

Bio Latin America Conference
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Industrial and Environmental Leadership Sessions
Regulatory Barriers to Growing the Bio-Based Economy

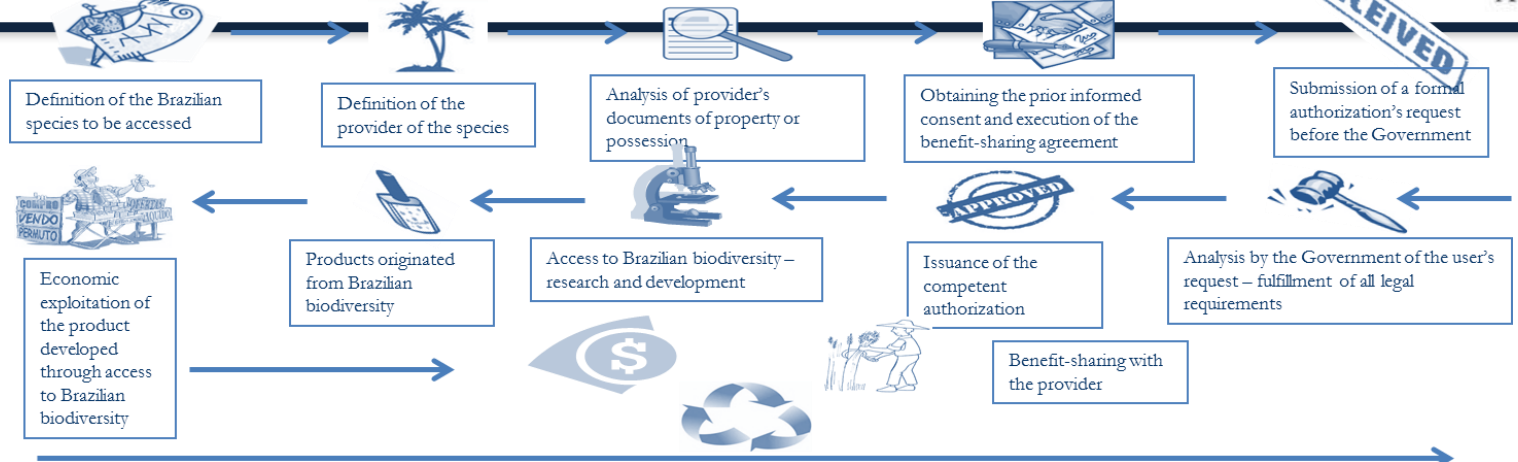
NASCIMENTO
& **M**OURÃO

ADVOGADOS

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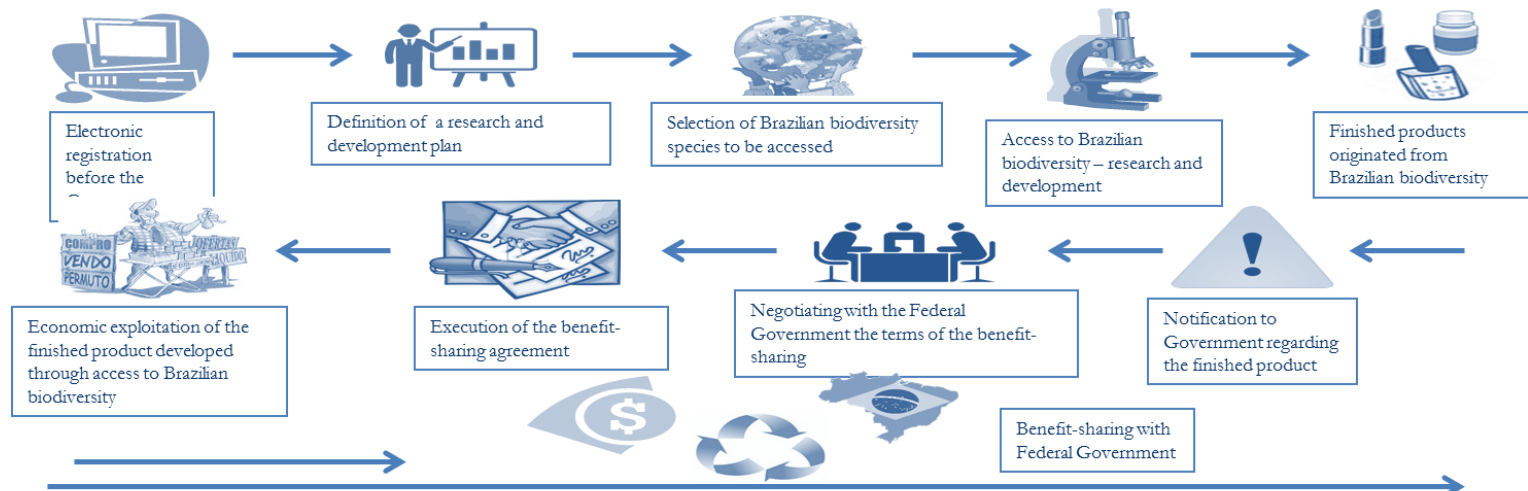
Challenges to comply with Brazilian Law: the previous law and the new.

Provisional Act's Flowchart – Access to Brazilian Biodiversity



APPROXIMATELY 2 YEARS OVERALL
(6 months to 1 year till issuance of authorization + 6 months to 1 year till economic exploitation)

New Regulation Flowchart – Access to Brazilian Biodiversity – in force as from 17.11.15



APPROXIMATELY 1 YEAR OVERALL
(1 to 3 months till start of access activities + 6 months to 1 year till economic exploitation)

Main differences between Provisional Act 2.186-16/2001 and Law 13.123/2015

| | Provisional Act 2.186/01 | Law 13.123/15 |
|---------------------------------------|--|---|
| Prior to access you should.... | Obtain an authorization before CGEN | Register the access before CGEN (which shall be done even after the access but prior to the commercialization) |
| Prior to ship samples abroad | Obtain an authorization before CGEN | Register the shipment before CGEN (it should be a declaration, not subjected to CGEN's approval). |
| Prior to commercialization | No particular obligation. You should only comply with the terms of the Benefit sharing agreement | Notify the products that are going to be commercialized and choose a modality of benefit sharing. |
| Beneficiary of the Benefit Sharing | Provider (owner of the area in which the genetic resource were obtained). | Union (<i>Ministério do Meio Ambiente</i>) |
| Benefit Sharing | Freely negotiated between the parties. There was no pre fixed amount nor a minimum term. | Pre fixed amount of 1% of net revenues of the product |
| Scope | Every entity that performed access to Brazilian biodiversity should obtain authorization and share benefits. | Only the manufacturer of the final product shall share benefits. But everyone on the supply chain shall register, when there is access to Brazilian biodiversity. |

Law nº 13.123/2015 – Purpose and Definition

The law is applicable to: The access to genetic heritage of the country, found in *in situ* conditions, including the domesticated species and the spontaneous population, or maintained in *ex situ* conditions, since found in *in situ* conditions in the national territory, in the continental shelf, in territorial waters and in the economic exclusive zone.

• **In situ concept of New Regulation:** Conditions that the genetic heritage exists in ecosystems and natural habitats and, in case of domesticated or cultivated species, in habitats that it's naturally have developed its own distinct characteristics, including those which form spontaneous population.

• **Domesticated population concept:** species which evolution process has been influenced by the human being in order to attend its necessities.

• vegetal and animal species introduced in the national territory shall only be considered genetic resources in *in situ* conditions when they constitute spontaneous population that have developed its own distinct characteristics within Brazilian territory. There is no official list describing *in situ* species. The Decree 8.772 (art. 113) foresees that MAPA will create a list of the *in situ* species used in agricultural activities.

• **Microorganism** - microorganism isolated from the national territory substrates, the territorial sea, the exclusive economic zone or the continental shelf is considered part of the genetic heritage in the country.

• **Agricultural activities** – activities of production, processing and commercialization of food, beverages, fibers, energy and planted forests.

- **Finished product** - product which nature does not require any additional production process arising from the access to the genetic heritage or to the associated traditional knowledge, which the component of the genetic heritage or the associated traditional knowledge be one of the main elements to the adding value to the products, being apt to be used by the final consumer, natural or legal entity.
- **Reproductive material** - material to vegetal spread or animal breeding from any genus, species or cultivation which arises from sexual or asexual reproduction;
- **Main elements adding value to the products** - elements which presence in the finished product is conclusive to the existence of the functional characteristics or to the marketing appeal development.
- **Shipping** - transfer of sample of genetic heritage for institution located outside the country in order to access the genetic heritage, in which responsibility for the sample is transferred to the recipient of the sample;
- **Sending Samples for services purposes** – sample that contains genetic heritage remitted abroad for services purposes, as part of the research or technological development carried out by a Brazilian institution, which shall be responsible for the sample.

Who should share the benefits?

- Benefit sharing in case of **exploitation of finished product or reproductive material** resulting from the access to genetic heritage of species found in *in situ*. (finished product shall use the genetic heritage as main element of adding value).
- The **manufacturer of the finished product or the producer of the reproductive material** are subjected to the payment of benefit sharing (regardless of who performed the access in the value chain).
- If the reproductive material or finished product has not been produced in Brazil, the importer, subsidiary and controlled companies, affiliated, linked or commercial representative of foreign producer in the country are **jointly liable** with the manufacturer for the benefit sharing
- The benefits resulting from the economic exploitation of the product arising from the access to genetic heritage or associated traditional knowledge **for agricultural activities** will be **shared over the commercialization of the reproductive material**, even if access or economic exploitation are performed by individuals or legal entities, subsidiary and controlled companies, affiliated, contracted, outsourced or linked.

Exemption from Benefit Sharing?

It is exempted from the benefit sharing the economic exploitation of finished product or reproductive material from the access to genetic heritage of species introduced in the country by human action, included domesticated species, **except:** (§ 3º, 18 – farming activities article)

I – those that form spontaneous population that acquired their own distinctive features in the country; and

II - local traditional variety or Creole or locally adapted breed or Creole.

Other cases of exemption of benefit sharing:

- a)Manufacturers of intermediate products or processes developers arising from the access (they shall make the register);
- b)licensing of intellectual property rights; and
- c)Micro and small enterprises.

Benefit-sharing Forms?

I – Monetary

- For Genetic Heritage: 1% of the net revenue
- For Associated Traditional Knowledge – free negotiation between provider and the user + 0.5% of the net revenue for the National Fund
- For non-identifiable Associated Traditional Knowledge – 1% of the net revenue for the National Fund

II – Non-monetary: 0.75% of the net revenue needed to implement the project

- Projects for conservation and sustainable use;
- Product available in the public domain;
- Transfer of technology;
- Licensing free and clear of any liens;
- Human resource capacity building;
- Free distribution of products.

III – BS for Associated Traditional Knowledge exempts payment for access to genetic heritage

In order to use Brazilian Biodiversity...

Developing a new product with Brazilian biodiversity (BDB)

Is there access?

NO

YES

Shall register

Intermediary product?

YES

no

Register prior to intermediary Product comercialization

Confirm if the BDB is Determinant to products function or to its marketing strategy

No need to notify. Shall not pay benefit sharing

no

yes

Finish product

Notify finished product prior to the first commercialization.

Choose the Benefit Sharing form

Monetary = 1%NR

Non monet. = 0,75% NR

Execute agreement with Union

Law 13.123/2015 is not applicable.

No need to register or pay benefit sharing

May send samples abroad and use biodiversity information on marketing

Shall not result on products developed as access result

How to register a research with Brazilian biodiversity?

Beginning of the research with BDB

Acquire BDB samples

Intends to remit samples or send abroad for services purposes

Technical development with BDB

Register previously

Register previously

Register previously

Register previously

Register and notify previously

Intends to file an intellectual property request related with the finished product developed with BDB.

Intends to share the results obtained with the research or technical development

Develops intermediary product and intends to start commercialization

Develops finished product and intends to start commercialization

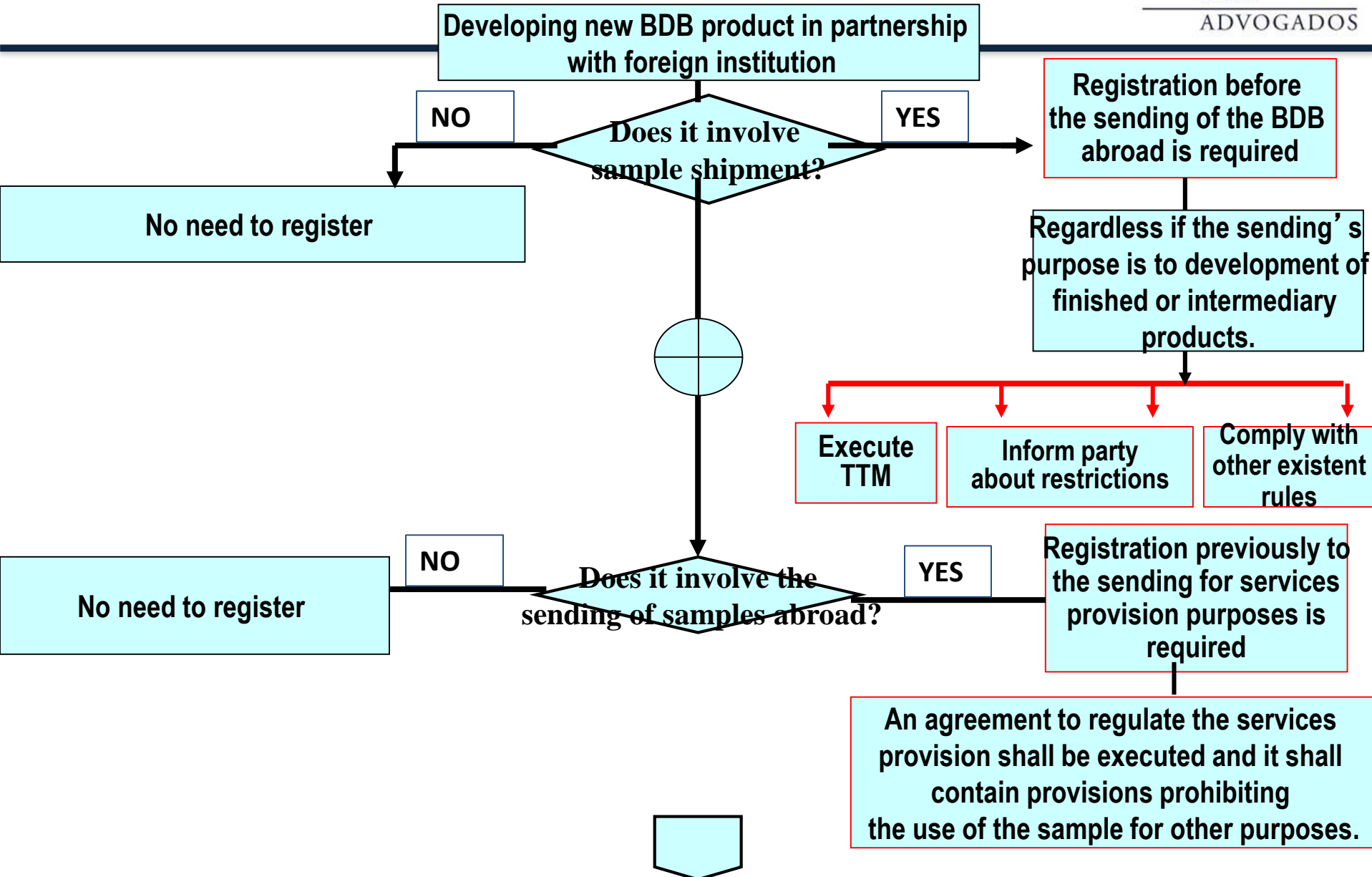
Registration is needed, but when?

And also when:

- Foreign access BDB in partnership with a Brazilian entity, in Brazil;
- Access is done outside Brazilian territory by a national entity.

Registration shall be annually updated.

Use of Brazilian Biodiversity Flow



1) Patent requests already presented before INPI, which involve national genetic resource (PG):

- It used to be required the presentation of access authorization, pursuant to Provisional Act No. 2.186-16.
- Regularization under the terms of the new law, in case the party has failed to obtain the referred authorization.
- Term: Within 1 year, as of the date SISGEN is released.

-2) Patent requests to be presented after SISGEN

- Registration of access or sample shipment previously to the requirement for intellectual property rights before INPI.

-3) Patent requests (to be) presented in under Law No. 13.123/2015 and before the releasing of SISGEN – Today.

- Considering that the registration system has not been released by the government, companies can not register before CGEN. In this sense, Decree No. 8.772/2016, sets forth in article 118 that the user who has required any intellectual property rights or has published results (final or partial), in the scientific community or media, in the period, shall registry its activities within the period of 1 (one) year, as of the date of release of SISGEN. Therefore, we recommend the company to already obtain information of the access, related to the intellectual property requirement it has done/will make.

- **4) Publication of results related to research or technological development in the scientific community.**

- The publication of results of researches with Brazilian biodiversity require previous registration. Considering that there is no definition of what “publication in the scientific community” means, a comprehensive interpretation of such concept is advisable (e.g. lectures, publications in general, quotation in seminars etc.).

Who should register?

- Access to genetic heritage or to associated traditional knowledge within the country held by national individual or legal entity, public or private;
- Access to genetic heritage or to associated traditional knowledge held by a foreign-based company associated with a national institution of scientific and technological research, public or private;
- Access to genetic heritage or to associated traditional knowledge held abroad by national natural person or legal entity, public or private;
- Sample shipment of genetic heritage abroad for the purpose of access in the cases of law;
- Sample Submission containing Genetic Heritage by national legal entity, public or private, in order to provide services abroad as part of research or technological development;
- The registration must be made prior to: (a) the shipment, or (b) the application of any intellectual property right, or (c) the commercialization of the intermediate product, or (d) the dissemination of results, final or partial, in scientific or other communication media, or (e) the finished product notification or reproductive material developed as a result of access.

Other important issues

- **Mercosur Nomenclature List - NCM:** The text adopted gives the Federal Union the power to create, by decree, the Benefit Sharing Classification List, without specifying the requirements of the list.
- **Art. 26 of Provisional Act:** Federal Union releases civil claims related to genetic heritage;
- **Regularization (Amnesty)** –activities performed after 2000, in violation of the Provisional Act, can be regularized by the execution of a Commitment Agreement which states: (i) retroactive payment of benefit sharing of the last five years; (ii) register; and (iii) notification regarding the product. Effects: extinction of enforceability of fines and reduction by 90% for cases of associated traditional knowledge.
- **Nagoya:** The benefit sharing provided for in the Nagoya Protocol does not apply to economic exploitation, for the purpose of agricultural activities, of the reproductive material of the species brought into the country by human action until the entry into force of this Treaty.

**Impacts to business: fines,
administrative procedures and licenses
for the use of Brazilian biodiversity**

1) PENALTIES – requirement of intellectual property right without previous registration

Article 80. Require intellectual property rights resultant from access to genetic resource or associated traditional knowledge, in Brazil or overseas, **without previous registration**:

Fine – ranging from BRL 3,000 to BRL 30,000.00, in case of natural person.

Fine – ranging from BRL 10,000.00 to BRL 200,000.00, in case of micro or small sized companies or traditional farmer cooperatives.

Fine – ranging from BRL 20,000.00 to BRL 10,000,000.00, in case of other legal entities.

2) PENALTIES – Publication of results without previous registration

Article 81. Publishing of results, final or partial, in the scientific community or media, without previous registration:

Fine – ranging from BRL 1,000.00 to BRL 20,000.00, in case of natural person.

Fine – ranging from BRL 10,000.00 to BRL 200,000.00, in case of micro or small sized companies or cooperatives.

Fine – ranging from BRL 50,000.00 to BRL 500,000.00, in case of other legal entities.

3) PENALTIES - Commercialization of intermediary product without previous registration

Article 82. Failure to register the access before the commercialization of intermediary product:

Fine – ranging from BRL 1,000.00 to BRL 20,000.00, in case of natural person.

Fine – ranging from BRL 10,000.00 to BRL 200,000.00, in case of micro or small sized companies or cooperatives.

Fine – ranging from BRL 50,000.00 to BRL 500,000.00, in case of other legal entities.

4) PENALTIES – Exploitation of finished product without the payment of benefit sharing

Article 85. Failure to pay installment annually due to the FNRB, as a result of economic exploitation of finished product or reproductive material, developed as of the access to genetic resource or associated traditional knowledge.

Fine – minimum of BRL 1,000.000 (one thousand reais) and maximum of BRL 100,000.00 (one hundred thousand reais), in case of natural person.

Fine – minimum of BRL 10,000.00 (ten thousand reais) and maximum of BRL 10,000,000.00 (ten million reais), in case of legal entities.

9. After November, 17th, what should my company do prior to start a P&D or comercialization of products containing Brazilian biodiversity?

- **1) If you are intermediary company:**

- Register the access to Brazilian biodiversity.
- In case the system is not ready as from November 17th, the user may notify CGEN in order to fulfill Law 13.123 requirements. Filling of manual forms may be required.

- **2) If you are final product manufacturer.**

- Register the access or sample shipment, if any made by the Company.
- In case of acquisition of raw material from a supplier, ask if it was made any access to Brazilian biodiversity in order to develop such raw material.
- In case of developing and manufacturing products with Brazilian biodiversity abroad, remember that companies which sell it in Brazil shall be jointly liable with the manufacturer for the benefit sharing

- **A. In case the biodiversity is essential to products function ou in case biodiversity is mentioned on the product name, label or in maketing contents:**

- Notify the product comercialization, informing which modality of benefit sharing the company chooses.
- Pay benefits annually, pursuant to the net revenues received (1% ou 0,75%).

- **B. In case biodiversity is not mentioned and if it is not essential to the product's function:**

- Notify the product comercialization, informing it is not the case of paying benefits

Thank you!
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