

Sao Paulo, October 28, 2018

To: Mr. José Roberto Borges
Director, Communities Initiative | Forest Trends

From: Sales & Kesselring Advogados

Ref.: **Legal Analysis on Brazilian Biodiversity Law - Accelerating Inclusion and Mitigating Emissions (AIME) program (agreement No. AID-OAA-A-13-00079).**

Dear Mr. Borges,

Please find below our analysis on legal aspects of Brazilian Biodiversity Law, in support to the Accelerating Inclusion and Mitigating Program. We hope our analysis responds to your inquiries and will be glad to provide Forest Trends with additional clarifications that may emerge in relation to this Legal Memorandum. We also take the opportunity to acknowledge the contribution of our colleague Grace Nogueira, environmental legal consultant who worked with us in this project.

Sincerely yours,

Rodrigo Sales, Partner

Overview of Brazilian Biodiversity Law and Identification of Legal Instruments and Strategies for Effective Participation of Traditional Communities in exporting and other commercial opportunities related to biodiversity assets.

1. Introduction

As a “mega diversity country”, Brazil plays a key role in the international efforts to protect global biodiversity. On its turn, Brazilian biodiversity constitutes a relevant potential for the country social and economic development resulting in potential benefits for its society as a whole. The premise is well assimilated by Brazilian society: Brazil was the first country to sign up for the Convention on Biological Diversity under the auspices of the 1992 United Nations Conference on Environment and Development (Rio- 92/UNCED), ratifying the text in 1994.

However, the country has been struggling through to convert such potential in actual investments to guarantee a fair balance between allowing the access to its genetic resources for various uses – i.e. research; medicinal; industrial, to quote some- and the fair share of the benefits deriving from the use and/or transformation of its biodiversity components into sellable products. Despite the complexity of several aspects advanced by the Biodiversity Convention and the expected challenges for its full implementation in every jurisdiction, the difficulties for its implementation in Brazil encompass overall structural, social economic and cultural hurdles Brazil still faces regarding shifting more traditional land use patterns to more sustainable (in relation to the three environmental, social and economic “pillars”) practices.

Among those difficulties, a key ongoing challenge for the ultimate fulfilment of the Biodiversity Convention objectives in Brazil, and of particular interest for this analysis, is the implementation of effective measures to guarantee a fair share of benefits with traditional communities - namely indigenous peoples, local communities, *quilombolas*, riverside communities, and traditional farmers - whenever they are the rightful primary owners of the knowledge subject to exploitation and trade.

The effort to secure traditional communities rights with regard to access to genetic resource and the sharing of its benefits (Access Benefit Sharing - ABS) is set primarily in the Convention on Biological Diversity itself as well as in other relevant international regimes. At the domestic level, Brazil recently enacted Law 13.123/2015, the country’s new legal regime on biodiversity, followed by Decree 8.772/2016 which enacts operational instructions to implement the law. Law 13.123/2015 replaced Provisional Measure Nº 2.186/01 (MP), which had been subject to warm criticism from different stakeholders in regard to its capacity to

stimulate and guarantee the effective implementation of the Biodiversity Convention in Brazil, as further discussed in this work.

Furthermore, aspects regarding domestic requirements to access genetic resources and associated traditional knowledge need special attention and coordination to allow an effective comprehension of the rights attributable to traditional communities and the identification of instruments to secure the fruition of such rights by those communities.

a. Convention on Biological Diversity: Summary of Main Objectives and Instruments

Prior to the Convention on Biological Diversity, access to biodiversity was part of a “global heritage of mankind” regime, the underpinning justification for that being that a loss of biodiversity in one place resulted in the loss of it everywhere. Unrestricted access to a country’s biodiversity was then unopposed under a justifiable rationale. To date, certain property rights obtained under this argument still holds, preventing source countries to benefit or receive economical dividends to a certain extent.

In general terms, the Convention on Biological Diversity (CBD) is the standpoint from which the set of rules addressing biodiversity shifted and protection with regard to crucial issues, such as the right to Parties’ self-determination in several areas regarding its biodiversity, were initiated. Parties to the Convention then inserted and adjusted those general guidelines to their domestic regimes attending to the specificities of every national case.

Thus, the CBD entails three primary goals straight in its article 1º: the conservation of biodiversity; the sustainable use of biodiversity components; and the sharing of the benefits deriving from the use of biodiversity. In summary: conservation-sustainable use-benefit sharing.

Most importantly, the Convention recognizes and establishes the sovereignty of every Party over its biological and genetic resources and the right of every Party to determine, via national regimes, the rules applicable to the access of their own biodiversity, in accordance to its environmental principles and policies. Moreover, the CBD establishes that Parties alone held the power to determine access to genetic resources in their jurisdictions in accordance with national regulations (article 15 and paragraphs of the Convention).

b. The Convention on Biological Diversity Guidelines – Evolution from revoked MP 2.186/2001 and the new Brazilian Biodiversity Law (13.123/2015)

Under the baseline framework of the CBD, Brazil has originally enacted Provisional Measure 2.186/2001 which established that access to its genetic resources and the traditional knowledge associated to it were to be authorized by the Union, via its National Council for Genetic Resources (CGEN), conceived under the Brazilian Ministry for the Environment (MMA).

Provisional Measure 2.186/2001 was revoked by the edition of the new Brazilian Biodiversity Law 13.123/2015 establishing specific regulations on: (i) access to the national genetic patrimony, (ii) the protection and access to traditional knowledge inherited in the genetic patrimony whenever it is the case and (iii) the sharing of benefits deriving from such an access¹.

The Provisional Measure 2.186-16/ 2001 faced criticism from different stakeholders since its creation in 2001, despite its merits in advancing the implementation of the CDB in Brazil. In general, the overall merits of the Provisional Measure was its attempt to instrumentalizing then novel and complex legal issues such as the protection of associated traditional knowledge and the sharing of benefits in connection with the use of the national genetic resources, and to create measures to combat biopiracy. However, the Provisional Measure ultimate design end up creating an inefficient, highly bureaucratic and rigid system that distorted the CDB objectives by inhibiting access to the biodiversity and the corresponding proliferation of research and bioprospecting activities in Brazil. The main hurdles imposed by the Measure included the need for the Union pre-approval (through the Genetic Heritage Management Council – CGEN, working under the Ministry of the Environment) of any attempt to access of Brazilian biodiversity and associated traditional knowledge. Such approval process included compliance with several burdensome “blue tape” requirements (applied even for Brazilian Researchers) and the ultimate execution of an “Agreement for the Use of Genetic Heritage and of Associated Traditional Knowledge “, (CURB contract).

Such contract (CURB) was then designed to regulate every step of access to the biodiversity and remittal of and sharing of associated benefits. In addition to the long length of time for the CGEN approval process, the structure of such contract was deemed inappropriate by significant number of academic researchers and biotechnology industry players. In particular, the contract model disregarded the uncertainties of research and development activities by demanding legal obligations upfront regardless the ultimate fruition of economic benefits resulting from the corresponding access, research & development, and commercialization cycle.

¹ Law 13.123/2015 Abstract

Further to the legal uncertainties on obligations of payment of benefits that could not materialize during the R&D cycle, there were uncertainties on the process of identifying the appropriate contractual beneficiaries of associated traditional knowledge.

As a result, the Provisional Measure lead to a very poor record of contracts signed (110 contracts, only one benefitting indigenous populations) and a toll of fines and prosecution proceedings against researchers who were deemed in violation with its complex and rigid requirements. This situation also created a grey area of projects that were considered in violation of the Provisional Measure, the regularization of which was also part of the requirements established by Law 13.123/2015, as discussed further in this work².

Box 1 – Comparing relevant concepts

Convention on Biological Diversity (CBD) - 1992	Provisional Measure 2.186/2001	Law 13.123/2015 Brazilian newest framework on ABS
<p><u>Biological Resources</u>: represented by genetic resources, organisms, or any other bio component with actual present or potential future value for humanity.</p> <p><u>Genetic Resources</u>: genetic material of actual present or potential future value.</p> <p><u>Genetic Material</u>: all sorts of materials from a vegetal, animal, microorganism or other containing functionable hereditary units to it.</p> <p><u>Biotechnology</u>: any technical application using biological systems, living organisms or its derivatives to manufacture or modify products or processes aiming at a specific use.</p>	<p><u>Access to genetic resources</u>: obtaining samples of genetic components for scientific research, technological development or bioprospecting aiming at an industrial usage of any kind or any other usage.</p> <p><u>Genetic Heritage</u>: it is the information deriving from a genetic source, contained in a sample of all or a part of vegetal, microorganisms or animals, in the form of molecules or substances derived from any of these components or extracts obtained from living or dead organisms.</p>	<p><u>Genetic Heritage</u>: information of a genetic base derived from vegetal, animal, microorganisms, or species of another nature, including the substances derived from the metabolism these living beings. The access refers to <i>in situ</i> materials – found within the country’s territory itself- or in <i>ex situ</i> conditions- when found in <i>in situ</i> conditions within the country’s territory, at the territorial sea or in the exclusive economic zone.</p> <p><u>Access to Genetic Heritage</u>: research or technological development initiated from a sample of the genetic patrimony.</p> <p><u>Access to Traditional Knowledge</u>: research or technical development initiated from the traditional knowledge on genetic resources which leads or facilitate the access to genetic resources to take place, even if based on secondary sources such as publications, fairs, inventories, films, scientific articles, files or any other form of systematization or register of associated traditional knowledge</p>

² TÁVORA, F. L. *et al.* Comentários à Lei 13.123, de 20 de maio de 2015: Novo Marco Regulatório do Uso da Biodiversidade. Núcleo de Estudos e Pesquisas da Consultoria Legislativa do Senado Federal (pg7-11)

		<p><u>Traditional knowledge:</u> information or practice held by a indigenous population, traditional community or traditional farmer on the properties, direct or indirect usages associated to genetic resources.</p> <p><u>Non Identifiable Traditional Knowledge:</u> the traditional knowledge whose roots cannot be traced back to only a single indigenous population, traditional community or traditional farmer.</p>
--	--	--

2. Brazilian New Biodiversity Law - Law 13.123/2015 – Key Aspects

Under the Brazilian New Biodiversity Law (13.123/2015), access to the country’s biodiversity is targeted at one of these two goals which may occur alone or combined: access to biodiversity to carry on baseline researches (for the production of scientific knowledge itself); access to biodiversity to foster technological development (for the development of new products or the improvement of existing products aimed at economic exploitation)³

Both modalities of access to biodiversity in the country must comply with legal requirements regulating “access” either to the Genetic Heritage (GH) or to the Associated Traditional Knowledge (ATK) cycles, again alone or combined.

Access to the Genetic Heritage itself focus on gathering tangible information about plant and animal species, microorganisms and alike and substances derived from their metabolism inclusive. In its turn, access to the Traditional Knowledge focus both on tangible or intangible information and practices from indigenous population, traditional communities, traditional farmers and others in order to obtain information which is historically linked to the properties of these genetic heritage components.

These are the baselines upon which all the new legal system on Biodiversity and Access to Benefit Sharing in Brazil (ABS – Brazil) unfolds and protection is regulated.

³ Law 13.123/2015 article 1º, I, in defining its scope establishes: “This law sets rules on assets of common use, rights and obligations as they relate to access to genetic heritage, a common good of the Brazilian peoples found in in situ conditions, domesticated and spontaneous species inclusive, or maintained in ex situ conditions, if so found in in situ conditions with the Brazilian National Territory, the Continental Platform, the Territorial Sea or in the country’s Exclusive Economic Zone.”

Starting with the broad conceptualization of genetic heritage (see footnote 2), the current biodiversity law points out the following primary groups⁴:

(i) microorganisms - so long as they were isolated from materials within the country's territory, its exclusive economic zone, territorial sea or continental platform;

(i) plant and animal: the country's plant and animal species as well as all the other plant and animal species introduced in the country and found in situ conditions once they have formed spontaneous populations which have acquired – within the country's national territory – their own distinctive characteristics.

When interpreting the scope of the legislation, it is relevant to make distinction for the case of raw materials and in nature goods under the Brazilian New Biodiversity Law (13.123/2015).

→ ***As a general rule, access to raw materials or in nature goods are not included in the concept of “access to genetic heritage” as such, nor is the trading of such materials domestically or abroad (i.e, natural oils, nuts, plants). However the processing of such materials for the manufacturing of other side intermediary or final products may entail responsibilities under the access to the associated traditional knowledge legal framework, dependant on whether the access to raw materials or in nature goods is aimed at developing new products based on the historical usage information/properties of specific goods almost certainly linked to a vast source of traditional knowledge footprints. Same rationale applies to exporting raw materials or in nature goods. Access, registry and benefit sharing procedures are triggered regardless of the location access to either Brazilian traditional knowledge or to genetic heritage takes place.***

2.1 Protection of genetic heritage Associated Traditional Knowledge (ATK)

Genetic Heritage Associated Traditional Knowledge (ATK) relates to all “information or practice of indigenous population, traditional community, or traditional farmers on the properties or direct or indirect uses associated with genetic heritage”⁵

Within the new legal regime (Law 13.123/2015)⁶, ATK is furthermore detailed in two distinct ways:

⁴ Regulating Decree 8.771,2016 , art 1º, §3º and 4º.

⁵ Law 13.123/2015 Art 2º, II.

- (i) Associated Traditional Knowledge of an Identifiable Origin: cases in which there exists the feasibility to link its origin to at least one singular indigenous community, local communities, quilombolas, farmers and riverside communities
- (ii) Associated Traditional Knowledge of Unidentifiable Origin - when linking the origin of access to one single traditional community is not possible.

The distinction is important as in the case in which ATK's origin can be identified, no research can be started before full consent from the traditional community which rightfully detains ownership over them. Here Prior Informed Consent (PIC) procedures apply⁷.

- ***Prior Informed Consent relating to R&D does not necessarily covers the consent for the economic exploitation of the final product itself. It is pivotal that prior informed consent covers both R&D combined with the economic exploitation of the final product.***
- ***Traditional Communities detain the right to deny access regarding the usage of their traditional knowledge. It is an upfront requirement for negotiators to fully disclose to communities they are entitled to do so before advancing the deal.***

2.2 Benefit Sharing⁸

Benefit sharing obligations are triggered by the economic exploitation of the final product derived from access to genetic heritage. According to the law a final product is one in which no additional industrial process is necessary before its offering to consumers/users (final product=end of pipe product).

In order to trigger the obligation to share benefits the following requirements need applying cumulatively:

- Existence of a "final product" (ready to be used by consumers/users)
- Final product derived from the access to genetic heritage or associated traditional knowledge
- Final Product manufactured within Brazil or abroad

The genetic heritage or the associated traditional knowledge component MUST be one of the pivotal elements adding value to the final product

⁶ Law 13.123/2015 Art 2º, II and III and art 8º and paragraphs.

⁷ Law 13.123/2015 Art 2º, VI and art 8º and paragraphs.

⁸ Law 13.123/2015 Art 17 to 26; Regulating Decree 8.771/2016 Art. 43 to 55.

Two elements compose the notion of added value amounting to a product being derived from genetic heritage or associated traditional knowledge:

Market Appeal: when reference to the genetic heritage or associated traditional knowledge is used as a distinction to “differentiate” the product, the product line, or the brand itself.

Functional Characteristics: all features of the genetic heritage or associated traditional knowledge that determines a product specific purpose or enhance related product’s purpose or also improve a product action.

→ ***The presence of only one of these components is enough to amount to the added value concept entailing benefit sharing.***

The manufacturer of the final product is the only one liable for the sharing of benefits, regardless of who else may have had previously accessed or commercially explored the other supply chain items of product’s manufacturing components (i.e. fragrances; oils).

However all intermediary raw materials developed from access to genetic heritage or associated traditional knowledge must be registered with SisGen, prior to its commercialization, request for patent, shipment or publication of results. Commercial establishments representing numerous raw material dealers, namely the distributors of raw materials need no registry with CGen.

The official document governing benefit sharing is the Benefit Sharing Contractual Agreement, applicable in the following cases:

- When access is derived from the use of genetic heritage a contract will be signed directly with the Federal Government, via the Ministry of the Environment
- When access occurred via the use of associated traditional knowledge of an identifiable origin, then contract will be signed directly with the community involved
- In cases where the final product derived both from genetic heritage combined with associated traditional knowledge in one same product, then associated traditional knowledge procedures prevails over genetic heritage

The Benefit Sharing Agreement must be presented: (i) at the moment when notification is registered in the system (SisGen) in cases access occurred over associated traditional knowledge of an identifiable source; (ii) up to 365 days from the notification that a final product is “ready-to-launch”.

Attention must be given to the fact that under the new Brazilian Biodiversity Law (Law 13.123/2015), there exist exemptions to the payment of benefit sharing. According to the

new legal framework, at least the following activities are exempt from benefit sharing payment:

- Intermediary products within a final product supply chain (benefit sharing is applicable to final product only)
- Final products or reproductive materials developed by micro, small or individual companies.
- Final products or reproductive materials derived from access to genetic resources concerning species which were introduced in the Brazilian territory, exception made to the spontaneous species which acquired its own distinctive features in the country, those local varieties and adapted creole varieties.
- Any operations to third parties relating to the transfer/licencing/authorization procedures of Intellectual Property Rights applicable to the final product.

Further notice must be given to some the exemptions on the agricultural sector with regard to the new legal framework. Benefit sharing procedures do not apply to the following activities: (i) final products or reproductive materials ⁹ developed by traditional farmers or cooperatives with a gross profit under the cap established by law¹⁰; (ii) access to genetic resources and/or to traditional knowledge target at developing agricultural final products commodities.

The obligation to registry the product with SisGen persists regardless of whether exemptions to sharing benefits may apply. Hence whenever the setting up of a product implies access to genetic resource or associated traditional knowledge registry with SisGen must unfold.

Due to the distinctions made on the possible ways to access Brazilian Biodiversity (via genetic heritage, via identifiable-origin traditional knowledge, via unidentifiable-origin traditional) the

National Fund for Benefit Sharing (FNRB) ¹¹, of a financial nature, was established to minimize potential problems, mainly with regard to legal actions when, i.e. more than one traditional community may claim ownership of same traditional knowledge.

The National Fund for Benefit Sharing (FNRB) will be the recipient of moneys deriving from benefit sharing (Monetary Benefit Sharing) as well as the penalties inflicted upon perpetrators (fines). Furthermore, FNRB will aim to support actions and activities that

⁹ Law 13.123/2015 Art1º, XXIX.

¹⁰ As defined by Complementary Law (Lei Complementar), 123/2006, art3º, II.

¹¹ Law 13.123/2015 art.30 to 33.

acknowledge the value of genetic heritage and associated traditional knowledge, promoting its use in accordance to sustainable principles.

A Management Committee and a National Benefit Sharing Program were set up to manage FNRB's resources and direct its entries to promote conservation of biological diversity; recovery, creation, and maintenance of ex situ collections of genetic heritage samples; prospecting and training of human resources associated with the use and conservation of genetic heritage or associated traditional knowledge; and gathering and inventory of genetic heritage, to name some of its scope.

Whenever the economic exploitation derives from GH or ATK with unidentifiable origin, the Federal Government is indicated as the recipient of the benefit sharing to be deposited in the FNRB. Here entries to the Fund are set at 1% of the annual net revenue obtained from the exploitation of the relevant product. However, this figure can be reduced to as much as 0.1% through a sectorial agreement.

In the cases of economic exploitation coming from ATK of identifiable origin, the deposit in the FNRB will be 0.5% of the annual net revenue, and there will be an extra amount-value to be negotiated and paid by the user/manufacturer of the ATK directly with the specific community.

In addition to the Monetary Benefit Sharing, the legislation also provides for Non-Monetary Benefit Sharing, which can be done by implementing numerous categories of projects, such as for conservation or sustainable use of biodiversity or for protection and maintenance of associated traditional knowledge; technology transfer; distribution of the product in the public domain; training of human resources; free distribution of products in social interest programs, etc.

Box 2 – Summary on Benefit Sharing¹²

BENEFIT-SHARING			
ACCESS	HOW?	WHO?	HOW MUCH?
Genetic heritage	Monetary modality – National Fund of Benefit-Sharing	Direct deposit to the National Fund of Benefit-Sharing	1% of net revenue
	Non-monetary project	Benefit-Sharing agreement with the Union to outline the Benefit-Sharing Project	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
	All other holders shall receive their share of the benefits from the National Fund of Benefit-Sharing		+ 0.5% of net revenue

3. Exportation of Genetic Material

Prior to the enactment of the new Biodiversity Law (Law 13.123/2015), questions relating to either the import/export of biodiversity elements derived from biodiversity dwelled in a certain grey zone. At the time, questions remained on whether products from the Brazilian biodiversity traded abroad were deemed to obey benefit sharing procedures with regard to access to genetic heritage or traditional knowledge.

Presently there remains no doubt that products deriving from access to genetic resources or associated traditional knowledge entails benefit sharing procedures regardless of the location in which they have been manufactured or are/will be traded.

The new registry system engendered by the new legal framework demands that product is notified by users/manufacture to SisGen with detailed explanation on location relating to product’s manufacturing and its final trading destinations.

Genetic Heritage can be transferred abroad in two possible modalities: shipment or sending¹³.

Shipment is considered more critical because it involves transferring a sample of Genetic Heritage to an institution located outside Brazil for the purpose of access. In this case, it is

¹² Guidebook on Access to Biodiversity – Access to the Brazilian Biodiversity, ABIHPEC(2018).

¹³ Law 13.123, art 2º, XIII and XXX.

necessary to sign a Material Transfer Agreement (MTA) between sender and recipient of the shipment abroad before shipment takes place and all data relating to the transaction must be filed with SisGen.

→ ***Under Shipment accountability regarding the sample is shifted to the foreign institution receiving relevant sample, which will then be obliged to the Brazilian Biodiversity Law rules, including that of sharing benefits.***

It is mandatory that, upon completion of the laboratory analyses, the samples sent are either destroyed or returned. Once the Mutually Agreed Term is set, a more robust legal instrument signed between the national institution responsible for the access and the partner or contracted institution will be required.

Sending consists of transporting a sample from Genetic Resources to be subject of specific services abroad, as part of research or technological development, in which the responsibility for the sample remains with whoever performs the access in Brazil. In other words, an interested party in Brazil hires the service of a foreign institution merely to help screening the relevant genetic heritage. Interested party is just hiring a service that it will itself benefit from.

In cases of sample submitted for genetic sequencing, a legal instrument between the parties involved will not be mandatory, only the formal communication to the partner institution or contractor about obligations and prohibitions defined by the law 13.123/2015.

→ ***Under Sending the accountability regarding the genetic material remains with whomever individual or enterprise accessed the genetic material in Brazil.***

In both cases (shipment or sending of materials), foreign researchers will be able to access native biodiversity only if associated with public or private Brazilian scientific and technological research institutions, which must take responsibility for registering the activity with SisGen.

→ ***If the final product is one which was manufactured abroad, the importer, subsidiary, controller in Brazil or any other legal entity acting on behalf of such international dealer will be subject to joint and several liability in case international dealer do not meet his benefit sharing obligations.***

To secure across-the-board accountabilities, there are innovative available means to trace products, such as the exchange of registry information, and at least the cross-matching with the following other registry entries: international transit of cultivar species and other agricultural commodities registry with the Brazilian Ministry for Agriculture; research and trade registry of genetically modified species registry with the Brazilian Ministry for Science,

Technology and Innovation; products' registry with the Brazilian Health Surveillance Agency; Import and Export registry system; intellectual properties system with the Brazilian National Institute of Intellectual Property(INPI).

→ ***Finally, as a general rule the exportation of raw materials or in nature goods is not deemed to observe the new rules applicable to the genetic heritage regime. Nevertheless, in cases in which there may be access to associated traditional knowledge related to access perpetrated abroad, the shipment of genetic heritage deliverables will generate benefit sharing obligations to the foreign institutions themselves or joint and several liability to the other parties involved (importer/exporter, controller, subsidiary, etc.), as pointed out previously.***

Box 3- Shipment # Sending of Samples of Genetic Materials Abroad¹⁴

	<u>Shipment</u>	<u>Sending</u>
<u>Purpose</u>	Access to genetic heritage	Hiring of services abroad
<u>Accountability regarding the sample sent abroad</u>	Recipient of the sample(foreign institution)	Whomever accessed sample in Brazil
<u>Sample availability</u>	Sample available for future usages, regardless of sender's participation in the choice of "future" to the sample. Material samples remains with recipient.	Sample usage restricted exclusively to the usages described in the legal document formalizing sample's sending. Material samples must be destroyed or sent back to senders after service is finished.
<u>Registry</u>	Must be <i>prior</i> to shipping product abroad	Must be <i>prior</i> to sending abroad

4. Registry Requirements

In order to systematized the country's access to biodiversity, the new law substituted the then prior authorization and pre-conditioning regime to an electronic registry in which users must declare their activities as they relate to access to genetic heritage or to associated traditional knowledge (SisGen/CGEN).¹⁵

Baseline researches can be initiated without previous entering the registry. However, registry is mandatory once a sample is to be shipped or to be sent; any requirement for intellectual property rights is issued, or any intermediary commercialization of products is due, or communication of research results (partial or final) in scientific or press channels is

¹⁴ Brazilian Ministry of Environment – National Council for Genetic Heritage web page

¹⁵ Regulating Decree 8772/2016, art. 22 to 26.

released, or notification of materials or new materials developed as a result of access is issued.

Likewise notice must be given to the fact that access to genetic resources with the sole purpose of research no longer entails prior authorizations from IBAMA, CNPQ or IPHAN as well (see articles 22, 24 and 25 of Decree 8.772/2016).¹⁶

As pointed out earlier, one of the most positive advances of the new law is exactly the replacement of the “previous authorization” system to access genetic resources (MP 2.186/16) by the current registry system which entails that such a registry can be carried out during the research and technological development phases themselves, reducing Brazilian bureaucratization on Research & Development significantly.

Numerous activities still encompass prior registration with SisGen (CGEN) though, namely:

- shipment of genetic heritage;
- application for intellectual property rights;
- marketing of an intermediate product;
- dissemination of results (final or partial);
- notification of a finished product or reproductive material developed from an access.

Mandatory Registry System under the new Brazilian Legal Framework

In Summary, the following activities requires entry in the National Access to Genetic Resources Registry System (SysGen)¹⁷:

I - Access to genetic heritage or traditional knowledge carried out in the country by a person or legal entity (public or private)

II - Access to genetic patrimony or traditional knowledge carried out by a legal entity established abroad in association with a national institution which carries out scientific or technical research, being the national institution public or private.

¹⁶ The Brazilian National Institute for the Environment (IBAMA) will still be involved in granted previous authorization for the access of genetic resources when species are listed under the CITES Convention (Convention of endangered species of FAUNA e FLORA)

¹⁷ Law 13.123/2015 includes activities that were not contemplated by the Provisional Measure 2.186/2001, such as research related to molecular taxonomy, phylogeny, molecular epidemiology, and molecular ecology, as well as the use of information from public genetic sequence databases, such as GenBank.

III - Access to genetic patrimony or to traditional knowledge carried out abroad by a person or a national legal entity, being this entity of a public or private nature.

IV - Activities of access and Shipment of samples of plant genetic resources aiming at accessing their genetic component when related to items I and III

V - Sending samples abroad containing genetic material as part of a service hired in Brazil to be carried out abroad relating to scientific research or technological development (genetic sequencing)

VI - Access to genetic heritage or to associated traditional knowledge in areas reputable important to national security. In these cases access only happens after confirmation by the national security authorities is dully granted

Corrective measures for past procedures carried out in inobservance of the Provisional Measure 2.186/2001 are mandatory to any activities encompassing: (i) access to genetic patrimony or associated traditional knowledge; (ii) transfer of samples abroad or (iii) the economic exploitation of a product resulting from access to genetic patrimony. The timeframe applicable to correction inflicts between June 30/2000 to November 16/2015. Hence if during this period a person or a legal entity...

- developed scientific research or carried out technical development derived from Brazilian genetic heritage or traditional knowledge
- accessed or explored the Brazilian genetic heritage or traditional knowledge for economic purposes
- sent abroad samples of the Brazilian genetic heritage
- published or issued or transmitted data or information constituting of Brazilian traditional knowledge

....regularization is required with the Genetic Heritage Management Council (CGEN registry system –SisGen). Deadline for presenting corrective measures ends one year after Sisgen is made available to the public which happens on November 6, 2017. Hence deadline closes at the 6 November 2018¹⁸.

→ ***All activities taking place before 30, June 2000 rest outside law 13.123/20015 requirements. Consequently they are not deemed illegal nor need corrective measures in place. Evidence must be provided that activities took place prior to***

¹⁸ The Council on Genetic Resources – CGEN informs no envisaging to extend due deadline, closing date for registry procedures remains 6/Nov/2018. SisGen is regulated by Federal Decree No. 8,772 of May 11, 2016.

relevant date mentioned, in accordance with the National Council to Genetic Resource prescriptions to this end.¹⁹

In order to proceed with the necessary adjustments for corrective measures, interested parties must sign up an Adjustment Term with the following scope: (i) register access to genetic resources or associated traditional knowledge; (ii) notify all finished products or reproductive materials object of economic use and (iii) start the sharing of relevant benefits from the entrance of present law onwards. If access was done with the sole purpose of research, then users are not obliged to sign up the Adjustment Term, but will be constricted to registry relevant information and obtain due authorization regarding the continuity research activity per se with CGEN.

→ ***It is important to emphasize that to comply with the legislation, an institution must first appoint a legal representative, who will be responsible for the institutional register and will alone have the power to represent it within SisGen. An institution may appoint more than one legal representative. The user can request a Certificate of Access Regularity from CGen.²⁰***

Box 4 -Registry Requirements in order to Access Genetic Heritage or Traditional Knowledge

ACTIVITIES	OBLIGATIONS
Access to Genetic Heritage or to Associated Traditional Knowledge	Prior registry (SisGen)
Shipping sample abroad to access genetic resources	Prior registry (SisGen)
Sending samples abroad as a consequence of hiring services abroad to perform genetic sequencing	Prior registry (SisGen)
Access genetic heritage or associated traditional knowledge in areas deemed as being national security	Prior authorization by the Brazilian National Defense Council
Access genetic heritage or associated traditional knowledge in jurisdictional waters, at the continental platform or at the exclusive economic zone	Prior authorization by the National Maritime Authority
Initiate economic exploitation to a final product	<i>Notification</i> (SisGen)

→ ***The notification is a declaratory procedure which must take place prior to the economic exploitation of the final product derived from the access to genetic***

¹⁹ Law 13.123/2015 ,Art. 118 and §1º

²⁰ See difference between Access Registry Statement and a Certificate of Access Regularity in the following page.

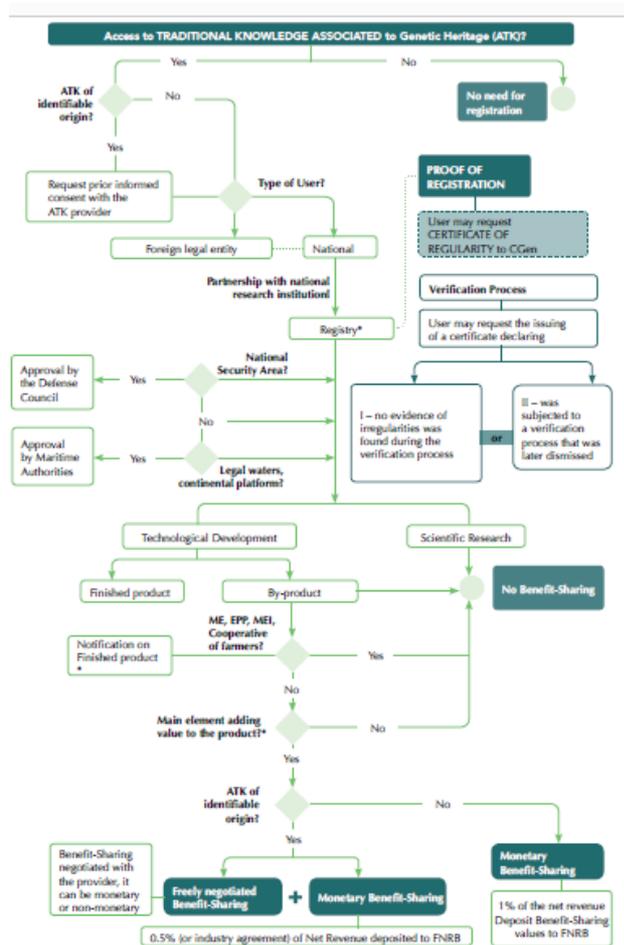
heritage or to associated traditional knowledge. In order words, precedes the launch of a final product that notification must be dully registered with CGen.

Distinction must also be made with regard to Access Registry Statement and that of the Certificate of Access Regularity as indicated below.

The Access Registry Statement is mandatory to whichever activities aimed at accessing either genetic heritage or associated traditional knowledge and it results in the following benefits: (i) requiring intellectual property rights; (ii) trading an intermediary product; (iii) publishing partial or final results of researches or technical developments in chosen media, (iv) allows notification of a final product be made, (v) triggers verification.

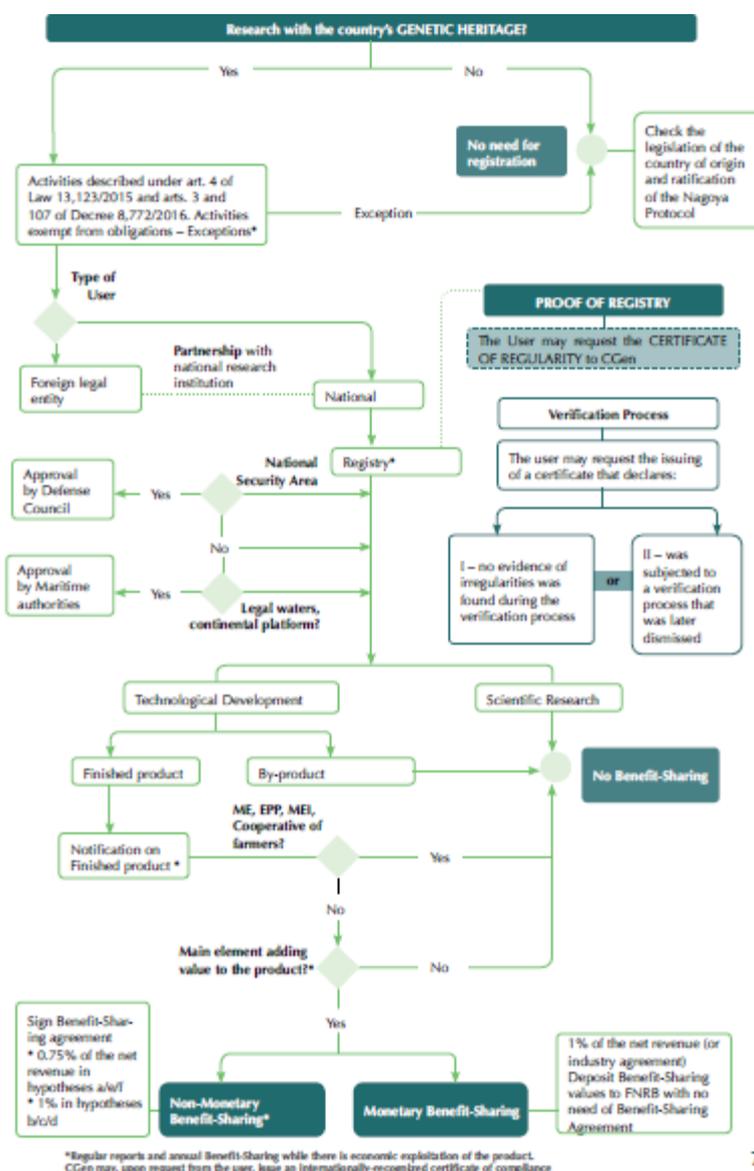
The Certificate of Access Regularity declares the regularity of the access which was carried out; hindrances the issuing of penalties by competent authorities or claims of noncompliance by directly affected or third parties.

Box 5 – Fluxogram on Access to Associated Traditional Knowledge²¹



²¹ Guidebook on Access to Biodiversity – Access to the Brazilian Biodiversity, ABIHPEC(2018).

Box 6 – Fluxogram on Research with Genetic Resources²²



79

5. Penalties

Infringement to the meet Law 13.123/2015 requirements ranges from adverting, fines or apprehension, i.e, of the samples containing genetic heritage of associated traditional knowledge materials. Fines may reach the sum of R\$ 5.000.000,00 (five million reais)

²² Guidebook on Access to Biodiversity – Access to the Brazilian Biodiversity, ABIHPEC(2018).

depending on the gravity of the penalty, perpetrator's track record with regard to the subject; recidivism; perpetrator's economic situation²³.

6. Conclusions

One of the most positive advances of the new law is the replacement of the previous authorization system to access genetic resources (MP 2.186/16) by the current registry system which entails that such a registry can be carried out during the research and technological development phases themselves, potentially reducing the obstacles on Research & Development significantly.

Moreover, the establishment that Benefit Sharing procedures are applicable solely to the final product brings clarity about which part of the supply chain of a relevant product is accountable to sharing benefits arising from its economic exploitation.

Notice must be given to the significance of the rights granted to traditional communities with respect to need for Prior Informed Consent for access to their traditional knowledge whenever they are sourced from identifiable origin. The proper exercise of such rights reinforces the sovereign rights of the communities to deny access to any component of their traditional knowledge they consider should remain confined to their inner circle. The combination of these factors allows the construction of a more robust negotiation position to these communities, leveraging their bargaining power in the corresponding transactions.

In the initial stages of implementing the new legal framework there exist legitimate expectations that enhanced access to the Brazilian Biodiversity resources may in fact materialize accompanied by biotechnological development and economic dividends fairly and equitably shared with traditional communities. In order to such dividends being materialized, it is crucial that the Brazilian traditional communities and their strategic partners be able to navigate through the new legal system, identifying valuable opportunities and managing associated risks. As part of this effort, this work recommends the following measures:

- a. Clear understanding of key elements of the legal concepts of "associated traditional knowledge", differentiating what may or may not be subject to protection. From there, it is pivotal to develop a good grasp on what consists of "associated traditional knowledge" from identifiable or unidentifiable origins. Not all knowledge guarded by traditional communities may be deemed as "associated traditional knowledge" arising from genetic resources as such.

²³ Law 13.123/2015, arts 27 to 28 and Decree 8.772/2016, arts 70 to 95.

- b. The claim for associated traditional knowledge from identifiable origins must be as robust as possible via a rigorous process of demonstrating its sources and exclusivity.
- c. Once the associated traditional knowledge is uncontroversial, the relevant community must take action to secure that any third party will not benefit from such knowledge without the community Prior Informed Consent.
- d. An official contract must ensue from any negotiations generated by the access of communities' traditional knowledge. Essential elements to the relevant contract encompass: (i) identification as clear as possible of the expected length of time of the research and development phase for each product in order to inform the best choice between receiving monetary or non-monetary benefits; (ii) attention to the cases listed by law with regard to exemptions applied to some players to share benefits with traditional communities; (iii) upfront definitions between providers of traditional knowledge and users/manufactures with regard to the allocation of intellectual property rights, with special attention to the exemptions applied to the licensing/transfer and permission of Intellectual Property rights to third parties; (iv) risks and benefits of granting exclusive rights over predefined products; among others
- e. Identification of proper legal vehicles to represent the traditional community in commercial transactions which allow the combination of flexibility to operate in a business environment and the incorporation of a governance structure that best safeguards each community. Such definition will also take into account possible transaction structures that optimize higher legal security and tax impacts.
- f. The fact that knowledge (information or practice) of a given community does not fit the eligibility criteria by the biodiversity law does not prevent the sustainable and economic exploitation of resources in accordance with other relevant legal regimes, such as the cultivars and the overall requirements applicable to the export of agroforestry commodities.
- g. Uncertainties remain on the scope of law with regards to some other important aspects as they relate to the rights of traditional communities and the access to their associated knowledge. Examples range from the type of necessary authorization (if any) in the cases where traditional knowledge derives from an unidentifiable origin to the cases in which a patent granted to products the creation of which benefitted from associated traditional knowledge may be passed on to third parties without payment to the relevant traditional community on the grounds of the exemptions established by the Biodiversity Law, among other issues.

The recommendations above are deemed to assist the construction of a matrix of legal analysis the ultimate design of which will depend on the particularities of each project. It also does not exhaust all possible interfaces with correlated legal regimes and corresponding arrangements to assist the traditional communities of Brazil securing effective participation in the potential market of products derived from the Brazilian biodiversity.

Respectfully Submitted,

Sales & Kesselring Advogados

Rodrigo Sales, Partner

7. References

Arranjos produtivos e locais na região do Médio Xingu e Transamazônica. GTZ (relatório final, 2009)

ABIHPEC. Guidebook on Access to Biodiversity – Access to the Brazilian Biodiversity. 2018.

ALVAREZ, A.R. et al. Sustentabilidade Ambiental no Brasil, Biodiversidade, Economia e Bem Estar Humano. IPEA, Eixos do Desenvolvimento Sustentável, Livro 7.

CDB. Convention on Biological Diversity. 1992.

CBD. Convention on Biological Diversity. Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the Convention on Biological Diversity.

COLLI, G.R. et al. A fragmentação dos ecossistemas e a biodiversidade brasileira: uma síntese. In: RAMBALDI, D.M.; OLIVEIRA, D.A.A. (org). Fragmentação de ecossistemas: causas, efeitos sobre a biodiversidade e recomendações de políticas públicas. Biodiversidade, Brasília. Secretaria de Biodiversidade e Florestas/MMA, n.6/2006

FERREIRA, S.N. et al. Biodiversidade e Conhecimentos Tradicionais Associados: Implementação da legislação de acesso e repartição de benefícios no Brasil. SBPC, 2013.

Lei n. 13.123/2015. Dispões sobre o acesso ao patrimônio genético e a proteção e o acesso ao conhecimento tradicional associado e a repartição de benefícios para a conservação e uso sustentável da biodiversidade. (Brazilian new law on Biodiversity Access and Benefit Sharing) and its regulating Decree n. 8.772/2016.

MOREIRA, Eliane Cristina Pinto; CONDE, Leandro Barbalho. A Lei n. 13.123/2015 e o Retrocesso na Proteção dos Conhecimentos Tradicionais. Veredas do Direito, Belo Horizonte, v.14, p175-205, mai/ago. 2017. Available on: <http://www.domhelder.edu.br/revista/index.php/veredas/article/view/1017>.

TESCARI, A. S. ; VARGAS, E.V. A biodiversidade como recurso estratégico: uma reflexão do ângulo da política externa. Dossiê CEBRI, Rio de Janeiro, v. 2, ano 6, p.3-29, 2007.

TÁVORA, F. L. et al. Comentários à Lei 13.123, de 20 de maio de 2015: Novo Marco Regulatório do Uso da Biodiversidade. Núcleo de Estudos e Pesquisas da Consultoria Legislativa do Senado Federal.

ZUCOLATO, G.F; FREITAS R.E. Propriedade Intelectual e Aspectos Regulatórios em Biotecnologia: Brasil, IPEA. 2017

SANTILLI, Juliana. Socioambientalismo e novos direitos: proteção jurídica à diversidade biológica e cultural. Ed. Peirópolis, Instituto Sociambiental e Instituto Internacional de Educação do Brasil, 2005.