



IFRA-IOFI Guidance Document for the Flavor and Fragrance Industry for dealing with the Nagoya Protocol and Access and Benefit Sharing (ABS) Regulations

Annex –Brazil



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1. Applicable Legislation

Despite not being a party to the Nagoya Protocol, although having signed it in 2011, Brazil is party to the following international treaties relevant for access to genetic resources and fair and equitable sharing of benefits ('ABS') principles:

- Convention on Biological Diversity ('CBD');¹
- International Treaty for Plant Genetic Resources for Food and Agriculture;²
- International Union for the Protection of New Varieties of Plants Convention ('UPOV').³

Brazil was expected to ratify the Nagoya Protocol at the end of 2015. During the same year, they had been revising the national ABS framework and taking internal measures in view of ratifying the Protocol, once the National Congress finished their analysis.⁴ However, such ratification has not yet taken place.

As a consequence, Brazil governs ABS principles through national legislation. Since 17 November 2015 a new legal framework on the subject entered into force in Brazil: Law 13.123 (hereafter the 'Brazilian ABS Law' or 'the Brazilian Biodiversity Law').⁵ Brazilian ABS Law is regulated by the Decree 8,772 of 2016. This Decree is legally binding from the day it was published in the Federal Official Gazette, i.e. since 12 May 2016.⁶ Additionally, designated competent authorities have established complementary norms, e.g. the Normative Instruction N. 03/2019, which lists the species not considered genetic heritage found *in situ* in the national territory. A monitoring of other potentially relevant decisions would be interesting to perform.

To complement the legislative framework a series of different administrative documents, such as Technical Orientations and Resolutions⁷ are discussed and negotiated to facilitate the regulation implementation. Among them, some are relevant to the F&F industry⁸ e.g. Technical Orientation (OT) #6 published on August 2018 (applicable for fragrances only).

In Brazil, Technical Orientations and Resolutions are legally binding.

Discussions are currently ongoing, and those administrative documents are updated from time to time. To ensure you are referring to the latest version or if you have any questions on the OT

¹ The 1992 United Nations Convention on Biological Diversity of 5 June 1992 (1760 U.N.T.S. 69). CBD was ratified and enacted in Brazil through Decree 2,519 of 16 March 1998.

² International Treaty on plant genetic resources for food and agriculture of 29 June 2004 (2400 U.N.T.S. 303).

³ International Convention for the Protection of New Varieties of Plants of 2 December 1961 (815 U.N.T.S. 89).

⁴ Federal Republic of Brazil Ministry of External Relations Environmental Division, *Submission of views in preparation for the Expert Meeting on the need for and modalities of a global multilateral benefit-sharing mechanism*, Brasilia, 30 September 2015, p.1 [Available at: <https://www.cbd.int/abs/submissions/Art10/Brazil-submissionArt10.pdf>]. [Accessed on 12 July 2018].

⁵ Law 13,123 of May 20, 2015 [Available in Portuguese at: http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Lei/L13123.htm]. [Accessed on 27 June 2018].

⁶ UEBT, *ABS in Brazil*, February 2017, p. 1 [Available at:

https://static1.squarespace.com/static/58bfcaf22994ca36885f063e/t/5a1fcbe771c10b2672d56ad3/1512033263622/UEBT-ABS-Brazil_version-web-Feb-2017.pdf]. [Accessed on 27 June 2018].

⁷ Resolutions and Technical Orientations are types of decisions issued by CGen for different purposes. According to [CGen Internal Regulation](#), Technical Orientations shall be used in order to clarify the meaning of certain terms, in cases where their doubt or imprecision impact of the comprehension of biodiversity norms (Article 18, IV, CGen Internal Regulation). On the other hand, Resolutions shall be used for issuing (i) technical norms about access and shipment of genetic heritage, protection and access to associated traditional knowledge and about benefit sharing for conservation and sustainable use of biodiversity; (ii) guidelines and criteria for development and compliance of benefit sharing agreement; (iii) criteria for creation of data bank for registration of information over genetic heritage and associated traditional knowledge and; (iv) guidelines for allocation of resources destined to the National Fund for Benefit Sharing (FNBR) (Article 18, I, CGen Internal Regulation).

⁸ As per the date of publication of this Guidance document.

and/or the application of the law, please contact the Brazilian Association of Essential Oils, Chemical Aromatic Products, Fragrance and Flavor Industry (ABIFRA) (abifra@abifra.org.br).

2. National Authorities and Relevant institutions

The **Council for the Management of Genetic Heritage** ('CGEN') is the national authority in charge of regulating access to genetic resources and associated Traditional Knowledge. It is composed of multiple representatives of Federal Government entities and is notably chaired by the Ministry of the Environment. CGEN has the following functions:⁹

- coordinating the development and implementation of policies for ABS;
- setting of norms and guidelines;
- monitoring access;
- accrediting *ex situ* collections;
- managing notification of final products;
- creating and maintaining SisGen, the online registration system¹⁰;
- granting research permits, authorizations for access.

In order to ensure the good functioning of the system, CGEN has delegated part of its role of granting authorizations to three institutions: the Federal Environment Agency, Brazilian Institute of Environment and Renewable Natural Resources ('IBAMA'), the National Science Research Council ('CNPq')¹¹ and the National Institute of Historic and Artistic Heritage of the Ministry of Culture ('IPHAN').

When it comes to inspecting and investigating on actions possibly constitutive of administrative offenses established under the Brazilian ABS Law, IBAMA is the main competent authority alongside the Navy Command which is competent in maritime areas under Brazilian's sovereignty legal waters and the continental platform, and the Ministry of Agriculture, Livestock and Food Supply, competent for access to Genetic Heritage for agricultural activities.¹²

The National Fund for Benefit Sharing ('FNRB') has notably been established to deal with the funds resulting from monetary Benefit-Sharing and therefore receives all company payments to that effect. It also has a more general objective of valuing and promoting the Genetic Heritage and associated Traditional Knowledge, to ensure their sustainable use. Additionally, the FNRB implements the National Program of Benefit-Sharing ('PNRB').¹³

⁹ Council for the Management of Genetic Heritage: M. DA SILVA, M.J. AMSTALDEN & M. SAMPIO (2014), "National Implementation of Access & Benefit-Sharing for Non-Commercial Academic Research", *op.cit.*, Annex 4.

¹⁰ The Brazilian National System of Management of Genetic Heritage and Associated Traditional Knowledge – referred to as "SisGen" – was launched online on November 6, 2017.

¹¹ The CNPq is under the Ministry of Science and Technology which is also one of the Ministries represented in CGEN.

¹² ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, pp.74-75. "ABIHPEC", is the Brazilian Association of the Cosmetics, Toiletry and Fragrance industry.

¹³ ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.41.

3. Access to Genetic Heritage and Traditional Knowledge

3.1. Material scope of the Brazilian ABS law

Under the Brazilian ABS Law, "Registration" is triggered by 'access', i.e. by the conduct of research and/or technological development on Genetic Heritage or associated Traditional Knowledge.¹⁴ Registration is done online through the SisGen electronic registration system,¹⁵ whereby details of the activities and materials involved must be disclosed.¹⁶ Research or technological development may start prior to registration. However, the registration must have taken place prior to initiating the following activities:¹⁷

- Shipping samples abroad;
- Applying for intellectual property rights;
- Marketing an intermediate product;
- Divulging final or partial results in scientific media or through means of communication;
- Notifying final products or reproductive material developed through access.¹⁸

3.2. Genetic Heritage

Both the nature and the origin of a material condition whether research and/or technical development activities conducted on a material trigger access.

3.2.1. The Nature of the Material

The definition of Genetic Heritage encompasses information of genetic origin from plant, animal or microorganisms, including metabolic substances.¹⁹ Whereas the term "information of genetic origin" is not defined in the Brazilian Law, the definition of Genetic Heritage suggests that this legislation covers both physical and intangible (genetic or biochemical information taken from sample) components of a material.²⁰

Art. 1§1 of Decree 8,772 of 11 May 2016 (hereafter the 'Decree 8,722')²¹ further details that "*it is considered part of the genetic heritage of the national territory, the microorganism that has been isolated from substrata of the national territory, of the territorial sea, of the exclusive economic zone or of the continental shelf*".

However, art. 107 of Decree 8,772 somehow narrows the scope of application of the Brazilian ABS Law with respect to information (by contrast with physical materials) when providing that, "the reading or consultation of information of genetic origin available in national and international

¹⁴ Art. 3, Law 13,123 of May 20, 2015.

¹⁵ The Brazilian National System of Management of Genetic Heritage and Associated Traditional Knowledge – referred to as "SisGen" – was launched online on November 6, 2017.

¹⁶ Art. 3, Law 13.123 of 20 May 2015.

¹⁷ Art. 12.V, §2, Law 13.123 of 20 May 2015.

¹⁸ Art. 12.V, §2, Law 13.123 of 20 May 2015.

¹⁹ Art. 2, I Law 13,123 of May 20, 2015.

²⁰ See e.g. the document 'ABS in Brazil' issued by the Union for Ethical BioTrade (UEBT), p. 2. Available at: http://ethicalbiotrade.org/dl/UEBT-ABS-Brazil_version-web-Feb-2017.pdf. Accessed on 29 January 2018.

²¹ Brazilian ABS Law is regulated by the Decree 8,772 of 2016. This Decree is legally binding from the day it was published in the Federal Official Gazette (i.e. 12 May 2016).

databases do not constitute access to genetic heritage, even if they are part of research and technological development".

3.2.2. The Origin of the Material

The Brazilian ABS Law primarily applies to Genetic Heritage i) found in *in situ* conditions, or ii) kept in *ex situ* conditions, provided that it is also found in *in situ* conditions.²²

The SisGen User Guide,²³ issued by the Brazilian Ministry of Environment to help companies understanding how to use the SisGen electronic system, implies that Genetic Heritage obtained in "*in silico* conditions" or through so-called "intermediary products" also falls within the scope of the Brazilian ABS Law.

In addition, species introduced in Brazil are found *in situ* either if they form spontaneous populations that have acquired their own distinctive characteristics in the country, or a variety that was developed or adapted by indigenous populations, traditional communities or traditional farmers, including natural selection combined with human selection in the local environment, which is not substantially similar to commercial cultivars.²⁴

Overall, a material is to be considered as found *in situ* conditions if:

- i. for domesticated/cultivated species, if it exists in the surroundings where it has developed its distinctive properties;
- ii. it exists within ecosystems and natural habitats;
- iii. for species introduced in Brazil, they are considered to be found *in situ* either if they form:
 - o spontaneous populations that have acquired their own distinctive characteristics in the country, or;
 - o a variety that was developed or adapted by indigenous populations, traditional communities or traditional farmers, including natural selection combined with human selection in the local environment, which is not substantially similar to commercial cultivars.

There is no official list of species to identify those which are to be considered as found *in situ*.

For identifying native and endemic species, a company should consult a recognized source of information, e.g. scientific publications or taxonomic studies.

Additionally, with regard to species introduced in Brazil, a company could refer to the "Normative Instruction No. 23", which entered into force on 22nd March 2019 and contains the reference lists of i) domesticated or cultivated vegetal species that were introduced in the national territory (which are therefore not considered to be found in *in situ* conditions) and ii) the variety of vegetal species introduced in the national territory which has acquired distinctive features in the country.²⁵ Normative Instruction should be periodically elaborated, revised and published by MAPA (Brazilian Ministry of Agriculture) and it is binding on Brazilian enforcement authorities.

This being said, it should be noted that Decree 8,772 provides that the reference list of the Normative Instruction No. 23/2019 contains species that were introduced in Brazil and are used in agricultural activities. This may limit the scope of the Normative Instruction No. 23/2019²⁶. The list of the Normative Instruction 03/2019 does not include all the domesticated or cultivated

²² Article 1, I, Law 13,123 of May 20, 2015.

²³ Available in Portuguese at https://sisgen.gov.br/download/Manual_SisGen.pdf. Accessed on 23 January 2018.

²⁴ Article 1 of Decree 8,772.

²⁵ To date, only one species is listed, namely *Lolium multiflorum Lam.*

²⁶<http://www.agricultura.gov.br/assuntos/sustentabilidade/tecnologia-agropecuaria/recursos-geneticos-1/especies-introduzidas>

species that were introduced in Brazil, but only some species elected by the MAPA as species that were introduced only for using in agricultural activities, other introduced species should be consulted in a recognized source of information before defining if it has to be considered or not under the scope of the Brazilian ABS law.

The ministry of Agriculture publishes online the list of such exempted introduced species²⁷.

➤ *Ex Situ*

When Genetic Heritage is **kept in ex situ conditions**, but **can be found in in situ conditions**, it falls within the scope of the legislation. In that context, *ex situ* conditions are “conditions under which genetic heritage is maintained outside its natural habitat”.²⁸

The SisGen User Guide provides that Genetic Heritage can be obtained in *ex situ* conditions under the following scenarios: i) biological collection;²⁹ ii) commerce/market;³⁰ iii) cultivation or breeder;³¹ and iv) other *ex situ* collection³².³³

➤ *In Silico*

Finally, whereas the Brazilian ABS Law is silent on the term ‘*in silico*’, Decree 8,772³⁴ and the SisGen User Guide imply that Genetic Heritage found in *in silico* conditions falls into the scope of the Brazilian ABS Law.³⁵ No further definition or description of the concept is provided in Decree 8,772 or in the SisGen User Guide.

According to the Oxford Dictionary, scientific experiments or research conducted or produced *in silico* can be defined as “by means of computer modeling or computer simulation”.³⁶ This may be read as encompassing e.g. digital sequence information.

➤ *Intermediary products*

The SisGen User Guide also implies that Genetic Heritage obtained directly in the form of an intermediary product, which was developed within the scope of another access activity, is encompassed by the Brazilian ABS Law.³⁷

According to the Brazilian ABS Law, an ‘intermediary product’ is defined as the “product whose nature is its utilization in a production chain, which will add the intermediate product in its

²⁷<http://www.agricultura.gov.br/assuntos/sustentabilidade/tecnologia-agropecuaria/recursos-geneticos-1/especies-introduzidas>

²⁸ Article 1, I, Law 13,123 of May 20, 2015.

²⁹ Biological Collection is defined by the Normative Instruction IBAMA nº 160/2007 as follows: “*collection of testimony biological material constituted with the objective of generating and subsidizing scientific or technological research, as well as promoting culture, education and conservation of the environment. Exceptions are living collections sheltered by zoos, breeding grounds, aquariums, oceanariums, animal centers, sorting centers, animal rehabilitation or recovery, as well as plant nurseries*”: Article 3, item III of the Normative Instruction IBAMA nº 160/2007. [Available in Portuguese at

http://www.uesc.br/colecoes_cientificas/arquivos/in_160_270407_colecoes.pdf]. [Accessed on 23 January 2018]. The Brazilian Institute of Environment – IBAMA – has the competence to enforce the Brazilian ABS Law. The Normative Instruction IBAMA nº 160/2007 is an administrative act which binds IBAMA.

³⁰ Commerce/Market: means obtained in a commercial establishment.

³¹ Cultivation or Breeder: means obtained in a cultivation or breeder establishment.

³² Other ex situ collections: means obtained from other *ex situ* collections, that do not fit into the definition of Biological Collection of the Normative Instruction IBAMA nº 160/2007.

³³ SisGen User Guide, p. 40 ff.

³⁴ Article 22, item II.1 and Article 22 § 1º, item I, Decree 8,772 of 2016.

³⁵ SisGen User Guide, p. 43.

³⁶ Available at https://en.oxforddictionaries.com/definition/in_silico

³⁷ SisGen User Guide, p. 44.

production process as an input, excipient and raw material for the development of other intermediate or final product".³⁸

3.3. Traditional Knowledge

'Traditional Knowledge' refers to "information or practices of indigenous population, traditional communities or traditional farmers on the properties or direct or indirect uses associated with genetic heritage".³⁹ Whenever such knowledge is applied to research and technological development activities to allow or ease access to certain Genetic Heritage, Traditional Knowledge has been accessed.⁴⁰

Such access may occur in two ways: i) through direct acquisition, where there is direct transmission of the knowledge from the holder thereof to the seeker, or ii) through secondary sources acquisition, where there is no direct contact but the knowledge is obtained through another source such as data banks, books, articles or other means where the information is stored and available.⁴¹

Consequently, the specific origin of the Traditional Knowledge may not always be known. Nonetheless, where the origin is identifiable, i.e. it can be linked to specific indigenous people, traditional communities or farmers, the agent involved in accessing such information must fulfill an additional obligation prior to registration: receiving prior informed consent from one of the sources providing the Traditional Knowledge.⁴²

3.4. Known Grey Zones

There is no official list of species under the scope of the Brazilian Biodiversity Law. The species of the Brazilian biodiversity are included in several lists, among which are the Brazilian Flora and Fauna Species Lists, which are, respectively, available at www.floradobrasil.ibpj.gov.br and <http://fauna.ibpj.gov.br/>. Another reference that can be consulted is the Ministry of Agriculture Normative Instruction (MAPA) No. 03/2019.

However, it is noteworthy that the lists are not exhaustive and are constantly updated. Therefore, they should be used as a reference. It is recommended that a professional expert in the taxonomic group of interest be consulted if questions remain about the taxonomic classification of a particular species, variety or breed as part of Brazilian biodiversity.

4. Benefit-Sharing

4.1. Principles and Requirements

Activities that qualify as access will trigger Benefit-Sharing requirements, where such access:

- i) leads to commercializing a finished product⁴³ ("A final product does not require any additional production process and is ready to be used by the final consumer"⁴⁴); and

³⁸ Art. 2, XVII of Law 13.123 of 2015.

³⁹ Art. 2.XXVII, Law 13.123 of 20 May 2015.

⁴⁰ ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.28.

⁴¹ ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.29.

⁴² Art. 9, 2.VI, Law 13.123 of 20 May 2015.

⁴³ UEBT, *ABS in Brazil*, February 2017, p.4.

⁴⁴ UEBT, *ABS in Brazil*, February 2017, p.4.

- ii) adds significant value to the product. ("Adding significant value implies that the Genetic Heritage or the Traditional Knowledge were/are a determinant element for the product's functional characteristics or its market appeal"⁴⁵).

In that respect, a product's functional characteristics refer to the characteristics of the accessed Genetic Heritage that contribute to the products' main uses, improve its actions or widen its functionalities.⁴⁶

Additionally, where in relation to a product or brand, a specific reference is made to Genetic Heritage, associated Traditional Knowledge, their distinctive features or origin, the market appeal of the finished product is presumed. The reference simply must exist, no matter the means used for the diffusion thereof.⁴⁷

The contribution that must be made to fulfill the Benefit-Sharing obligations, lays with "the manufacturer of the finished product or the producer of the reproductive material, irrespective of who has previously accessed it". Since the obligation is triggered by access to Brazilian resources, the benefits which must be shared encompass those products commercialized or manufacturer abroad.⁴⁸

However, when the finished product is manufactured abroad, the importer, subsidiary, controller, affiliate, associate or commercial representative of the foreign manufacturer in the Brazilian territory or the territory of a country with which Brazil has an agreement to this end, will bear joint and several responsibility for the Benefit-Sharing obligations before the inspection body.⁴⁹

4.2. Options for Benefit-Sharing

The Benefit-Sharing obligations arising from the economic exploitation of finished products or reproductive material resulting from access to Genetic Heritage or associated Traditional Knowledge, may be fulfilled in two ways (Figure 1).⁵⁰

The first option consists of '**monetary benefits**', where a direct deposit of 1% of the annual net revenue from the final product's sales is sent by the company to the National Fund for Benefit-Sharing ('FNRB').⁵¹ To ensure the competitiveness of a specific sector, the monetary benefits may be negotiated with the Brazilian Federal Union and reduced to up to 0.1%. The deposit to the FNRB is an annual contribution that must be made after the end of a company's fiscal year, within 30 days after presenting the necessary fiscal information to the Ministry of the Environment.⁵²

Resources deposited to the FNRB for Benefit-Sharing purposes, are destined to the holders of Traditional Knowledge when they are identifiable or to ex situ collections when the finished product results from access to Genetic Heritage from such collections. In the remaining cases, the amounts may notably be dedicated to "the drafting of community protocols; the analysis, supervision, management and monitoring of supported actions, activities and projects; and the

⁴⁵ UEBT, *ABS in Brazil*, February 2017, p. 4; Art. 17, Law 13.123 of 20 May 2015.

⁴⁶ ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.45.

⁴⁷ ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.45.

⁴⁸ Art. 17, §1, Law 13.123 of 20 May 2015, ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.48.

⁴⁹ Art. 17, §7, Law 13.123 of 20 May 2015.

⁵⁰ Art. 19, Law 13.123 of 20 May 2015

⁵¹ Art. 20, 21, Law 13.123 of 20 May 2015

⁵² ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.38.

remuneration and coverage of the expenses of the financial institution related to the administration of the Fund".⁵³

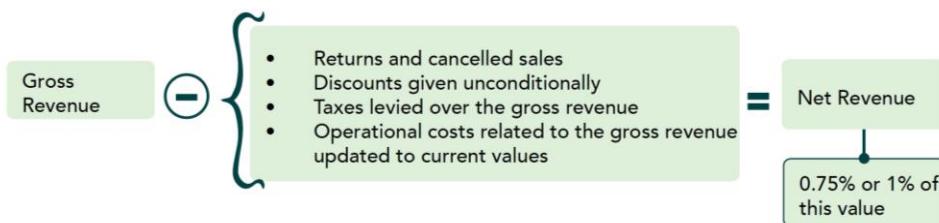
Figure 1: Summary of the three possibilities foreseen by the Brazilian ABS regulation to provide benefit sharing.

BENEFIT-SHARING			
ACCESS	HOW?	WHO?	HOW MUCH?
Genetic heritage	Monetary modality – National Fund of Benefit-Sharing Non-monetary project	Direct deposit to the National Fund of Benefit-Sharing Benefit-Sharing agreement with the Union to outline the Benefit-Sharing Project	1% of net revenue 0.75% or 1% according to the project outlined
Associated Traditional Knowledge of non-identifiable origin	The Benefit-Sharing should be integrally deposited to the National Fund of Benefit-Sharing	Direct deposit to the National Fund of Benefit-Sharing	1% of net revenue
Associated Traditional Knowledge of identifiable origin	The user can freely negotiate the means and values of the Benefit-Sharing with the ATK provider All other holders shall receive their share of the benefits from the National Fund of Benefit-Sharing	Negotiation + + 0.5% of net revenue	

Source: ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.37.

The Brazilian Association of the Cosmetics, Toiletry and Fragrance industry has published a guidebook in which it suggests a formula to calculate the net revenue from the sales of the final product (Figure 2).

Figure 2: Formula suggested by the Brazilian Association of the Cosmetics, Toiletry and Fragrance industry to calculate the net revenue from the sales of the final product under the scope of the Brazilian ABS regulation.



Source: ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.44.

The second option for Benefit-Sharing, is '**non-monetary benefits**' where the company will participate in certain projects according to the terms negotiated and set out in the Benefit-Sharing Agreement, concluded with the provider (if Traditional Knowledge) or the Brazilian Federal Union (if Genetic Heritage). The Agreement will constitute the Benefit-Sharing Project and should be presented in the 365 days following the notification of the finished product.

⁵³ ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.42.

Non-monetary projects should correspond to the allocation of 0.75% or 1% of the company's net revenue depending on the project that has been chosen.⁵⁴

When the finished product (or reproductive material) giving rise to Benefit-Sharing obligations results from access to Genetic Heritage, the company has the opportunity to change the Benefit-Sharing option initially chosen, through SisGen, at any time after having notified the finished product. It does not seem that a justification would be required for the change. However, once the change has been made, the company will have to comply with the legal requirements of the new option chosen for Benefit-Sharing, such as presenting their Benefit-Sharing Project within 365 days of notifying the final product or making the monetary deposit to the FNRB within the specific deadlines.

By contrast, where the finished product or reproductive material results from associated Traditional Knowledge, once the company has chosen monetary or non-monetary Benefit-Sharing, it must stick to this choice.⁵⁵

Non-monetary Benefit-Sharing may take the form of the allocation or contribution to the equivalent amount of 0.75% to 1% of the net revenue from the final product's sales in the following areas among others:⁵⁶

- Transfer of technology;
- Provision of the product to the public domain, without intellectual property protection or technological constraint;
- Licensing of products free of charge;
- Human resource training in topics related to conservation and sustainable use of the Genetic Heritage or associated Traditional Knowledge;
- Distribution of products free of charge in a social program;

These contributions can be granted to the following beneficiaries among others:⁵⁷

- Conservation units;
- Indigenous lands, populations;
- Rural settlements of family farmers;
- Traditional territories, communities and farmers;
- National public institutions of R&D;
- Activities related to safeguarding associated Traditional Knowledge.

4.3. Known Grey Zones

Intermediate products are not subject to benefit sharing. In the case of finished products, the above rules shall apply. For other situations on the nature of the annual revenue should be

⁵⁴ ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.39.

⁵⁵ ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.43.

⁵⁶ Art. 19.II a) to f), Law 13.123 of 20 May 2015.

⁵⁷ ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.40.

discussed by the respective trade associations with Government as well as be subject to a case-by-case assessment.

5. Exclusions

5.1. Explicit exclusions from the scope of the Brazilian ABS Law

Some materials are explicitly excluded from the scope of application of the Brazilian ABS Law by Decree 8,772, i.e.:

- Micro-organism shall not be considered as national Genetic Heritage if the user is able to demonstrate, upon request by the competent authority, that such material has been isolated from substrates other than the national territory and assimilated zones as well as the regularity of the importation of such material;
- Some specifically listed tests, exams and activities are excluded, provided that they are not part of research or technological development.⁵⁸ Interestingly, the reading or consultation of information of genetic origin available in national and international databases do not constitute access to Genetic Heritage, even if they are part of research and technological development;
- The genetic improvement of plant or animal made by indigenous population, traditional community or traditional farmer is exempted from registration.⁵⁹
- Introduced species⁶⁰.

5.2. Exemptions from the Benefit-Sharing obligation

There are a few exemptions from the Benefit-Sharing obligations listed below. However, an exemption from the Benefit-Sharing obligations does not entail that other obligations must not be fulfilled, i.e. Access. Research would still have to be registered and products must be notified in SisGen, alongside all other obligations established by the Brazilian ABS Law.⁶¹

Exemptions from Benefit-Sharing obligations may cover:

- “Producers of intermediary products and process developers from access to Genetic Heritage or associated Traditional Knowledge along the production chain”,⁶²
- “Microenterprises, small businesses, individual micro entrepreneurs”,⁶³
- “Traditional farmers and their cooperatives, with annual gross income equal to or less than the maximum limit set in art. 3 of L.123 of 14 December 2006”,⁶⁴

⁵⁸ See Art. 107, Decree 8,772 of 2016.

⁵⁹ See Art. 108, Decree 8,772 of 2016.

⁶⁰ <http://www.agricultura.gov.br/assuntos/sustentabilidade/tecnologia-agropecuaria/recursos-geneticos-1/especies-introduzidas>

⁶¹ ABIHPEC, *Guidebook on Access to the Brazilian Biodiversity*, March 2018, p.45.

⁶² Art. 17, §2, Law 13.123 of 20 May 2015.

⁶³ Art. 17, §5.I , Law 13.123 of 20 May 2015.

⁶⁴ Art. 17, §5.II , Law 13.123 of 20 May 2015.

- “Licensing, transferring or granting the permission to use intellectual property rights on a finished product, process or reproductive material obtained from the Genetic Heritage or associated Traditional Knowledge by third parties”;⁶⁵
- “In case of economic exploitation of reproductive material resulting from access to Genetic Heritage or associated Traditional Knowledge for purposes of agricultural activities exclusively destined to the manufacturing of finished products”;⁶⁶
- “The economic exploitation of finished products or reproductive material resulting from access to Genetic Heritage of introduced species on the national territory by human action, even if domesticated, except where they formed spontaneous populations or an adapted tradition/local/creole race”.⁶⁷

6. Adequacy and Regularization

Since the launch of SisGen on 6 November 2017, all companies that have accessed Brazilian Genetic Heritage, associated Traditional Knowledge, or that have commercially exploited final products or materials derived from these, in the period ranging from 30 June 2000 until 17 November 2015, had one year to adequate and/or regularize their activities in accordance with the Brazilian ABS law.

The regularization obligation is applicable to companies who have: i) carried out activities in accordance with the previously applicable Brazilian ABS legislation⁶⁸ ('Adequacy') and or/ ii) infringed the previous ABS framework ('Regularization').

The Adequacy procedure applied to activities carried out in accordance with the previously applicable Brazilian ABS legislation between June 30, 2000 and November 17, 2015. If the activities only involved access to Genetic Heritage or associated Traditional Knowledge, registration would be required. If the access led to economic exploitation of a final product or of a reproductive material, the new Brazilian ABS Law also requires Benefit-Sharing for the economic exploitation carried out from 17 November 2015 onwards (except if Benefit-Sharing was made in accordance with the previous Brazilian ABS legislation).

The Regularization obligation is applicable to companies that have carried out activities not in compliance with the previous Brazilian ABS legislation. Again, if access was limited to research activities, companies only have the obligation to registering on SisGen. However, if access resulted in commercialization of a final product or reproductive materials, a Benefit-Sharing commitment covering all benefits realized from the moment the product or material was launched must be concluded. Such commitment extends to a maximum period of five years preceding the conclusion of the commitment and its conclusion suspends any sanction applicable for breach of the previous ABS legislation.

⁶⁵ Art. 17, §4, Law 13.123 of 20 May 2015.

⁶⁶ Art. 18, §2, Law 13.123 of 20 May 2015.

⁶⁷ Art. 18, §3, Law 13.123 of 20 May 2015.

⁶⁸ Medida Provisória 2.186 of 23 August 2001 [Available at : http://www.planalto.gov.br/ccivil_03/mpv/2186-16.htm]. [Accessed on 11 July 2018].

7. Sanctions

Administrative infringements of the Brazilian ABS Law may be sanctioned by fines up to BRL 10,000,000 (approx. EUR 2,591,345 depending on current exchange rate). Moreover, depending on the seriousness of the fact, background and economic situation of the offender, and recidivism, sanctions may extend to (i) seizure of the samples, instruments or products derived from the access; (ii) temporary suspension of the manufacture and sale of the final product; (iii) embargo; (iv) partial or total prohibition of the establishment, activity or undertaking; (v) suspension or cancelation of the certificate or of the authorization.⁶⁹

The administrative sanctions may be applied cumulatively and are without prejudice to criminal and civil penalties.⁷⁰

8. Abbreviations

ABHIPEC	Brazilian Association of the Cosmetics, Toiletry and Fragrance industry
ABIFRA	Brazilian Association of Essential Oils, Chemical Aromatic Products, Fragrance and Flavor Industry
ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
CGEN	Council for the Management of Genetic Heritage
CNPq	National Science Research Council
FNRB	National Fund for Benefit-Sharing
IBAMA	Brazilian Institute of Environment and Renewable Natural Resources
IPHAN	National Institute of Historic and Artistic Heritage of the Ministry of Culture
ITPGRFA	International Treaty for Plant Genetic Resources for Food and Agriculture
MAPA	Brazilian Ministry of Agriculture
OT	Technical Orientation
PNRB	National Program of Benefit-Sharing
UPOV	International Union for the Protection of New Varieties of Plants Convention

⁶⁹ Article 27, §1, Law 13.123 of 20 May 2015.

⁷⁰ Article 27, §§1, 3 Law 13.123 of 20 May 2015.



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