

New Legal Framework for Biodiversity in Brazil: what changes?

A nine steps comparison guide to assess business impact

Current regulation - Provisional Act No. 2.186-16/2001¹

1. What does it say about the development of access to genetic resources of biodiversity species?

In order to perform such activities, prior to the start of the research and development the user (i.e. a company, a university, etc.) must obtain prior informed consent of the provider, execute a benefit-sharing agreement, file a authorization request before the Government and await the issuance of such authorization.

2. Considering these legal requirements, how does it impact a company's due diligence in the acquisition of products originated from Brazilian biodiversity?

*When negotiating and acquiring from a supplier, it is recommended that the company confirms if any activity characterized as access to genetic resource was performed throughout the development of the product and if it was done pursuant the competent Government's **authorization**.*

3. And what does it say about the moment of execution of the benefit-sharing agreement?

It must be executed with the provider of the species prior to the development of any access activity and presented when submitting the request for a Government's authorization. This requirement is waived only for scientific researches.

4. Who is the beneficiary of the benefit-sharing?

The beneficiary is the provider of the species to be accessed by the user which is the one that owns or hold possession of the land where the samples of such species are collected, whether a private owner or a public entity.

5. Is there a mandatory benefit-sharing value to be negotiated?

There is no mandatory parameters defined by law. The contracting parties have the liberty to establish the values in the agreement, which must be fair and equitable.

6. What does it say about the foreign research entity?

It can only perform access to Brazilian biodiversity in collaboration with national research and development entities.

7. And about the remittance of Brazilian biodiversity samples abroad?

The remittance of samples for access activity is subject to prior government authorization.

8. Is there any provision about the development of products with Brazilian biodiversity abroad?

There is no specific provision regarding this issue.

9. And what does it say about exemptions from benefit-sharing obligations?

There is no provision regarding exemptions from the law.

¹ The Nagoya Protocol has not been yet ratified by Brazil, the international treaty is current under review and awaits approval of the National Congress to enter into force

New regulation – Bill²

1. What does it say about the development of access to genetic resources of biodiversity species?

Prior to perform such activities, as a general rule, the user (i.e. a company, a university, etc.) needs only to fulfill an electronic registration with the Government. As an exception, an authorization may be requested in four particular cases.

2. Considering these legal requirements, how does it impact a company's due diligence in the acquisition of products originated from Brazilian biodiversity?

*When negotiating and acquiring from a supplier, it is recommended that the company confirms if any activity characterized as access to genetic resource was performed throughout the development of the product and if it was done upon the necessary **electronic registration**. The new regulation ensures the **traceability of the production chain**.*

3. And what does it say about the moment of execution of the benefit-sharing agreement?

It must be executed after product development. In case of access to genetic resources, the benefit-sharing agreement shall be presented 365 days after product development notification. In case of access to traditional knowledge, it should be presented jointly with such notification.

4. Who is the beneficiary of the benefit-sharing?

The beneficiary, in case of access to genetic resources, is a Fund to be set up by the federal government and to be managed by a steering committee. In case of access to traditional knowledge, the beneficiaries are the communities.

5. Is there a mandatory benefit-sharing value to be negotiated?

In case of access to genetic resources, the manufacturer of the final product must share 1% of the annual net sales revenue arising from its exploitation. In case of access to traditional knowledge, it can be freely determined by the contracting parties, but a minimum of 0,5% of the annual net sales revenue shall be guaranteed for other communities that have similar knowledge.

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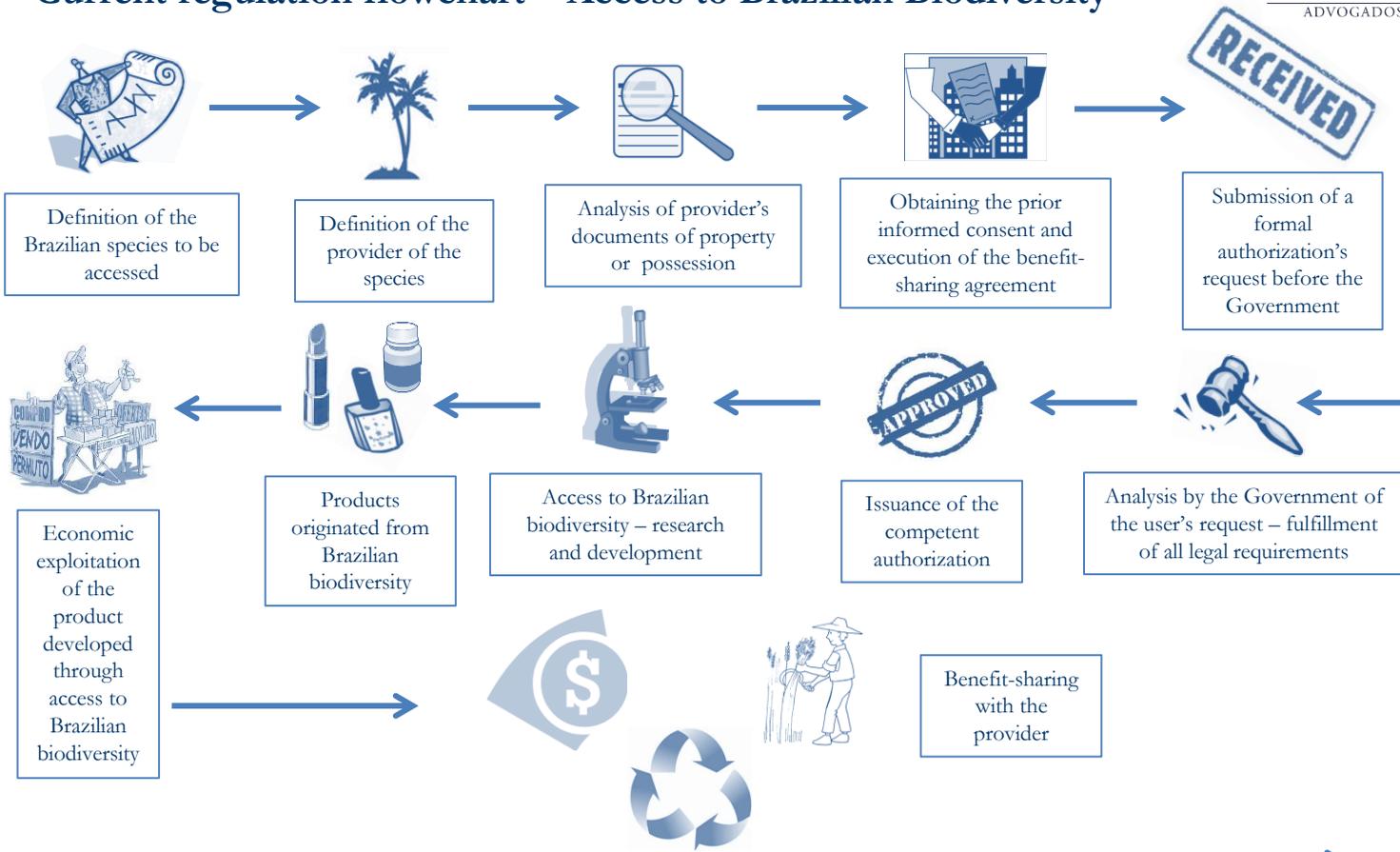
Yes. It sets forth that this activities are subject to Brazilian legislation. In order to enforce its compliance, it states that the product importer, the agent or a company controlled by or affiliated to the foreign manufacturer in Brazil or in a country in agreement with Brazil will respond jointly for the benefit-sharing.

9. And what does it say about exemptions from benefit-sharing obligations?

*It exempts from benefit-sharing obligations small and micro enterprises, individual micro entrepreneurs, traditional farmers and its unions. Also, it exempts the intermediate producer, not responsible for the finished product, and the manufacturer that in its finished product the Brazilian biodiversity does not represent the principal element of value's aggregation. However, **they are not exempt from the electronic registration**.*

² Bill under review by the National Congress and thus subject to changes. The version considered for this work was approved by Senate on April 7, 2015.

Current regulation flowchart – Access to Brazilian Biodiversity



New regulation flowchart – Access to Brazilian Biodiversity

