ACCESS AND BENEFIT SHARING LAW IN BRAZIL

Access to genetic heritage
Protection and access to associated traditional knowledge
Sharing of benefits for conservation and sustainable use of biodiversity

LAW Nº13,123
Dated of May 20, 2015

DECREE Nº. 8,772
Dated of May 11, 2016

The New Brazilian Legislation on Access to the Biodiversity

Access to genetic heritage
Protection and access to associated traditional knowledge
Sharing of benefits for conservation and sustainable use of biodiversity

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Introduction

Brazil became a Party to the Nagoya Protocol on June 2, 2021, once again assuming its important role in international discussions on ABS - Access and benefit sharing. The Nagoya Protocol is the main international instrument, which binds the countries Parties to the implementation of one of the main objectives of the Convention on Biological Diversity - CBD.

The CBD was signed during the United Nations Conference on Environment and Development held in Rio de Janeiro ("ECO 92"). The Convention was based on three main points: the conservation of biological diversity, the sustainable use of biodiversity and the fair and equitable sharing of benefits arising from genetic resources. Furthermore, the CBD, which currently has 196 signatory Parties, recognized the sovereignty of States as the competent authority to determine the procedures for accessing their genetic resources, which are subject to national legislation.

In Brazil, the issue was dealt with by Provisional Measure 2,186/2001 and its regulations, which remained in force for about 15 years. These rules on access to genetic heritage, associated traditional knowledge and benefit sharing were criticized by several actors, including their users and providers, which resulted in the enactment of the "New Legal Framework for Biodiversity". Law 13,123/2015 entered into force on November 17, 2015 and came with the promise of reducing the bureaucracy of the system of access to genetic heritage, strengthening the protection of associated traditional knowledge and ensuring fair and equitable benefit-sharing for the conservation of the Brazilian biodiversity.

Since 2009 working on ABS, GSS has consolidated itself in the market as a reference in the field. GSS works very closely with its customers and partners and has been innovating every day, aiming to improve its work.

With this in mind, the GSS published the 1st version of the compilation of Brazilian standards in 2016, and this year it has the support of CRODA in the organization of this booklet. Founded in 1925, Croda uses smart science to create high-performance ingredients and technologies that improve lives. Its ingredients provide customers with vital functionality with a low carbon footprint, as well as high-impact solutions to help them achieve their sustainability goals and those of society at large, and above all, it recognizes the potential of Brazilian biodiversity and knowledge of local communities for sustainable innovation.

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A GSS Carbon and Bioinnovation is a Brazilian company based in Curitiba (PR), São Paulo (SP) and Brasília (DF) formed by professionals with experience in national and international projects involving biodiversity, climate change and corporate sustainability.

The GSS team brings together the knowledge acquired in working with several companies in the public and private sector, providing its clients with strategic thinking and competitive capacity aligned with current challenges and opportunities.

The notion of corporate success has changed. It is not enough to achieve expressive numbers and results. Responsible companies need to be aware of the impacts generated throughout the production chain, from the extraction of raw material to the moment the product is discarded. This demand comes from civil society, the government and major players in the international community who constantly meet to discuss good practices and agreements. At GSS, we closely monitor all these movements to act quickly and efficiently, helping companies to achieve results in the best possible way: respecting our planet, mitigating their GHG emissions and valuing Brazilian biodiversity. Thus, we walk hand in hand with our customers and partners who are concerned with growing more sustainably.

We believe in our role, which is why coherence between speech and action is the fundamental premise of GSS.

The activities of GSS are broad and include:

Management Strategies for Sustainable Use of Biodiversity.

- Guidance on best practices in Benefit Sharing and Community Relations.
- Strategic monitoring with CGEN and competitive intelligence services.
- Monitoring national and international meetings, including the Conference of the Parties (COP).
- Support for designing a Benefit Sharing Policy.
- Participatory diagnosis of local communities.

- Field activities for managing the use of Biodiversity.
- Monitoring of projects and indicators.
- Prospecting for supplies, raw materials and potential communities that provide genetic resources.
- Participatory construction of community protocols.
- Community development, strengthening of local associations and cooperatives.

Diagnosis and risk assessment on the use of biodiversity.

- Risk assessment of activities involving the use of ingredients by the company in its products. Passive and preventive.
- Assessment of biodiversity supplies to identify the center of origin and any applicable national or international legislation.
- Evaluation of supplies, ingredients, raw materials and bibliographic references in order to identify access to associated traditional knowledge.
- Analysis of international legislation on access and benefit sharing and framework of activities under the Nagoya Protocol.

Process of registration, notification, adequacy and regularization of access with SisGen.

- Development of activities and strategies related to the use of biodiversity, access to genetic heritage, associated traditional knowledge and benefit sharing.
- Adequacy and regularization of activities carried out in disagreement with MP 2.186/01 under the terms of the new Biodiversity Law.
- Registration and Notification of research and products developed after the new Biodiversity Law came into force.

Intermediation and monitoring of Benefit Sharing Projects through the Environmental Projects Showcase – VBIO.

VBIO is a bioeconomy platform that assists organizations in capturing and allocating resources for Brazilian biodiversity projects. Founded in 2016, at COP 13 in Mexico, in 2022 it will once again be part of the integrated action of GSS.

Through its relationship network - which involves project proponent institutions; a team of specialists that unites technical knowledge on biodiversity and ESG, and covers all corporate areas for the development of projects; and a rigorous system of governance and compliance processes - VBIO selects the most inspiring projects to receive exclusive resources from Corporate Social Responsibility and Benefit Sharing actions under the Biodiversity Law.

Today, VBIO sums up R$ 33.5 million in mapped projects, of which R$ 10 million in quotas already reserved by supporters. These resources have the potential to contribute to improving the quality of life of more than 75,000 people - whether through education, income generation or food security - and to promote the protection of 130 native species of fauna and flora in the six Brazilian biomes. – including marine ecosystems.

Today, there are almost 600 registered organizations that are part of the VBIO network and that have already discovered the transformative potential of biodiversity.

CRODA

Smart science to improve lives™

CRODA is driven by an unwavering focus on its clients, collaborative work, a proactive attitude, and a capacity for thinking outside the box. We consistently seek to bring together our knowledge, passion, and entrepreneurial spirit in making a **positive impact on the environment and society.** CRODA strives to establish itself as the world's most sustainable supplier of innovative ingredients and provide solutions to some of the world's biggest challenges while helping our customers achieve their sustainability goals..

Innovation is at the heart of our business and CRODA's success depends on our ability to provide clients with innovative solutions. Our approach to innovation combines internal R&D with client collaboration and open partnerships in order to accelerate the development of disruptive technologies.

Our business is sustained by a focus on sustainability, which is a driving factor in everything we do. As we continue to fulfill **our 2030 Climate, Land and People Positive Commitment**, we will make a significant contribution to implementing targets established under the United Nations Sustainable Development Goals. This allows us to stand out on the level of support provided to our clients in meeting sustainability targets, aggregating value for both clients and our shareholders.

CLIMATE POSITIVE

We will continue to seek to **reduce our carbon footprint and increase our use of bio-based raw materials.** The benefits of using our ingredients will allow us to store more carbon than we emit during operations and throughout our supply chain.

LAND POSITIVE

CRODA's products allow us to preserve more land than we use to grow our bio-based raw materials. Our innovation will allow clients to preserve biodiversity and mitigate the impact of climate change and land degradation. **CRODA recognizes the benefits that its technologies can offer in protecting biodiversity and nature** and has initiated a program for measuring impacts in partnership with CISL (Cambridge Institute for Sustainability).

PEOPLE POSITIVE

We continuously strive to make a positive impact on the lives of our own employ-

ees and individuals around the world by developing **ingredients that promote health and well-being, as well as encouraging and providing incentives for diversity throughout our company.**

Summary

Legislation

Law n° 13,123, dated May 20, 2015

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 – 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 that 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;

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.

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.

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. [1]

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 – 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.

[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.

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
Katia Abreu
Armando Monteiro
Nelson Barbosa
Tereza Campello
João Luiz Silva Ferreira
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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.

Decree n°. 8772, from May 11th, 2016

Regulates Law No. 13,123, of May 20th, 2015, which 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.

The PRESIDENT OF THE REPUBLIC, using the powers conferred upon her by Art. 84, caput, item IV and VI, point "a" of the Constitution, and in view of the provisions of Law No. 13,123, from May 20th, 2015,

DECREES:

CHAPTER I

Preliminary Provisions

Art. 1 This Decree regulates Law No 13,123, from May 20th, 2015, which provides for access

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

Paragraph 1. It is considered part of the genetic heritage on national territory for the purposes of this Decree, the microorganism that has been isolated from the national territory substrates, territorial sea, exclusive economic zone or continental shelf.

Paragraph 2. The microorganism will not be considered national genetic heritage when the user, urged by the competent authority, proves:

I - that it was isolated based on substrates other than the national territory, territorial sea, exclusive economic zone or continental shelf; and

II - the regularity of its import.

Paragraph 3. The plant and animal species introduced in the country will only be considered genetic heritage found in situ within the national territory when forming spontaneous populations which have acquired distinctive characteristics in the country.

Paragraph 4. It is also considered genetic heritage found in situ the variety of species introduced in the country 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, which is not substantially similar to commercial cultivars.

Art. 2. The following activities are subject to the requirements of Law No. 13,123, 2015 , and to this Decree:

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

II - shipment of genetic heritage samples to foreign countries; and

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

Paragraph 1. For the purpose of provisions of item II of the *caput*, the practice of any activity of research or technological development that is carried out after November 17th, 2015, will be, regardless of the date of its beginning, considered as access performed after the entry into force of Law No. 13,123, 2015.

Paragraph 2. Activities carried out between June 30th, 2000 and November 17th, 2015 shall comply with the provisions of Chapter VIII of this Decree.

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

Paragraph 1. For the purposes of the *caput*, and when asked by the competent authority, the user must certify that all stages of access have been concluded before June 30th, 2000.

Paragraph 2. The evidence referred to in Paragraph 1 shall take place through:

I - In case of research:

a) publishing of articles in a scientific journal;

b) communication in scientific events;

c) deposit of patent application;

d) report of conclusion of research before with a public funding agency or entity; or

e) publication of completion of course work, dissertation, doctoral theses; and

II - in case of technological development:

a) filing of patent application;

b) registration of cultivar;

c) product registration with public agencies; or

d) proof of commercialization of the product.
Paragraph 3. in case of economic exploitation of finished or reproductive materials product, in addition to the provisions of sections I and II of paragraph 2, the user must prove that access completed was sufficient to obtain finished product or reproductive material object of economic exploitation.
Paragraph 4. For the purposes of paragraph 3, it is considered that the concluded access was sufficient for the obtention of the finished product or reproductive material object of economic exploitation when there has been no research activity or technological development after June 30th, 2000.
Paragraph 5. The Board of Genetic Heritage Management shall:
I - establish other means of evidence than those set out in items I and II of Paragraph 2; and
II - issue, upon request and proof, document certifying that the user falls into the category provided for in this article.

CHAPTER II

The Genetic Heritage Management Council – CGEN

Section I - General provisions

Art. 4 The Genetic Heritage Management Council - CGen, collegiate body of deliberative, legislative, advisory and appellate character has the following obligations:
I - to coordinate the preparation and implementation of policies for the management of access to genetic heritage, associated traditional knowledge and benefit sharing;
II - to establish:
a) technical standards;
b) guidelines and criteria for drafting and compliance with Benefit Sharing agreement; and
c) criteria for database creation for registering information on genetic heritage and associated traditional knowledge;
III - to monitor, in conjunction with federal agencies, or by agreement with other institutions, the activities of:
a) access and sample shipment containing genetic heritage; and
b) access to associated traditional knowledge;
IV - to decide on:
a) national accreditation of institution that holds *ex situ* collection of samples containing genetic heritage; namely:
1. public; or
2. non-profit private to keep popular herbals or community seed banks; and
b) the accreditation of national public institution to be responsible for database creation and maintenance mentioned in item X;
V - to certify the access regularity to genetic heritage or associated traditional knowledge referred to in Chapter IV of Law No. 13,123, of 2015;
VI - to register the receipt of notification of finished product or reproductive material and the presentation of benefit sharing agreement, pursuant to Art. 16 of Law No. 13,123, of 2015;

VII - to promote public debates and consultations on the topics dealt with in Law No. 13,123, of 2015;
VIII - to act as a higher court of appeal in relation to accredited institution decision and actions resulting from the application of Law No. 13,123, of 2015;
IX - to establish guidelines for the use of funds of the National Fund for Benefit Sharing - FNRB, as benefit sharing;
X - to create and maintain database related:
a) to access entries to genetic heritage or associated traditional knowledge and shipping;
b) to authorization of access to genetic heritage or associated traditional knowledge and shipping;
c) to terms of instruments and material transfer for sample submission and shipping;
d) to *ex situ* collections of accredited institutions that contain samples of genetic heritage;
e) to notifications of finished product or reproductive materials;
f) to Benefit Sharing agreements; and
g) to certificates of regularity of access;
XI - to inform federal agencies for the protection of rights from indigenous peoples, traditional communities and traditional farmers on registry of access to associated traditional knowledge; and
XII - to approve its bylaws, which will provide at least about:
a) organization and functioning of its meetings;
b) operation of Executive Secretariat;
c) procedure for appointment of its directors;
d) removal, prevention, suspicion and chances of interests conflict of directors;
e) publication of its technical deliberations and standards; and
f) composition and operation of Thematic and Sectoral Chambers.

Sole paragraph. CGen may, at the user's request, issue an internationally recognized certificate of compliance that will serve as proof that activities of genetic heritage or associated traditional knowledge were carried out according to provisions of Law No. 13,123, of 2015, and this Decree.

Art. 5 Without prejudice to the system established in Chapter IV of this Decree, CGen shall maintain its own system of traceability of activities resulting from access to genetic heritage or associated traditional knowledge, including those related to economic exploitation.

Paragraph 1. Under the terms of Art. 7 of Law No. 13,123, of 2015, the system provided for in *caput* will be managed by the Executive Secretariat of CGen and shall provide the needed information for the traceability of activities resulting from access to genetic heritage or associated traditional knowledge contained in databases of the systems:
I - of protection and registration of cultivars, of seeds and seedlings, of products, of agricultural establishments and inputs, of information on the international transit of agricultural products and inputs from the Ministry of Agriculture, Livestock and Supply;
II - of import and export registration under the Integrated Foreign Trade System - SISCOMEX, established by Decree No. 660 from September 25th, 1992;
III - of information on curricula, research groups, registered institutions on Lattes Platform of National Council for Scientific and Technological Development - CNPq;
IV - of Information on research and commercial release of genetically modified organisms and derived from the National Commission for Technical Biosafety- CTNBio of the Ministry of Science, Technology and Innovation;

V - of register of products of the National Health Surveillance Agency- Anvisa;
VI - of granting and guarantee of intellectual property rights of National Institute for Industrial Property - INPI;
VII - of national register of social information of Ministry of Social Development and Fight against Hunger; and
VIII - of information about cultural heritage of the National System of Information and Cultural Indicators - SNIIC, of the Ministry of Culture.

Paragraph 2. Organs and entities addressed by this article will adopt necessary measures to ensure access to information on the traceability system and the Ministry of Environment will adopt the necessary measures for the integration of information contained in the databases referred to in Paragraph 1.

Paragraph 3. If there is an impossibility of adopting the measures provided for in Paragraph 2. the information shall be directed to CGen within thirty days from the request.

Paragraph 4. CGen may also:
I - request additional information to agencies and entities provided in Paragraph 1;
II - require to other organs and entities of federal public administration information it deems necessary for the traceability of activities resulting from access to genetic heritage or associated to traditional knowledge; and
III - adopt measures to ensure access to information on the traceability system and the databases integration with several agencies and entities from those set forth in items I to VIII, Paragraph 1 of *caput*.

Paragraph 5. Organs and entities of federal government which provide confidential information to CGen shall state that fact explicitly, specifying, where appropriate, the classification of information to the extent and period of secrecy, according to provisions of Law No. 12,527 from November 18th, 2011, or in specific legislation.

Paragraph 6. CGen Executive Secretariat shall ensure the legal confidentiality of information, respecting the classification of information as to the extent and period of secrecy, where applicable.

Paragraph 7. For the purposes of *caput*, CGen shall have access to data systems of Federal Revenue of Brazil contained in the public domain registration and that do not inform the economic or financial situation of taxpayers.

Art. 6 CGen will work through:
I - Plenary;
II - Thematic Chambers;
III - Sectoral Chambers; and
IV - Executive Secretariat.

Section II – Plenary

Art. 7 CGen Plenary shall be composed of twenty one counselors, twelve representatives of agencies of federal government and nine representatives of civil society, distributed as it 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 Supply;
f) Ministry of Culture;
g) Ministry of Social Development and Fight against Hunger;
h) Ministry of Defense;
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 entities or organizations in the business sector, as it follows:
a) one appointed by the National Industry Confederation - CNI;
b) one appointed by the National Agriculture Confederation - CNA; and
c) an alternate and successively by the CNI and the CNA indicated;
III - three representatives of entities or organizations in academic sector, as follows:
a) one appointed by the Brazilian Society for Science Progress – SBPC;
b) one appointed by the Brazilian Anthropological Association - ABA; and
c) one appointed by the Brazilian Academy of Sciences - ABC; and
IV - three representatives of entities or organizations representing indigenous peoples, traditional communities and traditional farmers, as it follows:
a) one appointed by representatives of peoples and traditional communities and their organizations of the National Council of Traditional Peoples and Communities - CNPCT;
b) one appointed by representatives of family farmers and their organizations of the National Council for Sustainable Rural Development - Condraf; and
c) one appointed by representatives of indigenous peoples and organizations members of the National Council of Indigenous Policy - NCIP.
Paragraph 1. CGen shall be chaired by the director member of Environment Ministry and in his impediments or absences, by his alternate.
Paragraph 2. The representations of this art. shall be composed by one member and two alternates each, which will be indicated by the holder of federal public administration and by their legal representatives of entities and civil society organizations.
Paragraph 3. Members of CGen and alternates shall be appointed by act of the Environment Minister, within thirty days from the receipt of the information.
Paragraph 4. CGen Plenary will meet with the presence of, at least, eleven members, and its decisions shall be taken by simple majority.
Paragraph 5. The duties of directors shall not be paid and the exercise is considered relevant public service, leaving public agencies and representative civil society organizations defray the travel expenses and accommodation of their representatives.
Paragraph 6. It will be up to the Union defray the travel expenses and accommodation of directors referred to in section IV of *caput*.

Section III - Thematic Chambers and Sectoral Chambers

Art. 8 Thematic Chambers will be created by CGen to support the decisions of the Plenary as of technical discussions and proposals on specific themes or areas of knowledge related to access and benefit sharing.
Paragraph 1. The act of creation of Thematic Chambers shall provide for its duties, duration and composition, which shall observe the proportion of:

I - fifty percent of representatives of agencies and entities of Federal Government with responsibilities related to the theme of the Chamber;
II - Twenty-five percent of user representative organizations; and
III - Twenty-five percent of organizations representing associated traditional knowledge providers.
Paragraph 2. CGen may create a special Thematic Chamber to analyze and support the judgment by the Plenary of appeals of last instance..
Art. 9 The Sectoral Chambers will be created by CGen to support the decisions of the Plenary from technical discussions and proposals of interest to the business and academic sectors, as well as indigenous peoples, traditional communities and traditional farmers.
Sole paragraph. The act of creation of Sectorial Chambers shall provide for its atributions, duration and composition, which shall observe the parity of representation of the organs and entities of the federal government with competence related to respective House and corresponding civil society sector.
Art. 10. Members of Thematic Chambers and Sectoral Chambers shall be appointed by the directors of CGen Plenary considering the formation, practice or notorious knowledge in related field of the competence of the House.

Section IV - About Executive Secretary

Art. 11. The Executive Secretariat of CGen is responsible for:
I - providing technical and administrative support to CGen Plenary and its chambers;
II - promoting education and processing procedures to be submitted for CGen decision;
III - issuing, in accordance with CGen resolutions, the acts and decisions of its competence;
IV - promoting, in accordance with CGen resolutions, accreditation or disqualification of:
a) national institution which keeps *ex situ* collection of samples containing the genetic heritage; and
b) national public institution to be responsible for creation and maintenance of a database that addresses the item established in the points of section IX of paragraph 1 of Art. 6 of Law No. 13,123, of 2015; and
V - implement, maintain and operate the systems:
a) of traceability of information related to genetic heritage and associated traditional knowledge, provided for in Art. 5; and
b) provided for in Chapter IV of this Decree.

CHAPTER III

Associated Traditional Knowledge

Art. 12. It is guaranteed the right of participation of indigenous peoples, traditional communities and traditional farmers which create, develop, hold or preserve traditional knowledge in the decision-making process on issues related to access to traditional knowledge and benefit sharing arising from such access.
Paragraph 1. Access to associated traditional knowledge from an identifiable origin is subject to obtaining prior informed consent.

Paragraph 2. Access to associated traditional knowledge of unidentifiable origin does not depend on prior informed consent.
Paragraph 3. Any indigenous population, traditional community or traditional farmer which creates, develops, owns or retains certain associated traditional knowledge is considered the identifiable source of that knowledge, except in case of paragraph 3 from Art. 9 of Law No. 13,123, of 2015.
Art. 13. The indigenous population, traditional community or traditional farmer may refuse to consent access to their associated traditional knowledge of identifiable origin.
Art. 14. The provider of associated traditional knowledge of identifiable source will choose the form of proving their prior informed consent, freely negotiate its terms and conditions as well as those according to the Benefit Sharing agreement, including mode, guaranteed the right of refusing them.
Paragraph 1. The parties may establish a deadline for completion of the registration of access to associated traditional knowledge, object of consent, which may not exceed the time limit provided on Paragraph 2 of Art. 12 of Law No. 13,123, of 2015.
Paragraph 2. The federal bodies and entities of protection of rights, assistance or promotion of activities of indigenous peoples, traditional communities and traditional farmers shall, at the request of holders, assist the activities of obtaining prior informed consent and negotiation of the benefit sharing agreements.
Paragraph 3. For the purposes of Paragraph 2, federal bodies and entities may request technical support from the CGen Executive Secretariat.
Art. 15. Obtention of prior informed consent of providers of associated traditional knowledge shall comply with the traditional forms of organization and representation of indigenous peoples, traditional communities or traditional farmer and its Community protocol, if any.
Art. 16. The user must observe the following guidelines for obtaining prior informed consent:
I - clarification to the indigenous population, traditional community or traditional farmer on:
a) social, cultural and environmental impacts resulting from implementation of activity involving access to associated traditional knowledge;
b) rights and responsibilities of each party in performing activity and on its results; and
c) the right of indigenous peoples, traditional communities and traditional farmers to refuse accessing to traditional knowledge;
II - establishment, together with indigenous peoples, traditional community or traditional farmer, of the modalities for the allocation of benefits, monetary or non-monetary, derived from economic exploitation; and
III - respect for the rights of indigenous peoples, traditional communities and traditional farmers to refuse access to traditional knowledge, during the consent process.
Art. 17. Having been respected he guidelines referred to in Art. 16, the instrument of proof of prior informed consent will be formalized in a language accessible to indigenous population, traditional community and traditional farmer and will contain:
I – the description of historical process for obtaining prior informed consent;
II - the description of traditional forms of organization and representation of indigenous peoples, traditional community or traditional farmer;
III - the purpose of research and its methodology, duration, budget, possible benefits and sources of project funding;
IV - the intended use to associated traditional knowledge to be accessed; and

V – the geographical area covered by the project and indigenous peoples, traditional communities and traditional farmers involved.

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

Art. 18. Access to genetic heritage of traditional local variety or creole or locally adapted race or creole for agricultural activities includes access to associated traditional knowledge of unidentifiable origin that gave rise to the variety or race and does not depend on prior consent of indigenous population, traditional community or traditional farmer that creates, develops, owns and retains the variety or race.

Paragraph 1. Pursuant to subsection XXIV of Art. 2 of Law No. 13,123, of 2015, agricultural activity is considered the activity of production, processing and commercialization of food, beverages, fibers, energy and planted forests.

Paragraph 2. Biofuels, such as ethanol, biodiesel, biogas and electricity cogeneration from biomass processing are included on the concept of energy provided in Paragraph 1. .

Paragraph 3. For activities that do not fall within the concept of agricultural activity, access to genetic heritage of local traditional or creole variety or locally adapted or creole race comprises the associated traditional knowledge that gave rise to the variety or race, and follow the rules for access to traditional knowledge associated provided in Law No. 13,123, of 2015, and in this Decree.

Paragraph 4. In case of access to genetic heritage variety traditional local or creole referred to in *caput*, the user must deposit reproductive material of the variety object of access in *ex situ* collection held by a public institution, unless when the variety has been obtained in its own collection.

Art. 19. To indigenous peoples, traditional communities and traditional farmers which create, develop, hold or preserve traditional knowledge rights are guaranteed the right of using freely or selling products containing genetic heritage or associated traditional knowledge, subject to the provisions of Law No. 9,456 from April 25th, 1997, and Law No. 10,711, from August 5th, 2003.

Paragraph 1. Anvisa, under the powers referred to in Law No. 9,782, from January 26th, 1999, regulates the production and marketing of products referred to in *caput*.

Paragraph 2. Regulations provided for in Paragraph 1 shall establish simplified procedures and will count with participation of indigenous peoples, traditional communities and traditional farmers considering its customs, and traditions.

CHAPTER IV

The National system of genetic heritage and traditional knowledge associate aanagement - Sisgen

Section I - General provisions

Art. 20. It is created the National System of Genetic Heritage and Associated Traditional Knowledge Management - SisGen, an electronic system to be implemented, maintained and operated by the Executive Secretariat of CGen for managing:
I – registration of access to genetic heritage or to associated traditional knowledge, as well as registration of shipment of sample containing genetic heritage to provide services abroad;
II - registration of shipment of sample of genetic heritage and of the Material Transfer Agreement;
III - authorizations for access to genetic heritage or associated traditional knowledge and shipment abroad, for cases referred to in Art. 13 of Law No. 13,123, of 2015;
IV - the accreditation of maintaining institutions of *ex situ* collections containing samples of genetic heritage;
V - notifications of finished product or reproductive materials and Benefit Sharing agreements; and
VI - certificates of regularity of access.
Paragraph 1. The registration must be done prior to:
I - shipping;
II – requirement of any intellectual property right;
III – commercialization of intermediary product;
IV – dissemination of results, final or partial, in scientific or communication means; or
V – notification of finished product or reproductive material developed as a result of access.
Paragraph 2. If there are modifications de facto or de jure in the information provided to SisGen, the user must upgrade their registrations or notification, at least once a year.
Paragraph 3. The update referred to in Paragraph 2 shall also be made to include the information regarding requirement of any intellectual property rights or patent licensing.
Art. 20- A. Pursuant to the provisions of item "c" of item III of Paragraph 1 of art. 6 of Law No. 13,123, of 2015, the CGen may preferentially accredit the National Council for Scientific and Technological Development - CNPq as a national public institution responsible for creating and maintaining the records dealt with in items I and II of the *caput* of art. . 20 of this Decree, in a simplified way, when it comes to accessing genetic heritage or associated traditional knowledge or sending and shipment of sample that contains genetic heritage for the exclusive purpose of research that does not involve economic exploitation.
Sole paragraph. The records mentioned in the *caput* shall contain, at least, the information referred to in items "b" to "e" of item II of the *caput* of art. 22.
Art. 21. The information in SisGen is public, except those that, upon user request, are considered confidential.
Sole paragraph. The request of *caput* shall indicate the relevant legal basis and be accompanied by non-confidential summary.

Section II - On the access registration to genetic heritage or associated traditional knowledge and sample submission registration containing genetic heritage for service abroad

Art. 22. To carry out the access registration to genetic heritage or associated traditional knowledge, natural or legal entity must complete SisGen's electronic form, that will require:
I - user identification;

II - information on the research activities or technological development, including:
a) summary of activities and their objectives;
b) application sector, in case of technological development;
c) expected results or obtained, depending on the time of the registration;
d) responsible staff, including the partner institutions, if any;
e) activities period;
f) identification of genetic heritage in the strictest possible taxonomic level or associated traditional knowledge, as appropriate, in particular:
1. the origin of genetic heritage, including coordinated georeferenced in degree format, minute, and second, the place to get in situ, although they have been obtained from sources *ex situ* or *in silico*; and
2. the indigenous population, traditional community or traditional farmer providers of traditional knowledge, even if the knowledge has been obtained from secondary sources;
g) a declaration of whether genetic heritage is traditional local variety or creole or locally adapted race or creole, or if the species is listed in the official list of endangered species;
h) information of foreign-based institution associated with national institution, in case provided for in item II of Art. 12 from Law No. 13,123, of 2015; and
i) identification of national partner institutions, if any;
III - registration number or previous authorization in case of genetic heritage or associated traditional knowledge accessed from research or technological development carried out after June 30th, 2000;
IV - proof of obtaining prior informed consent in Art. 9 of Law No. 13,123, of 2015, and Art. 17 of this Decree, if applicable;
V - secrecy legal hypothesis recognition request; and
VI - statement, if appropriate, of legal framework in the event of legal exemption or not subject to benefit sharing.

Paragraph 1. When it is not possible to identify the georeferenced coordinate for the place to get in situ referred to in item 1 of item "f" from *caput*'s item II, and only in cases where the genetic heritage was obtained on a date prior to the entry into force of Law No. 13,123, of 2015, the origin may be informed on the basis of more specific possible geographical location, through one of the following:
I - identification of *ex situ* source of getting genetic heritage, with the information contained in the deposit record, when coming from *ex situ* collection; or
II - identification of the database source of genetic heritage with the information contained in the deposit record, when coming from *in silico* database.

Paragraph 2. The access records associated to traditional knowledge should:
I - identify the sources of obtaining the associated traditional knowledge; and
II - inform the georeferenced coordinate of the community, except in case of traditional knowledge of unidentifiable origin.

Paragraph 3. If it is not possible to inform the georeferenced coordinates referred to in item II of Paragraph 2., the user must inform the most specific geographical location possible.

Paragraph 4. CGen shall set in technical standard:
I - the strictest taxon level to be informed, in case of research in order to evaluate or elucidate the genetic diversity and evolutionary history of a species or taxonomic group;
II - how to indicate the most specific geographical location possible, where access is solely for research purposes as they are needed more than one hundred per registration provenance

records; and
III - the form to indicate the genetic heritage in case of access from sample substrates containing no microorganisms.
Paragraph 5. The user shall make a new registry when the access to genetic heritage or associated traditional knowledge changes or the purpose of the access.
Paragraph 6. The information referred to in sub-items "b" to "e" of item II of the *caput* that are inserted in the registry referred at art. 20-A will be automatically shared with SisGen.
Art. 22-A When the purpose of the research is not economic exploitation, in order to register access to genetic heritage or associated traditional knowledge, the individual or legal person shall fill out the specific electronic form available in the scientific research module of SisGen, which will contain:
I - the identification of the user;
II - the information on the genetic heritage and the research activities, including:
a) a summary of the activity and its goals;
b) identification of genetic heritage at the strictest possible taxonomic level or associated traditional knowledge, as the case may be, in particular:
1. the origin of the genetic heritage and the place of in situ collection, at least at the Municipal level, even if they were obtained from *ex situ* or *in silico* sources; and
2. the indigenous people, the traditional community, or the traditional farmers providers of associated traditional knowledge, even if the knowledge was obtained from secondary sources;
c) the declaration that informs if:
1. the genetic heritage is traditional local variety or creole or locally adapted race or creole; or
2. the species is on the official list of endangered species;
d) the informations of the institution based abroad associated with the national institution, in the case dealt with in item II of the *caput* of art. 12 of Law No. 13,123, 2015; and
e) the identification of the nacional partner institutions, if any;
III - the number of the previous registry or authorization, in the case of genetic heritage or associated traditional knowledge accessed from research or technological development carried after June 30, 2000;
IV - proof of obtention of the prior informed consent pursuant to art. 9 of Law No. 13,123, 2015, and art. 17 of this Decree, when applicable; and
V - the request for recognition of legal hypothesis of secrecy, when requested by the user.
Sole paragraph. The dispositions of Paragraph 4 and Paragraph 5 of art. 22 apply to the registration of access to genetic heritage or associated traditional knowledge related to research that does not have the purpose of economic exploitation.
Art. 23. Upon the filling of the form referred to in Art. 22 and art. 22-A, SisGen will issue automatically the receipt of the registry of access.
Paragraph 1. The receipt of the registry is a valid document to prove that the user provided the information required and which has the following effects:
I - allow, under the terms of Paragraph 2. of Art. 12 of Law No. 13,123, of 2015:
a) the claim of any property or intellectual rights;
b) the commercializing of intermediate product;
c) the publication of results, partial or final, of research or technological development, in scientific or communication media; and
d) the notification of a finished product or reproductive material developed as result of the access; and

II - establishes the beginning of the verification procedure set out in Section VII of this Chapter.

Paragraph 2. The user does not need to wait for the end of the verification procedure to carry out the activities referred to in item I of Paragraph 1..

Art. 24. The Sisgen will provide an electronic form for the access registry referred to at art. 22 and art. 22-A so the national legal person, public or private, can register the sending of samples containing genetic heritage for services abroad as part of research or technological development.

Paragraph 1. The national legal person, public or private, may authorize the natural person responsible for the research or technological development to fill the sending registry.

Paragraph 2. The sending registry established on *caput* will require:

I - informations about the recipient institution abroad, including contact informations and indication of legal representative; and

II - information about samples to be sent, containing identification of the genetic heritage to be sent.

Paragraph 3. The sending of sample that contains genetic heritage for services abroad under the terms of item XXX of Art. 2 of Law No. 13,123, of 2015, does not result in transfer of responsibility over the sample from the sending institution to the receiving institution.

Paragraph 4. For purposes of Paragraph 3., it is considered services abroad running tests or specialized technical activities performed by the partner institution of the national institution responsible for access or contracted by it, through remuneration or in exchange of something.

Paragraph 5. The remuneration or exchange provided for in Paragraph 4. may be waived when the partner institution integrate the research as co-author, subject to the provisions of Paragraph 6.

Paragraph 6. The legal instrument signed between the national institution responsible for access and the partner or contracted institution shall contain:

I - identification of the genetic heritage in the strictest possible taxonomic level, subject to the provisions of Paragraph 4. of Art. 22;

II - information on:

a) type of sample and form of packaging; and

b) number of containers, volume or weight;

III - description of the technical specialized service to be offered;

IV - obligation to return or destroy samples sent;

V - details of the period for the execution of services, with precise description of the activity to be performed, when applicable; and

VI - clauses prohibiting the partner or contracted institution of:

a) pass on the sample of genetic heritage or genetic information of the species object of the sending, including substances derived from the metabolism of these beings to third parties;

b) use the sample of genetic heritage or genetic information of the object sent for any purposes other than those provided;

c) economically exploit intermediate or finished product or reproductive materials resulting from access; and

d) require any kind of intellectual property right.

Paragraph 7. The legal instrument referred to in Paragraph 6. is not required in case of sending a sample for genetic sequencing.

Paragraph 8. In the event of Paragraph 7., the user must formally notify the partner or

contracted institution about the obligations contained in items IV and VI of Paragraph 6..
Paragraph 9. The registry of sample sending shall be carried out within the time limits set for the access registry.
Paragraph 10. The samples being sent must be accompanied by:
I - the legal instrument referred to in Paragraph 6; and
II - the prior informed consent, in case of sending samples of genetic heritage of a traditional local variety or creole or locally adapted race or creole for access in non-agricultural activities, when applicable.

Section III - Sample shipment registry of genetic heritage and Material Transfer Agreement

Art. 25. For the realization of genetic heritage sample shipment registry, the natural or national legal person must complete the electronic form SisGen that will require:
I - identification:
a) of the sender;
b) of genetic heritage samples in the strictest taxonomic level possible; and
c) of samples origin to be sent, pursuant to the provisions of number 1 of sub-item "f" of item II, in Paragraph 1. and in item II of Paragraph 4. of Art. 22;
II – information on:
a) the type of sample and the form of packaging;
b) the number of containers, volume or weight;
c) the recipient institution abroad, including information on the legal representative and contact information; and
d) access activities to be performed abroad of Brazil, including objectives, intended uses and sector to be applied the research project or technological development;
III - Material Transfer Agreement - MTA, signed between natural or national legal person and legal person based abroad; and
IV - prior informed consent expressly authorizing the shipment in case of genetic heritage of traditional local variety or creole or locally adapted race or creole for access in non-agricultural activities, when applicable.
Paragraph 1. The MTA referred to in item III of *caput* shall contain:
I - the information referred to in items I and II of the *caput* of this article.;
II - the obligation to comply with the requirements of Law No. 13,123, of 2015;
III - the indication that:
a) the MTA should be interpreted in accordance with Brazilian legislation and, in case of dispute, the competent jurisdiction is Brazil, assuming that arbitration is agreed between parties.
b) the genetic heritage recipient institution will not be considered the provider of the genetic heritage; and
c) the recipient institution will require from third parties to sign a MTA that establishes the obligation to comply with requirements of Law No. 13,123, of 2015, including the provision of sub-item "a" of this item;
IV- clause that authorizes or prohibits the transfer of the sample to third parties; and
V - information on access to associated traditional knowledge, as applicable.
Paragraph 2. In the event of authorization referred to in item IV of Paragraph 1., the trans-

fer of the sample to third parties will also depends on the MTA signature that contains the clauses set out in Paragraph 1.

Paragraph 3. The provision of Paragraph 2. applies to all subsequent transfers.

Art. 26. Upon completing the filling of the form referred to in Art. 25, SisGen will issue automatically the shipment registry receipt.

Paragraph 1. The shipment registry receipt is a valid document to prove that the user provided the information that was required and it has the following effects:

I - allows the execution of the shipment, pursuant to Paragraph 2. of Art. 12 of Law No. 13,123, of 2015; and

II - establishes the beginning of the verification procedure set out in Section VII of this Chapter.

Paragraph 2. For the purposes of the provisions in item I of Paragraph 1., besides the shipment registry receipt, the samples must be accompanied by the respective MTA to be regularly sent.

Paragraph 3. The user does not need to wait for the completion of the verification procedure referred to in item II of Paragraph 1. to carry out the shipment.

Section IV - Access permits to genetic heritage and associated traditional knowledge and shipment abroad, for cases referred to in Art. 13 of Law No. 13,123, of 2015

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

I - National legal person, which controlling shareholders or partners are natural persons or foreign legal persons;

II - National institution of science and technology research, public or private, when access is made in association with legal person headquarter abroad; or

III - Brazilian natural person associated, funded or contracted by a legal entity based abroad.

Paragraph 1. For the purposes of *caput* are considered indispensable areas for national security the borderland strip and oceanic islands.

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

Paragraph 3. In the event that the company corporate structure is composed of other entities, the user must identify the respective corporate structure, until the individuals on the quality of partner or controlling shareholder are identified.

Paragraph 4. Authorizations for access and shipment may be required jointly or separately.

Paragraph 5. The filling of access and shipment registry information includes the automatic request for prior authorization and consent of the National Defense Council or the Navy Command, as appropriate.

Paragraph 6. The national institution referred to in item II of *caput* to perform multiple accesses in association with the same foreign legal person may receive a single license for all accesses.

Paragraph 7. Access or shipment registry will not be completed until it is obtained the consent from the National Defense Council or the Navy Command.
Art. 28. Provided the information, SisGen will, within five days, notify the Executive Secretariat of the National Defense Council or the Navy Command, which must respond within sixty days, considering the national interest.
Paragraph 1. The request for additional information or complementary documents by the Council of National Defence or Navy Command will suspend the deadline for its manifestation until the effective delivery of what was requested.
Paragraph 2. The provisions of this section do not suspend the terms of the administrative verification procedure mentioned in Section VII of this Chapter.
Art. 29. Obtained the approval of the National Defense Council or Navy Command the access or shipment is automatically authorized.
Paragraph 1. Changes in the corporate structure or in the shareholding control occurred after obtaining the consent must be informed to SisGen within thirty days.
Paragraph 2. The National Defense Council or the Navy Command may, in a reasoned decision, revoke the approval previously granted.
Paragraph 3. In the case provided for in Paragraph 2 the user will have thirty days to present its defense.
Paragraph 4. If the user's arguments are not accepted, the National Defense Council or the Navy Command will revoke the approval and inform CGen, so it can cancel the access or shipment registry.

Section V - Accreditation of national maintainer institutions of *ex situ* collections containing samples of national genetic heritage

Art. 30. The national accreditation of national institutions that maintain collection of *ex situ* samples containing genetic heritage aims to gather the information necessary to create the database referred to in sub-item "d", item IX, Paragraph 1 of Art. 6 of Law No. 13,123, of 2015, in order to guarantee access to strategic information on ex situ conservation of genetic heritage in the country.
Paragraph 1 Pursuant to the provisions of Paragraph 2 of Art. 32 of Law No. 13,123, of 2015, may only receive resources from the FNRB the national institution that maintains *ex situ* collections that are accredited in the terms of this Section.
Paragraph 2 The private non-profit institutions that maintain popular herbaria or community seed banks may be accredited as nationals institutions that maintain *ex situ* collections as long as they comply with the provisions in this Section.
Paragraph 3 The criterias for receiving the funds mentioned in this Art. shall be defined by the Management Committee of FNRB.
Art. 31. For the accreditation of national institution that maintain *ex situ* collections of samples containing genetic heritage, the legal person must fill SisGen's electronic form, which will require:
I - identification of the institution; and
II - information on each of the *ex situ* collections including:
a) identity of curators or responsible person;
b) types of samples stored;

c) collected taxonomic groups; and
d) method of storage and conservation.
Paragraph 1 Completed filling out the form by the legal person, the CGen pursuant to Art..6, Paragraph 1., section III, item "b" of Law No. 13,123, of 2015, will deliberate on the accreditation provided in *caput*.
Paragraph 2 The national institution shall maintain the informations provided in items I and II of *caput* updated.
Art. 32. Samples of genetic heritage held in *ex situ* collections in national institutions managed with public resources and the information associated with them can be accessed by indigenous peoples, traditional communities and traditional farmers.
Paragraph 1. The institution that receives the request shall, within a period not exceeding twenty days:
I - communicate the date, location and availability of the genetic heritage;
II - indicate the reason for the total or partial impossibility of complying with the request; or
III - report that does not have the genetic heritage.
Paragraph 2. The period referred to in Paragraph 1 may be extended by ten days, upon express justification, of which the applicant will be informed.
Paragraph 3. May be charged only the amount necessary to compensate the costs for regeneration or multiplication of samples or availability of information on genetic heritage.
Paragraph 4. The availability of sample should be free of charge when carried out by national institutions that maintain *ex situ* collections that receive funds from the FNRB.

Section VI - Notifications of finished product or reproductive materials and Benefit Sharing agreements

Art. 33. The user must notify finished product or the reproductive material originated from access to genetic heritage or associated traditional knowledge carried after Law No. 13,123, of 2015, has entered into force.
Paragraph 1. The notification of the caput must be carried out before the start of the economic explotation.
Paragraph 2. For the purposes of Paragraph 1, economic exploration is considered to have started when the first sales invoice is issued for finished product or reproductive material.
Art. 34. To carry out the notification of finished product or reproductive material originated from access to genetic heritage or associated traditional knowledge, the user must fill SisGen's electronic form, which will require:
I - identification of the applicant, natural or legal person;
II - commercial identification of the finished product or reproductive material, and application field;
III - information if the genetic heritage or associated traditional knowledge used in the finished product is decisive for the formation of marketing appeal;
IV - information if the genetic heritage or associated traditional knowledge used in finished product is crucial to the existence of functional characteristics;
V - forecast of the local, regional, national or international scope of the manufacture and commercialization of the finished product or reproductive material;
VI - registry number, or equivalent, of product or cultivar in body or competent authority,

such as Anvisa, Ministry of Agriculture, Livestock and Supply and Brazilian Institute of Environment and Renewable Natural Resources – IBAMA;
VII - deposit number of the request for the intellectual property right of a product or cultivar at the Ministry of Agriculture, Livestock and Supply or at the INPI, or at offices abroad, if any;
VIII - the date scheduled for the beginning of commercialization;
IX - indication of the mode of benefit sharing;
X - presentation of benefit sharing agreement, if applicable;
XI - numbers of access registries to genetic heritage or associated traditional knowledge that gave rise to finished product or reproductive material, observing the provisions of Art. 2 and in Chapter VIII of this Decree;
XII - numbers of shipping registries that gave rise to finished product or reproductive materials, if any;
XIII - request for recognition of a legal hypothesis of secrecy; and
XIV - proof of eligibility in the event of legal exemption or 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 - within three hundred sixty-five days from the notification of the finished product or reproductive material.
Art. 35. After completing the form referred to in art. 34 SisGen will automatically issue proof of notification.
Paragraph 1. The proof of notification is a document capable of demonstrating that the user has provided the information required and has the following effects:
I - allow the economic exploitation of finished product or reproductive materials, observing the provisions of art. 16 of Law No. 13,123, of 2015; and
II - establishes the beginning of the verification procedure set out in Section VII of this Chapter.
Paragraph 2. The user does not need to wait for the end of the verification procedure referred to in item II of Paragraph 1. to start the economic explotation.

Section VII - Administrative verification procedure

Art. 36. The administrative verification procedure under this Section shall be applied in cases of:
I - access registry to genetic heritage or associated traditional knowledge mentioned in Section II of this Chapter;
II - genetic heritage sample shimpment registry, mentioned in Section III of this Chapter; and
III - notification of finished product or reproductive material, which is mentioned on Section VI of this Chapter.
Art. 37. In the verification period, the Executive Secretary of CGen.:
I – will inform counselors of CGen on the registers or on the notification;
II - will forward to members of the competent sectoral chambers information related to the species being accessed and the municipality of its location, in a dissociated way from the respective registers and other information contained therein;
III – will inform, under the terms of item X of Art. 6 of Law No. 13,123, of 2015, federal

bodies for the protection of the rights of indigenous populations and traditional communities on the registry of access to associated traditional knowledge; and
IV – may identify, ex officio, any irregularities in the registry or notification, at which time it will request the ratification of the information or proceed to the correction of formal errors.
Paragraph 1. The provisions of *caput* shall be made by the Executive Secretariat of CGen within:
I - fifteen days, regarding items I, II and III; and
II - sixty days, regarding item IV.
Paragraph 2. The counselors of CGen will have access to all available information, including those considered confidential and may not disclose it, under penalty of accountability under the terms of the law.
Paragraph 3. In cases of obvious fraud, the President of CGen may preliminarily suspend the ad referendum registries and notifications of the Plenary.
Paragraph 4. In the event of Paragraph 3, the preliminary decision will be forwarded for consideration at the next plenary session.
Art. 38. The counselors of CGen may identify indications of irregularities in the information contained in registries and notification within sixty days from the date of acknowledgment referred to in item I of *caput* of Art. 37.
Paragraph 1. The counselors may, within the period mentioned in the *caput*, receive grants from:
I - the sectoral chambers;
II - the bodies referred to in item III of *caput* of Art. 37;
III - the Executive Secretariat of CGen; and
IV - directly from holders of traditional knowledge or from their representatives.
Paragraph 2. In the hypothesis of the *caput*, the counselor will forward a request of verification of evidences of irregularity duly substantiated for deliberation by the CGen Plenary.
Paragraph 3. In agricultural activities, the fact that the species is domesticated cannot be considered, by itself, as basis of irregularity evidence in the access registry to the genetic heritage on the grounds of access to associated traditional knowledge.
Art. 39. CGen Plenary will judge the admissibility of the request referred to in Art. 38 and shall determine:
I - notification of the user, if there is evidence of irregularity; or
II - the filing of the request, if there is no evidence of irregularity.
Paragraph 1. In case of item I of *caput*, the user will have a period of fifteen days to submit its manifestation.
Paragraph 2. Manifestations presented after the deadline set out in Paragraph 1. will not be received.
Art. 40. After the deadline for presenting the manifestation, the Executive Secretary will forward the process for deliberation of CGen Plenary, which can:
I - not accept the merits of the request; or
II - accept the request, at which:
a) will determine that the user rectifies the access or shipment registers, or even the notification, if the irregularity can be remedied, under penalty of cancellation of the respective registers or notification; or
b) will cancel the access or shipment registers, or even the notification, if the irregularity is irremediable, and will notify:

1. The bodies and entities referred to in arts. 93 and 109; and
2. the user, in order to make new registries or notification.

Paragraph 1. are irremediable irregularities:

I - the existence of associated traditional knowledge of identifiable origin when the registries or notification indicate only genetic heritage;

II - the existence of associated traditional knowledge of identifiable origin, when the registries or notification indicates only associated traditional knowledge of unidentifiable origin; and

III - obtaining prior informed consent in violation of the provisions of Law No. 13,123, of 2015, and this Decree.

Paragraph 2. If the finding of the irregularities referred to in items I, II and III of Paragraph 1 occurs when the economic exploitation of the finished product or reproductive material has already started, CGen, exceptionally, and provided that it does not constitute bad-faith, may determine that the user rectifies the registries or the notification, and submits, within ninety days, the benefit-sharing agreement with the provider of associated traditional knowledge.

Paragraph 3. In the hypothesis of Paragraph 2., the benefit sharing for the entire corresponding calculation period will be calculated and collected in favor of the beneficiaries and in the amounts provided for in the benefit sharing agreement in force on the date of payment.

Art. 41. The user may request the issuance of a certificate stating that the respective access and shipments registries, as well as the notification:

I - were not admitted requests for verification of evidence of irregularities during the verification process; or

II - were object of a verification request and which was not accepted.

Sole paragraph. The certificate provided for in the *caput* enables the user to be initially warned by the supervisory body or entity before receiving any other administrative penalty, if the notice occurs on facts reported in their access and shipment registries as well as the notification.

Section VIII - Regularity access certificate

Art. 42. CGen may issue the certificate of access compliance referred to in item XXII of Art. 2 of Law No. 13,123, of 2015, upon users request.

Paragraph 1. The certificate provided in the *caput* states that the access registry complied with the requirements of Law No. 13,123, of 2015.

Paragraph 2. Pursuant to the provisions of item IV of Paragraph 1 of art. 6 of Law No. 13,123, of 2015, the granting of a certificate of access compliance will be subject to prior deliberation by CGen, according to procedures to be established in its internal regulations.

Paragraph 3. Once granted, the certificate of access compliance:

I - declares regular access until the date of issue by CGen; and

II - prevent the application of administrative sanctions by the body or competent entity specifically in relation to access activities carried until the issue of the certificate.

Paragraph 4. In the situation described in item II of Paragraph 3., if an error or fraud is found in the access already attested by CGen, the supervisory body or entity shall adopt administrative measures together with CGen to deconstruct the certificate previously granted.

CHAPTER V

Benefit Sharing

Section I - General provisions

Art. 43. The benefit sharing mentioned in Law No. 13,123, of 2015, will be due as long as there is economic exploitation of:

I - finished product resulting from access to genetic heritage or associated traditional knowledge performed after entry into force of Law No. 13,123, of 2015; or

II - reproductive material derived from access to genetic heritage or associated traditional knowledge for agricultural purposes performed after entry into force of Law No. 13,123, of 2015.

Paragraph 1. In the case of finished product referred to in item I of *caput*, the component of genetic heritage or associated traditional knowledge must be one of the key elements of value adding to the product.

Paragraph 2. Pursuant to the provisions of item XVIII of article 2 of Law No. 13,123, of 2015, key elements of value adding are those that the presence in finished product is crucial to the existence of functional characteristics or the formation of the marketing appeal.

Paragraph 3. For the purposes of this Decree, it is considered:

I - marketing appeal: reference to genetic heritage or associated traditional knowledge, its origin or differentials arising therefrom, related to a product, product line or brand, in any means of visual or hearing communication, including marketing campaigns or highlight on the product label; and

II - functional characteristics: characteristics that determine the main purposes, improve the action of the product or expand its purposes.

Paragraph 4. It will not be considered decisive for the existence of functional characteristics the use of genetic heritage, exclusively as excipients, vehicles or other inert substances, that do not determine functionality.

Paragraph 5. The substance originating from microorganism metabolism will not be considered decisive for the existence of functional characteristics when identical to the substance of fossil origin that already exists and that is used to replace it.

Paragraph 6. SisGen will provide a specific field in the access registry referred to in art. 22 so that the user, if interested, can indicate and prove the framework in the situation described in Paragraph 5.

Art. 44 It is subject to benefit sharing only the manufacturer of finished product or the producer of reproductive material, regardless of who carried out the access previously.

Paragraph 1. In case of agriculture, the sharing of benefits shall be due by the producer responsible for the final link in the productive chain of reproductive material.

Paragraph 2. For the purposes of the provisions of Paragraph 1., it is considered the final link in the productive chain, the producer responsible for selling reproductive material for the production, processing and trading of food, beverages, fibers, energy and planted forests.

Paragraph 3. In case of economic exploitation of reproductive material arising from access to genetic heritage or associated traditional knowledge for the purpose of agricultural activities and destined exclusively for the generation of finished products in productions chains that do not involve agricultural activity, benefit sharing will only occur on the economic exploitation of finished product.

Art. 45 The calculation of net revenue referred to in arts. 20, 21 and 22 of Law No. 13,123, of 2015, will be done as determined by Paragraph 1 of Art. 12 of Decree-Law No. 1,598, of December 26th, 1977.

Paragraph 1. For the purposes of *caput*, the manufacturer of finished product or producer of the reproductive material shall declare the annual net revenue of each fiscal year, obtained with the economic exploitation of each finished product or reproductive material, and shall present suitable documents to prove it.

Paragraph 2. The information provided in the *caput* must be presented to the Ministry of the Environment, in a format defined by it, within ninety days after the end of the fiscal year.

Paragraph 3. The Ministry of Finance and Ibama will provide informations and technical support necessary to comply with the provisions of this article.

Paragraph 4. For purposes of Paragraph 3., the Ministry of Finance shall observe the provisions of Paragraph 2. of Art. 198 of Law No. 5,172, from October 25th, 1966 - National Tax Code.

Art. 46. In case of finished product or reproductive material produced outside of Brazil, and for the purposes of determining the calculation basis referred to in Paragraph 8. of Art. 17 of Law No. 13,123, of 2015, the Ministry of Environment may request the manufacturer of finished product or producer of reproductive material or to the jointly liable companies provided on Paragraph 7. of Art. 17 of Law No. 13,123, of 2015, data and information, duly accompanied by respective evidence.

Paragraph 1. The data and information requested must be presented in a format compatible with systems used by the Ministry of Environment or in a means defined by it.

Paragraph 2. It is the duty of the notified party to provide all data and information requested, being responsible for veracity of its content or its omission.

Paragraph 3. The Ministry of Finance will provide informations and technical support necessary to comply with the provisions of the *caput*.

Paragraph 4. For purposes of Paragraph 3, the Ministry of Finance will observe the provisions of Paragraph 2. of Art. 198 of Law No. 5,172, from October 25th, 1966 - National Tax Code.

Art. 47. Benefit sharing can be in monetary and non-monetary modalities.

Paragraph 1. In case of economic exploitation of finished product or reproductive material from access to genetic heritage, the user will have to choose one of the modalities of benefit sharing provided for in the *caput*.

Paragraph 2. In case of economic exploitation of finished product or reproductive material from access to associated traditional knowledge of unidentifiable origin, the benefit sharing will be given on monetary modality and will be deposited in the FNRB.

Paragraph 3. In the hypothesis of economic exploitation of finished product or reproductive material from access to traditional knowledge associated 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 FNRB corresponds to 0.5% (five percent) of the annual net revenue obtained from economic exploitation or half of that provided for in a sectoral agreement.

Section II - Monetary benefit of sharing

Art. 48 The monetary benefit sharing will be intended for:
I - indigenous peoples, traditional communities and traditional farmers in cases of associated traditional knowledge of identifiable origin, as agreement negotiated in a fair and equitable manner between the parties, pursuant to Art. 24 of Law No. 13,123, of 2015; and
II - FNRB, in cases of economic exploitation of finished product or reproductive material from access:
a) of genetic heritage, in the amount of one percent of the net revenue of finished product or reproductive material, except if a sectoral agreement was celebrated as referred to in art. 21 of Law No. 13,123, of 2015;
b) of associated traditional knowledge of unidentifiable origin, in the amount of one percent of the net revenue of finished product or reproductive materials, except if a sectoral agreement was celebrated as referred to in Art. 21 of Law No. 13,123, of 2015; and
c) of associated traditional knowledge of identifiable origin related to the portion referred to in Paragraph 3. of Art. 24 of Law No. 13,123, of 2015.
Art. 49 The monetary benefit sharing destined for FNRB will be collected regardless of a benefit sharing agreement and will be calculated after the end of each fiscal year, considering:
I - information on the notification of finished product or reproductive materials;
II - annual net revenue derived from economic exploitation of finished product or reproductive material; and
III - current sectoral agreement applicable to finished product or reproductive material.
Paragraph 1. The amount of benefit sharing will be collected within thirty days after providing the information referred to in Paragraph 2. of Art. 45 while there is economic exploitation of finished product or reproductive materials
Paragraph 2. The first payment of the amount of benefit sharing shall include the benefits earned from the beginning of economic exploitation to the end of fiscal year in which there is:
I - presentation of Benefit Sharing agreement; or
II - notification of finished product or reproductive material in cases where the sharing of benefits is deposited directly in the FNRB, including prior years, if any.
Paragraph 3. If a sectoral agreement was celebrated, the amount of benefit sharing due from the year of its entry into force will be calculated for the entire fiscal year, based on the defined rate.
Paragraph 4. For the purposes of Paragraph 8 of Art. 17 of Law No. 13,123, 2015, if there is no access to information on the net revenue of the manufacturer of finished product or reproductive material produced outside Brazil, the calculation basis of benefit sharing will be the net revenue of the importer, subsidiary, controlled, affiliate, linked or commercial representative of the foreign producer in the national territory or outside of Brazil.

Section III - Non-monetary benefits sharing

Art. 50. The non-monetary benefit sharing will be made through an agreement signed:
I - with indigenous peoples, traditional communities and traditional farmers, providers of associated traditional knowledge of identifiable origin, in cases of economic exploitation of the finished product or reproductive material derived from this knowledge, negotiated in a fair and equitable manner between the parties in terms of Art. 24 of Law No. 13,123, of 2015; or

II - with the Union, in cases of economic exploitation of finished product or reproductive material from access to genetic heritage.

Paragraph 1. In benefit sharing agreements implemented through instruments referred to in sub-itens "a", "e" and "f" of item II of Art. 19 of Law No. 13,123, of 2015, the sharing of benefits will be equivalent to seventy-five percent of the amount foreseen for monetary modality.

Paragraph 2. In the benefit sharing agreement implemented through instruments not provided for in Paragraph 1., the benefit sharing will be equivalent to the amount foreseen for monetary modality.

Paragraph 3. The expenses for project management, including planning and accountability, can not be counted to reach the percentage set out in Paragraph 1. and Paragraph 2..

Paragraph 4. In order to prove the equivalence mentioned in Paragraph Paragraph 1 and 2, the user must present an estimative, based on market values.

Paragraph 5. The benefit sharing agreements concluded by the Union will be implemented, preferably, through the instrument referred to in sub-item "a" of item II of Art. 19 of Law No. 13,123, of 2015.

Paragraph 6. The user may not use funds from the non-monetary benefits in marketing campaigns or any other form of advertising for the benefit of its products, product lines or brands.

Art. 51. In case of item II of Art. 50, the non-monetary benefit sharing referred to in sub-item "a" and "e" of item II of Art. 19 of Law No. 13,123, of 2015, will be used to:

I - protected areas;

II - indigenous lands;

III - remaining territories of quilombos;

IV - rural settlement of family farmers;

V - traditional territories under the terms of Decree No. 6,040, from February 7th, 2007;

VI - national public institutions of research and development;

VII - priority areas for conservation, sustainable use and benefit sharing of Brazilian biodiversity, in accordane with an act of the Minister of State for the Environment;

VIII - activities related to safeguarding associated traditional knowledge;

IX - *ex situ* collections maintained by accredited institutions in terms of the provisions of Section V of Chapter IV; and

X - indigenous peoples, traditional communities and traditional farmers.

Art. 52. In case of item II of Art. 50 the non-monetary benefit sharing referred to in sub-itens "b", "c", "d" and "f" of item II of Art. 19 of Law No. 13,123, of 2015, will be dedicated to national bodies and public institutions running programs of social interest.

Art. 53. The Ministry of Environment can create and maintain the database of proposals for the allocation of non-monetary benefit sharing, which will be given wide publicity, including through its website, to meet the requirements of item II of Art. 19 of Law No. 13,123 of 2015.

Sole paragraph. The proposals mentioned in the *caput* must be intended for the conservation and sustainable use of biodiversity, for valorization and protection of associated traditional knowledge, attended public interest.

Section IV - About Benefit Sharing exemptions

Art. 54. It is exempted from benefit sharing the economic exploitation of:
I - finished product or reproductive material developed by traditional farmers and their cooperatives, with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No. 123 from December 14th, 2006;
II - finished product or reproductive materials developed by micro, small businesses and individual microentrepreneurs, as provided in Complementary Law No. 123, of 2006;
III - licensing operations, transfer or permission to use any form of intellectual property right on finished product, process or reproductive material from the access to genetic heritage or associated traditional knowledge by third parties;
IV - intermediate products along the production chain;
V - reproductive material along the production chain of reproductive material, except the economic exploitation carried out by the final link in the production chain;
VI - reproductive material originated from access to genetic heritage or associated traditional knowledge for purposes of agricultural activities and intended solely for the generation of finished products; and
VII - finished product or reproductive material originated from access to genetic heritage of species introduced into the national territory by human action, even if domesticated, except as provided in items I and II of Paragraph 3. of Art. 18 of Law No. 13,123, of 2015.
Paragraph 1. Also it is exempt from the Benefit Sharing obligation, the exchange and dissemination of genetic heritage and associated traditional knowledge practiced among themselves by indigenous peoples, traditional community or traditional farmer for their own benefit and based on their uses, customs and traditions;
Paragraph 2. The exemption from benefit sharing referred to in *caput* does not exempt user from the obligation to notify finished product or reproductive materials, as well as from complying with other obligations of Law No. 13,123, of 2015.
Paragraph 3. The provisions of Paragraph 2. do not apply to the cases provided for in Paragraph 4. of Art. 8 of Law No. 13,123, of 2015.
Paragraph 4. The user that does not fulfill the exemption requirements of Law No. 13,123, of 2015, will share benefits in the following fiscal year.
Paragraph 5. In cases provided for in itens IV, V and VI of the *caput*, the user must declare that the product or reproductive material is classified as an intermediate product and will be used only for activities and processes along the reproductive chain.

Section V - Benefits sharing agreement

Art. 55. The benefit sharing agreement between user and provider will be negotiated in a fair and equitable manner between the parties, taking into account parameters of clarity, loyalty and transparency on agreed clauses, which must indicate conditions, obligations, types and duration of short, medium and long term benefits, without prejudice to other guidelines and criteria to be established by CGen.

Section VI - About sectorial agreements

Art. 56. The sectoral agreements aim to guarantee the competitiveness of the productive sector in cases where the application of the share of 1% (one percent) of the annual net revenue obtained from economic exploitation of finished product or reproductive material originated from access to genetic heritage or associated to traditional knowledge of unidentifiable origin characterizes material damage or threat of material damage.

Paragraph 1 For the purposes of this Decree, it is considered productive sector the company or group of companies that produce a certain product or similar characterized in the reduction request.

Paragraph 2. In the case provided for in *caput*, the percentage of the monetary benefit sharing can be reduced to 0.1% (one-tenth percent) of the annual net revenue obtained from economic exploitation.

Art. 57. The request for a reduction in the value of monetary benefit sharing will be addressed to the Ministry of Environment and will depend on the demonstration that the payment of this percentage resulted or will result in material damage.

Paragraph 1. The information referred to in the *caput* and thus identified by the interested party will be treated as confidential information contained in the request, provided that the request is duly justified, and in this case, it cannot be disclosed without the express authorization of the interested party.

Paragraph 2. The interested party who provided confidential information shall submit a summary to be published, with details that allow its understanding, under penalty of being considered non-confidential.

Paragraph 3. If the Ministry of Environment considers the request for confidential treatment to be unjustified and the interested party refuses to adapt it for annexation in non-confidential records, the information will not be known.

Art. 58. The request for the benefit sharing reduction will only be known when the signatory companies hold more than:

I - fifty percent of the value of the sectoral output, in case the production is concentrated in up to twenty companies; and

II - Twenty-five percent of the value of the sectoral output, in case the production is concentrated in over twenty companies.

Paragraph 1. For the purposes of this Art., it is considered industry output value estimating the value of domestic production of finished product or reproductive material from access to genetic heritage or associated traditional unidentifiable source knowledge as characterized in the application for reduction.

Paragraph 2. The request shall be signed by the legal representatives of each signatory and shall contain:

I - documents that prove a causal link between the material damage or its threat and the payment of monetary benefit sharing corresponding to the portion of 1% (one percent) of the annual net revenue; and

II - characterization of the finished product or reproductive material for which there is an intention to reduce the share of 1% (one percent) provided for in Art. 56.

Paragraph 3. The characterization indicated in item II of Paragraph 2. includes the following information:

I - genetic heritage accessed;

II - associated traditional knowledge accessed;

III - raw materials;

IV - chemical composition;
V - physical characteristics;
VI - standards and technical specifications;
VII - production process;
VIII - uses and applications;
IX - degree of substitutability; and
X - distribution channels.

Paragraph 4. The request will not be known if there is an ongoing verification covering the same or similar products.

Art. 59. Demonstrated the conditions of Art. 58, the Ministry of Environment will:
I - publish an act initiating the verification of the material damage or its threat; and
II - notify:
a) the companies concerned;
b) the Ministry of Development, Industry and Foreign Trade; and
c) the bodies referred to in the sole paragraph of Art. 21 of Law No. 13,123, of 2015.

Paragraph 1. The act referred to in item I of *caput* will specify the finished product or the reproductive material object of verification and the signatory companies of the request.

Paragraph 2. The manifestation by the Ministry of Development, Industry and Foreign Trade is a condition for the analysis referred to in Art. 62 and will be presented within sixty days.

Paragraph 3. The bodies referred to in sub-item "c" of item II of the *caput* may present a manifestation within a period of sixty days from the date of notification.

Paragraph 4. Submissions of empowerment procedure from other parties that consider themselves interested are allowed within twenty days from the date of publication of the act referred to in item I of the *caput*.

Art. 60. The finding of material damage or its threat will be based on evidence and include an objective examination of the effect of benefit sharing on the product price and the consequent impact on the productive sector.

Paragraph 1. The examination referred to in *caput* include, among others, the evaluation of the following factors and economic indicators:
I - real or potential drop of:
a) sales;
b) profits;
c) production;
d) market participation;
e) productivity; and
f) level of use of the capacity installed;
II - real or potential negative effects on:
a) stocks;
b) employment;
c) wages; and
d) growth of productive sector;
III - the shrinkage in demand or changes in consumption patterns;
IV - competition between domestic and foreign producers; and
V - export performance.

Paragraph 2. For the purposes of this article, shall be segregated the effects of the payment

of monetary benefit sharing corresponding to the share of 1% (one percent) of the annual net revenue of the effects resulting from other causes that may have generated material damage or its threat.

Paragraph 3. For the examination of the impact referred to in *caput*, it will be considered if the value of benefit sharing had the effect of depressing sales significantly.

Art. 61. The Ministry of Development, Industry and Foreign Trade will carry out the analysis referred to in art. 60 and will forward a technical report on the request to reduce the value of the benefit sharing to the Ministry of the Environment, within the period referred to in Paragraph 2 of art. 59.

Art. 62. Upon receiving the technical report referred to in art. 61, Ministry of Environment will issue a technical report that shall consider the manifestations of the following institutions:

I - the Ministry of Development, Industry and Foreign Trade; and

II - the official bodies of defense of indigenous peoples' rights, traditional communities or traditional farmers, when presented.

Paragraph 1. The companies interested will be notified to, within thirty days, to present a manifestation concerning the report referred to in *caput*.

Paragraph 2. The Ministry of Environment may accept the manifestations of interested companies, when it will make a new report.

Art. 63. The report will be submitted to the Minister of Environment who will decide, in a motivated manner, on whether or not to carry out the sectoral agreement.

Art. 64. The terms of the sectoral agreement in force apply to all products produced in the national territory that fall under the terms of the decision, even if produced by companies that have not signed the reduction request.

Art. 65. The sectoral agreement will be valid for sixty months from the publication of the decision referred to in Art. 63.

Paragraph 1. In the event of sectoral agreement in force at the time of the benefit sharing payment for a particular finished product or reproductive materials, the rate to be paid will be the one defined in the sectoral agreement.

Paragraph 2. Once finished the period referred to in the *caput*, and if there is no request for an extension, the sectoral agreement will be terminated.

Paragraph 3. The sectoral agreement may be extended if the conditions that gave rise to its celebration remain.

Paragraph 4. The request for renewal must be made by the interested party, within at least four months before its end.

Paragraph 5. During the analysis of the extension request, the sectoral agreement remains in force.

Art. 66. While the sectoral agreement is in force, the interested party may request a review of the rate, provided that at least thirty months have elapsed from the beginning of the agreement's entry into force.

Paragraph 1. The request referred to in the *caput* must be accompanied with evidence that the circumstances that justified the application of reduced rate given the time have changed.

Paragraph 2. The analysis of the review request will follow the provisions of this section and will consider only new facts that justify the request.

Art. 67. The final decision on the review request will be up to the Minister of Environment and will be limited to the reduction or not of the rate.

Art. 68. If the review request is accepted, an additional term to the sectoral agreement in

force will be formalized.
Art. 69. An act of the Minister of Environment will establish complementary rules to the provisions of this Section.

CHAPTER VI

Violations and Administrative Sanctions

Section I - General provisions

Art. 70. It is considered an administrative infraction against genetic heritage or associated traditional knowledge of the provisions of arts. 78-91 of this Decree.
Art. 71. Without prejudice to the applicable criminal and civil liabilities, administrative penalties will be punished with the following sanctions:
I - warning;
II - fine;
III – seizure of:
a) samples containing the genetic heritage accessed;
b) instruments used in acquisition or processing of genetic heritage or associated traditional knowledge accessed;
c) products arising from access to genetic heritage or associated traditional knowledge; or
d) products obtained 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 Law No 13.123 of 2015;
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 Law No 13.123 of 2015; or
VIII - cancellation of the certificate or the authorization referred to in Law No 13.123 of 2015.
Sole paragraph. The penalties provided for in sections I to VIII of *caput* may be applied cumulatively.
Art. 72. The fining agent, when registering the infraction notice, will indicate the penalties set forth in this Decree, noting:
I - the severity of the fact;
II - the background of the offender, as to comply with legislation relating to genetic heritage and associated traditional knowledge;
III – repeat offense; and
IV - the economic situation of the offender, in case of fine.
Sole paragraph. For the application of this Art., the competent entity or body may establish, through technical standard, additional criterias for the aggravation and mitigation of administrative penalties.
Art. 73. The fine will be arbitrated, for each infraction, by the competent authority, and

may vary::
I – from BRL 1,000.00 (one thousand reais) to BRL 100,000.00 (one hundred thousand reais), whenever the infraction is committed by a natural person; or
II – from BRL 10,000.00 (ten thousand reais) to 10,000,000.00 (ten million reais) when whenever the infraction is committed by a legal person, or with its aid.
Art. 74. The occurrence of new infraction by the same offender, on the period of five years from the final administrative decision by which the agent has been condemned for a previous infraction, implies in:
I - application of three times the amount of the fine, in case of committing the same infraction; or
II - application of two times the amount of the fine, in case of committing a distinct infraction.
Paragraph 1. The occurrence of new infraction will be determined in the new infraction procedure, which shall record, by copy, the previous infraction notice and the judgment that confirmed it.
Paragraph 2. Before the trial of new infraction, for apply an aggravated new penalty, the environmental authority shall verify the existence of previous infraction notice confirmed in judgment
Paragraph 3. Given the existence of infraction notice previously confirmed in judgment, the environmental authority shall:
I - aggravate the penalty as established in *caput*;
II - notify the offender to be fined to manifest on the aggravation of the penalty within ten days; and
III - judge the new infraction considering the aggravation of penalty.
Art. 75. For the penalties provided for in itens III to VI of Art. 71, apply, where applicable, the provisions of Decree No. 6514 from July 22nd, 2008

Section II - Limitation periods

Art. 76. Under the terms of Law No. 9,873, from November 23th, 1999, it prescribes in five years the right to action of the public administration aiming to investigate the practice of administrative infractions against genetic heritage and associated traditional knowledge, counted from the date of the practice of the act, or, in the case of a permanent or continuing infraction, from the day on which it ceased.
Paragraph 1. The investigation of infraction against genetic heritage and associated traditional knowledge is considered initiated with the drafting of the infraction notice by the competent authority or administrative notification.
Paragraph 2. The intervening limitation applies to the verification procedure of the infraction notice that has been paralyzed for more than three years, pending judgment or order, whose records will be filed *sua sponte* or upon request of the interested party, without prejudice to the determination of the functional responsibility resulting from the stoppage.
Art. 77. The limitation of action is interrupted by:
I - the offender notification by any means, including by public notice;
II - any unequivocal act of the public administration that implies verification of the fact; and
III - appealable condemnatory decision.
Sole paragraph. For the purpose of the provisions in item II, it is considered an unequivocal act of the public administration, the ones that imply production of evidence in the process.

Section III - Infractions against genetic heritage and associated traditional knowledge

Art. 78. Economically explore finished product or reproductive material from access to genetic heritage or associated traditional knowledge without previous notice.
Minimum fine of BRL 3,000.00 (three thousand reais) and a maximum of BRL 30,000.00 (thirty thousand reais), in case of natural person.
Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 200,000.00 (two hundred thousand reais), when it is a legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No. 123 from December 14th, 2006.
Minimum fine of BRL 30,000.00 (thirty thousand reais) and a maximum of BRL 10,000,000.00 (ten million reais), for others legal persons.
Paragraph 1. The penalty provided for in the *caput* will be applied per finished product or reproductive material, regardless of the number of species accessed for the preparation of the finished product or reproductive material..
Paragraph 2. The penalty of fine is doubled if the finished product or reproductive material developed as a result of access is sold outside of Brazil.
Paragraph 3. Anyone who presents a benefit sharing agreement in disagreement with the period of time defined in items I and II of Paragraph 1 of art. 34 shall be submitted to the same penalties provided for in this artile .
Art. 79. Send, directly or through an intermediary, a sample of genetic heritage to outside of Brazil without prior registry or in disagreement with it..
Minimum fine of BRL 20,000.00 (twenty thousand reais) and a maximum of BRL 100,000.00 (one hundred thousand reais), in case of natural person.
Minimum fine of BRL 50,000.00 (fifty thousand reais) and a maximum of BRL 500,000.00 (five hundred thousand reais), when it is legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No.123, 2006.
Minimum fine of BRL 100,000.00 (one hundred thousand reais) and a maximum of BRL 10,000,000.00 (ten million Reais), for other legal persons.
Paragraph 1. The penalty provided for in *caput* will be applied:
I - by species;
II - triple if the sample is obtained from a species appearing on the official list of Brazilian endangered species or Annex I of the Convention on International Trade in Plant Species of Wild Fauna and in Endangered - CITES, promulgated by Decree No. 76,623, from November 17th 1975; and
III - double if the sample is obtained from species listed only in Annex II of CITES, promulgated by Decree No. 76,623 from 1975.
Paragraph 2. If the shipping is carried out for the development of biological or chemical weapons, the penalty provided for in *caput* will be quadrupled and shall be applied embargo penalties, suspension or partial or total ban, activity or enterprise, of the responsible for shipping.
Art. 80. Apply for right to intellectual property arising from access to genetic heritage or associated traditional knowledge, in Brazil or outside of Brazil, without prior registry.

Minimum fine of BRL 3,000.00 (three thousand reais) and a maximum of BRL 30,000.00 (thirty thousand reais), in case of natural person.
Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 200,000.00 (two hundred thousand reais), when it is legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No.123, 2006.
Minimum fine of BRL 20,000.00 (twenty thousand reais) and a maximum of BRL 10,000,000.00 (ten million Reais), for other legal persons.

Art. 81. Disclose results, final or partial, in scientific or communication media without prior registry:
Minimum fine of BRL 1,000.00 (one thousand reais) and a maximum of BRL 20,000.00 (twenty thousand reais), in case of natural person.
Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 200,000.00 (two hundred thousand reais), when it is legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No.123, of 2006.
Minimum fine of BRL 50,000.00 (fifty thousand reais) and a maximum of BRL 500,000.00 (five hundred thousand reais), for other legal persons.

Paragraph 1. The penalty of fine may be replaced by warning, when there are favorable circumstances provided for in Art. 72.

Paragraph 2. The provisions of Paragraph 1. shall not apply to cases where the infraction conduct involves access to associated traditional knowledge or when the offender is a repeat offender under the terms of this Decree.

Art. 82. Failure to carry out access registry before the sale of intermediate product.:
minimum fine of BRL 1,000.00 (one thousand reais) and a maximum of BRL 20,000.00 (twenty thousand reais), in case of natural person.
minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 200,000.00 (two hundred thousand reais), when it is it is legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No.123, of 2006.
Minimum fine of BRL 50,000.00 (fifty thousand reais) and a maximum of BRL 500,000.00 (five hundred thousand reais), for other legal persons.

Paragraph 1. The penalty of fine may be replaced by warning, when there are favorable circumstances provided for in Art. 72.

Paragraph 2. The provisions of Paragraph 1. shall not apply to cases where the infraction conduct involves access to associated traditional knowledge or when the offender is a repeat offender under the terms of this Decree.

Art. 83. Access associated traditional knowledge of identifiable origin without obtaining prior informed consent or in violation of this.
Minimum fine of BRL 20,000.00 (twenty thousand reais) and a maximum of BRL 100,000.00 (one hundred thousand reais), in case of natural person.
Minimum fine of BRL 50,000.00 (fifty thousand reais) and a maximum of BRL 500,000.00 (five hundred thousand reais), when it is legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No.123 from December 14th, 2006.

Minimum fine of BRL 100,000.00 (one hundred thousand reais) and a maximum of BRL 10,000,000.00 (ten million Reais), for other legal persons.

Sole paragraph. The same penalties apply to those who obtain prior informed consent with a defect of consent from the associated traditional knowledge provider, under the terms of Brazil's Civil Code.

Art. 84. Fail to indicate the origin of associated traditional knowledge of identifiable origin in publications, uses, explorations and disclosures of access results.

Minimum fine of BRL 1,000.00 (one thousand reais) and a maximum of BRL 10,000.00 (ten thousand reais), in case of natural person.

Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 50,000.00 (fifty thousand reais), when it is legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No.123 of December 14th, 2006.

Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 500,000.00 (five hundred thousand reais), for other legal persons.

Art. 85. Fail to pay the annual installment due to the FNRB arising from the economic exploitation of finished product or reproductive material developed as a result of access to genetic heritage or associated traditional knowledge.

Minimum fine of BRL 1,000.00 (one thousand reais) and a maximum of BRL 100,000.00 (one hundred thousand reais), in case of natural person.

Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 10,000,000.00 (ten million Reais), for legal persons.

Paragraph 1. Anyone who interrupts or partially fulfills the agreed benefit sharing, whether monetary or non-monetary, incurs in the same sanctions.

Paragraph 2. Subject to the limits provided for in the *caput*, the fine shall not be less than 10% (ten percent) nor greater than 30% (thirty percent) of the amount due annually.

Art. 86. Prepare or present information, document, study, expert evidence or report fully or partially false, or misleading, whether in official systems or in any other administrative procedure related to genetic heritage or associated traditional knowledge:

Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 50,000.00 (fifty thousand reais), in case of a natural person.

Minimum fine of BRL 30,000.00 (thirty thousand reais) and a maximum of BRL 300,000.00 (three hundred thousand reais), in case of legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No.123, of 2006.

Minimum fine of BRL 100,000.00 (one hundred thousand reais) and a maximum of BRL 5,000,000.00 (five million reais) for other legal persons.

Sole paragraph. In relation to the shipment or the sample submission for service abroad, the penalty provided for in *caput* will be doubled if the information, document, study, expert evidence or report are fully or partially false, or misleading.

Art. 87. Fail to comply with suspension, embargo or ban due to administrative infraction against the genetic heritage or associated traditional knowledge:

Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 100,000.00 (one hundred thousand reais), in case of natural person.

Minimum fine of BRL 50,000.00 (fifty thousand reais) and a maximum of BRL 500,000.00 (five hundred thousand reais), in case of legal person designated as very small business, small

business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No. 123, of 2006.
Minimum fine of BRL 200,000.00 (two hundred thousand reais) and a maximum of BRL 10,000,000.00 (ten million Reais), for other legal persons.

Art. 88. Obstruct or hinder the inspection of the obligations provided for in Law No. 13,123, of 2015:
Minimum fine of BRL 5,000.00 (five thousand reais) and a maximum of BRL 50,000.00 (fifty thousand reais), in case of a natural person.
Minimum fine of BRL 30,000.00 (thirty thousand reais) and a maximum of BRL 300,000.00 (three hundred thousand reais), in case of legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No.123, of 2006.
Minimum fine of BRL 100,000.00 (one hundred thousand reais) and a maximum of BRL 5,000,000.00 (five million reais) for other legal persons.

Art. 89. Fail to adjust on the period stipulated in Art. 37 of Law No. 13,123, of 2015:
Minimum fine of BRL 1,000.00 (one thousand reais) and a maximum of BRL 10,000.00 (ten thousand reais), in case of natural person.
Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 50,000.00 (fifty thousand reais), in case of legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No.123, of 2006
Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 300,000.00 (three hundred thousand reais), for other legal persons.

Paragraph 1. The penalty provided for in the *caput* will be applied by finished product or reproductive material or by each access activity, separately, that fails to promote its respective adequacy, regardless of the number of species accessed.

Paragraph 2. The penalty of fine may be replaced by warning, when favorable the circumstances provided for in Art. 72.

Paragraph 3. In the event of access to genetic heritage or associated traditional knowledge carried out solely for purposes of scientific research, the penalty of warning about facts related to the respective registry for purposes of adequacy must precede the application of any other administrative penalty.

Art. 90. Fail to regularize in the period stipulated in Art. 38 of Law No. 13,123, of 2015:
Minimum fine of BRL 1,000.00 (one thousand reais) and a maximum of BRL 10,000.00 (ten thousand reais), in case of a natural person.
Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 50,000.00 (fifty thousand reais), in case of legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No.123, of 2006.
Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 10,000,000.00 (ten million reais), for other legal persons.

Paragraph 1. The penalty provided for in the *caput* will be applied by finished product or reproductive material or by each access activity, separately, that fails to promote its respective regularization, regardless of the number of species accessed

Paragraph 2. The penalty of fine may be replaced by warning, when favorable the circumstances provided for in Art. 72., and it is:

I – natural person; or
II – legal person that has accessed genetic heritage or associated traditional knowledge solely for the purpose of scientific research.
Art. 91. Fail to meet legal or regulatory requirements within the period granted, when notified by competent authority:
Minimum fine of BRL 1,000.00 (one thousand reais) and a maximum of BRL 30,000.00 (thirty thousand reais), in case of natural person.
Minimum fine of BRL 10,000.00 (ten thousand reais) and a maximum of BRL 200,000.00 (two hundred thousand reais), in case of legal person designated as very small business, small business or traditional farmers' cooperatives with annual gross revenue equal to or less than the maximum limit established in item II of Art. 3 of Complementary Law No.123, of 2006.
Minimum fine of BRL 15,000.00 (fifteen thousand reais) and a maximum of BRL 5,000,000.00 (five million reais) for other legal persons.
Sole paragraph. The penalty of fine may be replaced by warning, when favorable circumstances provided for in Art. 72.

Section IV - Administrative process for investigation of infractions

Art. 92 Infractions against genetic heritage or associated traditional knowledge will be determined by an exclusive administrative process by the drafting of the infraction notice and its terms, guaranteed the right to a fair hearing and adversary proceeding.
Sole paragraph. The administrative process referred to in the *caput* shall be ruled by the provisions of Decree No. 6514, of 2008, except where there is a different provision under this Chapter.
Art. 93. The following authorities are competent to inspect and ascertain administrative infractions provided in this Decree:
I - IBAMA;
II – the Navy Command, within territorial waters and the Brazilian continental shelf; and
III – the Ministry of Agriculture, Livestock and Supply, regarding access to genetic resources for agricultural activities, pursuant to Art.. 3 of Law No.10,883, from June 16th, 2004.
Paragraph 1. When the infraction involved associated traditional knowledge, the official bodies for the defense of the rights of indigenous people, traditional communities and traditional farmers will support the Ibama enforcement actions.
Paragraph 2. A joint act of the Ministers of State for the Environment, Agriculture, Livestock and Supply and Defense will regulate the coordinated action of the inspection bodies.
Art. 94. The final decision by the bodies provided for in Art. 93 can be appealed to CGen, within twenty days.
Art. 95. A CGen Act will establish criteria for the destination of seized samples, products and instruments, referred to in Paragraph 4 of art. 27 of Law No. 13,123, of 2015.
Sole paragraph. As long as the act mentioned in the *caput* is not edited, the competent authority for inspection will make the destination, observing the provisions of Decree No. 6,514, of 2008.

CHAPTER VII

National fund for benefit sharing and about national benefit sharing program

Art. 96. The National Fund for Benefit Sharing - FNRB, established by Law No. 13,123, of 2015, under the Ministry of Environment, has financial nature and is intended to support actions and activities that aim to enhance the genetic heritage and associated traditional knowledge and promote its use in a sustainable way.

Paragraph 1. FNRB resources are composed by:

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

II - donations;

III - funds collected from the payment of administrative fines imposed due to non-compliance with the Law No 13.123, of 2015;

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 2. 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 actions, activities and projects for the benefit of holders of associated traditional knowledge.

Paragraph 3. The revenues destined to the FNRB and eventual returns of resources will be collected directly to the Fund, according to the procedures defined by the Management Committee.

Art. 97. The FNRB will be managed by the Manager Committee collegial body composed by:

I - one representative and two substitutes:

a) from Ministry of the Environment, who shall preside;

b) from Ministry of Finance;

c) from Ministry of Agriculture, Livestock and Supply;

d) from Ministry of Social Development and Fight against Hunger;

e) from Ministry of Agrarian Development;

f) from Ministry of Science, Technology and Innovation;

g) from National Indian Foundation - FUNAI; and

h) from Historical and Artistic Heritage Institute - IPHAN;

II - seven representatives of entities or organizations representing indigenous peoples, traditional communities and traditional farmers, as follows:

a) two persons nominated by the National Council of Traditional Peoples and Communities - CNPCT;

b) two persons nominated by the National Council for Sustainable Rural Development - Condraf;

c) two persons nominated by the representatives of indigenous people and indigenous organizations members of the National Council of Indigenous Policy - CNPI; and
d) a representative from the indigenous people, traditional community or traditional farmers nominated by the National Council of Food and Nutrition Security - CONSEA; and
III - a representative of the Brazilian Society for Science Progress - SBPC.

Paragraph 1. The representatives and their substitutes shall be nominated by the Environment Minister, after nomination of their bodies and entities.

Paragraph 2. The representatives and substitutes are nominated for a two years term, renewable for the same period.

Paragraph 3. In impediments or absences of the Chairman, the Manager Committee will be chaired by the substitute representative of the Environment Ministry.

Paragraph 4. Participation in the FNRB Manager Committee is considered of relevant public interest and will not be paid.

Paragraph 5. To comply with the provisions of item IV of Art. 10 of Law No. 13,123, of 2015, travel expenses and the stay of representatives referred to in item II of the *caput* shall be paid by FNBR.

Paragraph 6. The Ministry of Environment may bear the costs referred to in Paragraph 5º in the first two years of the FNBR.

Paragraph 7. The Manager Committee may invite other representatives, without voting rights, to attend its meetings.

Art. 98. It is up to the Manager Committee:
I – to decide on the management of monetary resources deposited in FNRB, subject to the guidelines for application of the resources established by CGen;
II – to set annually the percentage of monetary resources deposited in FNRB arising from economic exploitation of finished product or reproductive material from access to genetic heritage from *ex situ* collections, which will be used for the benefit of these collections;
III – to approve the FNRB Operations Manual, establishing conditions and procedures for financial implementation and application of resources, including the collection of revenues and contracting, execution, monitoring and evaluation of actions and activities supported by the FNRB;
IV - to approve the four-year operational plan and revise it every two years;
V – to approve actions, activities and projects to be supported by FNRB;
VI – to decide on the hiring of studies and research by FNRB;
VII - to approve annual reports on:
a) activities and financial execution;
b) performance of financial institution;
VIII - to establish instruments for cooperation, including federal States, Federal District and cities;
IX - to establish instruments of cooperation and transfer of funds to national public research institutions, education and technical support, including financial support from FNRB to monitor the actions and activities supported by FNRB; and
X - to prepare and approve its internal regulations.

Sole paragraph. The percentage mentioned in item II of *caput* can not be less than sixty percent or more than eighty percent.

Art. 99. The FNRB's funds will be kept in a federal financial institution, which will be responsible for the administration and financial execution of the resources and the operation of

the Fund.

Paragraph 1. The depository financial institution will remunerate the Funds, at least, by the reference average rate of the Special System for Settlement and Custody - Selic.

Paragraph 2. The obligations and liabilities of the financial institution, as well as its remuneration will be defined in the contract.

Art. 100. The National Programme of Benefit Sharing – PNRB, established by Art. 33 of Law No. 13,123, of 2015, aims 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, as defined by the Manager Committee of FNRB.

Paragraph 1. The FNRB can support projects and training activities for the servants of the bodies and entities referred to in Paragraph 2 of Art. 14.

Paragraph 2. The FNRB can support projects and activities related to the development of community protocols.

Art. 101. The FNRB resources must be used in PNRB to support actions and activities that promote the objectives provided for in Art. 100, through agreements, partnership, collaboration or promotion terms, arrangements, adjustments or other instruments of cooperation and transfer of funds provided by law.

Sole paragraph. The FNRB resources may also be allocated:

I – to the analysis, supervision, management and monitoring of actions, activities and supported projects;

II - to pay and cover the costs of the financial institution for the management of the Fund.

Art. 102. The Ministry of Environment will act as the Executive Secretary of the FNRB Management Committee and will provide technical and administrative support necessary for the functioning of the FNRB and the implementation of the PNRB.

CHAPTER VIII

Transitional Provisions on the Suitability and Adjustment of Activities

Art. 103. It must comply with the terms of Law No. 13,123, of 2015, and this Decree, within one year from the date of availability of the registry by CGen, the user that performed, from June 30th, 2000, the following activities in accordance with Provisional Measure No. 2186-16 from August 23th, 2001:

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

II - economic exploitation of finished product or reproductive material from access to genetic heritage or associated traditional knowledge.

Paragraph 1. For the purposes of *caput*, the user, in compliance with Art. 44 of Law No. 13,123, of 2015, shall adopt one or more of the following, as applicable:

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

II - notify finished product or the reproductive material object of economic exploitation, in accordance with Law No. 13,123, of 2015 and this Decree; and

III - share the benefits arising from the economic exploitation carried out from the date of entry into force of Law No. 13,123, of 2015, pursuant to Chapter V of that Law and of Chapter V of this Decree, except when it has done in the form of the Provisional Measure No. 2186-16, of 2001.

Paragraph 2. In case of item III, Paragraph 1., the benefit sharing in the form of Provisional Measure No. 2186-16, of 2001, will be valid for a the period stipulated in the contract of use of genetic heritage and benefit sharing or in the form of the benefit sharing project agreed by CGen.

Art. 104. It must be regularized under the terms of Law No. 13.123, of 2015, and this Decree, within one year, counted from the date of availability of the registration by CGen, the user that between June 30th, 2000 and the date of entry into force of Law No. 13,123, of 2015, performed the following activities in disagreement with the legislation in force at the time:

I - access to genetic heritage or associated traditional knowledge;

II - access and economic exploitation of a product or process arising from access to genetic heritage or associated traditional knowledge, mentioned in Provisional Measure No. 2186-16, of 2001;

III - shipment of sample containing genetic heritage for outside of Brazil; or

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

Paragraph 1. The regularization provided for in the *caput* is subject to the signature of the Term of Commitment.

Paragraph 2. In the event that access to genetic heritage or associated traditional knowledge

solely for scientific research purposes, the user will be exempted from signing the Term of Commitment, if regularizing-through registry or authorization of the activity, as appropriate.
Paragraph 3. Registry and authorization referred to in Paragraph 2 extinguish the demandability of administrative penalties provided for in Provisional Measure No. 2186-16, of 2001 and specified in arts. 15 and 20 of Decree No. 5459 from June 7th 2005, provided that the infraction has been committed until the day preceding the entry into force of Law No. 13,123, of 2015.
Paragraph 4. For INPI regularization purposes, about the patent applications filed during the effectiveness of Provisional Measure No. 2186-16, of 2001, the applicant must present proof the registration or authorization referred to in this Art.
Paragraph 5. The user who conducted activities in violation of the Provisional Measure No. 2186-16, of 2001, although it has obtained authorization during the effectiveness of Provisional Measure may, at its discretion, join the regularization procedure provided for in Art. 38 of Law No. 13,123, of 2015.
Paragraph 6. For purposes of Paragraph 5., the contract for the use of genetic heritage and for the sharing of benefits or the benefit-sharing project agreed by the CGen shall form part of the term of commitment.

CHAPTER IX

Final Dispositions

Art. 105. For the purposes of item XVII of Art. 2 of Law No. 13,123, of 2015, the inputs used in agricultural activities are intermediate products.
Sole paragraph. It is considered as inputs for agricultural activities goods consumed in production activity or undergoing changes, such as wear, damage or loss of physical or chemical properties, as a result of the action directly exercised on the product being manufactured, provided it is not included in fixed asset.
Art. 106. CGen can create a database for voluntary registration of prior informed consent, granted or denied by traditional knowledge holders.
Art. 107. The following tests, exams and activities, when are not an integral part of research or technological development, do not constitute access to genetic heritage in accordance with Law No. 13,123, of 2015:
I - affiliation or paternity test, sexing technique and karyotype or DNA analysis and other molecular analyzes that aim to identify a species or specimen;
II - clinical diagnostic tests and examinations for the direct or indirect identification of etiologic agents or hereditary pathologies in an individual;
III - extraction, by grinding, pressing or bleeding method that results in fixed oils;
IV - purification of fixed oils that results in a product whose characteristics are identical to those of the original raw material;
V - test that aims to measure mortality, growth or multiplication rates of parasites, pathogens, pests and disease vectors;
VI - comparison and extraction of information of genetic origin available in national and international databases;

VI - extract processing, physical separation, pasteurization, fermentation, pH assessment, total acidity, soluble solids, bacterial and yeast counts, molds, fecal coliforms and total genetic heritage samples; and

VII - physical, chemical and physical-chemical characterization to determine the nutritional information of foods;

Sole paragraph. Reading or consulting information of genetic origin available in national and international databases does not constitute access to genetic heritage, even if they are an integral part of research and technological development.

Art. 108. Plant or animal genetic improvement carried out by an indigenous population, traditional community or traditional farmer is exempt from registry under the terms of item VI of art. 10 of Law No. 13,123, of 2015.

Art. 109. In order to comply with the provisions of Paragraph 2 of art. 12 of Law No. 13,123, of 2015, the user, when applying for an intellectual property right, must inform if there was access to genetic heritage or associated traditional knowledge, as well as if there is a registry of access carried out under the terms of this Decree.

Art. 110. If the registry does not exist or in the event of its cancellation, IBAMA or CGen will notify the body and entity provided for in art. 109 so it can inform the applicant of the intellectual property right to present proof of registry within thirty days, under penalty of filing the intellectual property right application process.

Sole paragraph. In the absence of registry, the period of one year referred to in Articles 36, 37 and 38 of Law No. 13,123, of 2015 will be observed.

Art. 111. CGen, with the collaboration of accredited institutions under item V of Art. 15 of Provisional Measure No. 2186-16, of 2001, will register in the system permits already issued.

Art. 112. It is approved on the basis of the Mercosur Common Nomenclature - NCM, the Benefit Sharing Ranking List referred to in Paragraph 9 of Art. 17 of Law No. 13,123, of 2015 attached to this Decree.

Sole paragraph. The illustrative list referred to in the *caput* will not exclude the application of the incidence rules of benefit sharing provided in arts. 17 and 18 of Law No. 13,123, of 2015.

Art. 113. The Ministry of Agriculture, Livestock and Supply will prepare, publish and revise periodically a reference list of species of animals and plants domesticated or cultivated that were introduced in the national territory, and that are used in agricultural activities.

Sole paragraph. The list of the *caput* shall indicate the species that form spontaneous populations and varieties which have acquired distinctive characteristic properties in Brazil.

Art. 114. A joint act of the Ministers of State for Agriculture, Livestock and Supply and Agrarian Development will publish a list of traditional local variety or creole or locally adapted race or creole.

Art. 115. The Ministry of Health and the Ministry of the Environment, in a joint Ordinance, will regulate a simplified procedure for the shipment of genetic heritage related to the situation of Public Health Emergency of National Importance - ESPIN, established in Decree No. 7,616, of 17 November 2011 .

Paragraph 1. The shipment provided for in the *caput* will be destined exclusively for research and technological development declared in the Material Transfer Agreement, necessarily linked to the epidemiological situation, being forbidden the use of such accessed genetic heritage for other purposes.

Paragraph 2. The benefits resulting from the economic exploitation of finished product or

reproductive material arising from research or technological development referred to in this article will be shared under the terms of Law No. 13.123, 2015, and this Decree.

Art. 116. The Ministry of the Environment, in coordination with the Ministry of Foreign Affairs, may celebrate cooperation agreements and agreements with authorities in other countries for the purpose of complying with the provisions of Law No. 13,123, of 2015.

Art. 117. The provisions of this Decree does not exclude the competence of the Ministry of Science, Technology and Innovation to supervise and control the activities of scientific research in national territory, when carried out by foreigners, involving entry into Brazil.

Art. 118. The user that requested any intellectual property right, that have exploited economically finished product or reproductive material, or have reported results, final or partial, in scientific circles or communication, between November 17th, 2015 and the date of availability of registration, must register the activities referred to in Art. 12 of Law No. 13,123, of 2015 and notify finished product or the reproductive material developed as a result of access.

Paragraph 1. The period for registration or notification of the *caput* will be one (1) year from the date of availability of registration by CGen.

Paragraph 2. Once the registration or notification is carried out in a timely manner, the user will not be subject to administrative penalty.

Art. 119. It is revoked:

I - Decree No. 3945 from September 28th, 2001;

II - Decree No. 4.946, from December 31th, 2003;

III - Decree No. 5.459 from June 7th, 2005;

IV - Decree No. 6.159 from July 17th, 2007; and

V - Decree No. 6.915 from July 29th, 2009.

Art. 120. This Decree shall enter into force on the date of its publication.

Brasilia, May 11th, 2016; 195th of Independence and 128th of Republic.

DILMA ROUSSEFF
Eugenio José Guilherme de Aragão
Kátia Abreu
Fernando de Magalhães Furlan
João Luiz Silva Ferreira
Izabella Mônica Vieira Teixeira
Patrus Ananias

ANNEX

Benefit Sharing Classification List

Section	Chapters	NCMs
Section I. LIVE ANIMALS AND PRODUCTS OF ANIMAL KINGDOM	Chapters 1-5	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 FROM ITS DISSOCIATION; PREPARED EDIBLE FATS; ANIMAL OR VEGETABLE WAXES	Chapters 15	15:01 to 15.15
Section IV. FOOD INDUSTRY PRODUCTS; BEVERAGES, ALCOHOLIC LIQUIDS AND VINEGAR; TOBACCO AND ITS MANUFACTURED SUBSTITUTES	Chapters 16 to 24	1601.00.00 to 24.03
Section VI. CHEMICAL PRODUCTS OR FROM ALLIED INDUSTRIES	Chapters 28 to 38	28.01 to 38.25
Section VII. PLASTICS AND ITS WORKS; RUBBER AND ITS WORKS	Chapters 39 or 40	3901 to 4017.00.00
Section VIII. SKINS, LEATHER, FURSKINS AND WORKS ORIGINATED FROM THESE MATERIALS; SADDLERY AND HARNESS; TRAVEL GOODS, BAGS AND SIMILAR CONTAINERS; GUT WORKS	Chapters 41-43	41.01 to 43.03
Section IX. WOOD CHARCOAL AND ARTICLES OF WOOD; CORK AND ITS WORKS; ESPARTO OR BASKET WORKS	Chapters 44-45	44.01 to 45.04

Section X. PULP OF WOOD OR OF OTHER CELLULOSIC FIBROUS MATERIAL; RECYCLIED PAPER OR CARD (WASTE AND SCRAP); PAPER AND PAPERBOARD AND ITS WORKS	Chapters 46 to 49	4601 to 4907.00
Section XI. TEXTILES AND ITS WORKS	Chapters 50-63	5001.00.00 to 63.10
Section XII. FOOTWEAR, HATS AND SIMILAR ARTIFACTS TO USE, UMBRELLAS, SUN UMBRELLAS, WALKING STICKS, WHIPS AND PARTS THEREOF; PREPARED FEATHERS AND ITS WORKS; ARTIFICIAL FLOWERS; HAIR WORKS	Chapters 64 to 67	64.01 to 67.04
Section XIV. NATURAL OR CULTURED PEARLS, PRECIOUS STONES OR SEMI-PRECIOUS, PRECIOUS METALS, METALS CLAD OR METALS PRECIOUS PLATED (PLAQUE), AND ITS WORKS; JEWELRY; COINS	71. Natural or cultured pearls, precious or semi-precious stones and precious metals, clad metals or precious metal (plated), and its works; jewelry; coins	- 71.01. Natural or cultured pearls, even worked or combined, but not strung, not mounted or set; Natural or cultured pearls, temporarily strung for convenience of transport. - 71.16. Articles of natural or cultured pearls, precious or semi-precious stones, synthetic or reconstructed.
XX section. DIVERSE GOOD AND PRODUCTS	Chapters 94 to 96	94.01 to 96.12

MINISTERIAL ORDINANCE No 427, OF SEPTEMBER 29, 2016

THE MINISTER OF STATE FOR THE ENVIRONMENT, using the powers conferred upon it and in view of the provisions of paragraph 2 of article 6 of Law No. 13,123, of May 20, 2015, and in item XII of article 4 of Decree No. 8,772 , of May 11, 2016, informs that the Genetic Heritage Management Council-CGen, in the use of the powers conferred on it by Law No. 13,123, of May 20, 2015, and Decree No. 2016, resolves:

Art. 1o Approve the Internal Regulations of the Council for the Genetic Heritage Management - CGEN, in the form of the Annex to this Decree.

Art. 2o This Executive Ordinance enters into force on the date of its publication.

Art. 3o Decree No. 413, of November 18, 2014, published in the Official Gazette No. 224, of November 19, 2014, Section 1, pages 68 to 71, is hereby revoked.

SARNEY FILHO

ANNEX

CHAPTER I

NATURE, COMPOSITION AND STRUCTURE

Art. 1 The Genetic Heritage Management Council (CGEN) is a collegiate body of deliberative, normative, consultative and appeal nature, responsible for coordinating the preparation and implementation of policies for the management of access to genetic heritage and associated traditional knowledge and benefit sharing, formed by representatives of agencies and entities of the Federal Public Administration and representatives of civil society, pursuant to Law No. 13,123 of May 20, 2015, regulated by Decree No. 8,772 of May 11, 2016.

Sole paragraph. CGen has its headquarters in Brasília, Federal District, and its meetings will be held, preferably, at the headquarters of the Ministry of the Environment.

Art. 2 CGen will be operate by means of

I - Plenary;

II - Thematic Chambers;

III - Sectorial Chambers; and

IV - Executive Secretary.

Art. 3 CGen plenary shall be composed of twenty councilors, eleven of whom shall be representatives of Federal Public Administration agencies and nine of whom shall be representatives of civil society, distributed in accordance with art. 7 of Decree No. 8,772, 2016.

Paragraph 1 CGen shall be presided over by a permanent councilor of the Ministry of the Environment and, due to his impediment or absence, by the respective substitute.

Paragraph 2 The representations referred to in this article shall be composed of one titular member and two (2) substitutes each, to be nominated by the titular members of the bodies of the Federal Public Administration AND by the respective legal representatives of the entities or organizations of the civil society.

Paragraph 3 The full and alternate members of CGen shall be appointed by an act of the Minister of Environment.

Paragraph 4 When the subject requires it, the Plenary or the President may decide to invite experts, who are not Council members, to take part in a plenary meeting, in order to support the decision making process.

CHAPTER II

NATURE, COMPOSITION AND STRUCTURE

Section I - Competencies

Art. 4 CGen has the following competencies:

I - to coordinate the development and implementation of policies for the management of access to genetic heritage and associated traditional knowledge and benefit sharing;

II – to establish the following:
a) technical regulations;
b) guidelines and criteria for the preparation and execution of the benefit sharing agreement; and
c) criteria for the creation of a database for the registration of information on genetic heritage and associated traditional knowledge;
III – to monitor, in coordination with federal agencies, or by agreement with other institutions, the activities of:
a) access and remittance of sample containing genetic heritage; and
b) access to associated traditional knowledge;
IV – to deliberate on
a) the accreditation of a national institution that maintains *ex situ* collections of samples containing genetic heritage; whether they are:
1. public; or
2. private non-profit organizations that maintain popular herbaria or community seed banks; and
b) the accreditation of a national public institution to be responsible for the creation and maintenance of the database referred to in clause X;
V – certify the regularity of the access to the genetic heritage or associated traditional knowledge referred to in Chapter IV of Law No 13,123 of 2015;
VI – to register the receipt of the notification of the finished product or reproductive material and the presentation of the benefit sharing agreement, pursuant to Article 16 of Law No 13,123 of 2015
VII – to promote debates and public consultations on the themes dealt with in Law No. 13,123, 2015
VIII – to act as a higher instance of appeal in relation to the decision of an accredited institution and the acts resulting from the application of Law No. 13,123 of 2015;
IX – to establish guidelines for the application of resources destined to the National Fund for the Sharing of Benefits – FNRB, for the purpose of benefit sharing;
X – create and maintain a database on
a) the registers of access to genetic heritage or associated traditional knowledge and shipment;
b) authorizations for access to genetic heritage or to associated traditional knowledge and for shipment; and
c) instruments and terms of transfer of material for sample and shipment;
d) *ex situ* collections of accredited institutions that contain samples of genetic heritage;
e) notifications of finished products or reproductive material;
f) benefit sharing agreements; and
g) certificates of regularity of access;
XI – to inform federal agencies for the protection of the rights of indigenous populations, traditional communities and traditional farmers about the registration in the registry of access to associated traditional knowledge;
XII – to approve its internal regulations, which will have at least the following provisions:
a) the organization and functioning of its meetings;
b) operation of the Executive Secretariat;
c) the procedure for appointing its counselors;

d) removal, impediment, suspicion and hypotheses of conflict of interests of its counselors;
e) publicity of its technical standards and deliberations;
f) composition and operation of the Thematic and Sectorial Chambers; and
XIII - issue, at the user's request, an internationally recognized certificate of compliance that will serve as proof that the activities on the genetic heritage or associated traditional knowledge have been carried out in accordance with the provisions of Law No 13,123, of 2015, and Decree no 8,772, of 2016.

Section II - Operation and Meetings

Art. 5 The Plenary, the highest decision-making body of the Council, will meet, on an ordinary basis, according to the schedule approved by the Plenary, and, extraordinarily, at any time, upon written call from its President, or from the absolute majority of its members, accompanied by a justified agenda.
Paragraph 1 The ordinary meetings shall be convened at least fifteen days in advance.
Paragraph 2 The regular meetings will have their calendar fixed at the last meeting of the previous year.
Paragraph 3 The approved calendar of meetings referred to in the *caput* of this article may be altered by decision of the Plenary.
Paragraph 4 In the event of any postponement of the ordinary meeting, a new date must be set, within a maximum period of fifteen consecutive days.
Paragraph 5 During extraordinary meetings, the Plenary may decide on matters, and the agenda and documents for deliberation must be sent to the directors at least forty-eight hours in advance.
Paragraph 6 The meetings of the Plenary will be numbered in ascending order, respecting the chronological order of their accomplishment.
Paragraph 7 For the purposes of the provisions of Paragraph 6 of art. 7 of Decree No. 8,772, of 2016, the counselor must confirm his/her presence or of the alternate at least 11 (eleven) calendar days prior to the date of the meeting.
Art. 6 The President of the Council will prepare the agenda to be submitted to the Plenary with the following information:
I - type of proposal or resolution;
II - subject;
III - appointment of the reporting member;
IV - indication of interested parties, when applicable;
V - protocol or registration number in the National System for the Management of Genetic Heritage and Associated Traditional Knowledge - SisGen, when applicable; and
VI - other information deemed necessary for the analysis of the matter.
Art. 7 The agenda of the ordinary meetings and related documents will be made available to the counselors at least ten calendar days before the date designated for the meeting, preferably in digital media.
Paragraph 1 The original documents or certified copies presented in printed version to the Executive Secretariat for instruction of the process will be digitalized and made available in digital media for the members of the Council.

Paragraph 2 The agenda previously sent to the directors, accompanied by the relevant documents, must be approved at the beginning of each meeting.
Paragraph 3 The processes listed in the agendas of previous meetings that are still pending judgment, will automatically appear in the next meeting.
Paragraph 4 The documents referred to in the *caput* do not include the report of the rapporteur, pursuant to art. 9 of this Internal Regulation.
Paragraph 5 The Plenary may be requested to adopt the urgency regime of any matter not included in the agenda.
Art. 8 The distribution of cases to councilors will occur during ordinary meetings, by drawing lots.
Paragraph 1 The draws of the processes must observe the following criteria:
I - the oldest one in the filing with the CGen Executive Secretariat; and
II - rotation system among the counselors.
Paragraph 2 The member drawn as rapporteur must present his opinion for deliberation on the process at the next ordinary meeting, pursuant to art. 9 of this Internal Regulation.
Paragraph 3 The distribution of processes will not be waived to the absent member.
Paragraph 4 In urgent cases, distribution may occur outside the meeting.
Paragraph 5 Processes almost prescribing will have priority in the distribution and judgment before the others.
Paragraph 6 Processes whose final term may occur within up to three months after the draw meeting are considered to be in the process of prescribing.
Art. 9 The rapporteur will forward his/her opinion, containing report and vote, in writing, to the Executive Secretariat of the CGen, up to 3 (three) business days prior to the meeting at which the process is scheduled to be discussed.
Paragraph 1 The rapporteur who does not present the report and vote in the form of the *caput*, may present it, with a justification, up to 3 (three) business days in advance of the next meeting, except in cases where there is a risk of prescription of the respective process, depending on a decision of the Plenary.
Paragraph 2 When the rapporteur does not present a justification for non-compliance with the *caput*, the event will be communicated to the body or entity he represents.
Paragraph 3 When the report and vote are not presented by the rapporteur at the second meeting at which the matter has been discussed, the report and vote will be prepared and resolved by the Plenary at the same meeting.
Paragraph 4 In the case of Paragraph 3, the Plenary may appoint an ad hoc rapporteur to support its decision.
Art. 10. The plenary meeting will be public, except when the subject to be examined is protected by secrecy, when the presence of the parties and the proxies will be allowed in their respective processes.
Art. 11. Plenary meetings will follow the following procedures:
I - quorum conference and installation of the works by the President;
II - approval of the agenda;
III - approval of the minutes of the previous meeting;
IV - decision on the agenda;
V - discussion of general matters; and
VI - closing of the works.

Paragraph 1 The Plenary of the CGen will meet with the presence of at least 11 (eleven) counselors.
Paragraph 2 The minutes will be read at the meeting only when they have not been forwarded to the directors previously.
Paragraph 3 The counselors may request the inclusion of matters on the agenda, in writing, accompanied by the relevant documents, within at least 10 (ten) consecutive days prior to the meeting, or after the installation of the works, by decision of the Plenary.
Paragraph 4 The President may, ex officio, or by instigation of a director, the parties or their respective representatives, with a justified reason, determine the postponement of the trial or the withdrawal of one subject of the agenda.
Paragraph 5 The President may call the work to order or suspend the meeting for a determined time, when he deems it necessary, or by request of any of the counselors, by decision of the Plenary.
Art. 12. The debates will be carried out in accordance with the rules of this Regulation, observing the following:
I - the presentation of proposals, indications, requirements and communications will be delivered in writing to the Board, so it can be included in the minutes of the meeting;
II - the statements of the directors may regard:
a) on the matter under discussion;
b) on matters of order;
c) to forward voting; and
d) to explain the vote;
III - the counselor will request the use of the floor from the President to engage in the debate;
IV - the intervention to speak will be allowed by the President, if the speaker consents, and it must keep correlation with the matter under debate or in question of order;
V - any questions regarding the interpretation and application of these Regulations or those related to the discussion of the matter will be considered, as decided by the Chairman of the Board.
Art. 13. In addition to the regular members, alternate members of the Council, the Federal Attorney General's Office, represented by the Legal Counsel of the Ministry of the Environment, as well as other bodies and institutions to which this right is assured, are assured the right to engage in the debate, within the limits of the attributions established by law.
Paragraph 1 The directors may grant the right to engage in the debate to external participants, when requested.
Paragraph 2 The President may warn or determine that anyone who disturbs the session in any way be removed from the room, as well as he may question the speaker or interrupt his speech, when used without due decorum.
Art. 14. Plenary decisions will be taken by simple majority.
Paragraph 1 The casting vote will be up to the President of the CGen.
Paragraph 2 The alternate member will only have the right to vote in the absence of the titular member of the Board, including in cases of suspicion or impediment of the counselor.
Paragraph 3 The abstention will be counted for the purpose of quorum.
Paragraph 4 The number of votes for approval of the resolution will be considered in accordance with the following table:

Quórum	Votes for approval of the resolution
11	6
12	7
13	7
14	8
15	8
16	9
17	9
18	10
19	10
20	11

Paragraph 5 If the minimum number of votes for approval of the deliberation is not reached, the referral proposal will be considered rejected.

Paragraph 6 In the case of Paragraph 5, the President may present a new proposal for referral.

Art. 15. Any counselor may ask to verify, only once, a matter submitted for deliberation before the voting process is announced by the Chairman.

Paragraph 1 In the event of urgency or risk of prescription, the request for viewing will only be granted after its approval by the Plenary.

Paragraph 2 Once the request for a review is made, the matter will be automatically removed from the agenda, and its discussion and voting will be transferred to the next ordinary or extraordinary meeting of the Plenary, at which time a new request for a review on the same matter will not be allowed and will have priority on the agenda.

Paragraph 3 The counselor authoring the request for a view shall prepare an opinion with a report and vote on the matter, in compliance with the provisions of art. 9 of this Regiment.

Art. 16. The decision of the subjects included in the agenda will obey the following steps:

I - the Chairman will give the floor to the reporting member, who will present his report and vote;

II - the President will give the floor to the interested parties, if present and upon request, for oral support of their reasons, for a period of up to 10 (ten) minutes, extendable for another 5 (five) minutes;

III - the other directors may take the floor and debate on issues relevant to the matter, with amendments being allowed by any director with due justification;

IV - any director may request a view, pursuant to art. 15 of these Rules of Procedure, before announcing the closing of the discussion by the President;

V - the President will announce the end of the discussion and, considering the vote of the rapporteur and the amendments presented, will forward the deliberation of the matter to:

a) approve (A);

b) approve with conditions (AC);
c) do not approve (NA); or
d) ask for clarification or diligence (PED);
VI - the Plenary will proceed with nominal voting in the order of devotion designated by the President; and
VII - the Chairman will read the result of the vote for the purpose of recording it in the minutes of the meeting.
Sole paragraph. In the event of sub-item 'b' of item IV of the *caput* of this article, the condition will be restricted to formal issues, and the Executive Secretariat will be responsible for verifying compliance.
Art. 17. In case of allegation of suspicion, impediment or conflict of interests of the director, the preliminary questions will be resolved before any stage of the judgment of the matter, observing the provisions of Sections VI and VII of this Chapter.

Section III - Of the Acts of the Council

Art. 18. The Board may decide on the matter submitted to its consideration, in the form of:
I - resolution: when dealing with the elaboration of:
a) technical norms on access and remittance of genetic heritage, on the protection and access to associated traditional knowledge, and on the sharing of benefits for the conservation and sustainable use of biodiversity;
b) guidelines and criteria for the elaboration and fulfillment of the benefit sharing agreement;
c) criteria for creating a database for recording information on genetic heritage and associated traditional knowledge; and
d) guidelines for the application of resources destined to the National Fund for Benefit-Sharing-FNRB, in accordance with art. 33 of Law No. 13,123, of 2015;
II - proposition: when dealing with a manifestation related to the topics dealt with in Law No. 13,123, of 2015, to be forwarded, in particular:
a) to the bodies and institutions of the Federal Public Administration, including collegiate bodies, on Public Policies and Programs; and
b) to the Committees of the Federal Senate and the Chamber of Deputies;
III- deliberation: when it comes to a decision on:
a) accreditation and disaccreditation of a national institution that maintains an *ex situ* collection of samples that contain genetic heritage;
b) accreditation and disaccreditation of a national institution to be responsible for creating and maintaining the database mentioned in item IX, Paragraph 1, of art. 6 of Law No. 13,123, of 2015;
c) granting a certificate of regularity of access to genetic heritage or associated traditional knowledge referred to in Chapter IV of Law No. 13,123, of 2015;
d) appeal in relation to the decision of an accredited institution and the acts resulting from the application of Law No. 13,123, of 2015; and
e) institution of the Chambers mentioned in Chapter III of these Rules;
IV - technical guidance: when it comes to clarifying the meaning of a term whose dubiousness or imprecision impairs the understanding and application of Law No. 13,123, of 2015, and

Decree No. 8772, of 2016; or
V - summary: when dealing with repeated resolutions of the Board, establishing an understanding on matters within its competence.

Section IV - Minutes of Meeting and Publicity of Acts

Art. 19. Minutes will be drawn up of each Board meeting, with sequential numbering.
Paragraph 1 The full texts of resolutions, technical guidelines, precedents and amendments to these Rules approved by the Plenary shall integrate the minutes of the meeting as annexes.
Paragraph 2 After being approved, the minutes of the meetings will be signed by the President and the Executive Secretary of the Council and filed with the Executive Secretary.
Paragraph 3 The minutes may be issued, signed and made available in digital media, pursuant to Decree No. 8,638, of January 15, 2016.
Art. 20. The resolutions, proposals, deliberations, technical guidelines and summaries approved by the Plenary will be signed by the President of the Council, and subsequently dated and numbered in a different order by the Executive Secretariat, which will publicize the acts of the CGen.
Paragraph 1 The resolutions, technical guidelines and summaries will be published in full and the deliberations in extract in the Official Gazette of the Union, preferably within 30 days.
Paragraph 2 The Executive Secretary of the Council will forward the approved proposals to the respective addressees.
Paragraph 3 The acts provided for in Paragraph 1 will be valid from the publication in the Official Gazette of the Union.
Art. 21. Will be issued through SisGen:
I - proof of access registration;
II - proof of remittance registration;
III - proof of notification;
IV - certificate of regularity of access, after approval by CGen; and
V - certificate referred to in art. 41 of Decree No. 8,772, of 2016, after the verification procedure.
Art. 22. The Executive Secretariat will make available on the CGen website the acts provided for in art. 20 and the documents provided for in art. 21 or its information, except for those with legal confidentiality protection.

Section V - Resources

Art. 23. The Council will decide, pursuant to item VII of Paragraph 1 of art. 6 of Law No. 13,123, of 2015, the appeals filed against:
I - decision of an accredited institution;
II - final decision of the original judging authority on infringement against genetic heritage and associated traditional knowledge under the terms of Law no. and
III - deliberation of the Plenary.
Sole paragraph. In the case of item II, the appeal legitimacy is conferred on the assessed

person, without prejudice to the other appeal admissibility requirements.
Art. 24. The decisions of the Plenary are unappealable and we will decide on appeals.
Art. 25. The appeal is timely when lodged within a period of 20 (twenty) days, excluding the start date and the expiration date.
Paragraph 1 The appeals dealt with in item I of art. 23 must be filed with the accredited institution that issued the contested decision and the period will start counting from the date of knowledge of the decision by the interested party.
Paragraph 2 The appeals mentioned in item II of art. 23 must be brought before the judging authority that issued the second-instance sentencing decision and the period will start counting from the date of knowledge of the decision by the assessed person.
Paragraph 3 The appeals mentioned in item III of art. 23 must be filed with the Executive Secretariat of the CGen and the deadline will start from the date of publicity of the contested decision or its knowledge by the interested party.
Paragraph 4 The term is considered extended until the first following business day if the due date falls on a day in which there are no working hours or this is closed before the normal time.
Paragraph 5 Except for reasons of force majeure duly proven, the procedural deadlines are not suspended.
Paragraph 6 The knowledge of the interested party will take place from the publication of the decision in the Official Gazette of the Union.
Art. 26. The cases to be distributed for judgment must be accompanied by an extract, containing an objective summary of the records, including, at least, the following information:
I - timeliness;
II - existence of a term of commitment signed with the competent body;
III - limitation period;
IV - type of offense;
IV - recidivism;
V - sanction applied; and
VI - value of the fine.
Art. 27. The rapporteur councilor will cast his/her vote, at which time he/she must propose to the Plenary:
I - not knowing about the appeal; or
II - to know about the appeal and:
a) deny it; or
b) grant.
Art. 28. The resource will not be known when verified:
I - the untimeliness;
II - the illegitimacy of the appellant;
III - the non-application of the appeal; or
IV - the termination of the process for loss of the object.
Sole paragraph. Promoted the regularization through registration or authorization, as the case may be, of activities of access to genetic heritage or associated traditional knowledge solely for scientific research purposes, pursuant to art. 38, Paragraph 2, of Law No. 13,123, of 2015, the appeal filed is prejudiced, due to loss of object.
Art. 29. After discussion, voting will be open to the other directors, who may or may not follow the vote cast by the rapporteur.

Art. 30. If the vote of the reporting member is not accepted by the Board, the Chairman, based on the discussions and suggestions, will make a new proposal for referral for voting.
Art. 31. The prescription will be regulated in accordance with the provisions of arts. 76 and 77 of Decree No. 8,772 of 2016.
Art. 32. Once the appeal is decided, the Executive Secretariat of the CGen will arrange for the return of the case to the Brazilian Institute of the Environment and Renewable Natural Resources-IBAMA, to the Navy Command or to the Ministry of Agriculture, Livestock and Supply, pursuant to art. 93 of Decree No. 8,772, of 2016, to comply with the decision and notify the appellant.

Section VI - Impediment and Suspicion

Art. 33. The director will be prevented from exercising his/her duties:
I - in whose process:
a) has acted as the launching authority of the infraction notice or practiced a decision-making act;
b) has a direct economic or financial interest in the subject matter; and
c) your spouse, partner or relatives, consanguineous or similar, in a straight line or collateral, up to the third degree, whether the assessed person, his/her legal representative or is applying as a lawyer (a) from the party;
II - when providing or having provided consultancy, advice, legal or accounting assistance to the interested party, or who receives remuneration from him/her under any title, from the beginning of the administrative proceeding until the date of its judgment; and
III - when acting as a lawyer, signing petitions, in a lawsuit whose object, matter and request are identical to the appeal in trial.
Art. 34. The director who has close friendship or notorious enmity with the assessed person or with a person directly interested in the outcome of the administrative process, or with their respective spouses, partners, relatives related up to the third degree.
Sole paragraph. The counselor may declare himself a suspect for reasons of an intimate nature, without having to state his reasons.
Art. 35. The impediment or suspicion must be declared orally by the director himself or may be raised by the other directors or by those directly interested in the matter under deliberation, in the first chance.
Paragraph 1 The argument will take place during the plenary meeting, guaranteeing the defense, at the same opportunity, of the raised party.
Paragraph 2 If the impediment or suspicion is not recognized by the defendant, the matter will be submitted to the Plenary for deliberation, and within the parameters set by the Plenary, and once the complexity has been verified, a deadline may be opened for the presentation of a written defense.
Paragraph 3 The counselor who declares himself, or will be declared by the Plenary, impeded or suspected, will not be able to exercise his functions in the matters referred to in the *caput*, being the responsibility of the) alternate to participate in the discussions and deliberations, as long as they are not in the same situation as the incumbent.
Art. 36. If the rapporteur and his/her alternates are declared impeded or suspected, the case

files will be redistributed to the new rapporteur within five days , reopening the counting of the regimental deadlines for the new rapporteur from the receipt of the records, and the process will be considered at the next meeting.

Section VII - Withdrawal and Conflict of Interest

Art. 37. For the purposes of these Internal Regulations, a conflict of interest is considered to be the situation generated by the confrontation between public and private interests, which may compromise the collective interest or improperly influence the performance of the counselor's role, through:
I - disclosure or use of privileged information, for one's own benefit or that of third parties, obtained as a result of the role of director;
II- exercise of activity that implies the provision of services or the maintenance of a business relationship with an individual or legal entity that has an interest in the decisions of the CGen or of other bodies and institutions in the exercise of the attributions that Law no.
III - exercise, directly or indirectly, of an activity that, due to its nature, is incompatible with the attributions of the role of director, considering as such, including the activity developed in related areas or matters;
IV - receiving gifts from those who are interested in a decision by the CGen outside the limits and conditions established for public agents in the legislation in force; and
V - provision of services, even if occasional, to the individual or legal entity that performs a regulated activity within the scope of CGen's powers.
Sole paragraph. For the purposes of item I, privileged information is considered to be information that concerns confidential matters or that relevant to the decision-making process within the scope of the Federal Executive Branch that has economic or financial repercussions and that is not widely public knowledge.
Art. 38. The principal or alternate representative will be removed from the role of director who
I - be in a condition of conflict of interest as provided in art. 37; or
II - lose the link with the Federal Public Administration body represented in the form of art. 3 of these Rules of Procedure, or with the institution linked to it.
Sole paragraph. The removal provided for in the *caput* will oblige the body or institution to appoint, within 30 (thirty) days, a new titular or alternate member to compose the CGen, under penalty of not being able to participate in the deliberations.

CHAPTER III
THEMATIC AND SECTORAL CHAMBER

Section I - Thematic Chambers

Art. 39. The Thematic Chambers will be created by the CGen Plenary to support its decisions based on technical discussions and presentation of proposals on specific topics or areas of

knowledge related to access and benefit sharing, or any other related to what is provided for in Law 13,123 of 2015.

Sole paragraph. The Thematic Chambers are responsible for analyzing matters relating to the powers provided for in the legislation and those delegated to them by the Plenary of the Council, as well as:

I - prepare, together with the Executive Secretariat, the calendar and agendas of its meetings;

II - prepare and forward to the Plenary subsidies for decision making;

III - express an opinion on the consultation that has been forwarded to it; and

IV - propose items for the Board meeting agenda, respecting the period of 10 (ten) days in advance of the meeting.

Art. 40. The Thematic Chambers will be established by the Plenary, upon proposal of any of the counselors, by means of deliberation, which will provide for their attributions, duration and composition, which must observe the proportion of:

I - fifty percent of representatives of bodies and entities of the Federal Public Administration with competences related to the subject of the respective Chamber;

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

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

Sole paragraph. In the composition of the Thematic Chambers, the technical nature of the subject within their competence, the purpose of the bodies or entities represented, as well as the technical training of their members or their notable performance in the area, must be considered.

Art. 41. CGen may create a special Thematic Chamber to analyze and support the judgment by the Plenary of appeals filed in the last instance.

Section II - Of the Sectorial Chambers

Art. 42. The Sectoral Chambers will be created by the CGen to support the Plenary's decisions based on technical discussions and the presentation of proposals of interest to the business and academic sectors, as well as indigenous populations, traditional communities and traditional farmers.

Art. 43. The Plenary, upon proposal of any of the directors, will decide, through deliberation, on the specific attributions, the duration and composition of each Sectorial Chamber.

Sole paragraph. The Sectorial Chambers will be composed of a maximum of 12 (twelve) members, observing the parity between the representation of the bodies and entities of the Federal Public Administration with competences related to the respective Chamber and the representation of the corresponding civil society sector.

Section III - Meetings and the Functioning of the Chambers

Art. 44. The members of the Thematic Chambers and the Sectorial Chambers will be appointed by the councilors at an ordinary meeting of the CGen, considering their training, performance or notorious knowledge in the area related to the Chamber's competences.

Sole paragraph. Institutional representation in the Chamber may be exercised by a techni-

cian appointed by a counselor.

Art. 45. The coordination function of the Thematic and Sectoral Chambers will be attributed to the representation of an organ or entity that is part of the Council, by decision of the Plenary.

Sole paragraph. The Coordination will be institutional, characterizing the Coordinator as the holder indicated by the body or entity, who must be replaced in his/her absences and impediments by the respective alternates.

Art. 46. The meetings of the Thematic and Sectoral Chambers will be convened by the Coordinator, with the support of the Executive Secretariat, at least ten days in advance.

Sole paragraph. The Executive Secretariat will make available to the members of the Chambers, ten days prior to the meeting, the agenda, documents and other materials sent by the respective coordinators, and the agenda may be made available on the CGen Electronic Site.

Art. 47. The meetings of the Thematic and Sectoral Chambers will be public.

Paragraph 1 The meetings of the Thematic Chambers may have a reserved character, according to the subject on the agenda, observing the provisions of Chapter V of these Rules.

Paragraph 2 Those interested in participating as listeners in the Thematic Chambers' meetings must submit a request to the Executive Secretariat of the Council.

Art. 48. The Thematic and Sectoral Chambers may establish a permanent forum in a virtual environment to carry out discussions, forward and elaborate proposals in the interstice of the meetings.

Paragraph 1 The virtual environment mentioned in the *caput* may include the transmission of information in text, audio or image.

Paragraph 2 The personal and institutional identification of the members to participate in the discussion forum must be ensured.

Paragraph 3 The Coordination of the Thematic or Sectorial Chamber shall prepare a report with a summary of the main discussions and referrals carried out in a virtual environment to be forwarded to the Executive Secretariat for purposes of publicity and transparency.

Paragraph 4 The Executive Secretariat of the CGen will have access to the forum to monitor the discussions, keep a record of the proposals and referrals formulated and, when requested, provide technical and administrative support to the respective Chamber.

Art. 49. The Coordinators of the Thematic and Sectoral Chambers may invite specialists or representatives of interested segments to participate in the meetings, as a way of subsidizing their work.

Art. 50. It is incumbent upon the Plenary of the Council to forward matters for consideration by the Thematic and Sectoral Chambers.

Art. 51. Simplified minutes of the meetings of the Thematic and Sectoral Chambers will be drawn up in which the relevant discussions, conclusions, referrals on each topic on the agenda and the appointment of a new meeting, if applicable, will be recorded.

Paragraph 1 The minutes will be prepared by the Coordinator, with the support of the Executive Secretariat, and made available to the participants of the meeting, who will have three working days to present amendments.

Paragraph 2 After the deadline for submitting amendments, these will be compiled into the final version of the minutes, which will be signed by the Coordinator of the respective Thematic or Sectorial Chamber.

Art. 52. The conclusions and referrals of the Thematic and Sectoral Chambers will be approved by consensus.
Sole paragraph. If consensus cannot be reached, all positions expressed during the discussions, identified the respective authors, will be taken to the Plenary, when the matter is forwarded for deliberation.

CHAPTER IV
EXECUTIVE SECRETARIAT

Art. 53. The Executive Secretariat will be composed of:
I - by the Executive Secretary of the Council; and
II - by the team of the Ministry of the Environment unit, with attributions related to the management of genetic heritage and associated traditional knowledge, in order to provide technical and administrative support to the functioning of the Council.
Art. 54. The Executive Secretariat of the CGen is responsible for:
I - provide technical and administrative support to the CGen Plenary and its Chambers;
II - promote the instruction and processing of the processes to be submitted to the deliberation of the CGen;
III - issue, in accordance with the CGen's deliberation, the acts and decisions within its competence;
IV - promote, in accordance with the CGen's deliberation, the accreditation or de-accreditation of:
a) national institution that maintains an *ex situ* collection of samples containing genetic heritage; and
b) national public institution to be responsible for the creation and maintenance of a database dealing with items related to the items of item IX of Paragraph 1 of art. 6 of Law No. 13,123, of 2015; and
V - implement, maintain and operate the systems:
a) traceability of information related to genetic heritage and associated traditional knowledge, provided for in art. 5th of Decree No. 8,772, of 2016; and
b) referred to in Chapter IV of Decree No. 8,772, of 2016.
Sole paragraph. The Executive Secretary of the CGen may ask the Legal Consultancy of the Ministry of the Environment to prepare an opinion to support the decision of the Plenary.

CHAPTER V
ASSIGNMENTS

Art. 55. The duties of the Chairman of the Board are:
I - to convene and preside over the Plenary meetings, with the casting vote;
II - order the use of the word;
III - refer matters to the Thematic and Sectorial Chambers; in accordance with the decision of the Council;

IV - submit the matters to be decided upon for consideration by the Plenary;
V - intervene in the order of the work, or suspend them whenever necessary;
VI - sign the resolutions, deliberations, propositions, technical guidelines and summaries approved by the Council, after manifestation of the Legal Consultancy of the Ministry of the Environment, when requested;
VII - sign the minutes approved at the Plenary meetings;
VIII - submit the Council's annual report to the Plenary for consideration;
IX - resolve omissions or doubts about the interpretation of these Regulations, ad referendum of the Council, when there is no opportunity for the Council to express itself in advance;
X - ensure compliance with the provisions of this Regulation, taking, for this purpose, the necessary measures;
XI- invite, by decision of the Plenary, specialists to participate in a plenary meeting of Thematic or Sectoral Chambers, in order to support decision making; and
XII - delegate to the Coordinators of the Thematic and Sectoral Chambers, upon authorization of the Plenary, the competence to invite specialists to participate in the Thematic or Sectoral Chamber meeting, as per the previous item.

Art. 56. Board members are responsible for:
I - attend Council meetings;
II - discuss the matters under discussion;
III - request information, measures and clarifications from the President and the Executive Secretary;
IV - present an opinion containing a report and vote, orally and in writing, within the established deadlines, on the matter to be submitted for decision by the Plenary, when designated as Rapporteur;
V - ask for a view of the matter, in the regimental form;
VI - participate in the activities of the Council, with the right to voice and vote;
VII - propose themes and subjects for decision and action by the Plenary, in the form of proposed resolutions, proposals, deliberations, summaries or technical guidelines;
VIII - propose the development of educational materials, dissemination strategies, training and dissemination on issues related to Law No. 13,123, of 2015;
IX - coordinate, when designated, the work of the Thematic or Sectoral Chambers;
X - propose points of order in plenary meetings;
XI - request verification of quorum; and
XII - observe, in its manifestations, the basic rules of coexistence and decorum.

Sole paragraph. The counselors representing indigenous populations, traditional communities and traditional farmers may request, from federal agencies and entities for the protection of their rights, assistance or promotion, technical and legal advice for the performance of their attributions, respecting all obligations related to the confidentiality of the information.

Art. 57. The Thematic or Sectorial Chamber Coordinator is responsible for:
I - to convene and coordinate the meetings of the Chamber;
II - order of the use of the word;
III - ask the President of the CGen to include a matter on the Plenary agenda;
IV - intervene in the order of the work, or suspend them whenever necessary;
V - sign the minutes approved at the meetings;
VI – submit an annual report on activities to the members of the Chamber; and

VII - to invite, by its own decision or at the request of the other members, specialists to participate in the meeting of the Thematic or Sectoral Chambers, in order to support decision making.

Art. 58. The Executive Secretary is responsible for:

I - assist the President and Coordinators of the Thematic and Sectoral Chambers, within the scope of their attributions;

II - establish permanent communication with the CGen and Thematic and Sectoral Chambers councilors and keep them informed and guided about the activities and proposals of the CGen;

III - advise and assist the President of the CGen in his/her relationship with Federal Public Administration bodies, civil society organizations, users and providers, and international organizations;

IV - to subsidize the CGen Plenary, the Thematic and Sectoral Chambers with information and technical studies to assist in the formulation and analysis of the proposals considered by the CGen; and

V - direct, coordinate and guide the planning, execution and evaluation of the Executive Secretariat's activities, without prejudice to other attributions entrusted to it by the President of the CGen.

CHAPTER VI

ADVERTISING AND CONFIDENTIALITY

Art. 59. The Executive Secretariat will allow interested parties, or their duly constituted representatives, to view the proceedings in progress at the Council, in its premises.

Paragraph 1 The person interested in having a view of the processes that are being processed in the Council, must address a written request to the Executive Secretary, which will be attached to the respective records, in which he declares himself aware of the consequences associated with the improper use of the information obtained, in the form of civil, criminal and administrative legislation in force, and undertake to cite the sources, in case non-confidential information is disclosed by any means.

Paragraph 2 Interested parties or their legal representatives may obtain certificates, extracts or copies of parts of the case file, upon prior request to the Executive-Secretary of the Board and reimbursement of the corresponding cost , observing the obligations related to confidentiality.

Art. 60. The Executive Secretariat will adopt the necessary measures to protect the confidentiality of information specially protected by law, provided that this information does not fall under constitutionally guaranteed private or collective interests.

Paragraph 1 In order to protect the confidentiality referred to in the *caput* of this article, the applicant must send an express and reasoned request to the Executive Secretary, containing the following information:

I - specification of the information whose confidentiality it intends to protect, and a non-confidential summary for each of the indicated information;

II - justification of the need for secrecy, including the legal basis of the claim; and

III - declaration that the protection of secrecy requested does not harm private or collective

interests constitutionally guaranteed confidentiality.
Paragraph 2 The Executive Secretary will reject the request, if there is just reason, by means of a reasoned order, and this decision may be appealed to the Plenary within 20 (twenty) days, counting from the notification, guaranteeing confidentiality until the end of the appeal period.
Paragraph 3. Once the appeal is filed, the secrecy will extend until its judgment by the Plenary, which will necessarily take place in a reserved session.
Paragraph 4 In all oral or written manifestations made by the members of the Council, the reservation of information recognized as confidential in the form of this article must be ensured.
Paragraph 5 The disclosure of information recognized as confidential will subject the person in charge, public agent or not, to the civil, criminal and administrative consequences provided for in current legislation.
Art. 61. The following may have access to information recognized as confidential within the scope of the Council:
I - public agents who, in the exercise of a public position, function, activity or job, need to know confidential information; and
II - citizens who prove the existence of a collective or private interest constitutionally guaranteed on the information recognized as confidential.
Paragraph 1 The Executive Secretariat will ask everyone who has access to information recognized as confidential within the scope of the Council to sign terms of commitment, by which they declare that they are aware of the consequences associated with the violation of confidentiality, in the form of civil, criminal and administrative legislation in force, and commit themselves to if they do not reveal or disclose the data or confidential information of which they have knowledge, even after their departure from the Board.
Paragraph 2 In the event provided for in item II of the *caput* of this article, when the information declared confidential is of particular constitutionally guaranteed interest, access to it will only be allowed to the person to whom the information relates.
Paragraph 3. The servants of the Executive Secretariat of the CGende must sign the term of commitment mentioned in Paragraph 1.

CHAPTER VII

GENERAL PROVISIONS

Art. 62. CGen will approve the 2016 meeting schedule at its first regular meeting.
Art. 63. The Council's Internal Regulations may be amended upon proposal by at least eleven councilors and approved by at least two-thirds of the Plenary.
Sole paragraph. The regimental changes approved in the *caput* of this article will take effect after their publication.
Art. 64. Omissions or doubts regarding the interpretation of these Rules of Procedure will be decided by the Plenary.
Art. 65. This Internal Regulation enters into force on the date of its publication.

SARNEY FILHO

MINISTERIAL ORDINANCE No 381, OF OCTOBER 3, 2017

The MINISTER OF THE ENVIRONMENT, in the use of its legal attributions and in view of the provisions of Paragraph 2 of art. 6 of Law No. 13,123, of May 20, 2015, in item XII of art. 4 of Decree No. 8,772, of May 11, 2016, and contained in Administrative Process No. 02000.001360/2016-20, resolves:

Art. 1 To amend the Internal Regulations of the Council for the Genetic Heritage - CGEN, as per art. 2 of this Decree.

Art. 2 Art. 8 of the Annex to Ordinance No. 427, of September 29 of 2016, shall take effect with the following redaction:

"Art. 8 The distribution of the processes to the counselors, for reporting purposes, will occur during the ordinary meetings, by drawing lots.

Paragraph 2 In the hypothesis foreseen in item II, article 23, the following will be excluded from the drawings of lots:

I - representatives of entities or organizations from the business sector, in the case of an appeal filed by an appellant from this sector;

II - representatives of entities or organizations from the academic sector, in case of appeal filed by an appellant from this sector; and

III - representatives of entities or organizations representing indigenous populations, traditional communities and traditional farmers; in the case of an appeal filed by an appellant from this sector. (NR)

Paragraph 3 The counselor selected as reporter must present his/her opinion for deliberation on the process at the following ordinary meeting, pursuant art. 9 of these Internal Rules.

Paragraph 4 The distribution of cases will not be dismissed to the absent member.

Paragraph 5 In cases of urgency, the distribution may take place outside the reunion.

Paragraph 6 Processes almost prescribing will be given priority in distribution and trial before the others.

Paragraph 7 The following processes are considered to be under statute of limitations whose final term may occur within three months after the meeting of the draw."

Art. 3 This Ordinance goes into effect on the date of its publication.

SARNEY FILHO
MINISTER OF THE ENVIRONMENT

MINISTERIAL ORDINANCE No 1, OF OCTOBER 3, 2017

Implements and makes available the National System for the Management of Genetic Heritage and Associated Traditional Knowledge - SisGen starting on November 6, 2017.

The EXECUTIVE SECRETARY OF THE GENETIC PATRIMONY MANAGEMENT COUNCIL – CGen, using the powers conferred upon it and in view of the provisions of art. 48 of Law No. 13.123, of May 20, 2015; in arts. 11 and 20 of Decree No. 8.772, of May 11, 2016; and in art. 21-A of Annex I of Decree No. 8.975, of January 24, 2017, resolves:

Art. 1 Implement and make available the National System for the Management of Genetic Heritage and Associated Traditional Knowledge– SisGen, as of November 6, 2017, at the electronic address https://sisgen.gov.br.

Sole Paragraph. The counting of deadlines provided for in Law No. 13,123, of May 20, 2015, and in Decree No. 8,772, of May 11, 2016, related to the availability of the registry and system, as provided for in Law No. 9,784, of January 29, 1999, begins from the date provided for in the caput.

Art. 2 This Ministerial Ordinance goes into effect on the date of its publication.

RAFAEL DE SÁ MARQUES

Resolutions

Resolution nº 2, of October 5, 2016

Establishes rules and procedures for the alteration of the modality of benefit sharing after the notification to SisGen.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in the terms of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, resolves:

Art. 1º To establish rules and procedures for the alteration of the modality of benefit sharing after the notification, in cases of finished product or reproductive material originated from access to genetic heritage.

Sole paragraph. This resolution does not apply to notification of finished product or reproductive material originated from access to associated traditional knowledge.

Art. 2º The modality of benefit sharing indicated in The National System Of Genetic Heritage And Traditional Knowledge Associate Management – Sisgen – may be altered by the user at any moment, through update of the respective notification in SisGen, observed the demands of the Law and its regulations.

Sole paragraph. The alteration of the modality of benefit sharing does not configure a new notification of product.

Art. 3º In cases of alteration from a monetary modality to a non-monetary modality, the effects shall reflect on the benefit sharing owed starting from the tax year of the alteration.

Paragraph 1. In the hypothesis foreseen in the *caput*, the benefit sharing agreement shall be presented in 365 (three hundred and sixty five) days counting from the notification date, or the moment of the alteration, if elapsed more than 365 (three hundred and sixty five) days from notification.

Paragraph 2. The alteration foreseen in the *caput* does not have effects over the benefit sharing owed in tax years previous to the alteration.

Art 4º In case of alteration from non-monetary modality to the monetary modality, the effects will take place from the fiscal year of calculation following the last fiscal year committed to the obligations under the benefit sharing agreement.

Paragraph 1. In the hypothesis of the alteration foreseen in the *caput* be carried out in a date previous to the presentation of the benefit sharing agreement, the effects shall be retroactive to the notification date and the user must share the benefits in the monetary modality relative to tax year previous to the alteration, if the economic exploitation of finished product or reproductive material has already began.

Paragraph 2. In the case the term for calculation of the net revenue, referred in Paragraph 2. of article 45, and the term for the benefit sharing collection, referred in Paragraph 1. of article 49 of the Decree nº 8.772/2016, have already elapsed, the benefit sharing collection owed shall be carried out in 30 (thirty) days, counting from the date the modality was altered in SisGen.
Paragraph 3. The value to be collected referred to in Paragraph 2. must be corrected by the reference rate of Special System for Settlement and Custody – Selic, applied to the period between the payment date and the date referred in Paragraph 1. of art. 49 of the Decree nº 8.772, de 2016.
Art. 5º The user that does not satisfy the requirements for exemption foreseen in the Law nº 13.123/2015 must update the information regarding the option of modality of benefit sharing in the notification of finished product or reproductive material, in 30 (thirty) days.
Sole paragraph. In the hypothesis of the user indicating that the benefit sharing will be carried out in the non-monetary modality, the benefit sharing agreement must be presented at the moment of the update.
Art. 6º If the benefit sharing agreement is not presented in the due time foreseen in the valid legislation and in this Resolution, the notification of finished product of reproductive material will be canceled.
Art. 7º This Resolution enters into force on the date of its publication.

JOSÉ PEDRO DE OLIVEIRA COSTA
President of the Counsel

Resolution nº 3, of August 15, 2017

Establishes the necessary requirements for the suspension of distribution of appeals in administrative processes of infraction notices to the Plenary of CGen

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in terms of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, resolves:

Art. 1º To establish the necessary requirements to suspend the distribution of appeals in administrative processes of infraction notices in case of third appeal instance to the Plenary of CGen.
Art. 2º For the purposes of the previous article, the appellant shall:
I – have solicited the suspension of the process distribution to the Plenary of CGen.
II – have protocolled the solicitation of celebration of the Term of Commitment with the State, in the terms of Law nº 13.123/2015; and
III – in cases where the signature of the Term of Commitment entails benefit sharing, in accordance with Chapter V of Law nº 13.123/2015:

a) have a Contract of Utilization of Genetic Heritage and Benefit Sharing – CURB, defined in the terms of the Provisional Measure nº 2.186-16, of august 23 of 2001, approved by CGen, provided that it hasn't been challenged by any of parties; or
b) have a Project for Benefit Sharing, established in the terms of CGen Resolution nº 40, of February 27 2013, approved by CGen, provided that it hasn't been challenged; or
c) present the Benefit Sharing Agreement – ARB, defined in the terms of Law nº 13.123/2015, signed with the beneficiary of the benefit sharing; or
d) present the receipt of payment of the benefit sharing to the National Fund for Benefit Sharing – FNRB.

Paragraph 1. The appellant that demonstrates that falls within one of the possibilities of exemption of benefit sharing foreseen in Chapter V of Law 13.123, of 2015, is exempted of complying with the requirement referred in item III of the *caput*.

Paragraph 2. In the hypothesis of access to the genetic heritage or the associated traditional knowledge solely for the purpose of scientific research, the appellant shall be exempted from the requirements established in items II and III of the *caput*, observed the provisions of Paragraph 2. of article 104 of the Decree nº 8.772, of 2016.

Art. 3º The process that falls within the risk of limitation shall not have its distribution suspended, in accordance with Paragraph 7. of article 8º of CGen's Internal Regiment.

Art. 4º The omissive cases or controversial issues shall be submitted to the Plenary of CGen analyses.

Art. 5º This Resolution shall enter into force on the date of its publication.

RAFAEL DE SÁ MARQUES
President of the Council

Resolution nº 16, of October 9, 2016

Establishes deadlines for the compliance of obligations foreseen in Law 13.123, of 2015 and its regulations, regarding activities that involve traditional local variety or creole or locally adapted race or creole.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in terms of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, resolves:

Art. 1º The obligations foreseen in Law 13.123, of 2015, and its regulations, for traditional local variety or creole or locally adapted race or creole starts from the date the act the included the variety or the breed in the list referred in art. 114 of Decree 8.772, of 2016, is published.

Sole paragraph. The obligations regarding the registry and notifications on the National System of Genetic Heritage and Associated Traditional Knowledge – SisGen – shall be complied by the user within 1 (one) year, counting from the date the act referred in the *caput* was

published.
Art. 2º This Resolution enters into force on the date of its publication.

THIAGO AUGUSTO ZEIDAN VILELA DE ARAÚJO
President of the Counsel

Resolution nº 19, of October 31, 2018

Establishes an alternative way to comply with the obligation of regularization in cases of access to the genetic heritage or associated traditional knowledge solely intended for scientific research.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in the terms of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 29 of 2016, resolves:

Art. 1º Establishes an alternative way to comply with the obligation of regularization in cases of access to the genetic heritage or associated traditional knowledge solely intended for scientific research.
Art. 2º The user whose regularization is foreseen in art. 38, Paragraph 2. of Law 13.123, of 2015, shall be able to regularize, alternatively, through the signing of a Term of Commitment foreseen in Annex VI of MMA Ministerial Ordinance nº 378, of October 1st of 2018, with a term of one year, counting from the date the Term of Commitment was signed by the representative of the State, to specify in proper annexes the activities to be regularize, and one more year to register activities of access to genetic heritage or associated traditional knowledge, to be regularize.
Art. 3º For the purpose of compliance with the terms and deadlines of submission of the Term of Commitment, it shall be considered as valid the date of posting, in accordance with art. 1.003, Paragraph 4. of Law nº 13.105, of March 16 of 2016 (Civil Process Code).
Art. 4º This Resolution enters into force on the date of its publication.

RAFAEL DE SÁ MARQUES
President of the Council

Resolution nº 20, August 07, 2019

Establishes procedures for the CGen's Executive Secretariat to

cancel registrations of access, shipment of samples, or notification of finished products or reproductive material, in the cases it specifies.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 29 of 2016, resolves:

Art 1º To order the Executive Secretariat of CGen to cancel the registrations of access, shipmentof samplesor product notification whenever:
I - requested by the user; or
II - the genetic heritage described as the object of the access or remittance refers exclusively to species included in the list referred to in art. 113 of Decree No. 8,772, of 2016, which do not form spontaneous populations or have not acquired their own distinctive characteristic properties in the country
Art. 2 The cancellation of the registrations mentioned in art. 1 shall render ineffective any vouchers, certificates, or certificates of regularity relative to the respective registrations, and shall take place without prejudice to the investigation, by the competent authorities, of civil, criminal and administrative responsibilities, in cases of non-compliance with Law 13,123, of 2015, and its regulations.
Art. 3 The Executive Secretariat of CGen shall inform the inspection bodies provided for in art. 93 of Decree No. 8,772, 2016, and the users responsible for the registrations about the cancellation, identifying the number of the canceled registration.
Art. 4 This Resolution shall enter into force on the date of its publication.

FABRÍCIO SANTANA SANTOS
President of the Counsel

Resolution nº 21, of August 07, 2019

Establishes how to comply with the requirement to present an Activity Report, and makes other provisions.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, resolves:

Art. 1 The requirement to submit Activity Reports, partial or final, by the institutions authorized to perform access to genetic heritage or associated traditional knowledge during the effectiveness of Provisional Measure No. 2,186-16, of August 23, 2001, shall be fulfilled by

updating the access registry corresponding to the authorized activity in the National System for the Management of Genetic Heritage and Associated Traditional Knowledge - SisGen, according to paragraphs 2 and 3 of Article 20 of Decree No. 8,772, 2016.

Paragraph 1 The presentation of the documents listed as attachments to the Activity Report is exempted, and users shall keep them under their custody for the purposes of presentation to the competent authority, when requested.

Paragraph 2 For the purposes of the provisions in the *caput*, the updating of the records corresponding to authorisations of access to genetic heritage issued during the duration of Provisory Measure no. 2. 186-16, of 2001 by the Brazilian Institute of the Environment and Renewable Natural Resources - IBAMA - or by the National Council for Scientific and Technological Development - CNPq, shall be carried out within 1 (one) year, as of the date of publication of the official act of the Executive Secretary of CGen provided in the Sole Paragraph of Article 2 of CGen Technical Orientation No. 10, of October 9, 2018.

Art. 2 From the date this Resolution goes into effect, the submission of Annual Reports by institutions accredited as bona-fide depositary is waived.

Sole Paragraph. The hypothesis foreseen in the *caput* does not apply to cases in which there is a succession of rights and obligations of the extinct receiving institution.

Art. 3 The information contained in the Activity Reports already received shall be inserted in the corresponding SisGen registry by the CGen's Executive Secretariat, with the collaboration of the institutions accredited according to item V of art. 15 of Provisional Measure no. 2,186-16, of 2001, with users remaining responsible for the information provided.

Art. 4 This Resolution comes into force on the date of its publication.

FABRÍCIO SANTANA SANTOS
President of the Counsel

Resolution Nº 24, February 19, 2020

Exempts the deposit of sub-samples of genetic heritage in bona-fide depositary institutions.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, decides:

Art. 1 Users that obtained authorization for access during the duration of the Provisory Measure no. 2,186-16, of August 23, 2001, are exempt from depositing sub-samples of the genetic heritage in bona-fide depository institutions.

Paragraph 1. In case of request by the competent authority, users shall submit a sub-sample of the genetic heritage referred to in the *caput*.

Paragraph 2. The obligation provided for in Paragraph 1 extinguishes with the expiry of

the access authorization.
Art. 2 This Resolution comes into effect on the first business day of the month following the date of its publication.

MARIA BEATRIZ PALATINUS MILLIET
President of the Counsel

Resolution nº 26, August 25, 2021

Provides for the Normative Consolidation of Resolutions referring to alternative ways of filling out specific fields in SisGen, and revokes CGen Resolutions No. 4, 6, 7, 8, 9, 10, 13, 17 and 17, 2018, and CGen Resolution No. 22, 2019.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, and considering what is contained in process No. 02000.003671/2021-91, resolves:

Art. 1 To establish, as an alternative way to identify, in the National System for the Management of Genetic Heritage and Associated Traditional Knowledge - SisGen, the genetic heritage and its origin, or the associated traditional knowledge and its source of obtaining, a document to be defined and made available by the Executive Secretary of CGen.
Sole Paragraph. The document referred to in the caption shall contain all the mandatory information for the identification of the accessed genetic heritage or associated traditional knowledge, as determined by Decree No. 8,772, of 2016, respecting the specificities listed in arts. 2, 3 and 4 of this Resolution.
Art. 2 For cases in which the access activity is carried out for the purpose of research to evaluate or elucidate the genetic diversity or evolutionary history of a species or taxonomic group. The strictest taxonomic level to be informed will be, at a minimum:
I - Domain, in the case of bacteria, microscopic fungi, and other microorganisms, except viruses;
II - Class, in the case of macroscopic algae;
III - Order, in the case of macroscopic fungi and animals; and
IV - Family, in the case of viruses and plants.
Art. 3 For cases in which the access activity is carried out with the exclusive purpose of research, in which more than one hundred records of provenance of the genetic heritage are required per registration, the way to indicate the most specific geographical location possible shall be, at least, the Municipality in which the genetic heritage was obtained, observed the provisions of Paragraph 1 of Art. 22 of Decree No. 8,772, of 2016.
Art. 4 For cases in which the access activity is carried out from substrate samples containing

non-isolated microorganisms, the way to indicate the genetic heritage will be, at least, the taxonomic level Domain.

Art. 5 The identification of genetic heritage and its provenance may be made by indicating databases, repositories or information systems in which the information required in item 1 of sub-item 'f' of item II of Art. 22 of Decree No. 8,772, 2016, has already been registered, for cases in which:

I - the access activity is performed with the exclusive purpose of research in phylogeny, taxonomy, systematics, ecology, biogeography and epidemiology; or

II - the samples of genetic heritage have been obtained *in silico*.

Paragraph 1. The identification of the genetic heritage and its origin in the cases referred to in the *caput* may be made by indicating databases, repositories or information systems in which the information required in item 1 of sub-item ' f ' of item II of art. 22 of Decree No. 8,772, 2016, has already been registered.

Paragraph 2. The databases, repositories, or information systems referred to in Paragraph 1 must be open and unrestrictedly accessible to the Brazilian State.

Paragraph 3. The indication referred to in Paragraph 1 must be made by presenting the registration numbers, unique indicators or the uniform resource locator (URL), or equivalent, where the information is registered in the databases, repositories or information systems referred to in Paragraph 2.

Paragraph 4. For the indication referred to in Paragraph 1, the user must observe the provisions of Paragraph Paragraph 1 and 3 of art. 22 of Decree No. 8,772, 2016, as well as the provisions of this Resolution.

Paragraph 5. If, at any time, it is detected that access to information is unavailable in the indicated databases, repositories or information systems, or to the uniform resource locator (URL), or equivalent, as per Paragraph 3, the user will have a period of 60 days, after becoming aware of this fact, to rectify the information presented, or to register in the SisGen standard form the identification and origin of the genetic heritage object of the access, under penalty of cancellation of the registration.

Paragraph 6. SisGen will make available an electronic form for complying with the provisions of this article.

Art. 6 For cases of regularization of access activity to associated traditional knowledge of identifiable origin, exclusively for meeting the requirement referred to in item IV of art. 22 of Decree No. 8,772, 2016, the "Provider's Term of Consent" shall be submitted in SisGen, in the field "Document containing the full Prior Informed Consent", a document that must contain all the elements indicated in art. 17 of Decree No. 8,772, 2016.

Art. 7 For cases of regularization of access activities to genetic heritage or associated traditional knowledge, exclusively for meeting the requirement to present a Term of Commitment, the user may attach to SisGen the draft Term of Commitment registered and under analysis by the Ministry of the Environment.

Sole Paragraph. If the Term of Commitment is not signed by the Ministry of the Environment, the regularization registration will be canceled.

Art. 8 The following are hereby revoked:

I - the CGen Resolution no. 4, of March 20, 2018;

II - the CGen Resolution no. 6, of March 20, 2018;

III - the CGen Resolution no. 7, of March 20, 2018;

IV - the CGen Resolution no. 8, of March 20, 2018;
V - the CGen Resolution no. 9, of March 20, 2018;
VI - the CGen Resolution no. 10, dated June 19, 2018;
VII - the CGen Resolution no. 13, of September 18, 2018;
VIII - the CGen Resolution no. 17, of October 9, 2018;
IX - the CGen Resolution no. 18, dated October 10, 2018; and
X - the CGen Resolution no. 22, of August 07, 2019.
Art. 9 This Resolution goes into effect on the first business day of the month following the date of its publication.

MARIA BEATRIZ PALATINUS MILLIET
President of the Counsel

Resolution nº 27, August 25, 2021

Provides for the Normative Consolidation of the Resolutions referring to "remittance", approves the model of the Material Transfer Agreement - MTA, and revokes CGen Resolutions No. 11, 12 and 15, 2018.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, and considering what is contained in process No. 02000.004436/2021-36, resolves:

Art. 1 Approve the models of the Material Transfer Agreement - MTA and Shipment Invoice, in the form of Annexes I and II of this Resolution.
Art. 2 As provided in Article 25 of Decree No. 8,772, 2016, the provisions contained in that article are mandatory and are contained in the clauses of the model MTA and the model Shipment Invoice attached to this Resolution.
Sole Paragraph. It is allowed the inclusion of clauses, provisions and additional information of specific interest to the sender or recipient, in the MTA's model and Shipment Invoice's model, as well as the exclusion of clauses, provisions and information in the MTA's model that are not applicable to a specific shipment of samples, provided that these changes do not conflict with the provisions of this Resolution or the relevant legislation.
Art. 3 The sender and the recipient may sign, at their discretion, one or more MTAs, which will be valid for a maximum period of 10 (ten) years, renewable.
Paragraph 1. For each one of the shipments linked to the MTA mentioned in the *caput*, the sender must register the shipment in the National System for the Management of Genetic Heritage and Associated Traditional Knowledge - SisGen.

Paragraph 2. Each one of the shipments linked to the MTA must contain the corresponding Shipment Invoice, numbered in sequential order, with the description of the samples of genetic heritage to be shipped, according to the model in Annex II of this Resolution.
Paragraph 3. When the shipment of different genetic resources occurs on the same date and to the same recipient, a single shipment registration may be made in SisGen, which must contain the MTA and the Shipment Invoice corresponding to the samples of genetic heritage to be transferred abroad.
Paragraph 4. In order to be regularly shipped, the samples of genetic heritage must be accompanied by three documents:
I - proof of the shipment registry;
II - copy of the MTA signed between sender and recipient; and
III - the Shipment Invoice.
Art. 4 The MTAs signed before the date this Resolution goes into effect will remain valid, for the term provided in them, and do not need to be replaced or changed.
Art. 5 The return to foreign institutions that maintain *ex situ* collections of Brazilian genetic heritage samples that have been loaned to national institutions does not fall within the concept of "remittance" provided for in item XIII of Art. 2 of Law No. 13,123, of 2015.
Paragraph 1. In order to prove the non-infringement provided in the *caput*, the samples of genetic heritage must be transferred abroad accompanied by a copy of the MTA, the Shipment Invoice or other documents legally constituted at the time, which formalized the loan and which contain the identification of the samples of genetic heritage to be returned.
Paragraph 2. If the user does not have at least one of the documents referred to in Paragraph 1, the transfer of the samples of genetic heritage to the foreign institution that maintains the *ex situ* collection is not considered a return, and the legislation in force for shipment applies.
Art. 6 If the receiving institution refuses to sign the MTA, the alternative form of compliance with the obligation to submit the MTA for the shipment registry, exclusively for the purposes of the regularization provided for in Art. 38 of Law No. 13,123 of 2015, will be the submission of:
I - statement from the sender that the recipient institution refused to sign the MTA; and
II - proof that the receiving institution has been informed of the obligations related to Law 13,123 of 2015, and has received a copy of the MTA, according to the model approved by CGen.
Sole Paragraph. The refusal referred to in the *caput* is characterized when there is a formal reply from the receiving institution, or when it does not reply to the sender within thirty (30) days of receiving the request.
Art. 7 If the recipient institution has been extinguished, the alternative form of compliance with the obligation to submit MTA for the shipment registry, exclusively for the purposes of the regularization provided for in art. 38 of Law No. 13,123, 2015, will be the submission of documentation that proves such extinction.
Sole Paragraph. The hypothesis foreseen in the *caput* does not apply to cases in which there is a succession of rights and obligations of the extinguished recipient institution.
Art. 8 The following are hereby revoked:
I - the CGen Resolution no. 11, of June 19, 2018;
II - CGen Resolution no. 12, of September 18, 2018; and
III - the CGen Resolution no. 15, of October 9, 2018.

Art. 9 This Resolution shall enter into force on the first business day of the month following the date of its publication.

MARIA BEATRIZ PALATINUS MILLIET
President of the Counsel

Resolution Nº 28, August 25, 2021

Provides for the Normative Consolidation of the Technical Guidelines regarding the "date of availability of the registration by CGen", and revokes CGen Technical Guidelines No. 5, 7 and 10, 2018, and CGen Resolution No. 3, 2019.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, and considering what is contained in process No. 02000.003697/2021-39, resolves:

Art. 1 For the purposes of applying the provisions of articles 36, 37 and 38 of Law No. 13,123, 2015, and arts. 103, 104 and 118 of Decree No. 8,772, 2016, "date of availability of the registration by CGen" shall mean the date of availability of a version of the National System for the Management of Genetic Heritage and Associated Traditional Knowledge - SisGen - that contains all the functionalities necessary for users to perform:
I - the registration of the activities dealt with in CGen Resolution no. 26, of August 26th, 2021;
II - of the registration of the information referred to in item 2 of sub-item 'f' of itemII of art. 22 of Decree No. 8,772, 2016, when it is not possible to obtain the number of the CPF (Cadastro de Pessoa Física - Individual Taxpayer Registration) of the provider of the associated traditional knowledge of identifiable origin;
III - of the notification of finished product or reproductive material referred to in art. 34 of Decree No. 8,772, 2016, when it is not possible to obtain the CPF number, or the number of the National Register of Legal Entities - CNPJ, in the case of foreign users;
IV - of the registration of the information referred to in number 1 of sub-item 'f' of item II of Art. 22 of Decree No. 8,772, 2016, when in the hypothesis provided by item I of Paragraph 1 of Art. 22 of Decree No. 8,772, 2016, the deposit record in the collection does not have information about "state" or "municipality" of origin of the genetic heritage; and
V - the registration of access activity or notification of finished product or reproductive material that requires information from the registration number of the authorization for access to the genetic heritage that was issued during the effectiveness of Provisional Measure (MP) 2,186-16, of August 23, 2001:
a) by the Brazilian Institute of Environment and Renewable Natural Resources - Ibama; or

b) by the National Council for Scientific and Technological Development - CNPq; and
VI - the genetic heritage origin register, when there is no registration number of the access that originated the intermediate product originating from access obtained from a third party.
Art. 2 For all other cases, "date of availability of the registration by CGen" shall be understood as the date of availability of SisGen, accordingto SECEX/CGen Ordinance No. 01, of October 3, 2017.
Sole Paragraph. The deadlines set forth in Law No. 13,123 of 2015 and Decree No. 8,772 of 2016, related to the availability of the registry and the system for the registration of the activities referred to in Art. 1, shall be counted from the date of publication of an official act of the Executive Secretary of CGen indicating the availability of a version of SisGen that contemplates the implementation of the functionalities referred to in Art. 1.
Art. 3 The following are hereby revoked:
I - the CGen Technical Orientation nº 5, of June 19th, 2018;
II - the CGen Technical Orientation no. 7, of September 18th, 2018;
III - the CGen Technical Orientation no. 10, of October 9th, 2018; and
IV - the CGen Resolution No. 23, of August 07th, 2019.
Art. 4 This Resolution shall enter into force on the first business day of the month following the date of its publication.

MARIA BEATRIZ PALATINUS MILLIET
President of the Counsel

Resolution Nº 29, August 25, 2021

Provides for the Normative Consolidation of the Technical Orientations regarding the "examination activities and tests that are not considered access to genetic heritage, under the conditions it specifies", and revokes CGen Technical Guidelines No. 9 and 11, 2018.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, and considering what is contained in process No. 02000.003698/2021-83, resolves:

Art. 1 The following are equivalent to the activities and tests provided for in article 107 of Decree No. 8,772, of 2016, and, when they are not an integral part of research or technological development, they do not constitute access to the genetic heritage under the terms of Law No. 13,123, of 2015
I - technical reports that include inventory, survey or monitoring of genetic heritage, for purposes of environmental licensing, evaluation of potential for exploitation of natural resources

or actions for environmental recovery and recomposition of degraded areas;
II - identification or confirmation of the taxonomic identification of the genetic heritage to be incorporated into the holdings of an *ex situ* collection
III - physical, chemical, physical-chemical or biochemical characterization of extracts, waxes, butters and oils
IV - quality control tests for products originating from access to genetic heritage or associated traditional knowledge, as well as proficiency tests carried out in laboratories; and
V - tests that use genetic heritage exclusively as target organisms.
Art. 2 For the purposes of applying the concept of access to the genetic heritage referred to in item VIII of Art. 2 of Law No. 13,123, 2015, for the renewable polymer sector, the activity of using the polymer to enable the desired applications does not constitute access to the genetic heritage by the polymer converter.
Art. 3 For the purposes of this Resolution, the following definitions are adopted
I - proficiency tests: interlaboratory studies used as tools for external evaluation and demonstration of reliability of laboratory analytical results;
II - target organisms: organisms intentionally affected as objects in tests of physical, chemical or biological agents; and
III - polymer use: production of a given article by changing the shape of the polymer, using heating or molding, in the same way as performed on polymers of fossil origin.
Art. 4 The following are hereby revoked:
I - the CGen Technical Orientation no 9, of September 18, 2018; and
II - CGen Technical Orientation no. 11, of February 19, 2020.
Art. 5 This Resolution shall enter into force on the first business day of the month following the date of its publication.

MARIA BEATRIZ PALATINUS MILLIET
President of the Council

Technical Orientations

Technical Orientation nº1, June 28, 2017

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, resolves:

Art. 1º The obligation to notify finished product or reproductive material for economic exploitation referred in article 16 of Law nº13.123, 2015, applies to:
I – the reproductive material, in the productive chains of agricultural activities, in accordance with definitions of item XXIV, article 2º of Law nº13.123, 2015, and paragraph 2., article 44 of Decree nº8.772, 2016;
II – the finished product, in other productive chains.
Sole paragraph. The user responsible for the economic exploitation of products coming from productive chains of agriculture activities and that are not reproductive material may, at its discretion, obtain a certificate to attest that it does not fall within the obligation to notify the product.
Art. 2º This Technical Orientation shall enter into force on the date of its publication.

JOSÉ PEDRO DE OLIVEIRA COSTA
On behalf of the Council

Technical Orientation Nº 2, June 28, 2017

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, resolves:

Art. 1º For the purpose of application of the concept of excipient referred in paragraph 4º, article 43, Decree 8.772 of 2016, for the Toiletry, Perfumery and Cosmetics sector, it shall not be considered as decisive for the existence of the functional characteristics the use of genetic heritage where utilized exclusively for the structure of the formula, being responsible for the stability, consistence or physical aspect, that do not determine the functionality.

Art. 2º This Technical Orientation enters into force on the date of its publication.

JOSÉ PEDRO DE OLIVEIRA COSTA
On behalf of the Counsel

Technical Orientation Nº 4, May 22, 2018

Clarifies the way to comply with the obligation to adjust the activities of access to the genetic heritage or associated traditional knowledge referred to in article 37 of Law 13.123, of 2015.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, resolves:

Art. 1º The obligation referred in item I, article 37 of the Law 13.123, of 2015, does not apply to the authorizations of access to genetic heritage or to the associated traditional knowledge that may have expired until the date Law nº 13.123, of 2015, entered into force
Art. 2º The measure referred in item I of the sole paragraph of article 37, Law 13.123/2015, applies to the authorizations of access to genetic heritage or associated traditional knowledge that have not expired until the date Law 13.123/2015 entered into force, and shall be considered as complied by the users when CGen register it, in accordance with the determinations of Paragraph 1 of art. 43 of Law nº13.123, de 2015.
Sole paragraph. The users referred in the *caput* shall request to the Executive-Secretariat the ratification of information registered at any time.
Art. 3º This Technical Orientation shall enter into force on the date of its publication.

RAFAEL DE SÁ MARQUES
On behalf of the Counsel

Technical Orientation Nº 6, June 20, 2018

Clarifies the application of the concept "main elements of added value to the product" for the purpose of application of rules foreseen in article 43, Paragraph 3., item II, Decree nº 8.772 of May 11 of 2016, exclusively for the fragrance sector.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law nº13.123 of May 20 of 2015, and the Decree nº8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance nº 427 of September 28 of 2016, resolves:

Art. 1º For the purpose of application of the provisions of article 43, Paragraph 3., item II, Decree nº 8.772 of May 11 of 2016, for the fragrance sector, it shall be considered as "main elements of added value to the product" the ingredients originated from access to genetic heritage that determine the predominant scent family of the fragrance used in the finished product, where the purpose of the genetic heritage in the formula is exclusively to form the smell.
Art. 2º For the purpose of this Technical Orientation, the following definitions shall be adopt:
I – smell: substances noticed by the human olfaction;
II – ingredient: any synthetic substances or extracted from a natural raw-material that has smelling characteristics;
III – fragrance: intermediated product resulting from the mixture of various natural and synthetic ingredients whose functionality is to confer smell to finished products; and
IV – scent family: classification of fragrance ingredients or from the fragrance itself for the smell.
Art. 3º It shall be subjected to the sharing of benefits of the finished product whose fragrance originates from the same scent family that the ingredient originated from access to genetic heritage, where the purpose of the genetic heritage in the formula is exclusively to form the smell.
Art. 4º In order to have the notification processed by the National System Of Genetic Heritage And Traditional Knowledge Associate Management – Sisgen, the user must present a declaration from the perfumer attesting the scent family of the fragrance of the finished product and the ingredient originated from genetic heritage where it is not a main element of added value, in accordance with article 1º of this Technical Orientation.
Art. 5º The Executive-Secretary of CGen may elaborate a classification list of the scent families of genetic heritage used by the fragrance sector for the purpose of harmonizing its placement, safeguarding the confidential information when justified.
Sole paragraph. For the elaboration of the list mentioned in the *caput* the appropriated sectors shall be consulted.
Art. 6º This Technical Orientation does not apply to cases with marketing appeal in the finished product, in accordance with the provisions of article 43, Paragraph 3., item I, Decree nº8.772 of 2016.
Art. 7º This Technical Orientation shall enter into force on the date of its publication.

RAFAEL DE SÁ MARQUES
President of the Counsel

Technical Orientation Nº 8, September 18, 2018

Clarifies the meaning of "shipment" and "sending of samples" referred in items XIII and XXX of article 2° and items IV and V of art. 12 of Law n° 13.123, of May 20 of 2015, combined with article 24, II, sub-item 'b' and article 25, II, sub- item 'b' of the Decree 8.772, of May 11 2016.

THE GENETIC HERITAGE MANAGEMENT COUNCIL – CGEN, using the powers conferred upon it by Law n°13.123 of May 20 of 2015, and the Decree n°8.772 of May 11 of 2016, and in view of the provisions of its Internal Regulation, attached to the Ordinance n° 427 of September 28 of 2016, resolves:

Art. 1º For the purpose of application of the provisions foreseen in art. 25 of Decree n° 8.772, of May 11 of 2016, it shall be considered as "shipment" the transfer of samples of genetic heritage that falls within the conditions listed in sub-item 'b', itemII of art. 25 od Decree n° 8.772, of 2016, that regulated on information about volume or weight.

Art. 2º For the purpose of application of the provisions foreseen in art. 24 of Decree n° 8.772, of May 11 of 2016, it shall be considered as "sending of samples" the transfer of samples of genetic heritage that falls within the conditions listed in sub-item 'b', item II of Paragraph 6. of art. 24 of Decree n° 8.772, of 2016, that regulated information about volume or weight.

Sole paragraph. The transfer abroad, by digital means, of information relative to genetic heritage, regardless the purpose, does not fall within the concepts of shipment and sending of samples aforementioned.

Art. 3º This Technical Orientation enters into force on the date of its publication.

THIAGO AUGUSTO ZEIDAN VILELA DE ARAÚJO
President of the Council

Ministerial Ordinance

Ministerial Ordinance Nº 378, October 1ST, 2018

Modifies Annexes I to VII of Ministerial Ordinance No. 422, dated November 6, 2017.

THE MINISTER OF STATE OF THE ENVIRONMENT, using the powers conferred upon it by items I and II of the sole paragraph of art. 87 of the Constitution, in view of the provisions of Law No. 13.502, of November 1, 2017, Decree No. 8.975, of January 24, 2017, Law No. 13.123. of May 20, 2015, and what is contained in Administrative Proceeding No. 02000.00093312017-89, resolves:

Art. 1 To alter, in the form of the attachments to this Ordinance, the instruments of Term of Commitment - TC referred to in art. 2 of MMA Ordinance No. 422, of November 6, 2017, available at <http://www.mma.gov.br/patrimonio-genetico/reparticao-debeneficios-eregularizacao/termo-de-compromisso>.

Art. 2 For the purposes of compliance with the obligations established in art. 40 of Law No. 13,123 of 2015, the date of execution of the term of commitment shall be considered:

I - the date of its signature by the representative of the Ministry of the Environment, for the purposes of complying with the obligations established in items I and II of said article;

II - the date of its protocol before the Ministry of the Environment, for the purposes of complying with the obligations established in item III of the aforementioned article, as long as the deadline established by art. 38 of the aforementioned Law is observed.

Sole Paragraph. The provisions in the *caput* do not apply to the benefit sharing of 2018 and subsequent years, which shall comply with the legal and regulatory provisions in force.

Art. 3 The signatories of previous versions of the Terms of Commitment may use the deadlines contained in the attachments to this Ordinance.

Sole Paragraph. The initial term for the deadlines indicated in the *caput* is the publication date of this Ordinance.

Art. 4 This Ordinance enters into force on the date of its publication.

EDSON DUARTE

Ministerial Ordinance Nº 143, March 30 2020

Establishes the format for Declaration of information regarding the net revenue obtained from the economic exploitation of finished product or reproductive material from genetic heritage or associated traditional knowledge; and revokes MMA Ordinance No. 165, of May 28, 2018.

THE MINISTER OF THE ENVIRONMENT, using the powers conferred upon it by items I and II of the sole paragraph of art. 87 of the Constitution; Law No. 13,844, of June 18, 2019; Law No. 13,123, of May 20, 2015; Decree No. 8,772, of May 11, 2016; Decree No. 9,672, of January 2, 2019, and that contained in Administrative Proceeding No. 02000.005944/2018-36, resolves:

Art. 1 Establish the format for information provision on net revenue obtained with the economic exploitation of finished products or reproductive material originating from genetic heritage or associated traditional knowledge, as provided in art. 45, Paragraph 2, of Decree No. 8,772, of May 11, 2016.

Art. 2 The manufacturer of finished product or producer of reproductive material, under the terms of Law No. 13,123, of May 20, 2015, shall declare the annual net revenue for each fiscal year, obtained with the economic exploitation of each finished product or reproductive material within ninety days after the closing of each fiscal year, as long as there is economic exploitation.

Paragraph 1. The declaration of net revenue referred to in the *caput* must be made in the National System for Management of Genetic Heritage and Associated Traditional Knowledge - SisGen, in the respective notification of finished product or reproductive material, informing, in specific fields:

I - the gross revenue, in terms of art. 12 *caput*, of Decree-Law nº 1.598, of December 26, 1977;

II - the returns and canceled sales;

III - the discounts granted unconditionally;

IV - the taxes applicable over the gross revenue;

V - the amounts resulting from the adjustment to present value; and

VI - the net revenue, in the terms of paragraph 1 of art. 12 of Decree-Law nº 1.598, of 1977.

Paragraph 2. The documentation capable of proving the information referred to in items I to V of Paragraph 1 must be presented when requested by the competent authorities.

Paragraph 3. While SisGen does not have the specific fields referred to in Paragraph 1, the manufacturer of the finished product or the producer of the reproductive material must declare only the value referring to the annual net revenue in a specific field in the SisGen and attach the Net Revenue Declaration, duly filled in, according to the model attached to this Ministerial Ordinance.

Paragraph 4. The information requested in the Annex to this Ordinance should be filled in according to the equivalent data in the country of origin of each foreign manufacturer, when applicable.

Art. 3 For the declaration of net revenue that requires currency conversion, the official ex-

change rate shall be used according to the closing of the last day of the year, applying the PTAX rate from the Brazilian Central Bank.

Sole paragraph. For regularization purposes, in which retroactivity is required, the PTAX rate of the last day of the year of each fiscal year must be verified, according to the respective competence.

Art. 4 The deadline for compliance with the obligation to declare the net revenue starts from the date of publication of the official act of the Executive Secretary of the Genetic Heritage Management Council - CGen, making available a version of the SisGen with the functionalities necessary for the declaration of net revenue in the cases of:

I - foreign manufacturer of finished product or producer of reproductive material or the respective jointly liable parties provided for in Paragraph 7 of art. 17 of Law No. 13,123 of 2015; and

II - finished product or reproductive material exempt from the obligation of benefit sharing, in the terms of Paragraph 5 of art. 17 of Law No. 13,123, 2015.

Art. 5 The User that has made the notification of finished product or reproductive material, thus constituting the obligation to declare the net revenue obtained with the economic exploitation of finished product or reproductive material on a date prior to the entry into force of this Ordinance will have a period of thirty days, counted from the beginning of the effectiveness of this act, to make the declaration of the annual net revenue corresponding to the fiscal years prior to 2019.

Paragraph 1. A Net Revenue Declaration must be filled in, according to the model in the Annex to this Ordinance, for each fiscal year to be declared according to the *caput*, in a single file, in PDF format, containing the respective declarations, which must be attached to the SisGen.

Paragraph 2. The value referring to the annual net revenue declared in the specific field of SisGen must be the one corresponding to the sum of the annual net revenue values informed in each one of the Net Income Declaration in the form of the provisions in Paragraph 1 of this article.

Art. 6 The collection to the National Benefit Sharing Fund - FNRB of the amounts provided for by arts. 20, 23 and Paragraph Paragraph 2 and 3, of art. 24, all of Law No. 13,123, 2015, shall be made within 30 (thirty) days, as stipulated in Paragraph 1 of art. 49, of Decree No. 8,772, 2016.

Paragraph 1. The period of time mentioned in the *caput* starts to count from the end of the periods reserved for the declaration of net revenue respectively provided for in articles 2 and 5 of this Ordinance, or from when the means necessary for collection to the FNRB are made available, if it happens later.

Paragraph 2. The provisions contained in this article do not apply to users who are parties to regularization process, which must comply with the clauses set out in the term of commitment.

Art. 7 The Ordinance No. 165, of May 28, 2018, republished in the Official Gazette of the Union of June 11, 2018, is hereby revoked.

Art. 8 This Ordinance enters into force on the date of its publication.

RICARDO SALLES

ANNEX I

MODEL OF NET REVENUE DECLARATION
MINISTER OF THE ENVIRONMENT

NET REVENUE DECLARATION in accordance with § 1º and 2º, of art. 45 of Decree 8.772, of May 11 of 2016	
Name of Institution	
Tax Payer ID number (OR equivalent in the foreign manufacturer's country of origin)	
Name of the Legal Representative	
Fiscal year	
SisGen Notification Number	
	In R$
Gross revenue	
Devolutions and cancelled sales	
Discounts granted	
Taxes incidents on the gross revenue	
Values arising by the adjust of the present value	
Net revenue	
Place and date	
Signature of the Legal Representative	

Ministerial Ordinance Nº 199, Abril 22, 2020

Establishes the conditions necessary for the signing of a Term of Commitment by foreign institutions and the State, for the purpose of regularizing access to genetic heritage and associated traditional knowledge, under Law No. 13,123 of 2015.

THE MINISTER OF THE ENVIRONMENT, using the powers conferred upon it by items I and II of the sole paragraph of art. 87 of the Constitution; Law No. 13,844, of June 18, 2019; Law No. 13,123, of May 20, 2015; Decree No. 8,772, of May 11, 2016; Decree No. 9,672, of January 2 of 2019, and the content of the Administrative Process No. 02000.017082/2018-94, resolves:

Art. 1 This Ordinance aims to establish the conditions necessary for the signing of a Term of Commitment between foreign institutions and the State, for the purposes of regularization of access to genetic heritage and associated traditional knowledge, under Law No. 13,123, May 20, 2015.

Art. 2 The foreign legal person that, between June 30, 2000 and November 16, 2015, the date Law No. 13123 of 2015 came into force, carried out the following activities without association or partnership with a national institution, in disagreement with the legislation in force at the time, must regularize itself under the terms of Law No. 13.123 of 2015:

I - access to genetic heritage or associated traditional knowledge;

II - access and economic exploitation of a product or process arising from the access to genetic heritage or to associated traditional knowledge, referred to in Provisory Act (MP) No 2,186-16, of August 23, 2001;

III - shipment abroad of samples of genetic heritage; or

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

Sole paragraph. The regularization mentioned in the *caput* is conditioned to the signing of a specific Term of Commitment, signed by the legal representative of the foreign institution.

Art. 3 It is up to the foreign institution to sign a partnership or association with a national institution in accordance with art. 22 of Decree No. 8,772, of May 11, 2016, for the effectiveness of the access registry with the correct inclusion of information in the National System for the Management of Genetic Heritage and Associated Traditional Knowledge - SisGen.

Sole Paragraph. Non-compliance with the provisions referred to in the *caput* will result in the application of civil, criminal, and administrative sanctions.

Art. 4 The notification of finished product or reproductive material, when applicable, shall be performed by the User under the terms of art. 33 of Decree No. 8,772, 2016, without the need to associate with a national research institution.

Art. 5 The original version of the instrument of the Term of Commitment referred to in this Ministerial Ordinance will be made available within 30 (thirty) working days from the publica-

tion of this Ministerial Ordinance, on the Ministry of the Environment's website https://www.mma.gov.br/patrimonio-genetico/reparticao-de-beneficios-eregularizacao/term-of-commitment.

Art. 6 The deadline for the presentation of the Terms of Commitment necessary for the regularization of the activities of the foreign institutions ends after 1 (one) year from the publication of the official act of the Executive Secretary of the Genetic Heritage Management Council - CGen making available a version of the SisGen containing the functionalities necessary for the respective registries of access and notification to be made by the foreign institutions.

Sole Paragraph. The terms of commitment of foreign institutions referred to in this Ministerial Ordinance already filed in the format of Ministerial Ordinance No. 378, of October 1, 2018 and No. 422, of November 6, 2017 may be replaced by the new model to be made available by the Ministry of the Environment in the same administrative process already started.

Art. 7 Along with the signature of the term of commitment, the foreign institution must sign a term declaring that it is in regular operation and duly constituted according to the legislation of its State of domicile.

Art. 8 This Ministerial Order goes into effect on April 30, 2020.

RICARDO SALLES

Ministerial Ordinance Nº 144, Abril 22, 2021

THE MINISTER OF THE ENVIRONMENT, using the powers conferred upon it by itens I and II of the sole paragraph of art. 87 of the Constitution; Law No. 13,844, of June 18, 2019; Law No. 13,123, of May 20, 2015; Decree No. 8,772, of May 11, 2016; by what is contained in Decree No. 10,455, of August 11, 2020; and the content of the Administrative Process No. 02000.002335/2018-25, resolves:

Art. 1 This Ordinance provides for the form of non-monetary benefit sharing in cases of access to genetic heritage, and the procedures to be adopted for the proposal, analysis and signature of the Non-monetary Benefit Sharing Agreement - ARB-NM regarding the sharing of non-monetary benefits arising from the economic exploitation of finished products or reproductive material arising from access to genetic heritage.

Art. 2 The following Terms are approved, in the form contained in the stage of production of evidence:

I - The Non-Monetary Benefit Sharing Agreement - ARB-NM, digital version available at the link: https://www.gov.br/mma/pt-br/media/arquivo_arcordo_de_reparticao_de_beneficios/anexo_1___acordo_de_reparticao_de_beneficios_nao_monetaria___arb_nm_com_a_uniao.pdf;

II - Identification form of the finished product(s) or reproductive material(s) object of the benefit sharing, digital version available at the link: https://www.gov.br/mma/pt-br/media/arquivo_formulario_do_produto_acabado_ou_material_reprodutivo/anexo_2___formulario_do_produta-

do_acacabado_ou_material_reprodutivo.pdf; and
III - Non Monetary Benefit Sharing Proposal Submission Form - FRBNM, an integral and inseparable part of the ARB-NM, digital version available at the link: https://www.gov.br/mma/pt-br/media/arquivo_submissao_de_proposta/anexo_3___formulario_de_submissao_de_proposta_de_reparticao_de_beneficios_nao_monetaria___frbnm.pdf.

Paragraph 1. The Terms defined in this Article may not be altered, whether by suppression, addition, or erasure, and the user must specifically observe the fields intended for filling out.

Paragraph 2. The Secretariat of Biodiversity of the Ministry of the Environment may promote alterations in the Terms provided for in items I, II and III, when necessary for the good functioning of the evaluation mechanism of the proposal for non-monetary benefit sharing.

Art. 3 The user that wishes to celebrate an ARB-NM must send the Secretariat of Biodiversity two printed copies of the ARB-NM proposal, accompanied by the FRBNM, duly filled in, signed by the legal representative of the user and countersigned on all pages.

Paragraph 1. The proposals of ARB-NM must contain:
I - the FRBNM;
II - the identification form of the finished product(s) or reproductive material(s) object of the benefit sharing duly filled in;
III - the explicit agreement, as the case may be, of the direct beneficiary of the Benefit Sharing, when it is not the State; and
IV - the demonstration of equivalence referred to in paragraphs 1 and 2 of art. 50 of Decree No. 872, May 11, 2016, when applicable, based on market values.

Paragraph 2. The deadline for the execution of the benefit sharing proposal must be included in the physical-financial schedule detailed in the Annex(es) of ARBNM; and meet the following deadlines:
I - up to one year, for benefit sharing values of up to R$ 1,000,000.00 (one million reais);
II - up to two years, for benefit sharing values between R$ 1,000,000.01 (one million reais and one cent) and R$ 3,000,000.00 (three million reais);
III - up to three years, for benefit sharing values above R$ 3,000,000.01 (three million reais and one cent).

Paragraph 3. The projects that do not comply with the rules of values and deadlines foreseen in the previous paragraph must present the necessary justifications for the evaluation of the competent authority.

Paragraph 4. In cases of regularization, provided for in art. 38, of Law No. 13,123, of May 20, 2015, the amount allocated to the proposal must correspond to the total amount due as benefit sharing related to the economic exploitation of finished product or reproductive material, and may be applied in one or more projects, according to the interest of the User and evaluation of the Secretariat of Biodiversity.

Paragraph 5. In all other cases, the value of the proposal must correspond to the amount due as part of the benefit sharing referring to the economic exploitation of the finished product or reproductive material for the period of one fiscal year.

Paragraph 6. The alterations to be promoted in the annexes to the ARB-NM signed between the parties, as well as alterations to include the values of benefit sharing regarding the Net Revenue of a new fiscal year, shall take place by an additive term, observing what is established in this Ordinance.

Paragraph 7. The amounts corresponding to the modality of non-monetary benefit sharing

in cases of access to the genetic heritage, including cases of regularization, may be applied in one or more projects defined in a separate Non-monetary Benefit Sharing Proposal Submission Form - FRBNM.

Art. 4 The non-monetary benefit sharing arising from the economic exploitation of finished product or reproductive material arising from access to the genetic heritage shall be constituted according to the instruments provided in item II of Article 19 of Law No. 13,123 of 2015 and follow the requirements established in Article 50 of Decree No. 8,772 of 2016.

Sole paragraph. The user may not bind the benefit sharing payment to any other requirement other than those established in the ARB-NM and in the Benefit Sharing Instrument.

Art. 5 The proposals for non-monetary benefit sharing must show how the reach of its objectives and results contribute to the conservation and sustainable use of biodiversity, taking into account the socioeconomic development of the region/biome.

Sole Paragraph. For the purposes of the *caput*, the proposal for non-monetary benefit sharing must establish a comparison between the previous situation (baseline) and the situation to be reached with the conclusion of the benefit sharing.

Art. 6 The benefits arising from non-monetary benefit sharing must be fully allocated to the biome in which the access to the genetic heritage occurred.

Paragraph 1. The allocation of benefit sharing to another biome will only be allowed if the user proves that it is not possible to allocate the benefits arising from non-monetary benefit sharing to the biome in which the access to the genetic heritage occurred.

Paragraph 2. The alternative in the paragraph above will be evaluated by the Secretariat of Biodiversity, being forbidden the reexamination of the merit of the decision rendered.

Art. 7. The services resulting from non-monetary benefit sharing that require buildings or other civil works cannot be carried out in an area that is part of the user's property, as an natural or legal person.

Art. 8 The Secretariat of Biodiversity will analyze the proposal and issue a technical report on the terms of this Ordinance, by verifying the following requirements:

I - the FRBNM addresses the eligible themes, as provided in Art. 4, of this Ordinance;

II - the object foreseen in the FRBNM will be executed in the areas provided for by Art. 51, of Decree No. 8,772, of 2016, in the cases of sub-items "a" and "e" of item II of Art. 19 of Law No. 13,123, of 2015;

III - presentation of schedule and work plan consistent with the proposal in the FRBNM;

IV - the inputs presented correspond to the proposal contained in the FRBNM;

V - the value presented for the inputs and services corresponds to the market value; and

VI - if the proposal complies with the provisions of Articles 5 and 6, of this Ordinance.

Sole Paragraph. Other bodies linked to this Ministry and its specialists may be invited to issue technical report when the non-monetary benefit sharing proposals regard themes relevant to their respective areas of competence.

Art. 9 The mobile equipment and permanent materials acquired with resources from the non-monetary benefit sharing, in cases where they are not destined to the beneficiaries, target audience of the benefit sharing, will be, at the end of the execution of the benefit sharing, destined to a public or private non-profit organization, executor or not of the project, for its continuity or application in social-environmental programs of local, state or regional relevance.

Art. 10 The user must render accounts every six months, and at the end of the activities undertaken according to the schedule, when the schedule is longer than 6 (six) months, by means

of a report.

Paragraph 1. The account report referred to in the *caput* must contain:

I - a description of the activities carried out, and audiovisual and/or photographic record of the actions and results achieved so far, according to the proposal's work plan;

II - a description of the environmental and/or social benefits achieved; and

III - a statement of the equivalence referred to in Paragraphs 1 and 2 of Item II of Article 50 of Decree No. 8.772, 2016, when applicable, based on market values.

Paragraph 2. The market values can be proven through the presentation of price quotations taken from at least three suppliers in the same line of business.

Art. 11 – Once the obligations foreseen in the ARB-NM are concluded, the Secretariat of Biodiversity will issue a Term of Fulfillment, based on the information provided by the user and by the direct beneficiary of the Benefit Sharing, when this is not the State.

Art. 12 – The preparation or presentation of information, document, study, review or report that is totally or partially false or misleading in the scope of the ARB-NM instruction and that influences the decision making of this Ministry when issuing the term of fullfiment will lead to the suspension of the effects of the term.

Sole paragraph. The suspension of the effects of the term of fullfiment provided for in the *caput* will occur at any time, within the legal limits, by means of a reasoned decision by this Ministry, after the user has been notified to present a defense within a non-extendable period of 15 days.

Art. 13. The proposals of ARB-NM that have already been registered by the user, and that are under analysis by the Secretariat of Biodiversity, shall observe the present Ordinnce, as applicable, and proceed with the adjustment within 30 (thirty) working days from its entry into force.

Art. 14. The Secretariat of Biodiversity is responsible for signing the Non-Monetary Benefit Sharing Agreement.

Art. 15 Any cases not covered by this Ordinance will be resolved by an act of the Secretariat of Biodiversity of this Ministry.

Art. 16 – The Ministry of the Environment Ordinance nº 81, of March 5th, 2020, is hereby revoked.

Art. 17 This Ordinance enters into force on May 24, 2021.

RICARDO SALLES
Ministry of Environment

Nagoya Protocol

Legislative Decree No 136, Of 2020

Approves the text of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Derived from Their Use to the Convention on Biological Diversity, concluded during the 10th Meeting of the Conference of the Parties to the Convention, held in October 2010 (COP-10), and signed by Brazil on February 2, 2011, in New York.

The National Congress decrees:

Art. 1 It is approved the text of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Derived from Their Use to the Convention on Biological Diversity, concluded during the 10th Meeting of the Conference of the Parties to the Convention, held in October 2010 (COP -10), and signed by Brazil on February 2, 2011, in New York.

Sole paragraph. The approval referred to in the *caput* of this article is conditioned to the formulation, on the occasion of the ratification of the Protocol, of declarations which contain the following understandings:

I - in accordance with the provisions of art. 28 of the Vienna Convention on the Law of Treaties, regarding the application of the provisions of paragraph 2 of art. 33 of the Protocol, the provisions of the Nagoya Protocol, for the purposes of its implementation, shall not have retroactive effect;

II - in accordance with the provisions of sub-item "c" of art. 8 of the Protocol, economic exploitation for the purpose of agricultural activities, according to the definition contained in Law No. 13,123, of May 20, 2015, arising from reproductive material of species introduced into the country by human action until the entry into force of the Protocol will not be subject to the sharing of benefits provided for therein;

III - in accordance with the provisions of art. 2 combined with paragraph 3 of art. 15, both of the Convention on Biological Diversity, and considering the application of the provisions of arts. 5 and 6 of the Protocol, are considered to be found under in situ conditions the species or varieties that form spontaneous populations that have acquired their own distinctive characteristics in the country and the traditional local variety or creole or locally adapted race or creole breed, as defined in the internal regulations, namely in art. 2 of Law No. 13,123, of May 20, 2015, establishing that country in the concept of "country of origin" of these genetic resources;

IV - Law No. 13,123, of May 20, 2015, is considered the domestic law for the implementation

of the Nagoya Protocol.
Art. 2. Under the terms of item I of the *caput* of art. 49 of the Federal Constitution, any acts that may result in the revision of the aforementioned Protocol are subject to approval by the National Congress, as well as any complementary adjustments that entail burdens or obligations commitments to the national patrimony.
Art. 3 This Legislative Decree enters into force on the date of its publication.

Federal Senate, on August 11, 2020

Senator DAVI ALCOLUMBRE
President of the Federal Senate

This text does not replace the original published in the Federal Senate Gazette of 07/11/2020

NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",
Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention, and recognizing that this Protocol pursues the implementation of this objective within the Convention,
Reaffirming the sovereign rights of States over their natural resources and according to the provisions of the Convention,
Recalling further Article 15 of the Convention,
Recognizing the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention,
Recognizing that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,
Acknowledging the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustain-

ability and thereby contributing to achieving the Millennium Development Goals,
Acknowledging the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,
Recognizing the importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization,
Further recognizing the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,
Recognizing also the vital role that women play in access and benefit-sharing and affirming the need for the full participation of women at all levels of policy-making and implementation for biodiversity conservation,
Determined to further support the effective implementation of the access and benefit-sharing provisions of the Convention,
Recognizing that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent,
Recognizing the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change,
Recognizing the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,
Recognizing the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,
Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,
Acknowledging ongoing work in other international forums relating to access and benefit-sharing,
Recalling the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,
Recognizing that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,
Recalling the relevance of Article 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilization of such knowledge,
Noting the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities,
Recognizing the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities,

Mindful that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities,
Further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity,
Noting the United Nations Declaration on the Rights of Indigenous Peoples, and
Affirming that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,
Have agreed as follows:

ARTICLE 1.
Objective

The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

ARTICLE 2.
Use of Terms

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:
(a) "Conference of the Parties" means the Conference of the Parties to the Convention;
(b) "Convention" means the Convention on Biological Diversity;
(c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;
(d) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;
(e) "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

ARTICLE 3.
Scope

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention

and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

ARTICLE 4.
Relationship with International Agreements and Instruments

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.
2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.
3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.
4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

ARTICLE 5.
Fair and Equitable Benefit-sharing

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.
2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.
3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.
4. Benefits may include monetary and non-monetary benefits, including but not limited to those

listed in the Annex.
5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

ARTICLE 6.
Access to Genetic Resources

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.
2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.
3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:
(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;
(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;
(c) Provide information on how to apply for prior informed consent;
(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;
(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;
(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and
(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, inter alia:
(i) A dispute settlement clause;
(ii) Terms on benefit-sharing, including in relation to intellectual property rights;
(iii) Terms on subsequent third-party use, if any; and
(iv) Terms on changes of intent, where applicable.

ARTICLE 7.
Access to Traditional Knowledge Associated with Genetic Resources

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

ARTICLE 8.
Special Considerations

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:
(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;
(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;
(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

ARTICLE 9.
Contribution to Conservation and Sustainable Use

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

ARTICLE 10.
Global Multilateral Benefit-sharing Mechanism

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

ARTICLE 11.
Transboundary Cooperation

1. In instances where the same genetic resources are found in situ within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.
2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

ARTICLE 12.
Traditional Knowledge Associated with Genetic Resources

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.
2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.
3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:
(a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;
(b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and
(c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.
4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

ARTICLE 13.
National Focal Points and Competent National Authorities

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:
(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;
(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and
(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.
The national focal point shall be responsible for liaison with the Secretariat.
2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.
3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.
4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.
5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

ARTICLE 14.
The Access and Benefit-sharing Clearing-House and Information Sharing

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:
(a) Legislative, administrative and policy measures on access and benefit-sharing;
(b) Information on the national focal point and competent national authority or authorities; and
(c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.
3. Additional information, if available and as appropriate, may include:
(a) Relevant competent authorities of indigenous and local communities, and information as so decided;
(b) Model contractual clauses;
(c) Methods and tools developed to monitor genetic resources; and
(d) Codes of conduct and best practices.
4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

ARTICLE 15.
Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.
2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.
3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

ARTICLE 16.
Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing for Traditional Knowledge Associated with Genetic Resources

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.
2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.
3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

ARTICLE 17.
Monitoring the Utilization of Genetic Resources

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:
(a) The designation of one or more checkpoints, as follows:
(i) Designated checkpoints would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate;
(ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;
(iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;
(iv) Checkpoints must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre commercialization or commercialization.
(b) Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and
(c) Encouraging the use of cost-effective communication tools and systems.
2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.
3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that

mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.
4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:
(a) Issuing authority;
(b) Date of issuance;
(c) The provider;
(d) Unique identifier of the certificate;
(e) The person or entity to whom prior informed consent was granted;
(f) Subject-matter or genetic resources covered by the certificate;
(g) Confirmation that mutually agreed terms were established;
(h) Confirmation that prior informed consent was obtained; and
(i) Commercial and/or non-commercial use.

ARTICLE 18.
Compliance with Mutually Agreed Terms

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:
(a) The jurisdiction to which they will subject any dispute resolution processes;
(b) The applicable law; and/or
(c) Options for alternative dispute resolution, such as mediation or arbitration.
2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.
3. Each Party shall take effective measures, as appropriate, regarding:
(a) Access to justice; and
(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.
4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

ARTICLE 19.
Model Contractual Clauses

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.
2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

ARTICLE 20.
Codes of Conduct, Guidelines, and Best Practices and/or Standards

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.
2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

ARTICLE 21.
Awareness-raising

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, inter alia:
(a) Promotion of this Protocol, including its objective;
(b) Organization of meetings of indigenous and local communities and relevant stakeholders;
(c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;
(d) Information dissemination through a national clearing-house;
(e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;
(f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;
(g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;
(h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and
(i) Awareness-raising of community protocols and procedures of indigenous and local communities.

ARTICLE 22.
Capacity

1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties

should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.

2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity-building and development to implement this Protocol.

3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.

4. In support of the implementation of this Protocol, capacity-building and development may address, inter alia, the following key areas:

(a) Capacity to implement, and to comply with the obligations of, this Protocol;

(b) Capacity to negotiate mutually agreed terms;

(c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and

(d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.

5. Measures in accordance with paragraphs 1 to 4 above may include, inter alia:

(a) Legal and institutional development;

(b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;

(c) The monitoring and enforcement of compliance;

(d) Employment of best available communication tools and Internet-based systems for access and benefit-sharing activities;

(e) Development and use of valuation methods;

(f) Bioprospecting, associated research and taxonomic studies;

(g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;

(h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;

(i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and

(j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources.

6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

ARTICLE 23.
Technology Transfer, Collaboration and Cooperation

In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

ARTICLE 24.
Non-Parties

The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.

ARTICLE 25.
Financial Mechanism and Resources

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.
2. The financial mechanism of the Convention shall be the financial mechanism for this Protocol.
3. Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States among them, and of Parties with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.
4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.
6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

ARTICLE 26.
Conference of the Parties Serving as the Meeting of the Parties to this Protocol

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.
3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol. 4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:
(a) Make recommendations on any matters necessary for the implementation of this Protocol;
(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;
(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;
(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;
(e) Consider and adopt, as required, amendments to this Protocol and its Annex, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and
(f) Exercise such other functions as may be required for the implementation of this Protocol.
5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.
6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat and held concurrently with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol.

Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held concurrently with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

ARTICLE 27.
Subsidiary Bodies

1. Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

Article 28.
Secretariat

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

ARTICLE 29.
Monitoring and Reporting

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals and in the format to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement this Protocol.

ARTICLE 30.
Procedures and Mechanisms to Promote Compliance with this Protocol

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention.

ARTICLE 31.
Assessment and Review

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, four years after the entry into force of this Protocol and thereafter at intervals determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, an evaluation of the effectiveness of this Protocol.

ARTICLE 32.
Signature

This Protocol shall be open for signature by Parties to the Convention at the United Nations Headquarters in New York, from 2 February 2011 to 1 February 2012.

ARTICLE 33.
Entry Into Force

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.
2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.
3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

ARTICLE 34.
Reservations

No reservations may be made to this Protocol.

ARTICLE 35.
Withdrawal

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from this Protocol by giving written notification to the Depositary.
2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

ARTICLE 36.
Authentic Text

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.
IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol on the dates indicated.
DONE at Nagoya on this twenty-ninth day of October, two thousand and ten.

ANNEX.
Monetary and Non-monetary Benefits

1. Monetary benefits may include, but not be limited to:
(a) Access fees/fee per sample collected or otherwise acquired;
(b) Up-front payments;
(c) Milestone payments;
(d) Payment of royalties;
(e) Licence fees in case of commercialization;
(f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
(g) Salaries and preferential terms where mutually agreed;
(h) Research funding;
(i) Joint ventures;
(j) Joint ownership of relevant intellectual property rights.
2. Non-monetary benefits may include, but not be limited to:
(a) Sharing of research and development results;
(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
(c) Participation in product development;
(d) Collaboration, cooperation and contribution in education and training;
(e) Admittance to *ex situ* facilities of genetic resources and to databases;
(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
(g) Strengthening capacities for technology transfer;
(h) Institutional capacity-building;
(i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
(l) Contributions to the local economy;
(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
(o) Food and livelihood security benefits;
(p) Social recognition;
(q) Joint ownership of relevant intellectual property rights.

General Information

Access to Associated Traditional Knowledge from secondary sources

- Street markets
- Publications
- Inventories
- Films
- Scientific articles
- Registries
- Other forms of systematization and record of associated traditional knowledge

Forms of Prior Consent

- Term of prior consent
- Audiovisual record of consent
- Report of the competent official body
- Accession as provided for in a Community protocol

Activities considered as exceptions to the registry requirement

- Human genetic heritage
- Access completed before June 30, 2000
- Plant or animal genetic improvement carried out by an indigenous population, traditional community or traditional farmer
- Also, it is not access to genetic heritage - when it is not an integral part of research or technological development -, tests, exams and activities related to: affiliation or paternity test, sexing technique and karyotype or DNA analysis and other molecular analyzes that aim to identify a species or specimen
- tests and clinical diagnostic exams for the direct or indirect identification of etiologic agents or hereditary pathologies in an individual
- extraction, by grinding, pressing or bleeding method that results in fixed oils;
- purification of fixed oils that results in a product whose characteristics are identical to those of the original raw material;
- test that aims to measure mortality, growth or multiplication rates of parasites, pathogens, pests and disease vectors;
- comparison and extraction of information of genetic origin available in national and international databases;
- extract processing, physical separation, pasteurization, fermentation, pH assessment, total acidity, soluble solids, bacterial and yeast counts, molds, fecal coliforms and total genetic heritage samples; and
- physical, chemical and physical-chemical characterization to determine the nutritional information of foods or consulting information of genetic origin available in national and international databases, even if they are an integral part of research and technological de-

velopment

What shall be registered

- Acccess to genetic heritage or associated traditional knowledge carried out within the country by national legal or natural person, public or private.

- 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.

- Access to genetic heritage or associated traditional knowledge carried out abroad by national legal or natural person, public or private.

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

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

When should the research be registered?

Registration must be done in advance:

- to the shipment;
- the request of any intellectual property right;
- the commercialization of the intermediate product;
- to the publication of results, partial or final, in scientific or communication media;
- to the notification of a finished product or reproductive material developed as result of the access.

What informations should be registered?

- Identification of the user
- Information on research or technological development activities
  - summary of the activity and its respective objectives
  - sector of application (in cases of technological development)
  - expected or obtained results
  - responsible team (+ partner institutions, if any)
  - period of activities
  - statement whether the genetic heritage is a local traditional local variety or creole or locally adapted race or creole, or is threatened of extinction
  - identification of the genetic heritage at the most strictest taxonomic level and geographic coordination
  - information on the foreign institution
  - identification of national partner institutions, if any
- Number of registry and prior authorization (from the provider of the raw material)
- Request for recognition of a legal hypothesis of secrecy
- Declaration, as the case may be, informing the framework or incidence of benefit sharing

What shall be notified?

The notification is the declaratory instrument that precedes the beginning of the economic exploitation of the finished product or reproductive material, in which the user declares com-

pliance with the requirements of the Law and indicates the mode of benefit sharing.

The Law clearly defines that the finished product is only that in which the component of the genetic heritage is one of the one of the key elements of value adding to the product, being able to be used by the final consumer. In this way, the final product, whose raw material is considered native to Brazilian biodiversity, must have its access duly registered in SisGen, not being necessary to notify it.

Benefit Sharing Agreement

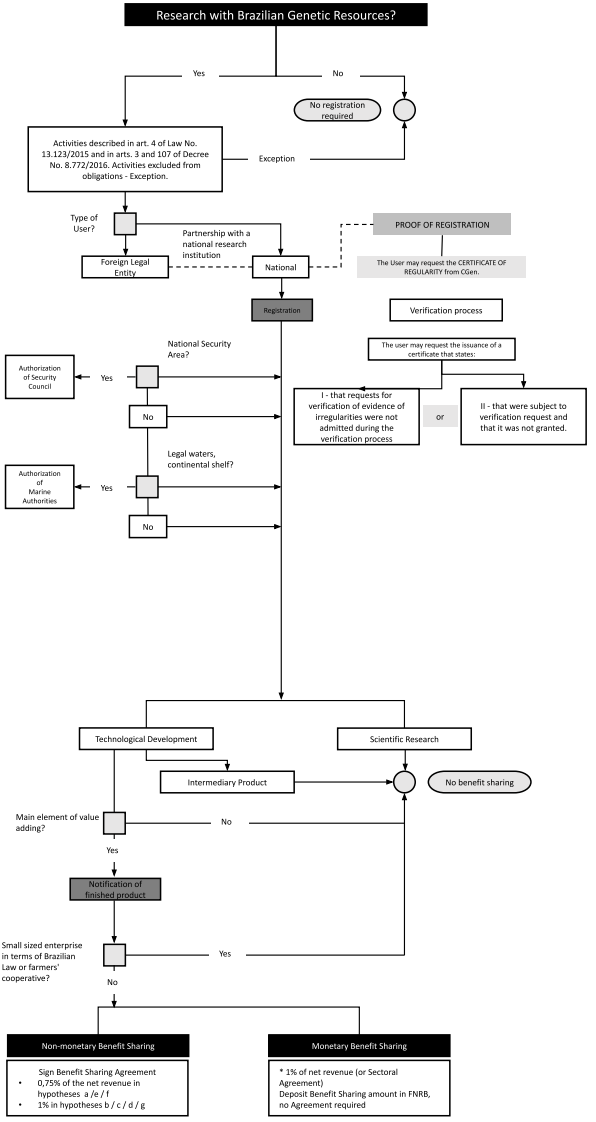
The benefit sharing agreement shall be signed between the User and the State and shall be presented in 365 days, from the moment of the notification of the finished product or reproductive material, except for cases that involve associated traditional knowledge of identifiable origin.

Examples of Non-Monetary Benefit Sharing

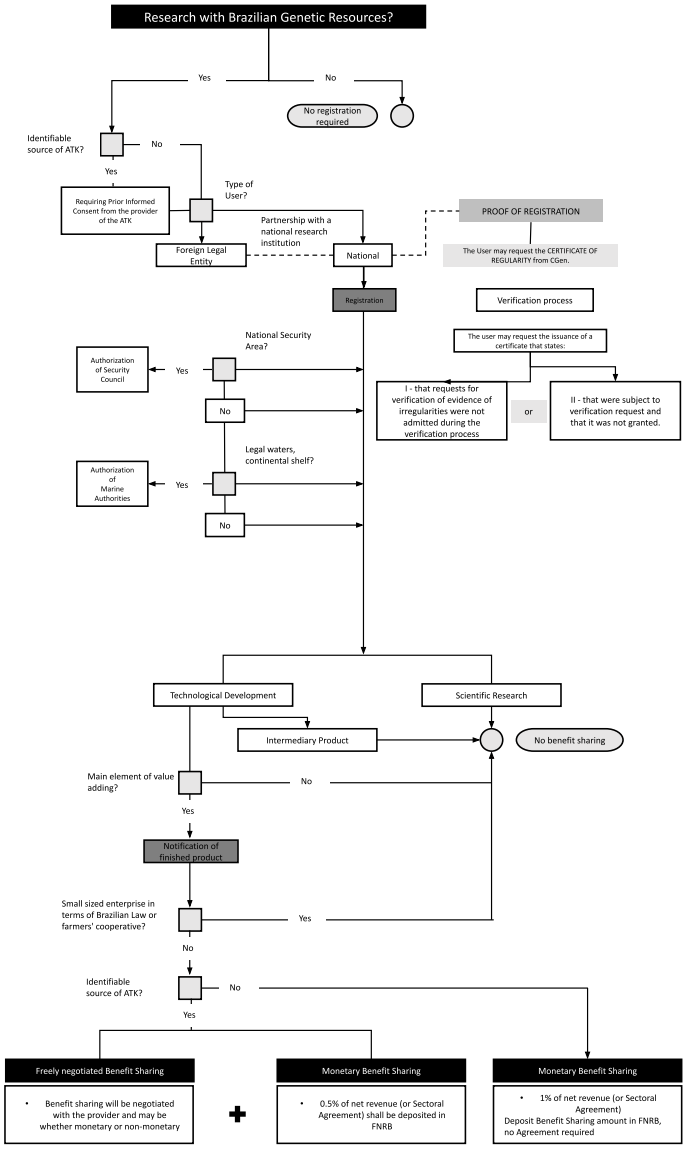
- Projects of conservation or sustainable use of biodiversity or protection and maintenance of knowledge, innovations or practices of indigenous communities, traditional communities or traditional farmers.
- Technology transfer
- Availability of product in the public domain, without protection by intellectual property rights or technological restrictions
- Licensing of products free of charge
- Training of human resources on topics related to conservation and sustainable use of genetic heritage or associated traditional knowledge
- Free distribution of products in programs of social interest

GENETIC PATRIMONY

Native Species, Domesticated or Spontaneous Population and microorganism isolated in national territory



TRADITIONAL KNOWLEDGE ASSOCIATE



Periodic reports and annual benefit sharing for as long as there is economic exploitation of the product.
CGen may, at the user's request, issue a certificate of international compliance.


Coordination:
gss
CARBONO E BIOINOVAÇÃO
www.gss.eco
Institutional Support:
vbio
www.vbio.eco
Institutional Support:
CRODA
Smart science to improve lives™