*Article*

# Data-Driven Assessment on the Brazilian Regulatory Framework for Biodiversity Access and Benefit Sharing (ABS)

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**Abstract:** This study presents a detailed assessment on the impact of the Brazilian legal framework related to the access and benefit sharing provisions of the UN Convention on Biological Diversity. The research is based on a comprehensive dataset that was systematically collected over several years, directly from the official government bodies responsible for its implementation. The aim of the study is to contribute to a fact-based discussion on the effectiveness of national ABS laws, focusing on the Brazilian legal framework, first established in the year 2000 and revised in 2015, as a case example. This study balances the costs and benefits of the Brazilian ABS system and assesses the regulatory challenges it poses to individuals, companies, and institutions that perform research, share knowledge, develop, manufacture or market products derived from Brazilian biodiversity. The study indicates that, after over 22 years of operation, the regulatory challenges are still real and relevant, and that the significant volume of data collected from users on access, prior commercialization and shipment of genetic materials abroad was never systematically assessed by the agencies in charge. Besides, it shows that the costs incurred by the government in managing the policy itself have been higher than the economic benefits it has made possible, and that the institutional mechanisms in place since 2015 have not been able to allocate the monetary benefits contributed by users to the National Benefit Sharing Fund to any projects aimed at developing sustainable uses or preserving Brazilian biodiversity.

Keywords: Convention on Biological Diversity; Nagoya Protocol; ABS access and benefit sharing; Brazil ABS law; genetic resources; associated traditional knowledge

## 1. Introduction

The Convention on Biological Diversity (CBD) was one of the main achievements of the United Nations Conference on Environment and Development (Rio 92)i. The CBD came into force in December 1993ii. Brazil signed the Convention in 1992 and became a party in 1994iii. The CBD established the principle that states have sovereign rights over native natural resources originating from their territories and have substantial freedom and authority to regulate and impose obligations on access to and use of the corresponding genetic resources (GR). The CBD commits countries to: (1) the preservation of *in situ* biodiversity, through the creation and adequate supervision of natural reserves; (2) the identification, *ex-situ* conservation of and research on microorganisms, plants, animals and all types of living beings, and (3) the promotion of sustainable uses of the biodiversity for development purposes, through the provision of monetary resources and non-monetary incentives for the development of value-added products based on biological materials, obtained in a sustainable way. This last objective stems from the perception that the

 doi:10.20944/preprints202212.0106.v1



development of sustainable uses can allow the generation of necessary income for traditional communities, while preserving the natural environment. Thus, in addition to promoting the development of sustainable exploitation of biodiversity, countries must also ensure a fair and equitable sharing of the economic results of such activities. Activities aimed at achieving CBD objectives related to research, development and innovation based on biological materials are known as provisions on "Access and Benefit Sharing", or simply ABS.

Since the CBD's inception in 1992, the Convention has been ratified and implemented by 196 Partiesiv. Since then, many countries have developed national ABS legislations, which implement the CBD provisions. Brazil was one of the pioneers to set up its ABS legislation. Its first version was a Provisional Measure (PM) issued by the Executive Branch without Congress' previous approval, in June 2000. To keep those provisions in effect, PM 2,816 of 2001v was re-edited sixteen times. Its requirements did not provide meaningful and effective incentives for research and development (R&D). Instead, they established extensive and complex procedures for users to legally access biological resources, for *ex-situ* storage and research on the Brazilian "genetic heritage" (GH) - a concept introduced in that piece of legislation. Prior authorization was strictly required for any kind of access to GH. The development of products was the object of additional requirements, which were more extensive in case they had relied on access to "associated traditional knowledge" (ATK). The ways economic benefits, arising from the commercialization of those products, would be shared with the government and the traditional communities were to be decided on a case-by-case basis.

After 15 years, in November 2015, Law 13,123vi came into force, revoking the Provisional Measure and introducing new concepts, an ABS online management system, compliance obligations and sanctions. It abandoned the need for prior authorization and established a standard key for benefit sharing.

*PM 2,186/2001 was revoked after 15 years, and Brazil adopted Law 13,123/2015 as its new ABS regime.*

As academic and business R&D activities on new sustainable uses of the Brazilian GH are cornerstones for achieving the second and third objectives of the CBD, there were plausible concerns about the impact of the ABS regulations.

The central objective of this paper is to assess the effectiveness of national ABS regulations, focusing on the Brazilian ABS legal framework as a unique case example. This study makes use of systematic methods to obtain reliable data, which can be replicated in other countries. It can thus enrich international discussions related to ABS. This article is based on data collected from 2015 to August-2022, directly obtained through the Brazilian government authorities' information systems, and through legal inquiry procedures (based on citizen access to government data), as well as from national and international non-government organizations, from their freely available sources on the internet. All those data are presented amid their discussion.

## 2. **Materials and Methods**

### *2.1. ABS data collection*

As established by the current ABS legislation, Brazil has implemented the online National ABS Management System (SisGen), allowing the government to have a robust public database vii, available for consultation. The SisGen system was designed and developed to host all the compliance data defined by law 13,123/2015, further detailed by the Regulatory Decree 8,722/2016viii.

*SisGen is Brazil's public ABS compliance database*

 doi:10.20944/preprints202212.0106.v1



Data from the first ABS policy that was in force from June 2000 to November 2015, has been included and taken into consideration to address fines and other consequences still being prosecuted under the current ABS framework.

All data were obtained through direct requests to the Brazilian authorities, by means of formal consultation mechanisms established by the Brazilian Law of Access to Information, or LAIix. Dr. Diana Jungmann, co-author of this paper, has independently requested, collected, and systematized that information for over 5 years.

The raw data was received from the Brazilian Ministry of the Environment, Ministry of Agriculture, Ministry of Science and Technology, Brazilian Navy and from the Brazilian Institute of the Environment and Renewable Natural Resources (IBAMA). The full disclosure of over 50 requests for information and 5 appeals due to incomplete responses, covering protocol numbers, dates and the authorities involved are presented in Appendix A.

*The Freedom of Information Act is a powerful tool to foster transparency, governance, and accountability*

Table I shows that apart from SisGen and the Brazilian LAI, other sources of national and international public information were accessed: e.g., the Brazilian Transparency Portalx and the CBD Status of Contributions websitexi.

**Table I.** Source of public data used in the study.

| Source of Data | Internet Link |
|---|---|
| Federal Government Law on Access Information Portal | https://www.gov.br/acessoainformacao/pt-br |
| Federal Government Transparency Portal | https://www.portaltransparencia.gov.br/ |
| Data Sebrae | https://datasebraeindicadores.sebrae.com.br/resources/sites/data-sebrae/data-sebrae.html |
| The Convention on Biological Diversity | https://www.cbd.int/convention/ |

Appendix B presents the list of questions addressed to the authorities via LAI requests aiming to get compliance data on the Brazilian ABS legislation.

*2.2. Cost-benefit analysis*

Cost-benefit analysis (CBA) is a well-established and widely used approach for collecting, organizing, and analyzing information on policy. The rationale behind applying CBA in policy making is to ensure that society's scarce resources are allocated efficiently so that societal welfare is improved. The cost-benefit analysis involves tallying up all costs of a policy and comparing that amount with the total policy benefits. If the benefits outweigh the costs, the policy is providing positive results and impact. If, on the other hand, the costs outweigh the benefits, then authorities may want to rethink the policyxii.

In the United States, President Bill Clinton made cost-benefit analysis mandatory in 1993, as a mechanism capable of guiding public managers' decisions between different policy alternativesxiii. Its use is, however, controversial. In favor of CBA is its relative simplicity when compared to more sophisticated methods, such as those based on transaction costs, which are sometimes difficult to identify and measure. When the main costs or benefits of the policy at issue are of an intangible nature, their assessment can become excessively subjective, in the sense of being dependent on the monetary valuation that the analyst associates with assets that cannot be priced in the markets. Values associated with

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 doi:10.20944/preprints202212.0106.v1



the preservation of biodiversity could fall into this category, which would point to difficulties in using the CBA to assess the CBD's legal framework.

The authors of this study advocate that those difficulties do not arise in the evaluation of the Brazilian ABS policy analyzed in this paper. Rather, conventional CBA analysis seems to be well suited for addressing and providing answers to the main questions raised in this study.

The belief relies on the prescriptive nature of the legislation itself. A systematic reading of the Brazilian legal framework allows us to infer that the purpose of the CBD of preserving biodiversity is translated into two mechanisms whose effective results are easy to measure objectively, which are: (1) the detailed information on all activities of users to access Brazilian GH/ATK from *in situ*, *ex situ* and *in silico* (including digital sequence information or DSI) origins, either for scientific, technological or commercial purposes; and (2) the non-monetary and monetary value of the benefits shared by users of the Brazilian biodiversity with the government and/or directly with the traditional communities, according to the law's provisions so that, in part, they are destined for the conservation and for the development of sustainable uses of the biodiversity.

The benefit measurement is indeed simple in this case, as the contributions expected from the ABS policy are the supplementary financing of biodiversity preservation-related projects through the National Benefit Sharing Fund (NBSF) and the non-monetary benefit-sharing (BS) projects. The total amount of those resources is thus a maximum ceiling of the total benefits generated by the policy.

Part of the costs directly associated with the ABS legislation can also be easily computed. The Brazilian ABS framework defines clearly which actions are required from government agents, individuals, research institutions, and businesses to assure full compliance, making it possible to establish a minimum floor in the estimation of total costs required for compliance. They consist, without further consideration, of the expenses incurred by governmental bodies, to guarantee the operation and enforcement of the legal framework, and by GH/ATK users to bear the obligations introduced by it. The public part of the cost was estimated in this work, based on the information provided by the authorities.

The monetary costs of the Brazilian ABS policy covered in this paper include the following operational costs:

- Genetic Heritage Department (GHD) personnel remuneration
- Travelling costs
- Meetings costs
- SisGen software development
- IBAMA capacity building on ABS enforcement and GH/ATK protection

For the sake of a broader view, the study also assessed the following costs:

- CBD annual contributions
- Nagoya Protocol annual contribution for 2022

The actual total costs associated with ABS/CBD implementation in Brazil are higher than the values herein assessed. A comprehensive cost-benefit analysis would require that every potential cost associated with the policy is outlined, which can uncover non-obvious factors like intangible costs, whose non-availability, as mentioned before, is one of the limitations of CBA-based methodologies. Other costs in the operation of Brazil's ABS policy may be related to public awareness promotion, education and training for users and providers, and others. A comprehensive CBA should also consider Individuals', companies' and academic institutions' costs, which were not dealt with, for the sake of simplicity. The total amount of costs computed in this study should be seen as a floor, and as such were considered in this study.

The costs taken into consideration were compared to the following benefits:

- Monetary benefits shared by GH/ATK users and other resources allocated to the NBSF

 doi:10.20944/preprints202212.0106.v1



- Equivalent amount of non-monetary benefit sharing projects signed between users and providers and between users and the Union

For the cost-benefit analysis, values were made comparable by applying a monetary adjustment index which aligned them to Brazilian Real of August 31, 2022. In 2019, the Brazilian Supreme Court fixed the IPCA-E (Special Consumer Price Index) as an index of monetary correction for judicial debts of the Public Treasuryxiv. The authors used the IPCA-E index in this work, with the help of the Brazilian Central Bank Citizen Calculatorxv.

*2.3. Transaction costs, risks, and compliance analysis*

Relevant supplementary information extractable from the available data is related to compliance and fines, which may be the object of a transaction costs-based analysis. Thus, the authors added to the core of the CBA analysis considerations related to the normative impact of the policy.

## 3. Performance and Impact of the Brazilian ABS Policy: A Cost-Benefit Analysis

For the cost-benefit analysis (CBA), five selected costs presented in section 3.2 are compared with the benefits shared over six years and nine months of Law 13,123/2015 being in force, presented in section 3.1.

3.1. Monetary and non-monetary benefits under Law 13,123/2015

According to Law 13,123/2015, benefits arising from products obtained through access to Brazilian GH/ATK can be shared by users with the government and traditional communities in the monetary and non-monetary modalities. The monetary BS was established by the legislation as being 1%, levied yearly on the net revenue achieved through the commercialization of reproductive material (from selected agricultural activities) or finished products.

***Brazilian Monetary Benefit-Sharing is 1% of the annual net revenue*** *obtained from economic exploitation of finished product or reproductive material arising from access to GH/ATK*

For GH/ATK users who had been operating in non-compliance with PM 2,186/2001, the new Brazilian ABS law established in its Term of Commitment a regularization procedure to be signed between the non-compliant user and the Union. It introduced 5-year retroactivity for benefit sharing to be counted from the day the Term of Commitment was signed by both parties, meaning the benefits collected under Law 13,123 can cover a period prior to November 2015, when the law came into force, as is shown in section 3.1.1.

***Brazilian pineapple accessed for food and beverage products*** *– BS obligations to be met by the producer commercializing reproductive material*
***Brazilian pineapple species accessed for cosmetic product*** *– BS obligations to be met by manufacturer of the final consumer product*

Micro and Small businesses (total revenues lower than R$ 4.8 million/year)xvi are exempted from benefit sharing, but all other companies exploiting goods based on Brazilian GH/ATK can be required to share benefits. They must declare, each fiscal year, the net revenue obtained from the economic exploitation of each finished product or reproductive material, as well as retain and disclose documents to the authorities to justify their calculation. They must proceed annually with the payment of the BS to the National Benefit-Sharing Fund (NBSF).

3.1.1. Monetary benefit sharing

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The Brazilian National Benefit Sharing Fund or NBSF became operational in February 2020 and is being managed by the Brazilian National Bank for Economic and Social Development (BNDES)xvii . By the end of August 2022, 55 single GH/ATK users had contributed monetary benefits, and the total balance available at the NBSF was R$ 5,200,558.05. For the year 2021 alone, the monetary benefits shared by users with the Fund was R$ 610,555.85. According to the data sent by the Ministry of the Environment, R$2,106,414.09 came from GH/ATK regularization of prior activities and R$3,094,143.96 from new activities with GH/ATK.

In addition to the monetary BS revenues, the NBSF can also be supplied by:

**Law 13,123/2015 in force**
**(Nov/2015 - Aug/2022)**

**Total monetary benefits shared to NBSF R$5,200,558.05**

Total number of BS projects submitted = None
Total NBSF investment = R$ Zero

- Annual budgeted appropriations and additional credits by the Union
- Donations
- Fines arising from sanctions for non-compliance with the law
- Contracts, treaties, and agreements related to the purpose of the fund and
- Other revenues that may be dedicated to the NBSF

Despite the provision for those additional sources, the Ministry of the Environment formally informed that until August 2022, no other financial resources had been credited to the fund other than monetary benefit sharing contributions.

3.1.2. Non-monetary benefit sharing

According to the Brazilian ABS framework, the non-monetary benefit sharing must be done through an agreement:

**Non-Monetary Benefit Sharing**
**User-Union**
**(From inception to August 2022) - TOTALS**
Number of BS agreement proposals = 35
Single users = 25
Number of agreements signed = 7
Value of the projects = R$ 1,310,699.37
Projects initiated = None

- Directly with indigenous populations, traditional communities, traditional farmers or ATK providers of identifiable origin, in cases of economic exploitation of a finished product or reproductive material derived from this knowledge, negotiated in a fair and equitable manner between the parties. In this case, the BS will be equivalent to 75% of the forecast for the monetary modality of 1%, or
- With the Federal Government, in the case of the economic exploitation of a finished product or reproductive material arising from access to GH.

According to the Ministry of the Environment, until August 2022, they received 35 agreement proposals from 25 single GH/ATK users. Seven agreements were formally signed with the Union with a combined value of R$ 1,310,699.37. Twenty-six BS agreement proposals, involving 19 single users, were directly negotiated between the user and the GH/ATK providers. Seven of them were already signed between the parties with a combined value of R$ 121,975.16.

**Non-Monetary Benefit Sharing**
**User-Provider**
**(From inception to August 2022) - TOTALS**
Number of BS agreement proposals = 26
Single users = 19
Number of agreements signed = 7
Value of the projects = R$ 121,975.16
Projects initiated = None

 doi:10.20944/preprints202212.0106.v1



When asking the Ministry of the Environment about the number of projects initiated through the funds obtained, the answer was "none". This data implies that after 6 years and 9 months of the new Law being implemented in the country, the traditional communities in Brazil have not yet received any benefits derived from this public policy.

3.1.3. Supplementary overview on monetary benefit sharing under PM 2,816/2001

Before 2015, according to PM 2,816/2001, in addition to obtaining prior authorization (PIC), an applicant for commercial use was required to sign Mutually Agreed Terms (MAT) for access to GH detailing (1) the biological resources and the ATK accessed, (2) BS provisions, and (3) rights and obligations arising from the commercialization of the GH/ATK-based products, including intellectual property rights. The PM defined that the BS could be monetary or non-monetary, including options for royalty payments, technology transfer, free licenses for the use of products or processes, and human resources capacity building initiatives.

The official data requested by LAI showed that between 2000 and 2015, the total number of signed MATs was 243 of which 240 (99%) were signed between users and providers and 3 (1%) between users and the union. All 243 contracts were approved by the CGen, 18 (7%) of which were related to access to GH and ATK, and the remaining 225 (93%) were related only to access to GH. In addition to the MAT agreement, there were 40 benefit sharing projects signed between users and providers that were approved by the CGen, but no value was provided in response to this specific LAI request.

The total amount of BS raised during the 15 years of PM 2,816/2001 being in force, related to the 243 MATs, had a nominal value of R$ 8,326,767.00. After monetary adjustment with the IPCA-E index, that value is equivalent to R$ 12,160,251.49. From the total benefits, 48% came from only 3 MATs (1%), and were shared with traditional communities from the Extractive Reserve Middle Juruá in the Brazilian Amazon region. The other 52% (4.3 million reais) coming from 240 MATs were shared, but the Ministry of the Environment did not provide the community's identification names nor the overall results achieved with these funds.

*3.2. Costs of the Brazilian ABS policy under Law 13,123/2015*

The costs assessed in this study are explained in section 2.2. Table II illustrates two sets of costs incurred by the Brazilian government from January 2016 to August 2022: (1) operational costs and (2) CBD annual contributions. The IPCA-E index was used, to adjust the costs to the value in August 2022. The US dollar to Brazilian reals conversion rate was 5.20 BR/USD.

**Table II.** Compilation of five selected costs related to the Brazilian ABS operation and CBD annual contributions, from January 2016 to August 2022. Nagoya Protocol (NP) contribution is added in year 2022. Values adjusted to August 2022 by the IPCA-E index.

| Operation Cost | Nominal Value | Adjusted Value by IPCA-E index (Aug/2022) |
|---|---|---|
| Genetic Heritage Department Human Resource Remuneration | R$ 18,307,084.67 | **R$ 21,786,644,74** |
| Genetic Heritage Department Travel + Meeting expenses | R$ 530,694.99 | **R$ 733,247.62** |
| SisGen and SisGen Research Module | R$ 2,209,724.80 | **R$ 2,496,782.76** |
| IBAMA Capacity building on ABS enforcement and GH/ATK protection | R$ 263,936.80 | **R$ 322,366.05** |

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| | | |
|---|---|---|
| **Total Operation Costs** | R$ 21,311,441.26 | **R$ 25,339,041.17** |

| CBD Annual Contribution | Nominal Value | Adjusted Value by IPCA-E index (Aug/2022) |
|---|---|---|
| [A] Paid by Brazil 2016-2021 | R$ 9,908,277.15 | **R$ 11,962,699.28** |
| [B] Open balance in 2022 (CBD + NP) | R$ 3,113,474.00 | **R$ 3,113,474.00** |
| **Combined Costs Operations + CBD Contributions [A, B]** | R$ 34,333,192.41 | **R$ 40,415,214.45** |

According to the government response to LAI requests, in August 2022, the Genetic Heritage Department of the Ministry of the Environment had 21 professionals working on the operation of the ABS law. As for IBAMA's ABS capacity building program, 41 public servants attended the course and 27 of them were law enforcement agents.

*3.3. Cost-Benefit Analysis of the Brazilian ABS Policy under Law 13.123/2015*

Table III compares the government costs assessed in this study with the total value paid by users to the NBSF added to the total contracted value of non-monetary benefit-sharing projects, both between users-Union and users-providers.

**Table III.** CBA of the Brazilian ABS policy instituted by Law 13,123/2015 from January 2016 to August 2022. Source: SisGen (LAI) and CBD.

| Analysis Domain | Costs*1 [X] | Benefits*2 [Y] | Benefit – Cost Balance [Y] – [X] | Benefit – Cost Ratio [Y]/[X] |
|---|---|---|---|---|
| Operational costs | R$ 25,339,041.17 | R$ 6,633,232.58 | (R$ 18,705,808.59) | 1/3.8 |
| Operational costs + CDB paid contributions (2016-2021) | R$ 37,301,740.45 | R$ 6,633,232.58 | (R$ 30,668,507.87) | 1/5.6 |
| Operational costs + CDB paid contributions (2016-2021) + (CBD and NP*3) open balance (2022) | R$ 40,415.214.45 | R$ 6,633,232.58 | (R$ 33,782,008.87) | 1/6.1 |

*1 Adjusted Value by IPCA-E index August 31, 2022.
*2 Monetary contribution to NBSF R$ 5,200,558.05 + non-monetary project User-Union (contracted) R$ 1,310,699.37 + non-monetary project User-Provider (contracted) R$ 121,975.16.
*3 Convention on Biological Diversity plus Nagoya Protocol annual contributions combined.

As shown in Table III, ABS policy operational costs from January 2016 to August 2022 were 3.8-folds higher than the total monetary and non-monetary benefits shared by users in that same period. The total amount of those costs was more than 18 million reais higher than the generated benefits.

As explained in section 2.2, the costs considered in the analysis are a fraction of the costs actually incurred by government and users, and so it should be seen as a floor for the total costs, and the same applies to the balance and ratios presented in table III.

 doi:10.20944/preprints202212.0106.v1



Within the temporal scope of the study, the government costs operating the ABS framework in Brazil, is therefore many times higher than the amount of benefit shared by the registered users.

From 2016 to 2021, the total of CBD annual contributions, adjusted to August 2022, added more than 11.9 million reais. That amount is 1.8-folds higher than all benefits shared in the period under analysis. When the CBD contributions made by Brazil are added to the operational costs, the cost-benefit ratio increases to 5.6-folds. When the contributions to CBD and Nagoya Protocol to be disbursed (related to year 2022) are also added, that ratio increases to 6.1-fold.

**Table IV.** Benefit Sharing contributions and Investments from January 2016 to August 2022. Source: SisGen (LAI).

| **Benefit Sharing Modality** | Source of Benefit Sharing*[1,2] | BS Contribution Value*[3] | Invested Values*[4] |
|---|---|---|---|
| **Monetary** | Contributions to NBSF*[1] | R$ 5,200,558.05 | None |
| Non-monetary User-Union | Contracted projects*[2] | R$ 1,310,699.37 | None |
| Non-monetary User-Provider | Contracted projects*[2] | R$121,975.16 | None |
| Total | | R$ 6,633,232.58 | None |

*[1] Monetary contribution made by users to the National Benefit Sharing Fund.
*[2] Corresponding monetary value of the signed non-monetary BS contracts User-Union and User-Provider.
*[3] Status on August 31, 2022.
*[4] Benefit sharing resources invested in sustainable use and conservation projects up to August 31, 2022.

As mentioned in section 3.1.2, non-monetary benefit sharing projects have not yet been initiated. The actual benefit generated by the Brazilian ABS policy is therefore equal or smaller than the total value of benefit sharing shown in Table III. That amount must be understood as a ceiling for the actual policy benefit.

Table IV shows that until the end of August 2022, benefit sharing resources had not been invested in biodiversity conservation and sustainable use projects.

## 4. Regulatory Compliance Analysis

The Law 13,123/2015 brought new concepts related to the definition of GH, ATK, access and benefit sharing. Understanding them is essential for users to ensure compliance. The key concepts established by the law are shared in Appendix C.

### *4.1. Compliance of GH/ATK users with registration obligations*

SisGen became available online on November 6, 2017, allowing users to register their GH/ATK access. New collection, shipment, storage, research, development and innovation activities on the Brazilian biodiversity need to be registered retroactively to November 2015, when Law 13,123 came into force. However, for those users who did not comply with the Provisional Measure, the registration needed to be retroactive to June 2000, via a regularization procedure, and a Term of Commitment (TC) between the user and the Government, represented by the Ministry of the Environment, needed to be signed.

The registration must be undertaken by any individual or institution working with Brazilian genetic heritage. Up to August 2022, SisGen was not available to foreign entities, and they are required to work via a local organization, which creates additional legal hurdles and transaction costs.

#### 4.1.1. GH/ATK user registrations

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Art. 2. of Law 13,123/2015 defines a user as a natural or legal person who accesses GH or ATK or economically exploits a finished product or reproductive material based on access to Brazilian GH or ATK. Art. 11. § 1 of the legislation also expresses that access to the Brazilian GH and ATK by a foreign natural person is prohibited.

Figure 1 shows that up to August 2022 there was a total of 31,294 GH/ATK users registered on SisGen.

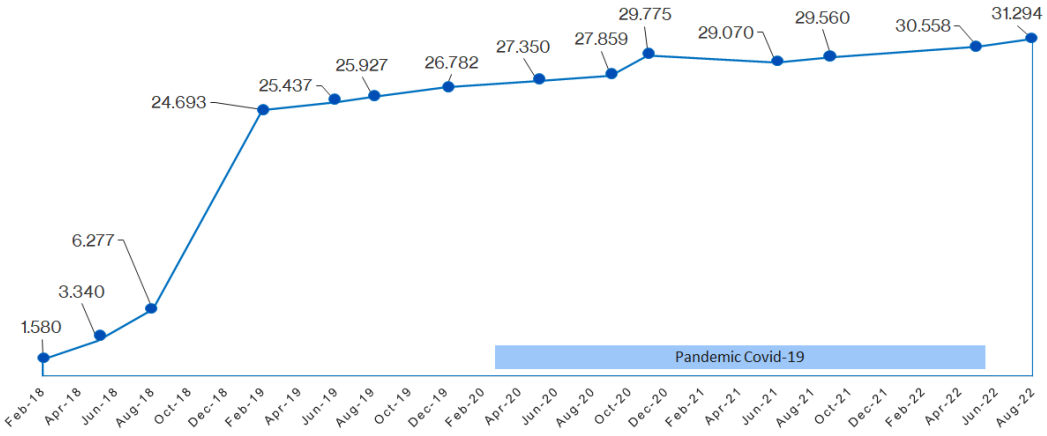


**Figure 1.** Evolution of the number of accumulated registrations of GH and ATK users in SisGen. Period from February 2018 to August 2022. Source: SisGen (LAI).

As highlighted in Figure 2-A, in December 2019, the total number of validated institutions in the SisGen was 708, of which 440 or 62% were companies and 268 were academic institutions (Figure 2-B). In August 2022, the total number of registrations increased by 99, reaching 807. However, it is worth noting that after December 2019, the Ministry of the Environment reported that it no longer discloses the division of academic and business records claiming that "it is not possible to process this consultation, as there are no specific filters in the system to distinguish institutions linked to academia and the private sector".

The fluctuation in the numbers was not explained. As there are no reasons for an entity to withdraw its registration, it may indicate that there were duplications or other errors in the system that were later corrected.

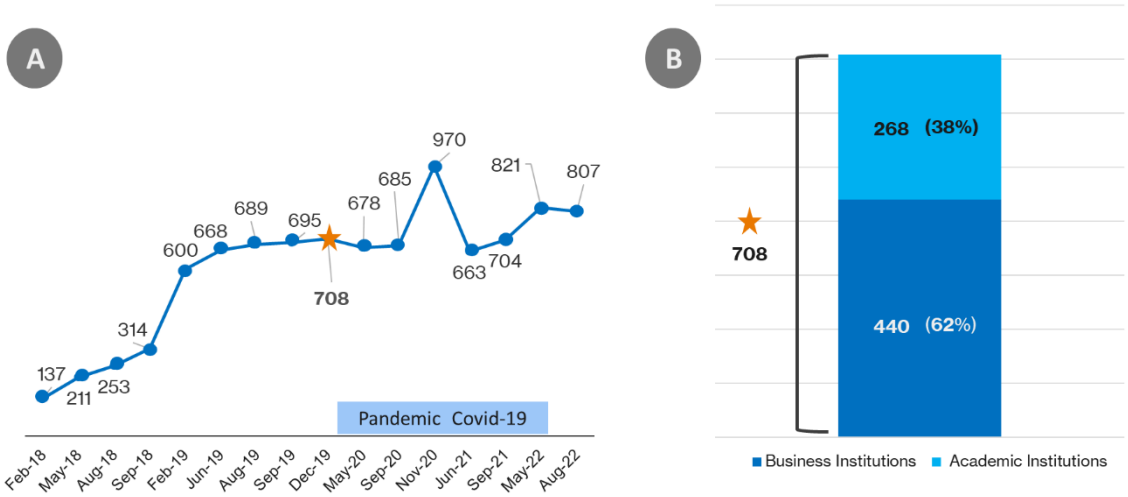

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**Figure 2.** [A] The evolution of the number of registered institutions in SisGen from February 2018 to August 2022. [B] Number of SisGen registrations by academic and business institutions in December 2019. Source: SisGen (LAI).

4.1.2. GH/ATK access registrations

Figure 3 illustrates the considerable increase in the number of registrations close to the end of the one-year adjustment and regularization period stipulated as a transitory provision for users that did not comply with the PM 2,186/2001, and a very slow-paced evolution since then. The Figure also shows both cumulative and non-cumulative registrations for more precise progress evaluation on the period covered.

While the PM was in force, i.e., from June 2000 to November 2015, there were 2,136 GH and ATK access authorizations; 2,019 (95%) were related to access to the GH only and the remaining 117 (5%) were related to access to the TK associated with the Brazilian GH. This reality of the predominance of access to the GH is repeated in compliance with Law 13.123/2015, as illustrated before.

The difference in the number of pre-authorizations or access registrations between the old and the new Brazilian ABS legislation is significant: 2,136 pre-authorizations in 15 years *versus* 67,056 access registrations in 6 years and 9 months.

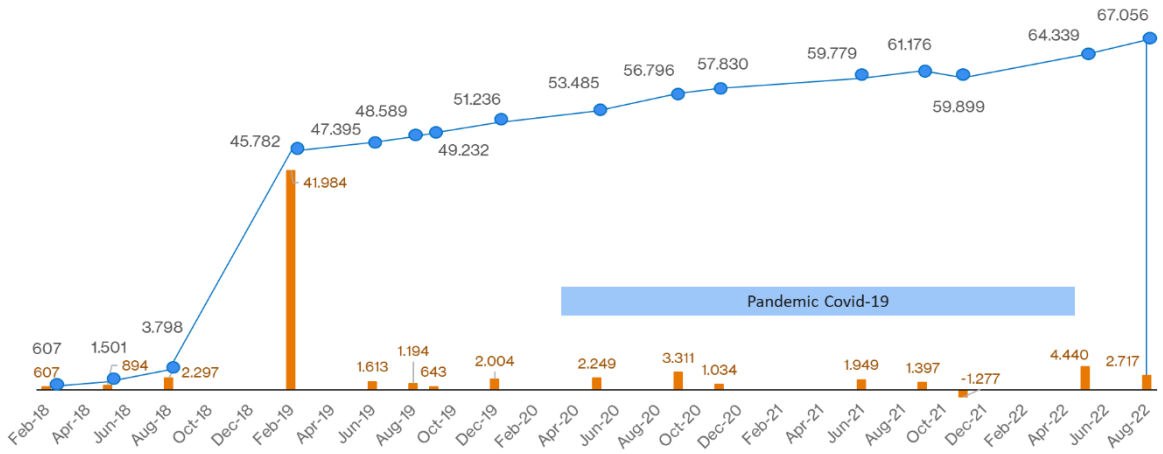


**Figure 3.** Evolution of the number of GH and ATK access records in SisGen for the period from February 2018 to August 2022 showing cumulative and non-cumulative data. Source: SisGen (LAI).

4.1.3. Registration by legal purpose

Law 13,123/2015 provided for a transitory provision of one year for adjustment and regularization procedures counting from the date SisGen was made available. The deadline ended in November 2018 (except for compliance features that were not yet made available by the system). As mentioned previously, up to August 2022, SisGen was not yet available to be accessed by foreigner users.

The "adjustment" procedure needed to be followed by users who accessed GH/ATK and/or undertook economic exploitation of finished products or reproductive material resulting from access to GH/ATK in compliance with PM 2,186/2001 since June 2000.

The "regularization" procedure was established for users who had used GH/ATK in disagreement with the Provisional Measure. The latter required the signing of a Term of Commitment (TC) between the user and the Union (Ministry of the Environment), if the user had performed any of the following activities:

- Access to GH and/or ATK;
- Economic exploitation of a product or process resulting from access to the GH and/or ATK referred to in the PM 2,186/2001;
- Sending a GH sample abroad; or

 doi:10.20944/preprints202212.0106.v1



- Disclosure, transmission or retransmission of data or information that were part of or constituted traditional knowledge associated with the Brazilian GH.

According to SisGen data received via LAI, in August 2022, the total number of registered adjustment procedures was 33,631 or 50.1% of all registrations, while new GH/ATK access activities reached 33.319 or 49.7% of all registrations.

Regularization accounted for 106 or 0.2% of the registrations in SisGen. The total number of TCs received by the Ministry of the Environment was 1,621. Up to the end of August 2022, the number of TCs signed by both parties was 900, while 233 TCs were canceled, and the rest are still being processed.

It is not immediate to make sense of those figures, which have indeed been reconfirmed by the authorities. The number of adjustment registrations (33,631) seems high in face of the authorized accesses (2.136) in the period PM 2,186/2001 was in force, while the number of regularization registrations (106) seems very low. The explanation given by the Ministry of the Environment for the fact was "only users who selected the option "Yes - Regularization" in SisGen form have been accounted for".

#### 4.1.4. Registration by type of access to GH and ATK

According to data received in August 2022, the total number of access registrations for GH corresponded to 55,477 or 82.7% of all access registrations in SisGen. Users registered 8,484 or 12.6% of accesses as involving both GH and ATK and 3,152 or 4.7% of the entries constituted access to ATK.

#### 4.1.5. Access registrations by GH origin

Up to August 2022, according to data received via LAI, most of the GH accessed by users came from *in-situ* sources, that is, directly from their natural habitat, totaling 39,026 or 55%. The GH records related to *ex-situ* access represented 34% of the access registrations (i.e., 23,910). Access to Brazilian GH information from *in silico* sources was equivalent to 1% of the total registrations, representing 822 registrations.

#### 4.1.6. Pre-Economic Exploitation Notification

As established by Law 13,123/2015, the product notification must precede the beginning of the economic exploitation of the reproductive material or finished product arising from access to GH/ATK. In the notification, the user declares compliance with the requirements of the legislation and indicates the benefit-sharing provisions, if applicable to its case. Economic exploitation begins when the first invoice for the sale of the finished product or reproductive material is issued. At the time of notification, also GH/ATK users exempted from the sharing of benefits must declare to the authorities their legal basis for exemption (example: proof of being a micro or small business).

As of August 2022, the total number of products notified in SisGen since the inception of Law 13,123/2015 reached 12,345, of which 3.6% were for reproductive materials and 96.4% were for finished products. When asked for the share of notifications by benefit sharing option, the Ministry of the Environment provided numbers which seem to be incomplete: i.e., 3,343 notifications for monetary BS; 4,281 for non-monetary BS, and 847 for being exempted from BS. According to these data, there are 3,874 notifications missing; no explanation was provided for this discrepancy.

### *4.2. Compliance by the government*

Section VII of Decree 8,772/2016 describes the administrative verification procedure. The verification is applicable to cases of (1) registration of access to GH and ATK, (2) shipment of GH, and (3) notification of a finished product or reproductive material. Therefore, it is a compliance obligation to be carried out by the government itself, under the responsibility of the Genetic Heritage Council (CGen).

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By the end of August 2022, the total number of activities needing verification by CGen amounts to 67,113. It is important to highlight that after 60 days, SisGen automatically issues a compliance "Certificate" to the user if (i) either no verification has been done, or (ii) the verification did not reveal reasons to suspend the administrative process. The data received via LAI showed that 66,105 or 98.5% of all activities needing verification were approved by "expiration date", *i.e.* were not verified, and the remaining 1,008 or 1.5% were still within the 60-day verification period. The data provided by the Ministry of the Environment also indicated that there were no effective administrative verifications carried out by the government and that none of the activities (registrations and notifications) was canceled.

In response to a request for explanation about this lack of active follow-up the Ministry of the Environment stressed that the fact that CGen has not been able to verify the validity of the new entries in the legally determined timeframe does not mean the unconditional invalidation of this administrative compliance obligation and that in cases of manifest fraud by a user, the President of CGen may cautiously suspend a registration or notification.

### *4.3. Fines and other risks of non-compliance under Law 13.123/2015*

#### 4.3.1. Compliance risks for GH/ATK users

According to Law 13,123/2015, a "user" is defined as a natural or legal person who accesses GH/ATK or economically exploits a finished product or reproductive material resulting from access to GH/ATK.

Because of the broad scope of the concepts defined in Law 13,123/2015, as described in Appendix C, its compliance requirements reach not only usual applications of GH/ATK in the agribusiness, pharmaceutical, or cosmetics sectors, involving research on and/or technological development from tangible biological materials. In addition, users who research and develop products or services based on GH/ATK information, such as precision agriculture services and educational products on Brazilian biodiversity may be impacted.

Companies operating in all those industries, if accessing GH/ATK information should be aware of the compliances triggers needing registration in SisGen.

To do a preliminary study on the level of compliance of companies with the requirements of Law 13,123/2015, the authors conservatively considered that after December 2019, all extra institutions validated on SisGen (see Figure 2) were business entities (i.e., 440 + 99 = 539 business entities duly validated in the system).

Some assumptions had to be made on the number of companies that developed at least one single activity with Brazilian GH and/or ATK, and thus should comply with the current regulatory framework, including registration on SisGen.

According to data from the SEBRAE Portal[xviii] retrieved in November 2021, there were 19 million companies (micro, small, medium and large) active in Brazil. Among them, 11.6 million or 59% of companies were from the Agriculture, Industry, and Service sectors (group A); and the remaining 41% or 7.4 million were from the Commerce and Civil Construction sectors (group B).

The authors selected Group A as a proxy to the potential universe of the GH/ATK users due to the higher probability of companies in this group to perform research and development activities based on Brazilian GH/ATK information.

Three compliance scenarios were considered in the analysis shown in Table VI. Scenario 1: 0,01% of the companies of Group A accessed Brazilian GH/ATK; Scenario 2: 0,1% of companies of Group A did so; and Scenario 3: 1% of the total accessed GH/ATK.

**Table VI.** Three compliance scenarios considered for business users of the Agriculture, Industry, and Service sectors (Group A) related to the current Brazilian ABS legislation. Company data from SEBRAE Portal and SisGen data from LAI.

| Companies in | Number of companies | Hypothetical |
|---|---|---|

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| Group A | 11,618,307 | compliance level |
|---|---|---|
| Business Institutions Validated on SisGen (August 2022) | 539 | 100 % |
| Scenario – 1: ≥ 0,01% | 1,162 | 46.38 % |
| Scenario – 2: ≥ 0,1% | 11,618 | 4.64 % |
| Scenario – 3: ≥1% | 116,183 | 0.46 % |

This simple comparative analysis illustrates that either the level of companies compliance with the Law 13,123/2015 is very low, or the current volume of research and development of new products based on Brazilian biodiversity is very low, or both are substantially low.

4.3.2. Fines from enforcement operations carried out during the PM 2,816/2001

As provided for in Decree 5.459/2005 related to PM 2,186/2001xix, the failure of users to comply with their obligations incurred different types of penalties, including fines, confiscation of samples and products, suspension of product sales, closure of establishments, suspension or cancellation of registrations, patents, licenses or authorizations, prohibition of contracting with the public administration and restriction of tax incentives.

While the Provisional Measure was in effect, IBAMA exercised its environmental police enforcement powers for compliance with the ABS legislation. Between 2010 and 2013, IBAMA deployed "Operation Novos Rumos I and II" with the objective of enforcing the compliance of the GH and ATK users through inspectionxx. The results were: 134 infraction notices in Operation I and 321 in Operation II, with fines totaling R$ 107,014,100.00 and R$ 103,967,850.00, respectively. Thus, the number of infraction notices under PM 2,186/2001 amounted to 455, with total fines of R$ 210,981,950.00. Table V shows the nominal values and the values adjusted by IPCA-E (recalculated for August 2022).

**Table V.** The values of fines applied during IBAMA Enforcement Operations "Novos Rumos I and II" under PM 2,186/2001 between 2010 and 2013. Nominal values and updated values after monetary adjustment by the IPCA-E for August 2022 are provided.

| IBAMA Operation | Nominal Value | Adjusted Value by IPCA-E index (Aug/2022) |
|---|---|---|
| Fines from "Novos Rumos I" (2010) | R$ 107,014,100.00 | **R$ 216,837,202.41** |
| Fines from "Novos Rumos II" (2011-2013) | R$ 103,967,850.00 | **R$ 180,122,543.07** |
| Total | R$ 210,981,950.00 | **R$ 396,959,745.48** |

The new legislation, through the transitory provision, provided for in Decree no. 8,772/2016, offered special conditions regarding the reduction and exemption of fines imposed on users who were non-compliant under PM 2,186/2001, if they proceeded with the regularization as outlined in section 3.2.3.

Brazilian courts can take a long time to build consolidated jurisprudence on complex subjects, which can produce legal uncertainty.

It is worth mentioning that, according to the Regulatory Decree 8.772/2016, the National BS Fund can receive funds from fines originated from non-compliance. Up to August 2022, no such funds were credited to the NBSF.

 doi:10.20944/preprints202212.0106.v1



## 5. Conclusion

Brazil is one of the most biodiverse countries on the planet. It is a CBD member-country and recently became a party to the Nagoya Protocol.

The central objective of this paper was to assess the effectiveness of the Brazilian ABS legal framework, by applying a cost/benefit assessment based on a comprehensive dataset which has been collected over several years in a consistent and structured manner.

In the present study, the procedures described in Brazilian regulatory Decree 8.772/2016 were used as a roadmap for the compliance obligations encountered by users and by the government. Data was requested and retrieved periodically based on the Brazilian Law of Access to Information. The latter is indeed a powerful tool to foster transparency, governance, and accountability. When applied to our study, it allowed a thorough analysis of the Brazilian current ABS regime.

The analysis of the official data showed that the ratio between the costs of implementing and operating the Brazilian ABS policy and the tangible benefits gained by the Brazilian society is unsatisfactory.

The monetary and non-monetary benefits resulting from the implementation of the Brazilian ABS framework do not even match the direct operational costs of the Brazilian government. On top, it is very likely that the transactional and/or compliance costs incurred by GH/ATK users, like companies, research centers, universities, and individuals face are even higher than those assessed operational costs. Users are also exposed to a significant risk of high fines in case of purported non-compliance.

Indeed, while the Provisional Measure was in place, for each R$ 1.00 obtained through monetary BS, R$ 25.34 (nominal value) or R$ 32.64 (adjusted to inflation until August 2022) were issued in fines.

Among the millions of businesses and thousands of academic institutions operating in Brazil, many of them potential GH/ATK users, only 807 entities were registered and validated as biodiversity users under Law 13,123/2015 in August 2022.

During more than 22 years, the total amount of benefits shared by GH/ATK users accounts for less than 18 million reais (around 3.5 million USD in August 2022), or less than 1 million reais per year (less than 200 thousand USD in August 2022).

So, from the perspective of generating benefits, the current policy is not able to make a significant contribution neither in face of the current environment policies nor of the R&D fostering policies in Brazil. On the other hand, for users, mainly from the business sector, the legal uncertainty associated with the Brazilian ABS legislation represents significant risks, which likely disincentivize R&D on the Brazilian biodiversity.

The achievement of the main purposes of ABS policies requires incentivizing the research and development of innovative sustainable economic activities based on the biodiversity, which can engage the traditional populations and replace predatory or non-sustainable activities, while possibly increasing traditional population average income.

Based on the assessment presented in this study, we conclude that the Brazilian ABS policy needs to be improved for those objectives to be more easily achieved. Brazil's rich biodiversity can represent actual opportunities to generate sustainable occupations and income improvement for traditional populations, both as compensation for their work in the new activities and for valuable knowledge associated with the Brazilian GH. Continuous and systematic investments can indeed bring improvements to the country's economy. The authors believe those opportunities will unfold more effectively if ABS policies foster and help support the intended R&D activities, instead of imposing regulatory and monetary barriers on their execution.

 doi:10.20944/preprints202212.0106.v1



**Author Contributions**: Both authors contributed to the conceptualization, writing, reviewing, and editing of the article. The authors have read and agreed to the published version of the manuscript. The views and opinions expressed in this article are those of the authors in their personal capacity.

**Statement:** The dataset presented was obtained from public sources, consolidated, and assessed independently over the last five years by Dr. Diana Jungmann. It is also available as a "Master Class" with an annually updated version. The publication of this article was enabled through funding by the International Federation of Pharmaceutical Manufacturers and Associations, CropLife International and DSM.

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## APPENDICES

A – List of LAI requests

B – List of questions to authorities

C – Concepts of Law 13,123/2015 and Regulatory Decree 8.772/2016