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ACCESS, BENEFIT SHARING AND
BIODIVERSITY CONSERVATION
IN BRAZIL: AN ASSESSMENT OF
THE CURRENT REGULATORY
FRAMEWORK AND ITS IMPACTS.

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BRAZIL: AN ASSESSMENT OF IMPACTS OF THE CURRENT REGULATORY
FRAMEWORK**

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ACCESS AND BENEFIT SHARING AND BIODIVERSITY CONSERVATION IN BRAZIL: AN ASSESSMENT OF IMPACTS OF THE CURRENT REGULATORY FRAMEWORK

I. Introduction

During the Convention on Biological Diversity (CBD) drafting process, provisions on sharing benefits derived from utilizing genetic resources (ABS) were conceived as a necessary counterpart to provisions addressing traditional issues in the field of biodiversity¹ (conservation and sustainable use). However, there is widespread recognition - particularly among developing countries - that full compliance with CBD's Third Objective (fair and equitable distribution of benefits) has not effectively materialized². This lack of materialization arises, *inter alia*, from the following.³

(1) The frustration due to the scarce economic and non-economic benefits (monetary and non-monetary) derived from different bioprospecting projects and, in general, from the implementation of ABS initiatives and partnerships.

(2) Cases of illegal access, misappropriation or "biopiracy" and the corresponding difficulties in finding cost-effective legal solutions within the framework of national ABS legislation or intellectual property law. Emblematic cases such as Maca in Peru, have frequently been quoted as justification for undertaking reform in intellectual property rights systems, particularly patents, which to date have been shown to be one of the main causes of claims about misappropriation or biopiracy.

(3) The CBD obligates Parties to take measures to ensure fair and equitable ABS (see in particular Article 15.7). However, prior to the Nagoya Protocol, many host countries of pharmaceutical, biotechnological, cosmetic or agricultural companies (which are largely developed countries) had not created domestic regulations that comply with these legally binding CBD obligations. Conversely, many developing countries have issued domestic regulations on ABS. The absence - or limited presence - of the so-called "user country measures" has been criticized as one of the reasons for the high transaction costs and the highly controlling nature of the current ABS legislation. These domestic regulations are particularly important⁴ due to the cross-border nature of ABS's⁵ business relationships and the inadequacy of national laws and regulations to address samples, information on

¹ Cfr. Gloyka, L., Burhenne-Guilmin, F. y Synge, H., *A Guide to the Convention on Biological Diversity*, UICN, Gland, Switzerland y Cambridge, U.K., 1994

² Cabrera Medaglia, Jorge and Lopez Silva Christian, *Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty*. IUCN, Bonn, 2008.

³ Cabrera Medaglia, Jorge, *La Implementación del ABS y del Protocolo de Nagoya en ALC 3 años después de su vigencia: retos legislativos y de política*, Programa ABS, GiZ-CCAD, San Salvador, 2018.

⁴ Cfr. Barber, Charles, et al., *User Measures: options for developing measures in User Countries to implement the access and benefit sharing provisions of the Convention on Biological Diversity*, UNU/IAS, Japan, 2003, Godt, Christine, *Enforcement of Benefit-sharing duties in User Countries y Isozaki, Hiroji, Enforcement of ABS agreements in User States*, ambos en Kamau, Evanson y Winter, Gerd, *Genetic Resources, Traditional Knowledge and the Law. Solutions for benefit-sharing*, Earthscan, 2009.

⁵ Cfr. Young, Tomme, *Genetic Resources and Utilization of Genetic Resources: a legislative view*, documento presentado al Taller Internacional de Expertos sobre Acceso a Recursos Genéticos y Distribución de Beneficios, Cuernavaca, México, Octubre del 2004.

genetic resources or associated traditional knowledge that are transferred out of the provider country. This lack of "user measures" was one of the main reasons that led to the negotiation of the Nagoya Protocol and for the establishment of what are now called "compliance measures" (see Articles 15-18 of the Nagoya Protocol). Several developed countries have now enacted regulations to implement the Nagoya Protocol, incorporating "compliance measures" to support the legislation of the provider countries (see examples of these in the ABS-Clearing House www.cbd.int, particularly those established by member countries of the European Union⁶, Norway and Switzerland)

(4) ABS relationships are [often?] characterized by a lack of trust between the various actors involved in these processes. This generates an unfavorable scenario for the development of negotiations, either between countries at the international level or through contracts between providers and users of genetic resources and associated traditional knowledge.

In response to these difficulties implementing the CBD's ABS objective, and after more than six years of negotiations, the Nagoya Protocol became fully effective on October 13, 2014 (when ratified by 50 countries). Currently, (February 2023) approximately 139 nations are Parties of the Nagoya Protocol.

The Nagoya Protocol⁷ represents a milestone in the search for legal and political solutions regarding the use of genetic resources (GR) and their fair and equitable sharing of benefits derived from their utilization as well as the traditional knowledge (TK) associated with these resources. The Nagoya Protocol responds to long-standing demands from developing countries, including several in Latin America and the Caribbean. It presents great challenges and opportunities, especially in regions with high biological and cultural diversity and important scientific capacities, to generate a sustainable use of GR and associated TK. Its objective is the "fair and equitable sharing of the benefits arising from the utilization of genetic resources, including through appropriate access to genetic resources and through the appropriate transfer of relevant technologies, taking into account all rights over these resources and technologies and through appropriate financing, thus contributing to the conservation of biodiversity and the sustainable use of its components."

The Nagoya Protocol contains a high degree of ambiguity and flexibility in its main components, possibly because this was the only way to reach an agreement on its content. These flexibilities

⁶ For example, the European Union has regulated these measures through Regulation No. 511/2014 of the Council's Parliament of April 16, 2014 (and other supplementary instruments developed) regarding compliance measures by users of the Nagoya Protocol on access to genetic resources and fair and equitable participation in the benefits that derive from their use in the Union. Subsequently, they have developed other complementary measures to facilitate the application of the legal framework.

⁷ On the Protocol see: Mathias Buck, and Clare Hamilton, "*The 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*" (2011) 20 RECIEL; Union for Ethical Biotech, *Nagoya Protocol on Access and Benefit Sharing*, Technical Brief, 2010; Gurdial Nijar, "*The Nagoya Protocol on Access and Benefit-Sharing of Genetic Resources: analysis and implementation options for developing countries*" South-Centre, Research Paper No. 36, march 2011; Sebastian Oberthur and Rosendal Kristin (eds) *Global Governance of Genetic Resources: Access and benefit sharing after the Nagoya Protocol*, Routledge Research in International Environmental Governance, 2013; Thomas Greiber et al, *Explanatory Guide on the Nagoya Protocol*, IUCN Legal Paper No. 32, Bonn, 2012; Evanson Kamau, Bevis Fedder and Gerd Winter, "*The Nagoya Protocol on Access to genetic resources and benefit sharing: what is new and what are the implications for provider and user countries and the scientific community*" (2011) 6(3) Journal of Environment and Development; Meyer, Hartmut et al, *Nagoya Protocol on Access to Genetic Resources and the Equitable Sharing of Benefits Arising from Their Utilization: Background and Analysis*, Berne Declaration and Third World Network, 2013 y Cabrera Medaglia Jorge, La implementación del Protocolo de Nagoya en ALC: retos y desafíos. CISDL, Montreal, Diciembre del 2015

also involve challenges for translating the text provided in the Nagoya Protocol into national actions. Among other aspects, the Nagoya Protocol covers the following issues:

- scope of application;
- relationship with other international agreements and instruments;
- fair and equitable sharing of benefits;
- access to genetic resources;
- access to traditional knowledge associated with genetic resources;
- special considerations;
- contribution to conservation and sustainable use;
- traditional knowledge associated with genetic resources;
- cross-border cooperation;
- compliance with the ABS and associated TK frameworks of the provider countries;
- monitoring the use of genetic resources;
- model clauses and codes of conduct;
- capacity building;
- public awareness;
- transfer of technology; and
- cooperation and administrative and institutional components of the agreement.

II. The Brazilian experience on ABS and biodiversity conservation

As a megadiverse country, Brazil is both a provider and user of genetic resources. Further, Brazil has high socio-diversity and holds TK that is essential for biodiversity conservation (IBPES, 2019)⁸ and Brazil's sustainable development. Brazil is home to more than 300 indigenous ethnic groups, and millions of other Brazilians are officially recognized as local communities, such as rubber tappers, and herbal healers, among others.

Brazil's market of bio-based products is considerable and on the rise, which has created intense research and development conducted with biodiversity. Brazilian cosmetic, pharmaceutical and biofuel industries are heavy users of national biodiversity, and Brazilian consumers are more aware and demand social and environmental responsibility (UEBT, 2020).

Moreover, Brazil has over 30 years of legal experience in ABS matters. In 1988, Brazil proclaimed its Federal Constitution, which adopted the term genetic heritage for genetic resources (GH) and entrusted the national government with the duty of inspecting or monitoring entities dedicated to researching and handling genetic material.⁹

Brazil has had two very different experiences with ABS. In 2000, Brazil had the first ABS measure, the Provisional Act n°2.186, which was amended 16 times, and was in force for almost

⁸ According to IPBES Global Assessment, Indigenous Peoples and Local Communities (IPLCs) play an essential role, as well as the associated traditional knowledge they hold, for biodiversity conservation, restoration, and climate change mitigation. IPBES Global assessment Key message D5 states that “Recognizing the knowledge, innovations, practices, institutions and values of IPLCs, and ensuring their inclusion and participation in environmental governance, often enhances their quality of life and the conservation, restoration and sustainable use of nature, which is relevant to broader society. Governance, including customary institutions and management systems and co-management regimes that involve IPLCs, can be an effective way to safeguard nature and its contributions to people by incorporating locally attuned management systems and indigenous and local knowledge”. (IPBES, 2020) In this sense, it should be recalled that IPLC's Community Protocols on Access and Benefit-Sharing are customary institutions and management systems and co-management regimes that involve IPLCs also contributing to conservation.

⁹ Cite.

15 years. In 2015, the Act was revoked by Law No. 13,123, which is the current ABS law, known as the Biodiversity Law. In 2016, Decree No. 8,772 regulated the Biodiversity Law.

In November 2017, the SisGen started to operate. The SisGen is an electronic “one-stop-shop” registration platform, managed by the Council for the Management of Genetic Resources/*Conselho de Gestão do Patrimônio Genético* (CGen), the ABS Competent National Authority in Brazil, in which all ABS users and their activities and products must be registered.

Finally, in 2021, Brazil ratified the Nagoya Protocol on ABS.

1. First ABS Framework (2000 to 2015)

The first ABS legislation, the Provisional Act nº2.186-16, established cumbersome ABS measures – requiring Permits/Previously Informed Consent (PIC) and Mutually Agreed Terms (MAT) for every commercial activity, regardless of sector, or intention. All PIC and MAT had to be previously approved by the CGen plenary. There were no fixed parameters for benefit-sharing; all permits were analysed on a case-by-case basis and submitted on paper.

The CGen spent much effort clarifying concepts, incidence, and exemptions, which created many infra legal regulations that increased complexity. After almost 15 years, there were over 2600 PICs granted, and 295 benefit-sharing agreements (MATs) were approved by the CGen/Competent National Authority. Regarding monetary benefit-sharing, the CGen estimated the total amount in circa 8 million *reais* in 15 years, which is approximately US\$1.5 million.

2. Current ABS Framework

A paradigm shift from the Provisional Act was urged by all stakeholders, including the government. There were 5 main shifts in relation to GH:

<p>1. Nationalization of GH</p>	<p>There is no more private ownership over GH, which reduced PIC and MAT complexities, uncertainties, and transaction costs. GH now belongs to the Brazilian people and is the Federal Government’s responsibility to manage, control, and inspect ABS activities.</p>
<p>2. Pre-set rules for Benefit Sharing</p>	<p>Pre-establishing parameters in the Biodiversity Law, clear definitions, rights and obligations. Access and use are open, under terms and conditions.</p>
<p>3. The focus of regulation</p>	<p>From case-by-case prior authorization and MAT celebration, to focus on end-users for benefit sharing, for monitoring of access outcomes, and for results and value chain regularization through an online registration system, the SisGen.</p>
<p>4. Standardized Contract Required only for Non-monetary BS.</p>	<p>Move to a declaratory online registration system with no PIC, and optional MAT for GH.</p>

	Users adhere to the ABS Terms and conditions pre-set in Biodiversity Law/Decree. Users accept the predefined conditions by registering their ABS activities in an online system - the SisGen. Users adhere to the pre-set rules (ABS contract) by registering/notifying ABS activities through the SISGEN website.
5. Not every commercial access/use leads to benefit-sharing obligations.	Brazil expects to obtain indirect benefits from such exemptions, such as the creation, the strengthening and the diversification of sustainable value chains using Brazilian genetic resources, allowing GH value chains to generate sustainable rent locally as an alternative to predatory exploitation, while bio-based product commercialization generates monetary benefits for biodiversity conservation.

Regarding the new ABS measure, the Biodiversity Law's main objectives are to provide legal certainty and reduce transaction costs while assuring that benefits are fairly and equitably shared and necessarily channelled to biodiversity conservation. For this to happen, it was necessary to facilitate access and benefit-sharing mechanisms.

After more than a decade of effort, the government understood that an ABS policy should not solely control access and use activities relating to biodiversity. Instead, ABS policy should also address mobilizing economic, technological, and scientific resources for the conservation of biodiversity. Consequently, a facilitated ABS system was designed that contained predictable and clear requirements.

According to Novion and Brina 2018, Brazil's ABS reform created the following improvements:

- A facilitated mechanism for access to genetic resources that shifted from a focus on control of access to control of the economic exploitation of products or reproductive materials arising from access.
- The development of an online registration system called the National System for Genetic Heritage & Associated Traditional Knowledge (SisGen) to trace, track and oversee access to genetic resources and associated traditional knowledge activities. The SisGen electronic system is declaratory, as opposed to the old *modus operandi* of the Provisional Act in which a procedure for validation of documents was in place.
- The registration must only be carried out prior to specific moments such as shipment, request for intellectual property rights, publication of results and commercialization. Research and development activities that do not result in any of the above-mentioned activities are not required to be registered.
- Registration is not needed prior to access (research and development) itself when only the genetic resources are accessed, without access to traditional knowledge: these activities are not restrained by any prior administrative procedure for granting access.

- Prior informed consent (PIC) for access to genetic resources was granted by the Biodiversity Law: there is no administrative procedure for access to genetic resources; PIC for access to TK is mandatory and should be obtained directly with indigenous and local communities, or through their Community Protocols.
- Economic exploitation of a finished product or reproductive material was established as the single point of incidence of benefit-sharing obligations. This is the link of the value chain with the highest value added, discharging any research and development activity. Economic benefits are to be shared when they do exist.
- Because of the single point of incidence, the economic exploitation of any intermediate product is exempt from benefit-sharing obligations.
- The percentage of monetary benefit-sharing from products or reproductive material derived from the use of genetic resources is established as 1 percent of net revenues from the product or reproductive material sales. There is no speculation of values and no surprises for genetic resource users. This provides predictability and legal certainty to invest in bio-based products arising from access.
- The clearly established point of incidence combined with a defined percentage of benefit-sharing to be valued under a specific concept such as “net revenue” makes compliance monitoring feasible, since they are based on fiscal and accounting principles and rules.
- When the user chooses to share the benefits through non-monetary means, such as a conservation or social project, benefit-sharing is equivalent to 75 percent of the predicted value for the monetary modality. This concession considers expenses the user might have in implementing the project and encourages the non-monetary modality.
- Licensing, transferring, or permitting any use of intellectual property rights does not require benefit-sharing. Benefit-sharing obligations exist only when a finished product or reproductive material using the licensed intellectual property is commercialized to the final consumer.
- Micro-businesses, small businesses, micro individual entrepreneurs, traditional farmers, and their cooperatives are exempt from benefit-sharing obligations.

Another solution was the establishment of a National Benefit-Sharing Fund. The Benefit-Sharing Fund allows for centralization and subsequent redistribution of benefits arising from the use of genetic resources and associated TK through a management committee. It supports actions focused on research, development and conservation of GH and protection of associated traditional knowledge. The Benefit-Sharing Fund is managed by a collegial committee, composed of seven representatives from public administration institutions or entities, seven representatives from organizations representing indigenous peoples, traditional communities and traditional farmers and representation from the Brazilian Society for the Progress of Science (SBPC).

Once the due amount to be shared is pursuant to the Biodiversity Law (1 percent of net revenues from the product or reproductive material sales), where there are benefits to be shared, and registration and notification requirements are fulfilled, users can pay benefits directly to the Fund through an electronic voucher provided by SisGen. The need to sign the Benefit-Sharing Agreement (MAT), named *Acordo de Repartição de Benefício Não Monetário* ([ARB-NM](#)) will occur only when users decide for the non-monetary modality or when **ATK** is accessed.

There is a standardized ARB-NM model approved by the Ministry of Environment (MMA) available to users (link [here](#)). The MMA was appointed by the Biodiversity Law to represent the Federal Union on the signing of ARB-NM with users, on behalf of the Brazilian people. The Ministry can verify the information presented by users and evaluate project proposals' adequacy to the Biodiversity Law's objectives and conditions. There is also a standardized model for users to submit projects and other non-monetary benefit-sharing proposals (available [here](#)).

3. Legal structure of ABS

The Brazilian ABS legal structure is understood to comprise of the Biodiversity Law (no 13.123) dated as of 20th May 2015, its implementing Decree no. 8772 dated as of 11th May 2016, and all subsequent implementing norms, such as Ministerial Normative Instructions, as well as Resolutions and Technical Orientations approved by the CGen (available [here](#)). The **CGen** is still is the Competent National Authority, but was redesigned to also implement an electronic permitting system, the SisGen (see below).

The CGen Council's composition has expanded: 51% of its members are now from governmental bodies, and 49% of its members are appointed by representatives from Indigenous People and Local Communities (IPLCs), Academia, and the Private sector. All members have voting rights.

The Biodiversity Law and its decree empower the CGen to regulate ABS legislation with the view to improve the norms and the SisGen – which provides flexibility to interpret generalist clauses from the Law and the Decree. Also, in the current model, every register of access or product notification in SisGen is subject to an **ex-post** administrative verification process that starts **after** the registration is completed in SisGen by the user. This verification process, conducted by the CGen members and their surrogates, may point out errors to be corrected or identify frauds and wrongdoing, which are subject to fines and sanctions pursuant to the Biodiversity Law.

Moreover, the Law defines access as research or technological development carried out on GH¹⁰. The Law establishes predefined conditions and those that fulfil the prerequisites are authorized to access.

Since ABS activities registration is an ex-post, declaratory, and mandatory requirement, the registry has a disclosing nature and access registration must only be carried out prior to the listed situations: (1) GH remittance abroad; (2) prior to IPR applications, (3) before publishing any scientific research outcome and (4) prior to the notification of a finished product.

Users' research and development activities that do not result in any of the before-mentioned activities are not required to register in SisGen. All users are required to create a login (online registering account/profile) in SisGen, through which they provide the required institutional and legal information. In their SisGen profile, users register all their ABS activities, perform all exchanges of communications with the CGen, and obtain the corresponding certificates of compliance.

Moreover, in relation to Associated Traditional Knowledge - ATK, since previous informed consent for access to ATK is mandatory and must be obtained directly with IPLCs organizations, evidence of PIC must be uploaded in SisGen, by the User, before access takes place, and in the

¹⁰ **Biodiversity Law. Article 2** – In addition to concepts and definitions set forth by the Convention on Biological Diversity (CBD) promulgated by Decree no 2,519, dated March 16, 1998, the following terms are defined for the purposes of this Act:

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

format defined by the IPLCs that granted it. Joint access to a GH and ATK is now considered as access to ATK and follows the same rules applying to ATK - with PIC and MAT negotiated with the IPLCs that hold it.

4. CONSIDERATIONS ON SISGEN

According to the [MMA](#), in order to manage ABS information, CGen is required to implement, maintain, and operate the SisGen. The SisGen was officially implemented and made available to the public on November 6, 2017. According to the Law, all ABS activities must be registered and/or notified through the online website of SisGen – accessible through the link: <https://sisgen.gov.br/paginas/login.aspx>

The SisGen is an electronic “one-stop-shop” system to cover the management of registrations, prior authorizations, notifications, recognition of *ex situ* collections institutions that maintain samples of GH, and for users to obtain their certificates of compliance. Information in the system is public, except where the user has requested and provided legal justification for confidentiality. SisGen is managed by the CGen Executive Secretary (DPG/SBio/MMA).

To access SisGen, the Biodiversity Law also mandates that any user fulfilling the conditions to have a registering profile in SisGen (obtained after CGen’s Executive Secretariat validation), shall receive a username and password to login in SisGen, and to register, edit and declare their ABS activities in their personal profile in SisGen, according to each case.

Moreover, through the same SisGen Profile/Account, the user can require and obtain the respective certificates of compliance, according to their activities, under the terms and conditions of the Law. All institutions, individuals and companies must be a registered user (with a *Cadastro de Usuário*) and install the security module of SisGen (*Módulo de Segurança*) to be able to access the SisGen electronic system.

A step-by-step handbook on SisGen registration was published by the Brazilian Association of the Fine Chemistry, Biotechnology, and its Specialties Industries (ABIFINA). ABFINA’s Handbook of access to Brazilian genetic heritage and associated traditional knowledge (2018) presents, in English, the guidelines for registration at SisGen that have been taken from the SisGen User Guide, published by the Ministry of Environment, acting as CGEN’s Executive Secretariat.

5. BENEFIT – SHARING FOR BIODIVERSITY CONSERVATION

The Brazilian ABS Law states in its first article that the fair and equitable sharing of the benefits arising from economic exploitation are for conservation and sustainable use of biodiversity. The law also establishes the National Program for Benefit-Sharing (PNRB), with the purpose to promote the following:

- I - conservation of biological diversity;
- II - restoration, creation and maintenance of *ex situ* collections of genetic heritage sample;
- III - prospection and capacity-building of human resources on the use and conservation of GH or ATK;
- IV - protection, use and strengthening of the associated traditional knowledge;
- V - implementation and development of activities for the sustainable use and conservation of biological diversity, and for the benefit-sharing;
- VI - support for research and technological development related to the GH and ATK;
- VII - survey and inventory of genetic heritage, including those with potential uses, considering the current state of and the variance within their existing populations, and, when feasible, assessing any threat to those populations;

- VIII - support the efforts of IPLCs and small farmers for the sustainable management and conservation of genetic heritage;
- IX - conservation of wild plants;
- X - the development and transfer of appropriate technologies for improving the sustainable use of the genetic heritage and for the development of an efficient and sustainable system of ex situ and in situ conservation.
- XI - monitoring and maintenance of the viability, the degree of variation and the genetic integrity of the genetic heritage collections;
- XII - adoption of measures to minimize or, if possible, eliminate threats to the genetic heritage;
- XIII - development and maintenance of any cropping system that promotes the sustainable use of genetic heritage;
- XIV - development and implementation of the Sustainable Development Plans of IPLCs; and
- XV - further actions related to access to the GH and ATK, according to the regulation.¹¹

Moreover, the economic exploitation of a finished product was established as the single point of incidence of monetary benefit-sharing obligation in the productive chain. That means that research and development activities, regardless of intention, are exempt from the obligation. In addition, the Biodiversity Law states that the finished products can only be marketed after the product notification is concluded through SisGen.

The product notification marks the countdown of one year to the payment of benefit sharing and establishes the beginning of the verification procedure. The user does not need to wait for the completion of the verification procedure to start commercialization. Moreover, only the manufacturer of the finished product, even if produced outside the country, must share benefits, regardless of who has previously carried out access activities.

Every new product requires a new notification, and the same product with a new formula is considered as a new product. Product notification is an electronic declaration made through SisGen. In the notification, the user declares compliance with the Biodiversity Law and indicates the benefit sharing modality.

A finished product (1) does not need any additional processing, (2) the GH or ATK component is a key main element of value adding to the product, and (3) it is ready for use by the final consumer. Under the Biodiversity Law, it doesn't matter how many utilizations were made, how many different GHs were used in the product, or what was the percentage or the importance of the GH in the composition of the formula; if any Brazilian GH was used and it adds functionality to the product or is used to form the commercial appeal, the product is subject to the Biodiversity Law obligations.

Likewise, it should be stressed that the benefit sharing exemption does not release the user from complying with other obligations set forth in the Biodiversity Law. The user must register the research and development activity that led to the intermediate product. Thus, if another user develops a finished product from the intermediate product, this user will have to provide the corresponding registration number of the mentioned intermediate product in his finished product notification. That obligation is paramount because it ensures that all information regarding a specific productive chain is registered in SisGen, enabling traceability activities to link different finished products to the first access that allowed their development.

¹¹ Cite PNRB?

6. BENEFITS OF SHARING INFORMATION AND USERS AS ALLIES FOR TRACEABILITY

For Brazil, reversing the focus of regulation has allowed end-users to play a new role in ABS compliance. Every user wants to publish, patent, or economically explore results of access and use. They are interested in the legality of the accomplished result, as they do not want to take the risk of seeing a product or patent contested for failing to comply with the requirements of the correspondent law.

In this sense, the manufacturers of bio-based products become allies of the CGen in guaranteeing the best and most precise information, as well as in the traceability of their own productive chain. That is because users must declare in their product notification all previous links in the value chain that led to their finished product.

End-users must disclose relevant information on their access activities. This requires providing information on the registering of eventual patents and which intermediate products were eventually used in the development of the notified final product. Every final product notification must have each of its previous steps in the productive chain (scientific publications; IPR; intermediary products; and final product) declared in the user's profile or be already registered in SisGen (even if it was done by another user).

In the end, all steps must be declared in the product registration, linking the finished product to the initial access activities. In short, if one of those steps in the notification of a product is not correctly informed, this product can be checked, cancelled, and eventually collected from the shelves of the markets, apart from fines, sanctions and potential damages to the company's image and brand.

Focusing the Biodiversity Law's ABS requirements onto the end-user ensures compliance. This is because, while the end-user is in the greatest hurry to commercialize the product, they are also motivated to avoid mistakes because every step will be subject to the CAN verification procedure. As such, noncompliance creates the risk of monetary consequences.

The Biodiversity Law has a monetary impact on end-users in Brazil, which is summarized by the article "Connecting the dots: Biodiversity conservation, sustainable use and access and benefit sharing" (Laird, S.A. and R. Wynberg. 2021):

[T]he law creates a model with two options from which users can choose. The first requires companies or users to pay money directly into a national fund. The second option enables companies or users to perform their own projects or hire NGOs to execute projects. A 25% "discount" is offered to users that pursue this option but is limited to conservation and sustainable use projects; capacity building linked to achieving the objectives of the law; and social projects. Companies adopting the project-based option are required to promote conservation and sustainable use through such initiatives, and it is also expected that this could provide an important way in which scientific work can be supported and synergies promoted with IPLCs. Applicants are required to present concrete projects with clear indicators that are feasible to achieve in a short period of time. A declaration of compliance is provided only following the completion of the project. One of the intentions of this approach is to encourage companies to build relationships with communities.

Regarding the monetary benefit sharing, the Laird and Wynberg recall the following:

For those users choosing the first option, monies are deposited into a national fund and are ringfenced ad infinitum for conservation and sustainable use, preventing their repurposing.

The money is not perceived as a tax or a royalty payment but rather a new form of funding that belongs to the people or, where TK is involved, to IPLCs. Detailed guidelines have been developed to guide users and public servants in the dissemination of funds, with oversight through a Board that comprises 50% IPLCs and 50% government representatives.

Regarding Associated Traditional Knowledge, the study describes that “[t]he system also helps to deal with TK issues, specifying (1) that all TK is collectively owned; and (2) the need to negotiate with a reputable organization. There are two ways of addressing TK. If TK is of identifiable origin, no fixed percentage of benefits apply and TK holders freely negotiate an agreement in the PIC and MAT process. If TK is considered to be from an unidentifiable origin, 1% of annual revenues arising from its commercial use will be deposited into the fund and there is no requirement for PIC and MAT. In both instances, the fund will direct benefits to IPLCs.”¹²

7. ABS integration into conservation in Brazil

According to Laird and Wynberg, Brazil has developed national laws that integrate ABS and conservation:

In Brazil, the link between benefit sharing and conservation historically has not been clear, relying to a large extent on the willingness of the user to integrate conservation measures, rather than obliging them to do so. However, Law 13.123, passed in 2015, changed this landscape and provides the legal architecture to channel benefits to conservation. The decree sets out conservation priorities and lists a number of options for applicants to select, including support to high biodiversity areas, promoting sustainable use and supporting Indigenous Peoples in protected areas.¹³

[...]

Experiences to date suggest that the new approach has both improved the uptake of conservation measures and has also enhanced the effectiveness of permit approvals and improved transparency. For example, prior to the new law, 2600 permits had been granted over a 15-year period, whereas in the 3-4 years since implementation of the new law some 57 000 access activities have been registered, equivalent to obtaining PIC, and over 3 500 product notifications, indicating the conclusion of ABS contracts. An electronic information system (SISGEN) that integrates data across all systems and which is linked to biodiversity and enhanced management and traceability reportedly enables public servants to be more efficient and to track conservation impacts. All notifications and access registries are available, in Portuguese, through the Competent National Authority website <https://sisgen.gov.br/paginas/publicidade.aspx>.

Since the aforementioned study was published, SisGen’s numbers have increased. However, it is important to review some milestones in SisGen’s implementation to better understand these accomplishments. Recall that the SisGen electronic platform was launched in November 2017, that the law gave one year (after the SisGen was implemented) for Users to notify their products, and an extra year to calculate and collect the benefit-sharing. Users have been declaring revenues to the SisGen since November 2019. Moreover, if the User decides for the non-monetary benefit – sharing, the law gives an extra year to the conclusion of the contract (ARB-NM) and the approval by the Ministry of Environment of the conservation or social project proposed by the user in its contract (as an annex).

¹² CITE

¹³ (Laird, S.A. and R. Wynberg. 2021),

8. Products notified (MATs), Benefits declared, and shared.

After four years of operation, SisGen has recorded impressive numbers, which are available through its non-confidential publicizing website: <https://sisgen.gov.br/paginas/publicidade.aspx>. SisGen has so far¹⁴ recorded 68,498 R & D registries. Recall that access means research and development. Further, recall that according to the new ABS model, each complete registration is equivalent to a PIC or a Permit obtention.

SisGen has so far recorded 13,310 product notifications, which are considered equivalent to a MAT celebration. Each of which will share benefits if the products/seedlings are being commercialized.

Moreover, the current legislation already shows some interesting results in terms of benefit sharing amounts to be paid by users that already have concluded product notification in SisGen.

According to the MMA, Monetary Benefit-sharing (which shall be paid directly to the BS Fund - with no MAT required) amounts to near 1,1 million US dollars, as declared by users in their SisGen registries.

On the other hand, non-monetary benefit-sharing declared in SisGen by Users, to be directly invested in conservation activities, amounts to 3,3 US million dollars.

Bearing in mind the aforementioned milestones and that conservation or social projects must be approved by the MMA, from the 3,3 million dollars declared by users to be paid in the non-monetary modality, so far 10 conservation projects were approved, covered by seven different Non-monetary Benefit-Sharing Contracts (ARB-NM). The total amount covered by those seven contracts is 250 thousand dollars. So, there is still an extra circa 3 million dollars of benefit-sharing to be implemented directly into conservation and sustainable use, once the MMA concludes the analysis of the proposals and the signing of the correspondent ARB-NM.

According to the MMA, details on the approved or to be approved projects are part of contracts, protected by confidential rights (commercial secrecy), and only the entitled parties (users and eventual beneficiaries of the project), and authorities (CGen members and surrogates, compliance agencies, and the MMA) have full access to them.

On the other hand, non-confidential summaries of all those projects approved by the Ministry will be published in the near future in the Government Official Gazette.

III: Final remarks

One final observation deserves to be made regarding areas where the Brazilian model could be improved. Besides all the relevant instruments that are not fully implemented, although foresaw in the Law, The National Fund for Biodiversity Conservation deserves a special remark.

Building from the information provided herein, and bearing in mind that the Benefit-Sharing National Fund has not been able to channel the monetary benefits collected (due to technical and political reasons), one necessary improvement that Brazilian model requires is the full implementation of the benefit-sharing instruments foreseen in the Biodiversity Law and regulations, in particular the Fund.

¹⁴ 14/11/2022

According to the Biodiversity Law, The National Fund is the implementer of the National Program for Benefit-Sharing (PNRB). Thus, Brazil's current inability to implement the Fund poses a concrete challenge for the Programme to succeed.

The Fund's management Committee (CG-FNRB) has not been able to convene in its full capacity, with all the duly appointed members from government and civil society institutions. Due to this constraint, many important decisions were postponed, and the funds are standing still in a bank account. Although the return on the money is guaranteed by the bank that manages the Fund's account (a Federal Bank named BNDES), no amount has been channelled by the Fund for conservation or to any beneficiary, including IPLCs.

It is expected that with the change of government and the full return of the IPLC's participation in the CG-FNRB, the Fund's resources will be invested in conservation. [This will lead to?] greater social control over the contracts (ATB-NM) and their results will be able to generate the necessary information to assess whether the law and its instruments are in fact delivering their goals.

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