual fund returning, shall be collected directly into the Fund, according to procedures defined by the Managing Committee.

Article 97. The FNRB shall be managed by a Managing Committee, collegial agency comprised of:

I - One representative and two substitutes:

a) Of the Ministry of Environment, which presides;

b) Of the Ministry of Finance;

c) Of the Ministry of Agriculture, Livestock and Supplies;

d) Of the Ministry of Social Development and Combating Hunger;

e) Of the Ministry of Agrarian Development;

f) Of the Ministry of Science, Technology and Innovation;

g) Of the National Foundation for Indigenous Peoples - Funai; and

h) Of the National Institute for Historic and Artistic Heritage - Iphan;

II - By seven representatives of agencies or organisations representing indigenous peoples, traditional communities and traditional farmers, namely:

a) Two appointed by the National Council of Traditional Peoples and Communities-CNPCT;

b) Two appointed by the National Council for Sustainable Rural Development - Condraf;

c) Two appointed by representatives of indigenous peoples and organizations members of the National Council for Indigenous Policy - CNPI; and

d) One representative of the indigenous population, traditional community or traditional farmer indicated by the National Council for Food and Nutritional Safety - Consea; and

III - By one representative of the Brazilian Society for the Progress of Science - SBPC.

§ 1 The representatives and their substitutes shall be appointed by the Minister of Environment, after an indication by the respective agencies and bodies.

§ 2 The representatives and substitutes shall have a two-year term, renewable for an equal period.

§ 3 With the impediment or removal of its Chairman, the Managing Committee shall be

chaired by the substitute representative of the Ministry of Environment.

§ 4 Participation in the FNRB Managing Committee is considered of relevant public interest and shall not be remunerated.

§ 5 In order to meet the provisions made in item IV article 10 of Law No. 13,123, 2015, the representatives' travel and accommodation expenses mentioned in the "*caput*" shall be covered by the FNBR.

§ 6 The Ministry of Environment may cover the costs mentioned in §5 for the first two years of operation of the FNBR.

§ 7 The Managing Committee may invite other representatives, without the right of vote, to participate in its meetings.

Article 98. It is the responsibility of the Managing Committee to:

I - Decide on the management of monetary resources deposited into the FNRB, in compliance with the guidelines for application of resources established by the CGen;

II - Establish, annually, the percentage of monetary resources deposited into the FNRB deriving from economic exploitation of finished product or reproductive material resulting from access to genetic heritage from "*ex situ*" collections, which shall be allocated for the benefit of these collections;

III – Approve the FNRB Operations Manual, establishing conditions and procedures for the financial execution and implementation of resources, including the collection of revenue and the recruitment, implementation, monitoring and evaluation of actions and activities supported by the FNRB;

IV – Approve the quadrennial operating plan and review it biennially;

V - Approve actions, activities and projects to be supported by the FNRB;

VI - Decide on hiring studies and research by the FNRB;

VII – Approve annual reports on:

a) Activities and financial execution;

b) Performance of the financial institution;

VIII - Establish cooperation instruments, including with the States, the Federal District and with Municipalities;

IX - Establish cooperation instruments and transfer of resources with national public institutions for research, education and technical support, including with financial support of the FNRB, to monitor the actions and activities supported by the FNRB; and

X - Develop and approve its internal regulations.

Sole paragraph. The percentage mentioned in item II of the "*caput*" shall not be less than sixty percent nor greater than eighty percent.

Article 99. The budgetary funds of the FNRB shall be kept in a Federal financial institution, responsible for the administration and financial implementation of the resources and the operationalization of the Fund.

§ 1 The depository financial institution must also compensate the liquid assets of the Fund, by at least the average reference rate of the "*Sistema Especial de Liquidacao e de Custodia*" (Special System for Settlement and Custody) - Selic.

§ 2 The obligations and responsibilities of the financial institution, as well as its remuneration shall be defined in the contract.

Article 100. The National Programme for Benefit-Sharing - PNRB, established by article 33 of Law No. 13,123, 2015, aims to promote the:

I - Conservation of biological diversity;

II - Recovery, creation and maintenance of "*ex situ*" collections of genetic heritage samples;

III - Prospection and qualification of associated human resources with the use and conservation of genetic heritage or associated traditional knowledge;

IV - Protection, promotion of use and recovery of associated traditional knowledge;

V - Implementation and development of activities related to the sustainable use of biological diversity, its conservation and benefit-sharing;

VI - Encourage research and technological development associated with genetic heritage and associated traditional knowledge;

VII - Survey and inventory genetic heritage, considering situation and degree of variation of existing populations, including those of potential use and, when feasible, evaluating any threat to them;

VIII - Support the efforts of indigenous peoples, traditional communities and traditional farmers in the sustainable management and conservation of genetic heritage;

IX - Conservation of wild flora;

X - Development of an efficient and sustainable conservation system ""*ex situ*"" and "*in situ*" and development and transfer of appropriate technologies for this purpose viewing to improve the sustainable use of genetic heritage;

XI - Monitoring and maintenance of viability, of the degree of variation and of the integrity of the genetic heritage maintained by collections;

XII - Adoption of measures to minimize or, if possible, eliminate threats to genetic heritage;

XIII - Development and maintenance of the various farming systems that favour the sustainable use of the genetic heritage;

XIV - Development and implementation of the Plans for Sustainable Development of Traditional Populations or Communities; and

XV - Other actions related to access to genetic heritage and associated traditional knowledge, as defined by the FNRB Managing Committee.

§ 1 The FNRB may support projects and training activities of staff of the agencies and bodies referred to in §2 article 14.

§ 2 The FNRB may support projects and activities related to the elaboration of community protocols.

Article 101. The FNRB resources must be employed in the PNRB to support actions and activities that promote the objectives referred to in article 100, through covenants, terms of partnership, of collaboration or promotion, agreements, adjustments or other instruments for cooperation and transfer of resources provided for in law.

Sole paragraph. The FNRB resources may also be allocated for:

I - The analysis, supervision, management and monitoring of the actions, activities and projects supported;

II - The remuneration and covering of expenses of the financial institution concerning the administration of the Fund.

Article 102. The Ministry of Environment shall exercise the function of Executive Secretariat of the FNRB Managing Committee and provide the technical and administrative support necessary for the FNRB's operation and implementation of the PNRB.

CHAPTER VIII
TRANSITIONAL PROVISIONS ON THE APPROPRIATENESS AND THE LAWFULNESS OF ACTIVITIES

Article 103. Must meet the terms of Law No. 13,123, 2015, and this Decree, within one year as of the date of availability of the registry by CGen, the user that carried out, as of the 30th of June, of 2000, the following activities in accordance with the Provisional Measure No. 2,186-16, of the 23rd August 2001:

I - Access to genetic heritage or associated traditional knowledge; and

II - Economic exploitation of finished product or reproductive material resulting from access to genetic heritage or associated traditional knowledge.

§ 1 For the purposes of the provisions made in the "*caput*", the user, subject to article 44 of Law No. 13,123, 2015, shall adopt one or more of the following measures, as applicable:

I - Registering the access to genetic heritage or associated traditional knowledge;

II - Notifying the finished product or reproductive material object of economic exploitation, in accordance with Law No. 13,123, 2015 and this Decree;

III - Apportioning the benefits relating to economic exploitation carried out as from the date of entry into force of Law No. 13,123, 2015 in accordance with Chapter V of the Law and Chapter V of this Decree, except when it was made under the terms of Provisional Measure No. 2,186-16, 2001.

§ 2 In case of item III §1, the benefit-sharing agreed upon under the terms of Provisional Measure No. 2,186-16, 2001, shall be valid for the period stipulated in the contract for use of genetic heritage and benefit-sharing or the benefit-sharing project agreed upon by the CGen.

Article 104. Shall make adjustments in accordance to the terms of Law No. 13,123, 2015, and this Decree, within one year of the date of availability of the registry by the CGen, the user who, between the 30th of June of 2000 and the date of entry into force of Law No. 13,123, 2015, 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 resulting from access to genetic heritage or associated traditional knowledge, referred to in the Provisional Measure No. 2,186-16, 2001;

III - Overseas shipment of a genetic heritage sample; or

IV - Disclosure, transmission or retransmission of data or information that integrates or constitutes associated traditional knowledge.

§ 1 The regularization referred to in the "*caput*" is conditional to the signature of a Term of Commitment.

§ 2 In case of access to genetic heritage or associated traditional knowledge solely for purposes of scientific research, the user shall be exempted from signing the Term of Commitment, regularizing through registration or authorization of the activity, as the case may be.

§ 3 The registration and authorization referred to in §2 discharges the enforceability of the administrative sanctions provided for in Provisional Measure No. 2,186-16, 2001, and those specified in articles 15 and 20 of Decree No. 5,459, 7th June 2005, provided that the infringement has been committed until the day before the date of entry into force of the Law No. 13,123, 2015.

§ 4 For INPI adjustment purposes of the patent applications filed during the term of the Provisional Measure No. 2,186-16, 2001, the applicant shall submit the receipt of registration or authorization referred to in this article.

§ 5 The user that carried out activities in disagreement with the Provisional Measure No. 2,186-16, 2001, even though obtaining authorization during the duration of the Provisional Measure, may, at one's discretion, participate in the regularization process provided for in article 38 of Law No. 13,123, 2015.

§ 6 For the purposes of the provisions made in §5, the contract for use of genetic heritage and benefit-sharing or the benefit-sharing project agreed upon by the CGen shall integrate the Term of Commitment.

CHAPTER IX
FINAL PROVISIONS

Article 105. For the purpose of the provisions made in section XVII article 2 of Law No 13,123, 2015, the inputs used in agricultural activities are intermediate products.

Sole paragraph. Are considered as inputs to agricultural activities the goods that are consumed in the production activity or undergo modifications, such as wear, damage or loss of physical or chemical properties, due to the action directly exerted on the product in manufacturing, as long as they are not included in the fixed assets.

Article 106. The CGen may create a database for voluntary registration of prior informed consents granted or denied by the holders of associated traditional knowledge.

Article 107. The following tests, exams and activities, when not an integral part of research or technological development, do not configure access to genetic heritage as referred to in Law No. 13,123, 2015:

I - Filiation or paternity test, sexing technique and karyotype or DNA analysis and other molecular analysis for identification of a species or specimen;

II - Tests and clinical diagnostic examinations for the direct or indirect identification of etiological agents or hereditary diseases in an individual;

III - Extraction, by milling method, crushing or bleeding that results in fixed oils;

IV - Purification of fixed oils resulting in a product whose characteristics are identical to those of the original raw material;

V - Tests which aim to assess rates of mortality, growth or multiplication of parasites, pathogens, pests and disease vectors;

VI - Comparison and extraction of genetic origin information available in national and international databases

VI – Processing extracts, physical separation, pasteurization, fermenting, pH assessment, total acidity, soluble solids, bacteria and yeasts, moulds, faecal coliforms count and totals of genetic heritage samples; and

VII - Physical, chemical and physical-chemical characterization for determining the nutritional information of food;

Sole paragraph. Does not configure access to genetic heritage the reading or querying of information on genetic origin available in national and international databases, even though they are an integral part of research and technological development.

Article 108. The vegetable or animal improvement conducted by indigenous people, traditional community or traditional farmer is exempt from registration pursuant to the terms of item VI of article 10 of law No. 13,123, 2015.

Article 109. In order to meet the provisions made in §2 article 12 of law No. 13,123, 2015, the user, at the time of application for intellectual property right, should inform if there was access to genetic heritage or associated traditional knowledge, as well as if there is a registry for access in accordance with this Decree.

Article 110. Verifying the absence of the registration or its cancellation, the Ibama or the CGen shall notify the agency and the body referred to in article 109, so they may notify the applicant for intellectual property right to submit receipt of registration within thirty days, under penalty of dismissal of the application for the intellectual property right.

Sole paragraph. In case of lack of registration, observation of the one year period referred to in articles 36, 37 and 38 of Law No. 13,123, 2015, applies.

Article 111. The CGen, with the collaboration of the institutions accredited pursuant to the terms of item V article 15 of Provisional Measure No. 2,186-16, 2001, shall register in the system the authorizations already issued.

Article 112. Is considered as approved, based on the "*Nomenclatura Comum do Mercosul*" (Standard Mercosur Classification) - NCM, the Benefit-Sharing Classification List referred to in §9 article 17 of Law No. 13,123, 2015, annexed to this Decree.

Sole paragraph. The list referred to in the "*caput*" shall have a sampling nature and does not exclude the application of the rules for incidence of benefit-sharing provided for in articles 17 and 18 of Law No. 13,123, 2015.

Article 113. The Ministry of Agriculture, Livestock and Supplies shall draw up, publish and periodically review, the reference list of animal and plant species domesticated or cultivated

that were introduced into the national territory, used in agricultural activities.

Sole paragraph. The list referred to in the "*caput*" shall indicate the species forming spontaneous populations and the varieties that have acquired distinctive characteristic properties in the country.

Article 114. A joint Act sanctioned by the Ministers of Agriculture, Livestock and Supplies and the Minister of Agricultural Development shall disclose a list of traditional local or creole varieties and locally adapted or creole breeds.

Article 115. The Ministry of Health and the Ministry of Environment, in a joint Ordinance shall discipline a simplified procedure for the shipment of genetic heritage related to the situation of "*Emergencia em Saude Publica de Importancia Nacional*" (Emergency in Public Health of National Importance) - ESPIN, referred to in Decree No 7,616, 17th November 2011.

§ 1 The shipment referred to in the "caput" shall be destined exclusively to research and technological development declared in the Terms of Transfer of Material, necessarily linked to the epidemiological situation, being prohibited the use of the genetic heritage accessed for other purposes.

§ 2 The benefits deriving from economic exploitation of finished product or reproductive material resulting from research or technological development referred to in this article shall be allocated in accordance with Law No. 13,123, 2015, and this Decree.

Article 116. The Ministry of Environment, in coordination with the Ministry of Foreign Affairs, may sign cooperation agreements and covenants with agencies in other countries for the purpose of compliance with the provisions of Law No. 13,123, 2015.

Article 117. The provisions of this Decree do not exclude the jurisdiction of the Ministry of Science, Technology and Innovation to supervise and control the activities of scientific research in the national territory, when carried out by foreigners, involving their entry into the Country.

Article 118. The user who required any intellectual property right, economically exploited finished product or reproductive material or released final or partial results, in scientific or communication circles, between the 17th of November of 2015 and the date of availability of the register, should register the activities referred to in article 12 of Law No. 13,123, 2015, and notify the finished product or the reproductive material developed as a result of the access.

§ 1 The deadline for registration or notification referred to in the "*caput*" shall be of 1 (one) year, as of the date of availability of the register by the CGen.

§ 2 With the timely notification or registration, the user shall not be subject to administrative sanction.

Article 119. Hereby are now repealed:

I - Decree No. 3,945, 28th September 2001;

II - Decree No. 4,946, 31st December 2003;

III - Decree No. 5,459, 7th June 2005;

IV - Decree No. 6,159, 17th July 2007; and

V - Decree No. 6,915, 29th July 2009.

Article. 120. This Decree shall enter into force on the date of its publication.

Brasilia, 11th May 2016; 195th of the independence and 128th of the Republic.

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ANNEX
Classification List of Benefit-Sharing

Section	Chapters	NCMs
Section I. LIVE ANIMALS AND ANIMAL PRODUCTS	Chapters 1 to 5	01.01 to 0508.00.00
Section II. VEGETABLE PRODUCTS	Chapters 6 to 14	06.01 to 14.04
Section III. ANIMAL OR VEGETABLE FATS AND OILS; PRODUCTS OF THEIR DISSOCIATION; PREPARED EDIBLE FATS; ANIMAL OR VEGETABLE WAXES	Chapter 15	15.01 to 15.15
Section IV. PRODUCTS FROM THE FOOD INDUSTRIES; BEVERAGES, ALCOHOLIC LIQUIDS AND VINEGARS; TOBACCO AND MANUFACTURED TOBACCO SUBSTITUTES	Chapters 16 to 24	1601.00.00 the 24.03
Section VI. CHEMICAL INDUSTRY PRODUCTS OR OF RELATED INDUSTRIES	Chapters 28 to 38	28.01 the 38.25
Section VII. PLASTICS AND ARTICLES THEREOF; RUBBER AND ARTICLES THEREOF	Chapters 39 to 40	39.01 to 4017.00.00
Section VIII. SKINS, HIDES, SKINS WITH FUR AND ARTICLES OF SUCH MATERIALS; SADDLERY OR HARNESS ARTICLES; TRAVEL GOODS, HANDBAGS AND SIMILAR ARTICLES; TRIPE ARTICLES	Chapters 41 to 43	41.01 to 43.03
Section IX. WOOD, CHARCOAL AND WOODEN ARTICLES; CORK AND ARTICLES THEREOF; ARTICLES OF STRAW AND PLAITING MATERIALS;	Chapters 44 to 45	44.01 the 45.04

*Unofficial translation

Section	Chapters	NCMs
Section X. WOOD PULP OR OF OTHER FIBROUS CELLULOSIC MATERIAL; PAPER OR PAPERBOARD FOR RECYCLE (WASTE AND SCRAP); PAPER OR PAPERBOARD AND ARTICLES THEREOF	Chapters 46 to 49	46.01 to 4907.00
Section XI. TEXTILE MATERIALS AND ARTICLES THEREOF	Chapters 50 to 63	5001.00.00 to 63.10
Section XII. SHOES, HATS AND ARTIFACTS OF SIMILAR USE, UMBRELLAS, SUN SHADES, WALKING STICKS, WHIPS AND PARTS THEREOF; PREPARED FEATHERS AND PARTS THEREOF; ARTIFICIAL FLOWERS; HAIR ARTICLES	Chapters 64 to 67	64.01 to 67.04
Section XIV. NATURAL OR CULTURED PEARLS, PRECIOUS OR SEMI-PRECIOUS STONES AND SIMILAR, PRECIOUS METALS, METALS PLATED OR CLAD WITH PRECIOUS METALS AND ARTICLES THEREOF; COSTUME JEWELLERY; COINS	71. Natural or cultured pearls, precious or semi-precious stones and similar, precious metals, metals plated or clad with precious metals and articles thereof; costume jewellery; coins	- 71.01. Natural or cultured pearls, even if crafted or arranged but not strung, mounted or set; natural or cultured pearls temporarily strung for convenience of transport. - 71.16. Articles of natural or cultured pearls, of precious or semi-precious stones or of synthetic or reconstructed stones.
Section XX. GOODS AND MISCELLANEOUS PRODUCTS	Chapters 94 to 96	94.01 to 96.12

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Link to the full text: https://www.planalto.gov.br/ccivil_03/_ato2015-2018/2016/decreto/d8772.htm

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