

**LAW N° 13,123**, dated May 20, 2015

**An Act**

To regulate paragraph 1, item II and paragraph 4 of Article 225 of the Federal Constitution; Article 1, Article 8(j), Article 10(c), Article 15, and Article 16, items 3 and 4 of the Convention on Biological Diversity, enacted by Decree n° 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 n°. 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 n° 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 n° 2,519, dated March 16, 1998, the following terms are defined for the purposes of this Act:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**XVI – finished product** – a product originating from access to genetic heritage or associated traditional knowledge that does not need any additional processing, in which the genetic heritage or the

traditional knowledge component is a key main element of value adding to the product, being it ready for use by the final consumer, whether a natural or a legal person;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## CHAPTER II

### COMPETENCE AND INSTITUTIONAL ATTRIBUTIONS

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

I – business sector;

II – academic sector; and

III – indigenous peoples, traditional communities and traditional farmers.

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

I – establish:

a) technical rules;

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

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

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

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

b) access to associated traditional knowledge;

III – deliberate on:

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

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

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

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

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

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

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

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

**IX** – create and maintain databases related to;

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

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

c) material transfer agreements and legal documents;

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

e) notifications of finished products or reproductive material;

f) benefit-sharing agreements;

g) certificates of access compliance;

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

**XI** – (VETOED); and

**XII** – approve its bylaws;

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

**Paragraph 3** – The CGen will create Thematic and Sectoral Chambers, with equal participation of the government and members of civil society, represented by business and academic sectors, and

representatives of the indigenous population, traditional communities and traditional farmers, to provide support for plenary decisions;

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

### **CHAPTER III**

#### **ASSOCIATED TRADITIONAL KNOWLEDGE**

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

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

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

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

**I** – scientific publications;

**II** – registries or databases; or

**III** – cultural inventories.

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

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



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

**I** – signed prior consent;

**II** – registered audiovisual consent;

**III** – statement from the official governing body; or

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

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

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

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

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

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

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

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

**V** – to freely use or sell products containing genetic heritage or associated traditional knowledge, in accordance with Law n°. 9.456, dated April 25<sup>th</sup>, 1997 and Law n°. 10.711, dated August 5<sup>th</sup>, 2003; and

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

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

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

## **CHAPTER IV**

### **ACCESS, SHIPMENT AND ECONOMIC USE**

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

**I** – access to genetic heritage or associated traditional knowledge;

**II** – shipment abroad of genetic heritage samples; and

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

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

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

**Article 12** – The following activities must be registered:

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

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

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

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

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

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

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

**Paragraph 3** – Information contained in the database referred to in Article (6)(1)(IX) are public, except for those that may jeopardize research, or technological or scientific development activities, or the commercial activities of third parties. In these cases, the information can be made available with the permission of the user.

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

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

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

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

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

**Paragraph 3** – (VETOED)

**Paragraph 4** – (VETOED)

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

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

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

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

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

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

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

## **CHAPTER V**

### **BENEFIT-SHARING**

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

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

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

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

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

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

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

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

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

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

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

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

**Paragraph 10** – (VETOED)

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

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

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

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

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

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

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

**I** – monetary; or

**II** – non-monetary, including, inter alia:

a) projects for conservation or sustainable use of biodiversity, or for protection and maintenance of knowledge, innovations, or practices of indigenous peoples, traditional communities or traditional farmers, preferable at the site where the species occurs in *in situ* conditions or where the sample was obtained, when the original location cannot be specified;

b) technology transfer;

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

d) licensing products free of charge;

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

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

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

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

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

**I** – participation in research and technological development;

**II** – information exchange;

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

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

**V** – establishment of technology-based joint venture.

**Paragraph 4 – (VETOED).**

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

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

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

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

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

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

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

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

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

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

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

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

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

**I** – in the case of economic exploitation of finished products or reproductive material originating from access to genetic heritage or associated traditional knowledge of unidentifiable origin:

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

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

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

a) the provider of the associated traditional knowledge; and

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

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

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

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

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



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

**I** – products that are object to economic exploitation;

**II** – time frame;

**III** – modality for benefit-sharing;

**IV** – rights and responsibilities of the parts;

**V** – intellectual property rights;

**VI** – termination;

**VII** – penalties; and

**VIII** – jurisdiction in Brazil.

## **CHAPTER VI**

### **ADMINISTRATIVE PENALTIES**

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

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

**I** - warning;

**II** - fine;

**III** - seizure of:

**a)** the samples containing the genetic heritage accessed;

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

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

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

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

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

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

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

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

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

**I** - the seriousness of the infraction;

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

**III** - recurrence; and

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

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

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

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

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

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

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

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

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

**Article 29.** (VETOED).

## **CHAPTER VII**

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

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

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

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

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

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

**II** - donations;

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

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

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

**VI** - funds arising from the benefit-sharing; and

**VII** - other resources.

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

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

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

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

**I** - conservation of biological diversity;

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

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

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

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

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

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

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

**IX** - conservation of wild plants;

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

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

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

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

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

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

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

## **CHAPTER VIII**

### **TRANSITIONAL PROVISIONS ON ADJUSTMENT AND REGULARIZATION PROCEDURES**

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

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

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

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

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

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

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

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

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

**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<sup>1</sup>.

**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

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<sup>1</sup> 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 N°. 2.186-16 due to lack of administrative procedures.

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

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

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

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

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

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

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

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

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

**I** - sign agreement or court settlement; or

**II** - give up the lawsuit.

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

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

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

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



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

## **CHAPTER IX**

### **FINAL PROVISIONS**

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

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

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

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

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

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

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

I - 1 (one) DAS-5;

II - 3 (three) DAS-4; and

III - 6 (six) DAS-3.

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

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

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

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