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MONITORING THE USE OF TRADITIONAL KNOWLEDGE:
how can Brazil
push this agenda?

INSTITUTO
ESCOLHAS

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1. Introduction

Traditional knowledge is information and practices embedded in traditional peoples and communities'[1] cultures, ways of life, and intimacy. Traditional knowledge, as developed, transmitted, and preserved collectively, is closely related to the territory and nature. Therefore, it is a precious intangible cultural heritage for biodiversity conservation.

An essential source of information on the active principles and functional characteristics of biodiversity species, the traditional knowledge that is associated with the Brazilian genetic heritage[2] is widely used by researchers, academia, research centers, and pharmaceutical, biotechnology, cosmetic, food, agricultural, and chemistry industries – as a starting point for the development of products and processes. This knowledge, developed by traditional people and communities over generations, is the basis of the bioeconomy[3].

For decades, a range of countries, including Brazil, has been concerned with the growing interest of industries in substances obtained from plant-based raw materials due to the likely impact caused by the unsustainable use of biodiversity resources and the undue appropriation of this heritage and its associated knowledge.

Why is knowledge deemed traditional?

There is a common association of traditional with that which is "old" or "outdated". However, this is not the meaning of tradition. Knowledge is traditional because it stems from a set of practices, customs, sciences, and activities of a particular group, being closely connected to its territory and cultural identity. Traditional knowledge is characterized by dynamism and the incorporation of innovative elements over time. Just like the Western science, traditional knowledge is also continuously evolving and changing.

1
For the purposes of this publication, the expression 'traditional peoples and communities' (PCTs) refers to indigenous peoples, *quilombolas*, traditional peoples and communities, and family farmers (PIQPCTAF).

2
Law 13,123/2015 defines genetic heritage as "Genetic-related information of plant, animal, microbial, or other species, including substances originating from the metabolism of these living beings" and traditional knowledge associated with genetic heritage as "information or practice of indigenous population, traditional community or traditional farmer on the properties or direct or indirect uses associated with the genetic heritage".

3
In this document, "bioeconomy" refers to economic activities that encompass all biodiversity value chains, guided by traditional knowledge, science and the search for innovations in the use of biological and renewable resources, aimed at generating circular, regenerative, sustainable, inclusive, economic activity, with collective and local benefits. The following are examples of bioeconomy: activities that carry out sustainable forest stewardship to extract products such as nuts, fruits, rubber, oils, wood, fish, fibers and medicinal plants; the industry that processes these products (food, beverages, cosmetics, pharmaceuticals, fashion, construction); sustainable agriculture, fish farming and tourism; environmental services; research and teaching for the development of the bioeconomy in the region.

Thus, the Convention on Biological Diversity (CBD) was open for signature in the 1990s. This UN multilateral international treaty, which acknowledges the sovereign right of countries over their genetic resources and promotes biodiversity conservation, encourages access to these resources in a transparent and mutually agreed manner. The CBD also establishes the mechanism for the fair and equitable sharing of benefits arising from the economic exploitation of genetic resources and associated traditional knowledge (ATK).

The mechanisms for access to genetic heritage (GH), associated traditional knowledge, and Benefit Sharing were detailed in a new complementary agreement to the CBD, the Nagoya Protocol, which came into force in 2014. The Nagoya Protocol acknowledges the intrinsic relationship between Genetic Heritage and Associated Traditional Knowledge. The document states that each signatory country must adopt appropriate legislative, administrative, or political measures to ensure that the Associated Traditional Knowledge used in its jurisdiction has been accessed through free, prior, and informed consent (FPIC)[4] of the Traditional Peoples and Communities (PCTs) and that the Benefit Sharing (BS) is carried out on mutually agreed terms.

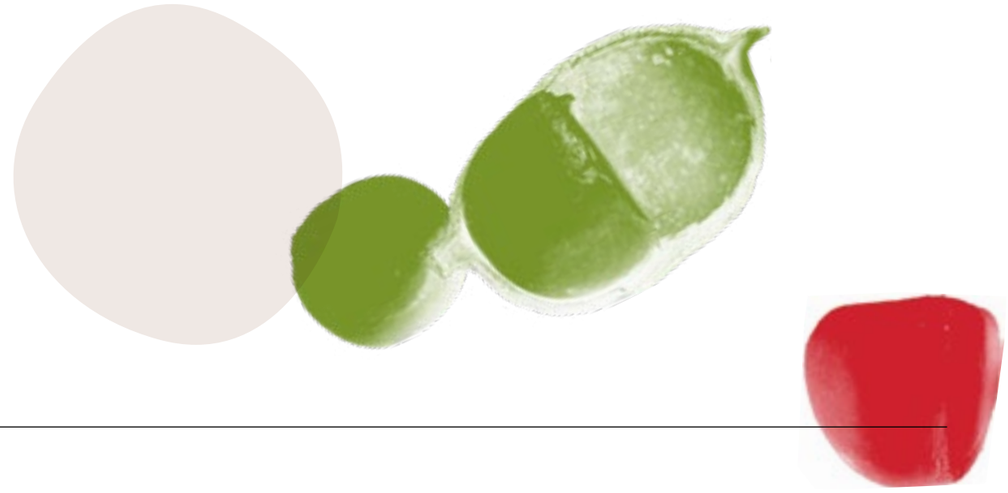
In Brazil, Law 13,123/2015 regulates access to the Genetic Heritage, the Associated Traditional Knowledge, and Benefit Sharing, following the guidelines of international agreements. Said Law regulates research, technological development, and economic exploitation of finished products[5] or reproductive material[6] derived from access to Genetic Heritage or Associated Traditional Knowledge.

Identifying holders of Associated Traditional Knowledge by those who use Brazilian genetic heritage is the first step towards ensuring compliance with the Law. Without proper identification, holders are not assessed concerning the authorization or refusal to use their knowledge; consequently, no benefit is shared.

Eight years after the creation of the legislation, holders' identification is still a bottleneck to be overcome. Most genetic heritage access records do not declare the Associated Traditional Knowledge. Information about already identified traditional knowledge is scattered and is often difficult to find. Agencies responsible for Associated Traditional Knowledge traceability and monitoring its use do not have adequate tools to verify all Associated Traditional Knowledge access records, patents and product notifications regularly.

This study by Instituto Escolhas investigated the strategies that can be implemented to overcome this bottleneck, thus improving the scenario for implementing Law 13,123/2015 and the fulfillment of the Traditional Peoples and Communities' right to prior consultation and Benefit Sharing.

Therefore, the study reviewed the use of the Associated Traditional Knowledge database to monitor access in other countries and the experiences in Brazil of access to Associated Traditional Knowledge and Benefit Sharing. Throughout this research, Instituto Escolhas also promoted discussions with representatives of Traditional Peoples and Communities, researchers and members of public authorities, to present the premise to be studied and the intermediate results and collected insights about them.



4
Law 13,123/15 defines FPIC as the "procedural standard of indigenous populations, traditional communities or traditional farmers that establishes, according to their uses, customs and traditions, the mechanisms for access to associated traditional knowledge and the sharing of benefits under said Law."

5
Law 13,123/15 defines finished product as "a product whose nature does not require any type of additional production process arising from access to genetic heritage or associated traditional knowledge, in which the component of genetic heritage or associated traditional knowledge is one of the main elements that adds value to the product, being suitable for use by the end consumer, regardless of whether it is an individual or legal person."

6
Law 13,123 defines reproductive material as "plant propagation or animal reproduction material of any gender, species or cultivation resulting from sexual or asexual reproduction."

RULES FOR ACCESSING ASSOCIATED TRADITIONAL KNOWLEDGE AND GENETIC HERITAGE AND SHARING BENEFITS IN BRAZIL

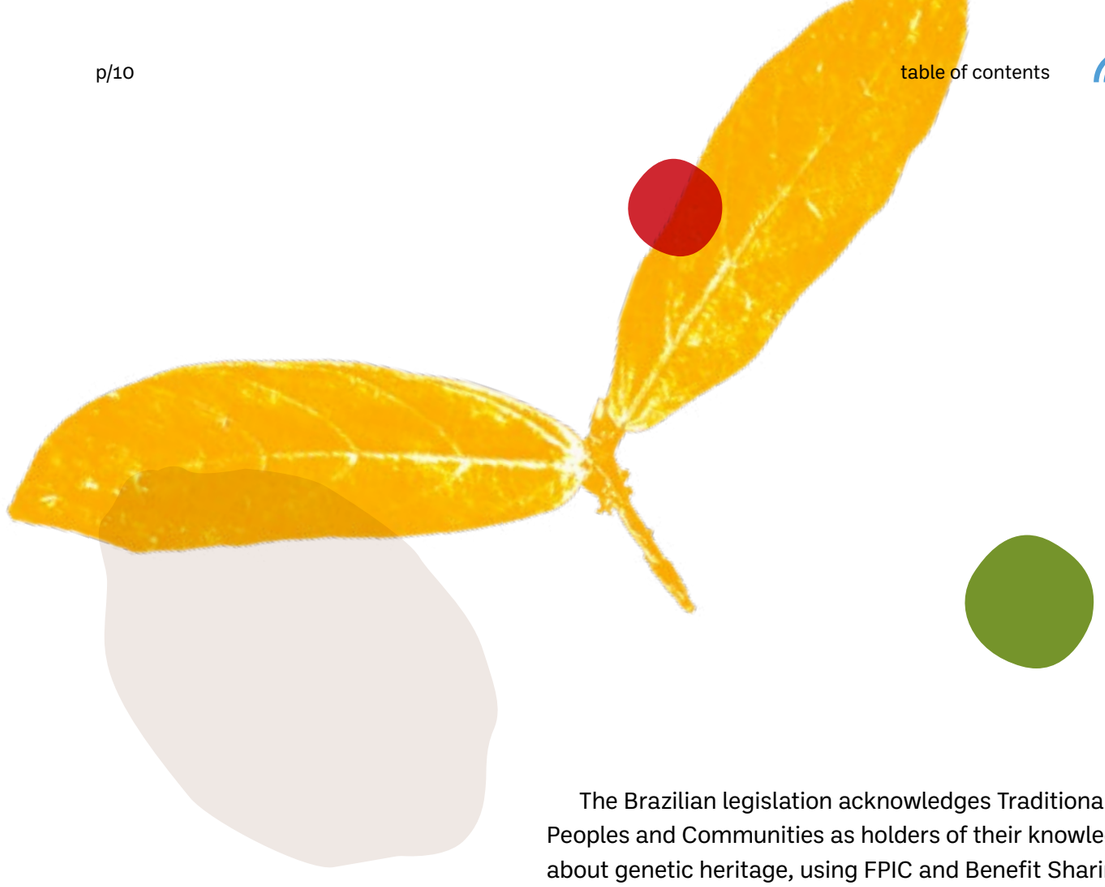
Any research or technological development carried out with the genetic heritage of Brazilian biodiversity species and Associated Traditional Knowledge must be registered on the electronic platform of the National Genetic Heritage and Associated Traditional Knowledge Management System (SisGen).

The user (an individual who carries out research or development) must, among other information, indicate the source of the genetic heritage (*in situ, ex-situ*, and/or *in silico*[7]) and its association (or not) with traditional knowledge of a particular nature. If the origin of the Associated Traditional Knowledge can be ascertained,[8] the FPIC is executed directly with the knowledge provider, and afterward, the activity is entered on the SisGen.

Finished products and reproductive materials developed from research and development with Genetic Heritage and Associated Traditional Knowledge must be reported to SisGen before marketing. The manufacturer of the finished product or the producer of the reproductive material must share the benefits arising from its economic exploitation, in monetary or non-monetary forms (as detailed below).

7
According to Law 13,123/15, '*in situ*' is the condition in which the genetic heritage exists in natural ecosystems and habitats and, in the case of domesticated or cultivated species, in the environments where they naturally developed their own distinctive characteristics, including those that form spontaneous populations. '*Ex situ*' are conditions in which genetic heritage is maintained outside its natural habitat. Finally, *'in silico'* is when the genetic heritage is accessed by computer simulation.

8
When the origin of knowledge can be linked to at least one traditional people or community.



The Brazilian legislation acknowledges Traditional Peoples and Communities as holders of their knowledge about genetic heritage, using FPIC and Benefit Sharing as instruments that effect this acknowledgment. In turn, SisGen is the mechanism used by the State to manage and monitor access to Genetic Heritage and Associated Traditional Knowledge. The system contains the information necessary to monitor whether Associated Traditional Knowledge users respect Traditional Peoples and Communities' rights.

BENEFIT SHARING FORMS IN BRAZIL

Monetary

GENETIC HERITAGE
1% of the annual net revenue from the finished product or reproductive material, to be paid to the National Benefit Sharing Fund (FNRB).

ASSOCIATED TRADITIONAL KNOWLEDGE OF IDENTIFIABLE ORIGIN
Considerations freely negotiated between the provider and the user + 0.5% of the annual net revenue of the finished product or reproductive material, to be paid to the FNRB.

UNIDENTIFIABLE ASSOCIATED TRADITIONAL KNOWLEDGE
1% of the annual net revenue from the finished product or reproductive material, to be paid to the FNRB.

NON-MONETARY

GENETIC HERITAGE
0.75% of the annual net revenue from the finished product or reproductive material, if the allocation occurs in one of the following modalities: (1) projects for conservation and sustainable use; (2) human resources training; (3) free distribution of products. For other forms of allocation, 1% applies.
.

ASSOCIATED TRADITIONAL KNOWLEDGE OF IDENTIFIABLE ORIGIN
Considerations freely negotiated between the provider and the user + 0.5% of the annual net revenue of the finished product or reproductive material, to be paid to the FNRB. The negotiable component of the distribution may be non-monetary, but in cases of access to Associated Traditional Knowledge, there is always a monetary payment to the FNRB.

Source: Biodiversity Law Handbook. Instituto Escolhas, 2019. Available here.

NUMBER OF CONNECTIONS TO GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE IN BRAZIL

The survey of the historical series (2017-2022) of SisGen data identified

150.538 registrations for access to GH and/or ATK.

87% (131.086) of these records only indicate access to GH, not associated with traditional knowledge.

ACTIVITY RECORDS WITH ACCESS TO GENETIC HERITAGE, ASSOCIATED TRADITIONAL KNOWLEDGE, AND GENETIC HERITAGE & ASSOCIATED TRADITIONAL KNOWLEDGE BETWEEN NOVEMBER 2017 AND DECEMBER 2022

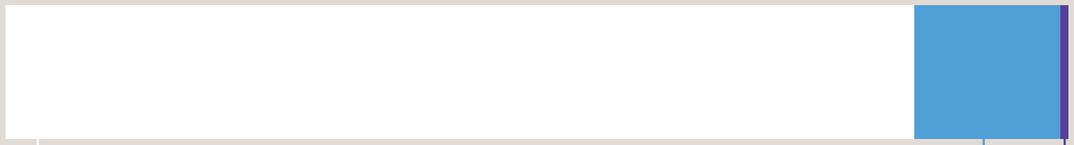
Year	ATK	GH & ATK	GH	Total
2017	15	25	459	499
2018*	1.941	9.797	88.660	100.398
2019	246	1.270	11.807	13.323
2020	792	3.164	9.525	13.481
2021	179	773	9.556	10.508
2022	208	1.042	11.079	12.329
Total	**3.381**	**16.071**	**131.086**	**150.538**
%	**2,25%** +	**10,68%**	**87,08%**	**100,00%**

Source: BRASIL/MMA/SisGen (2023).

Only
13% = 19.452 registrations (the sum of the ATK and GH & ATK categories)
of the SisGen registrations in the reviewed period indicate access to ATK

The historical series also shows that of

19.452 registrations that indicate access to ATK



85%
(16.551) are of **unidentifiable** origin and, therefore, waive authorization of Traditional Peoples and Communities.

14%
(2.722) are Associated Traditional Knowledge access records from origin directly **identifiable** with the provider.

1%
(178) are Associated Traditional Knowledge access records of origin identifiable from secondary sources[9].

*** The Ministry of the Environment made the SisGen available to the public in November 2017. Therefore, registrations increased significantly in 2018, when there was a high demand for regularization of research and technological development projects with GH and ATK.**

9
Such as fairs, publications, inventories, films, scientific articles, registers and other forms of organization and recording of associated traditional knowledge, in accordance with Law 13,123/15.

PRODUCT DEVELOPMENT FIGURES BASED ON ACCESS TO GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE IN BRAZIL

The study identified

19.354 notification records of finished products developed through access to GH and/or ATK between November 2017 and December 2022.

91% (17.639) of notifications refer to products developed only with GH, without ATK.

FINISHED PRODUCT NOTIFICATION RECORDS WITH ACCESS TO GH, ATK, AND GH & ATK

Year	ATK	GH & ATK	GH	Total
2017	3	2	2	7
2018*	240	376	969	1.585
2019	18	401	1.006	1.425
2020	29	150	1.821	2.000
2021	35	233	6.749	7.017
2022	62	166	7.092	7.320
Total	**387**	**1.328**	**17.639**	**19.354**
%	**2,00%** +	**6,86%**	**91,14%**	**100,00%**

Source: BRASIL/MMA/SisGen (2023).

Only

9% = 1.715 notifications (sum of ATK and GH & ATK categories)

of the notifications indicated that they had accessed ATK

*** The Ministry of the Environment made the SisGen available to the public in November 2017. Therefore, registrations increased significantly in 2018, when there was a high demand for regularization of research and technological development projects with Genetic Heritage and Associated Traditional Knowledge.**

Of all the

products notified with access to Associated Traditional Knowledge

48% (816) are of **unidentifiable origin.**

52% (897) are of **identifiable origin.**

Data from registrations in SisGen highlight the problem of non-identification of ATK. As the data presented here indicates, most GH access registrations declare that they have not accessed traditional knowledge or that the ATK accessed cannot be identified.

Representatives of Traditional Peoples and Communities argue that the possibility of declaring access to a non-identifiable ATK should be an exception, only in situations where there is no possibility of linking its origin to at least one indigenous population, traditional community, or traditional farmer, as defined in Law 13,123/15. In other words, what should be an exception provided for in the legislation has become a rule.

Without the identification of the Associated Traditional Knowledge, the rights of Traditional Peoples and Communities will not be enforced. The only way to solve this problem is to significantly improve the monitoring of the use of Genetic Heritage and Associated Traditional Knowledge by the bodies responsible for the traceability of its activities, including those related to the economic exploitation arising from this access. A tool with organized information about the Associated Traditional Knowledge already identified is essential for this effective monitoring.

2.
Database as a tool for monitoring the use of Associated Traditional Knowledge

Traditional knowledge is the gateway for Western science to access biodiversity species, their properties, and their uses. The researchers obtain insight, valuable research leads, and detailed information about managing biodiversity for various purposes from this knowledge.

In other words, all research and technological development on biodiversity starts from prior knowledge, from some evidence about the use of a particular species, and this knowledge generally has an origin, a people, or a traditional community that holds the information over time.

Proper identification of holders of traditional knowledge and monitoring of uses for research or industry means not only compliance with legislation but also a fundamental step for the bioeconomy in Brazil to develop with social inclusion through the generation of local income in the territories and for the people and communities who are guardians of biodiversity.

The Genetic Heritage Management Council (CGen) is responsible for the traceability of activities arising from access to Genetic Heritage or Associated Traditional Knowledge, including those relating to economic exploitation. CGen's responsibilities include gathering information to ensure traceability and monitoring the use of Genetic Heritage and Associated Traditional Knowledge. The collegiate body is responsible for managing SisGen, creating a database for records, and monitoring information on the topic with other public administration bodies and other institutions in Brazil and abroad.

However, eight years after the enactment of Law 13,123/15, CGen still has some restrictions while fulfilling its function of tracking and monitoring access to Associated Traditional Knowledge. There are recurring situations, for example, where users of Genetic Heritage and Associated Traditional Knowledge incorrectly fill out the registration of their research and/or product development in SisGen, such as:

1. the existence of an ATK of identifiable origin when the records or notification indicate only genetic heritage;

2. the existence of ATK of identifiable origin when the records or notification only indicate associated traditional knowledge of unidentifiable origin.

CGen does not have adequate tools to check all registrations methodically. Due to the body's lack of structure, many records that declare access only to a Genetic Heritage or a Genetic Heritage associated with traditional knowledge of unidentifiable origin are not verified. There is also no regular verification of the terms of consent entered in the access registration.

A database with information on ATK already identified could be an essential tool to support CGen in verifying irregularities. By making available, in a systematic way, existing information on ATK, the database would also support researchers and companies in their research activities, product development, and Benefit Sharing processes.

Additionally, as a repository of information about ATK, the database can safeguard this knowledge for future generations[10] . It is not easy to fit traditional knowledge into conventional models of protecting the right to intellectual property, which do not consider the collective construction of knowledge or its ancestry and are often transmitted orally through generations. For all these reasons, registries, inventories, and databases, developed in collaboration with the holders of this knowledge, are fundamental instruments for safeguarding this heritage and guaranteeing the rights of its holders.

In Brazil, the database is an instrument provided for by legislation to support activities relating to Law 13,123/2015, especially concerning improved traceability for Benefit Sharing purposes. CGen is responsible for establishing criteria for creating databases for recording information about GH and ATK. However, this has not yet been done, and no database in Brazil brings together information on traditional knowledge already identified, its holders, previous access, FPIC granted or denied, and executed Benefit Sharing agreements (ARB), among other instruments. In contrast, several databases compile information about the GH already identified in the country, with some presenting limited information about ATK[11].

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The safeguarding of traditional knowledge is already ensured by the National Historical and Artistic Heritage Institute (IPHAN), so an ATK database can represent complementary support for the body.

THE RISKS ASSOCIATED WITH ASSOCIATED TRADITIONAL KNOWLEDGE DATABASES

If, on the one hand, the creation of an ATK database can significantly improve the institutional environment that guarantees the enforcement of Traditional Peoples and Communities' rights over their knowledge, on the other hand, leaders of Traditional Peoples and Communities, experts and the literature on the subject identify some risks that need to be mitigated along this path.

The **first** of them concerns the degree of publicity of the information. Many actors identify the risk of losing control of sensitive ATK, considered sacred, intimate, or secret to Traditional Peoples and Communities. This knowledge would lose these attributes once made available to a broad audience.

To mitigate this risk, information maintained in a database must follow different rules regarding the degree of public access, which may be confidential, public, or a combination of both, with different access levels or restrictions applicable to different categories of ATK and users. Traditional Peoples and Communities must effectively participate in defining these rules and have guaranteed the right to refuse the publication of their knowledge in a database, if applicable. The database also needs to ensure that the information recorded there (ancillary data) has gone through processes to obtain consent for access. Security must be ensured against intrusions and improper access to the database's confidential information.

The **second** risk identified concerns the stiffening or atrophy of the ATK registered in a database. Once inserted into a database, ATK can lose its natural dynamic of constant updating and innovation, which is part of the culture of traditional communities, and, as a result, be considered old or outdated.

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The Marlene Freitas da Silva Herbarium, from the State University of Pará, and the Dataplamt, from the Federal University of Minas Gerais, are some examples.

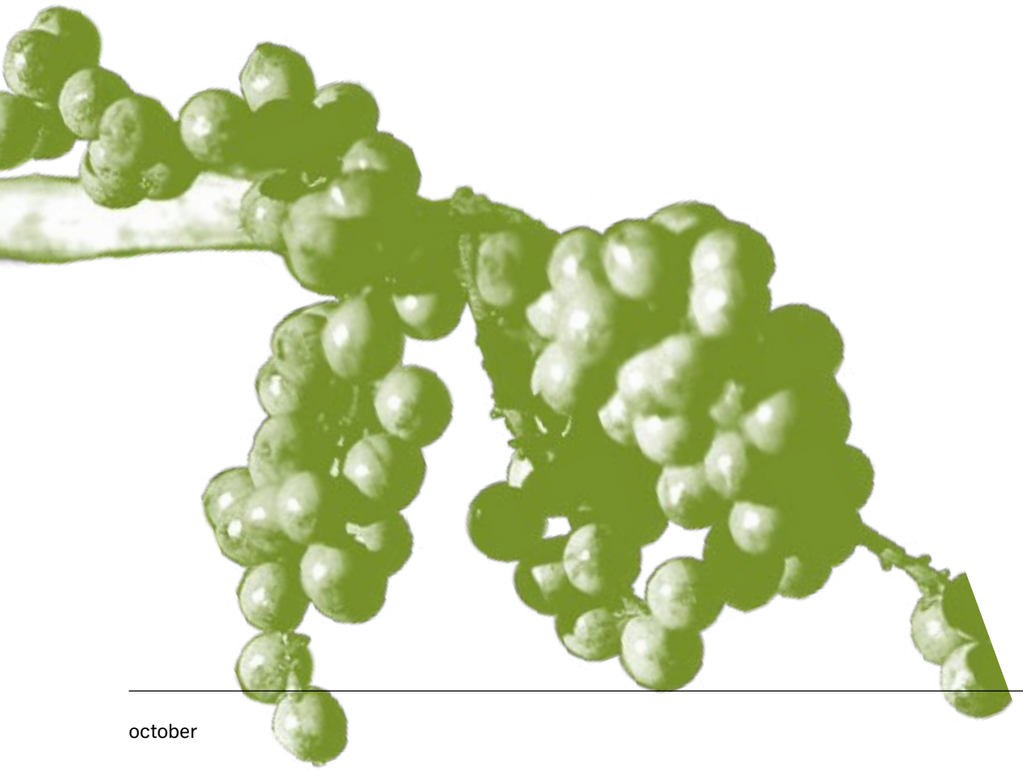
To mitigate this risk, holders may have the right to add, correct, remove, and manage information from the database, guaranteeing their autonomy and granting the dynamic nature of this knowledge.

The **third** risk is that the database is considered mandatory registration, so ATK holders have their rights acknowledged. Brazilian legislation already acknowledges the rights inherent to all traditional knowledge as intangible cultural heritage, regardless of its inclusion in any database. Under the legislation, a database will never be the only means of acknowledging ATK and will not replace other forms of acknowledgment, especially concerning direct relationships with communities that hold knowledge.

In this sense, to mitigate this risk, the database must have a non-mandatory and illustrative nature, consisting of another instrument for acknowledging ATK developed with the effective participation of Traditional Peoples and Communities.

In addition to these three risks, there is also opposition from some actors to the very creation of an ATK database, as they think that, instead of protecting, the tool exposes holders to researchers and companies by organizing and making it available in a single local information about their traditional knowledge. Although there is already much scattered public information about ATK, these actors believe that any additional publicity represents a problem in defending their rights.

Therefore, despite all the possible benefits from the development of an ATK database already highlighted, this study understands that such organization does not mean, according to legislation, that the ATK could be freely misappropriated. The study also confirms that Law 13,123/15 provides for the creation of the tool for traceability and protection of holders' rights.



Intellectual Property Law protection systems and traditional knowledge

Intellectual Property Rights (IPR) protection systems are a set of laws, regulations and mechanisms created by governments and international organizations to ensure legal protection and recognition of intellectual property rights. They originated in the context of Western industrialized society, with the emergence of the demand for protection of the intangible aspects of the production process, to prevent the misappropriation of creations, innovations and inventions without due permission or payment for use.

IPR protection systems can be important allies in protecting traditional knowledge. However, there are some challenges that need to be overcome. By 2023, conventional IPR systems:

1. do not adequately address the communal and shared characteristic of traditional knowledge, as they often focus on individuals;

2. have difficulty establishing the authenticity and origin of traditional knowledge for the purposes of legal protection, as it is transmitted orally and is often not documented in written or recorded formats;

3. have difficulty isolating traditional knowledge as intellectual property within conventional frameworks, as it is interconnected with the culture, language and daily practices of communities;

4. do not consider the dynamics, adaptation and evolution of traditional knowledge over time, which contrasts with the static nature of intellectual property protection;

5. do not consider that the protection of traditional knowledge cannot prejudice equitable access to information for cultural and educational purposes by communities nor violate their traditional practices;

6. do not dialogue with the governance mechanisms typical of traditional communities.

The *sui generis* systems

As a way of addressing issues not covered by IPR protection systems, the *sui generis* system (from the Latin “of its own gender”) emerged, aimed at protecting collective and traditional knowledge. The *sui generis* regime is proposed to build concepts, processes and mechanisms appropriate to the origin, purpose and functioning of ATK in the context in which they are inserted, incorporating essential principles and guidelines not only for the protection of ATK, but also for the conservation and preservation of biodiversity. In the same way as the IPR, the *sui generis* regime does not consider a single normative document, but a set of legal instruments that converge towards these objectives. The main representatives of the *sui generis* regime at the international level are Peru and Panama. The World Intellectual Property Organization (WIPO) acknowledges Brazilian Law 13,123/2015 as an example of a *sui generis* legal instrument.

3.
Experiences of Associated Traditional Knowledge database in other countries

This study considered the experiences of Peru, India, and Spain since they are active participants in the international debate about access to ATK and provide some lessons on documentation and organization of ATK.

THE PERUVIAN EXPERIENCE

Peru is one of the primary examples of a legal system of *sui generis* protection, as it protects, through a specific law (Law 27,811/2002), knowledge generated collectively and related to the use of biodiversity.

The country adopts the Common Regime on Access to Genetic Resources, established by Andean Decision 391, which defines Associated Traditional Knowledge as “all know-how, innovation or individual or collective practice, with an actual or potential value, that is associated with the resource genetic material, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes”[12] and provides procedures for their acknowledgment.

The step-by-step process for accessing the ATK in Peru can be summarized as follows:

1. submission of application with the contents and information about the project;

2. evaluation of the request by the competent national authority (Ministries of the Environment, Agriculture, or Production, depending on sectoral jurisdictions);

3. admission, which corresponds to the conclusion of the access contract with the involvement of the competent authority in negotiation and execution;

4. publication of the resolution in the Official Gazette or in a newspaper with national circulation, from which event the access will be considered granted;

12
CNI (Brazilian National Confederation of Industry). Accessing and sharing benefits on the global stage: Brazilian law compared to international standards / Brazilian National Confederation of Industry, GSS Sustainability and Bioinnovation, Natura Innovation and Product Technology – Brasília: CNI, 2017.

5. obtaining FPIC from the people who hold the respective ATK, as well as the obligation to inform other people who hold the same ATK.

Peruvian law provides for mandatory Benefit Sharing in two scenarios: (i) payment to the people who participate in the license contract; ii) in the case of ATK in the public domain[13], the allocation of a percentage of the value of gross sales of products to the Fund for Indigenous Development.

Peru also has one of the best-known experiences of confidential ATK documentation. The National Register of Collective Knowledge of Peoples can be accessed on the Portal de Conocimientos Tradicionales de los Pueblos Indígenas del Perú. As it is a confidential record, the platform only presents the terms in a list. For more information, it is necessary to contact the Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual (INDECOPI), the IPR protection body in Peru, responsible for managing the database, registering collective knowledge, technical assistance to indigenous communities and the availability of public data.

Community experiences of ATK cataloging are also found in the country, such as the database of traditional knowledge of the Quechua communities of Parque de la Papa, in Písac, in the Andes, with information available in the Quechua language. Access to the database is only possible through negotiation and the FPIC.

13
According to Peruvian legislation, knowledge accessible – for at least 20 years – to people other than indigenous peoples, through mass media, such as publications, or when referring to properties, uses or characteristics of a biological resource widely known outside the sphere of indigenous peoples and communities.

THE INDIAN EXPERIENCE

The Indian legislation does not provide legal provisions to regulate specific ATK access procedures. The same procedure is used to access genetic resources or traditional knowledge for research or commercial purposes.

The Biological Diversity Act and the Biological Diversity Rules determine the obligation of fair and equitable sharing of benefits arising from the use of traditional knowledge, and the Benefit Sharing may be either monetary or non-monetary. Payments are made to the National Biodiversity Authority (NBA) fund if the genetic resource provider or traditional knowledge provider is not identified or directly to the providers. Although the legislation does not mention the obligation to get the FPIC, the Benefit Sharing terms are mutually agreed upon among users, the NBA, and the providers.

The Biological Diversity Act also acknowledges that one way to respect and protect the ATK is through recording this knowledge at the local, state, or national level. India was a forerunner in the documentation of traditional knowledge, motivated by the need to combat biopiracy resulting from patents unduly granted internationally, and the cases of neem seeds and turmeric are outstanding.

Thus, the country has extensive experience in developing collaborative databases with the participation of civil society organizations, emphasizing the creation of the Traditional Knowledge Digital Library (TKDL)[14].

The TKDL is available in five languages (English, Japanese, French, German, and Spanish) and therefore allows access by foreign patent offices. The database is one of the global references for traditional knowledge records and houses a list of international patents linked to the Indian system of medicine. Even though it is a well-prepared catalog that largely contributes to preventing the improper use and recording of traditional knowledge, the TKDL was criticized for documenting knowledge based on majority literature, with the loss of essential values and connotations for original peoples, and for not involving ATK holders in the process[15].

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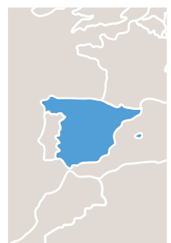
Other examples detailed in the research report are: Honey Bee Network, a public database managed by NGOs; Ayurvedic Pharmacopoeia, a platform organized by Bastyr University; Ayush Research Portal, managed by the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy; and Indian Medicinal Plants, Phytochemistry and Therapeutics (IMPPAT), a public database, coordinated by the Institute of Mathematical Sciences.

15
FREDRIKSSON, M. (2021). India's Traditional Knowledge Digital Library and the Politics of Patent Classifications. Available at: https://link.springer.com/article/10.1007/s10978-021-09299-7 . Accessed on June 2, 2022.

THE SPANISH EXPERIENCE



Spain has a long experience in studies and research on traditional knowledge, which began at the end of the 19th century, based on traditional medicine, popular medicines, and medical anthropology. It was a forerunner in Europe in initiatives concerning ATK, with the enactment of Law 42/2007 and the provision of legal instruments to protect ATK – among which is the possibility of cataloging through inventories.

While European Union Regulation 511/2014 defines ATK and genetic resources in a very vague and extensive manner, seven years earlier (2007), Spain had already

adopted a more detailed definition, incorporating natural and cultural elements into the concept as it defined it as the knowledge, inventions, and practices of local populations, linked to natural heritage and biodiversity, developed based on experience and adapted to the local culture and environment.

The ATK is safeguarded by the Intellectual Property Law (art.74 {5} of Law 42/2007). Thus, there is a specific procedure in the case of requesting and registering patents resulting from research and developments that have been accessed. Spanish legislation also determines that resources arising from sharing benefits for access to genetic resources are allocated to the Fund for Natural Heritage and Biodiversity and, as a priority, applied to the conservation and sustainable use of biodiversity. The Benefit Sharing resulting from access to ATK must be mutually agreed upon under the principles of the CBD and the Nagoya Protocol.

This legal provision also provides for the construction of inventories as mechanisms for pushing traditional knowledge. An example is the Spanish Inventory of Traditional Knowledge Relating to Natural Heritage and Biodiversity[16], coordinated by the Ministry of Agriculture, Fisheries, and Food and the main instrument for organizing and documenting ATK in the country.

In said publication, traditional knowledge is collected, recorded, and organized on cards. Only information obtained through ethnobiological techniques, using interviews and on-site observations, is included. Furthermore, the community must have practiced the knowledge in a given region for at least 30 years, a period in which transmission from one generation to the next and the adaptation of knowledge to the local culture and environment is considered likely[17].

Another exciting experience is the online platform CONECT-e, coordinated by the same Ministry. In the wiki format, CONECT-e is powered collaboratively. The platform aims to document and share traditional Spanish knowledge. In addition to entering information, citizens can comment on published data, and the content can be constantly revisited and revised. All their entries are georeferenced and validated by experts.

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Available at: < https://www.mapa.gob.es/images/es/tardio_etal2022_iectbavol2_tcm30-640207.pdf >.

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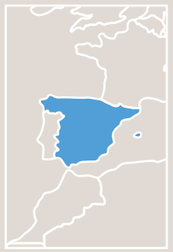
Summary table of international experiences with ATK databases

	Main ATK Databases	Type	Management	Objective(s)
PERU 	**Portal: Conocimientos Tradicionales de los Pueblos Indígenas del Perú**	Confidential registration	National Institute for the Defense of Competition and Protection of Intellectual Property (federal public body)	(1) Acknowledge traditional knowledge, through formal registration; and (2) guarantee INDECOPI a source of information to prevent biopiracy
ÍNDIA 	**Traditional Knowledge Digital Library (TKDL)**	Public database	National Institute for Scientific Communication and Information Resources (NISCAIR)	Protect knowledge of traditional medicine, preventing inappropriate appropriation or registration
	Honey Bee Network	Public database	Sustainable Technologies Research Society (NGO)	Document local innovations and traditional knowledge to (1) prevent inappropriate use; and (2) encourage innovation in impoverished areas
ESPANHA 	**Spanish inventory of traditional knowledge related to biodiversity**	Public inventory	Ministry of Agriculture, Food and Environment (federal public body)	(1) Know, conserve and promote traditional knowledge that promotes biodiversity and (2) compile data already published by the scientific community
	CONECT-e	Public database	Ministry of Economy and Competition and Ministry of Agriculture and Fisheries, Food and Environment (federal public body)	Encourage documentation and sharing of traditional knowledge

4.
An offer for an ATK database for Brazil

The offer presented here considers that the primary function of the database is to be a tool for monitoring the use and traceability of the ATK, managed by the relevant public bodies.

THE DATABASE GOVERNANCE

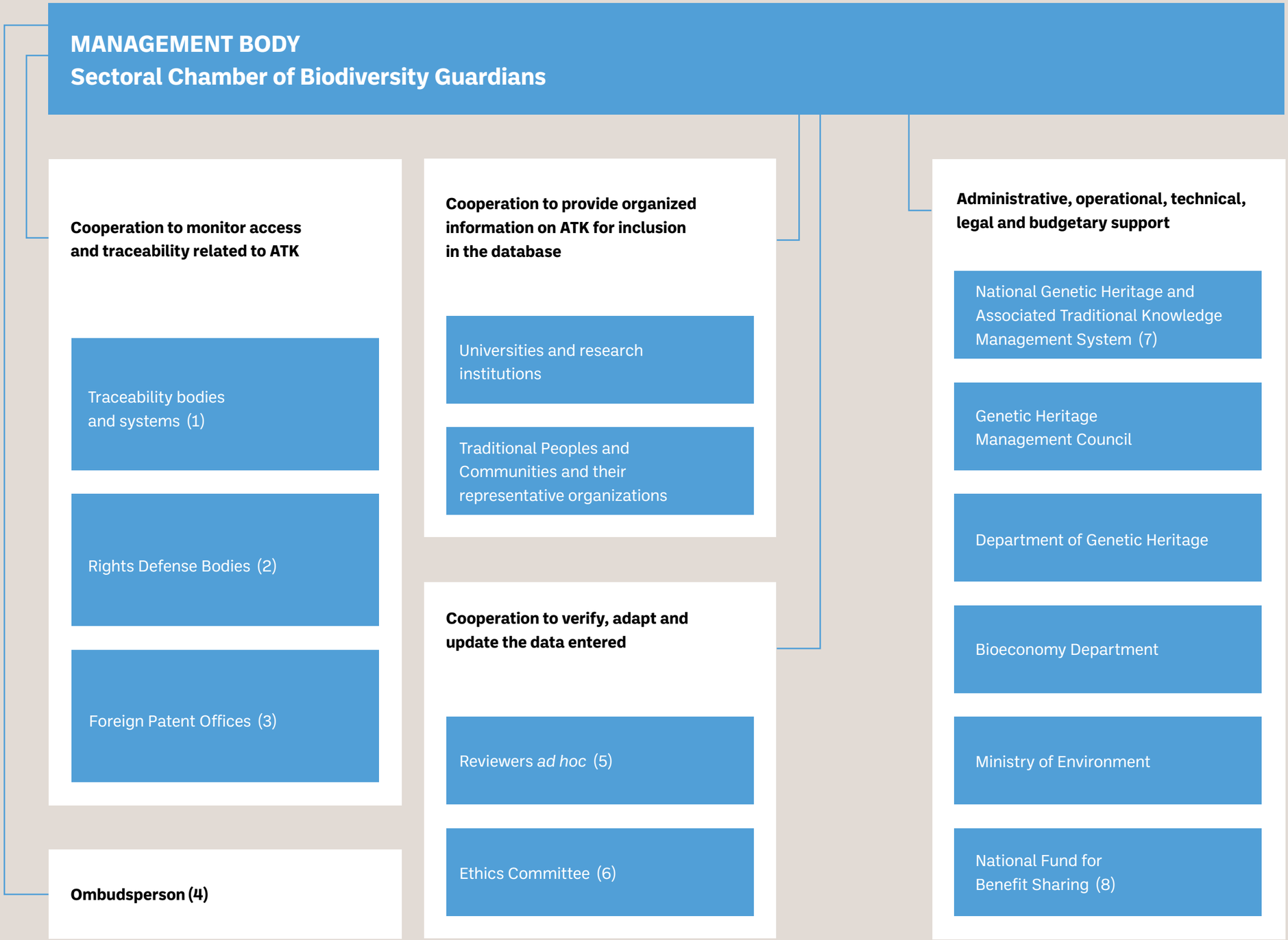
This offer considers that the Sectoral Chamber of Biodiversity Guardians, linked to CGen, is the appropriate body to manage the ATK database - considering the significance of the participation of Associated Traditional Knowledge's holders in defining the inclusion and disclosure rules of information and permission for consultation by different users.

With the technical, administrative, operational, and legal support of the Department of Genetic Heritage of the Bioeconomy Department of the Ministry of the Environment (DPG/SB/MMA), the Chamber would be responsible for implementing and managing the database and executing cooperation agreements or other equivalent legal instruments with other relevant bodies and actors, such as Traditional Peoples and Communities and their representative organizations.

It is also necessary to provide means to ensure that representatives of the communities in question culturally engage in the database governance.

On August 25, 2023, Instituto Escolhas delivered this offer for an ATK database to the Câmara Setorial das Guardiães e Guardiões da Biodiversidade (Sectoral Chamber of Biodiversity Guardians), an instance of the Genetic Heritage Management Council, as a way of subsidizing the body's actions relating to the traceability and monitoring of the use of ATK.

The proposed governance structure for Brazil's Associated Traditional Knowledge Database



(1) Cooperation with various public administration bodies to obtain information and collaborate to track ATK, namely: Ministry of Agriculture, Livestock, and Supply (MAPA); Integrated Foreign Trade System (Siscomex); National Council for Scientific and Technological Development (CNPq); National Technical Biosafety Commission (CTNBio), of the Ministry of Science, Technology, and Innovation; National Health Surveillance Agency (Anvisa); National Institute of Industrial Property (INPI); Ministry of Social Development and Fight Against Hunger; National System of Information and Cultural Indicators (SNIIC), of the Ministry of Culture; among other bodies, as provided for in article 5 of Decree 8,772/2016.

(2) Cooperation with bodies responsible for monitoring and investigating the commission of administrative infractions relating to access to GH and ATK, such as Navy Command; Ministry of Agriculture, Livestock and Supply; official bodies defending the rights of indigenous populations, traditional communities and traditional farmers, such as the Brazilian Institute of the Environment and Renewable Natural Resources (Ibama), the National Foundation of Indigenous Peoples (FUNAI), the Federal Public Ministry (MPF), among others, under the provisions of article 93 of Decree 8,772/2016.

(3) Cooperation with national bodies of other countries (such as the United States Patent and Trademark Office (USPTO)), foreign patent offices, or supranational bodies (such as the European Patent Office). By establishing partnerships, these bodies could consult the database to check the state of the art in patents applied abroad, thus preventing cases of biopiracy and misappropriation.

(4) A specific sector of database governance, a sector reporting to the General Ombudsman's Office would be responsible for receiving and addressing complaints and reports.

(5) Researchers ad hoc and representatives of the Traditional Peoples and Communities, who, through appointment, could carry out particular reviews on new entries in the database.

(6) A collegiate formed by representatives of Traditional Peoples and Communities and experts could be responsible for addressing and reviewing ethical issues.

(7) As it is an electronic system that already gathers information related to research activities carried out with access to the ATK, it must be integrated into the database.

(8) May provide resources for database implementation and maintenance.

THE DATABASE SOURCES

Ancillary data would be the primary source for developing the database. This refers to information that has already been previously disclosed and made public, such as: fairs, inventories, films, scientific articles, theses, dissertations, reports, records, catalogs, magazines, books, databases, teaching materials, booklets, other publications, and forms of organization and registration of ATK. Ensuring that this ancillary data is consistent with the provisions of Law 13,123/15 is essential. In other words, it must have been duly registered in SisGen.

The public authorities themselves already concentrate a series of organized information about Associated Traditional Knowledge in various bodies, departments, and initiatives, which could integrate the Associated Traditional Knowledge database, such as the National Historical and Artistic Heritage Institute (IPHAN), MAPA, the CNPq), CTNBio and other bodies.

Integration with SisGen is another critical step to ensure the database meets its goal of monitoring ATK use. Non-confidential information already made available by SisGen can expand the capacity of the ATK database, including:

SISGEN DATA	
User's information	• user's identification • responsible team and national and international partner institutions
Information about research or technological development activities	• actions, schedules, objectives, expected results, and application sector • request for acknowledgement of legal confidentiality case
Information about GH and ATK	• identification of the Genetic Heritage (origin, geographic coordinates, place of obtaining, variety – traditional, local, creole or breed – and whether it is an endangered species) • identification of Traditional Peoples and Communities providing the Associated Traditional Knowledge that has been accessed, even if it has been obtained from secondary sources, with georeferenced coordinates • proof of free, prior, and informed consent in case of identifiable ATK
Product information and Benefit Sharing	• declaration of legal exemption or non-incidence of Benefit Sharing • commercial identification of the finished product or reproductive material (sector of application; Anvisa, MAPA, and/or Ibama registration number and intellectual property right application filing number) • information on whether the GH or ATK used in the finished product is decisive for the formation of the market appeal and/or the existence of the functional characteristics of the product • forecast of the scope of manufacturing and marketing of the finished product or reproductive material (local, regional, national, or international) • access and shipping registration numbers that gave rise to the finished product or reproductive material • Benefit Sharing mode • Benefit Sharing Agreement (ARB)

THE DATABASE CONTENT

In order for the proposed database to fulfill the function of being primarily a tool for verifying ATK and GH access records and tracking access to ATK, the database must contain the following information:

TYPE OF INFORMATION	Information detail	Description
IDENTIFICATION OF THE GH TO WHICH THE ATK IS ASSOCIATED	**Species**	Scientific name
	Popular, traditional, local, or regional name(s) and other synonyms	Popular name of the species and other names by which it can be acknowledged, especially considering (i) regional variety and (ii) languages/dialects of the Traditional Peoples and Communities
	Genetic Heritage component type	According to the categorization used by SisGen, namely: fauna, flora (except algae), fungi, algae, microorganisms (except algae, fungi, and viruses), viruses or, if applicable, the impossibility of identification
TAXONOMY OF THE GH TO WHICH THE ATK IS ASSOCIATED	**Order**	Order to which the species belongs
	Family	The family to which the species belongs
	Gender	The genus to which the species belongs
LOCATION OF THE GH TO WHICH THE ATK IS ASSOCIATED	**Biome(s)**	The biome (s) in which the species is located
	State(s) - (Federative Unit(s)).	State(s) in which the species is located
	Transnational	The existence of the species in other countries
	Countries identified	Countries in which the species was located

TYPE OF INFORMATION	Information detail	Description
ATK	**Origin**	Identifiable Unidentifiable Locally adapted or creole breeds Traditional local or creole varieties Absent
	Usage Category	Includes traditional medicine; food; ways of living; modes of production Modes of cultivation; ecology; sacred; others; absent
	Usage subcategory	Indicates the subcategory, within an Associated Traditional Knowledge usage category, including: • Indicates the subcategory, within an Associated Traditional Knowledge usage category, including: • traditional medicine: integumentary, skeletal, joint, muscular, nervous, circulatory, respiratory, digestive, urinary, endocrine, others • food: human food, animal food • ways of living: arts, clothing, toys, paints, ornaments, sacred and/or religious, decorative, cosmetic, cleaning products • modes of production: tools, architecture, crafts, hunting, fishing • modes of cultivation: agriculture, livestock, fish farm, fishing, hunting, meliponiculture • ecology: animal, plant, fungus, microorganisms, climate, geology • sacred: to be defined by communities • others: toxic or harmful use, combustible use, aromatic Absent
	Respective use	Describes the use made by the guardian community of the Associated Traditional Knowledge
ATK	**Traditional Peoples and Communities (TPC)**	Indicates the name of the people or traditional community that holds the Associated Traditional Knowledge and also co-holders
	TPC Category	Indian people; quilombolas; traditional peoples and communities; family farmers or absentee
	TPC Location	• municipality in which the TPC holding the Associated Traditional Knowledge is located • geographic coordinates of the guardian community
	Community protocol	Informs whether or not there is a community protocol that guides the process of prior consultation and access to the Associated Traditional Knowledge prepared by the people or the holding community
	Acess	• indicates whether the Associated Traditional Knowledge is connected to an access record in SisGen • provides additional information about the access carried out, including the purpose of access, SisGen registration number, and results obtained
REFERENCES	**Images**	Informs whether or not there are images, including photos or drawings, in the secondary source of the reference
	Author/ organization	Informs the author or organization responsible for the secondary source of the reference
	References	Provides full reference details
	Insertion or cataloging date	Informs the date on which the information was entered on the platform or the date of publication of the article or book

DATABASE ACCESS RULES

The database must be consulted through user registration, identification with login and password, and adherence to its usage policy. Individual registration and login would allow the consultant's identification and the establishment of the time, place, and object of the query.

Different query permissions must be defined according to the user and information classification. To this end, the study proposes the following query environments[18]:

QUERY ENVIRONMENTS	
Registered public	Area available to the broad public, as long as the party is registered, where information authorized by the management body is permitted to be consulted, excluding that information classified as confidential, sensitive, and sacred.
Restricted – governance members	Area reserved for members of governance, with specific consultation authorizations granted by the management body that are necessary to carry out their work.
Restricted – Traditional Peoples and Communities holding ATK	Area reserved for Traditional Peoples and Communities holding Associated Traditional Knowledge to insert, delete, check, and update information about their knowledge.
Restricted – management body	Area reserved for members of the management body with free access to information.

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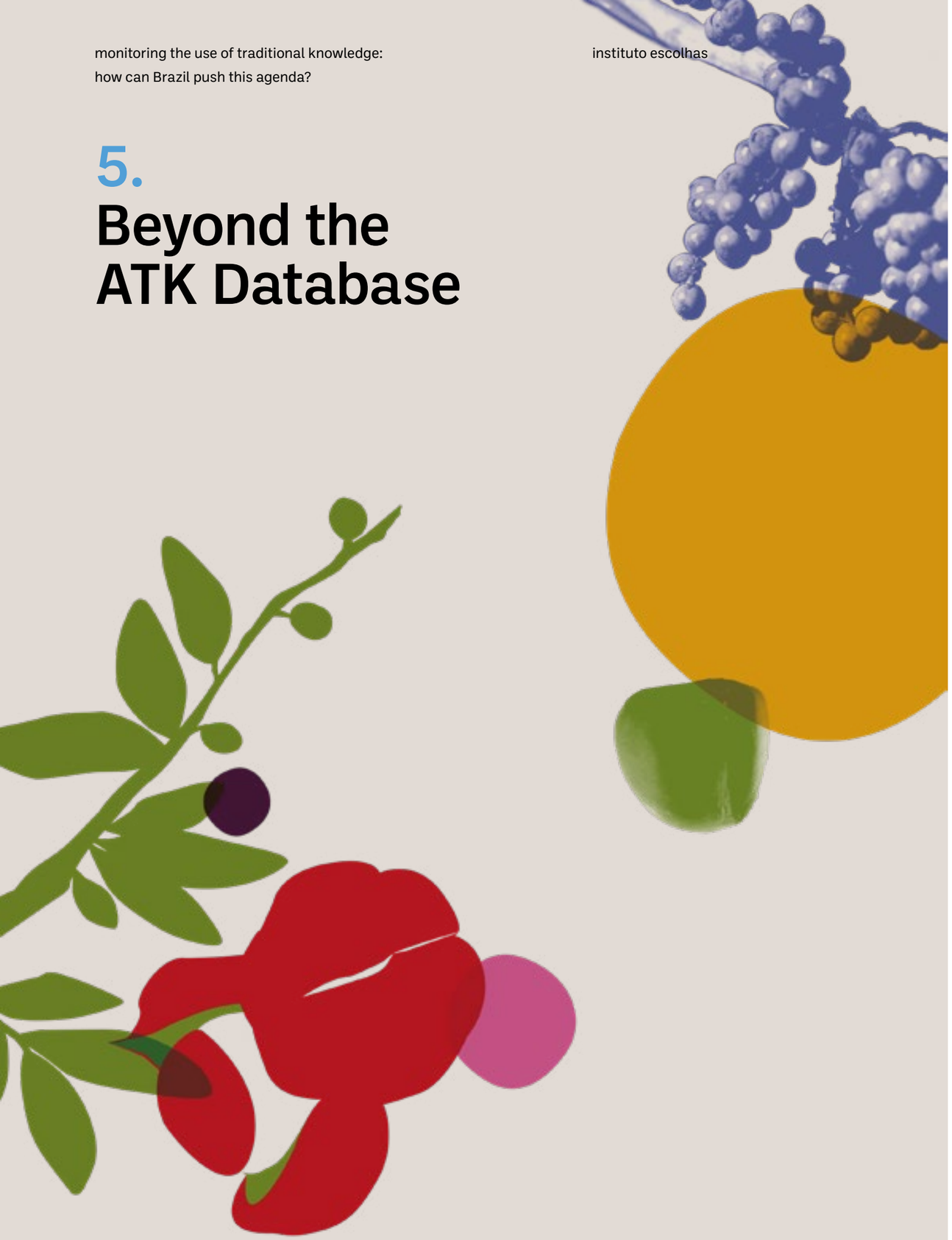
Inspired by the proposed regulation of the World Intellectual Property Organization (WIPO).



5. Beyond the ATK Database

In addition to trying to understand the challenges of creating an ATK database, the Instituto Escolhas study also sought to identify other mechanisms and actions that could improve the implementation of Law 13,123/15, concerning the enforcement of the rights of Traditional Peoples and Communities. To this end, representatives of Traditional Peoples and Communities who had experience with FPIC processes and Benefit Sharing were interviewed.

Three aspects appeared to be highly relevant to improving the experiences of Traditional Peoples and Communities with users who access Associated Traditional Knowledge: (i) knowledge of the legislation and its implementation processes; (ii) access to technical legal assistance; and (iii) transparency of information in ARB negotiations.

Even knowing what the legislation establishes on access to ATK, representatives of Traditional Peoples and Communities reported difficulties regarding the operational details of the Law that involve negotiation with researchers and companies.

According to interviewees, few researchers present research objectives previously and, subsequently, their results to ATK holders. Representatives of Traditional Peoples and Communities also stated, for the most part, that there are no rules in their communities, formal or informal, for people outside the community (external users) to access, use, or economically explore the ATK.

Training courses on Law 13,123/15 and its implementation, aimed at Traditional Peoples and Communities, are among the actions most mentioned by interviewees as necessary to improve the relationship between ATK providers and users[19].

Within the scope of ARB negotiations, the cases

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In May 2022, Instituto Escolhas promoted the course "Good Practices for research that accesses Genetic Heritage and Associated Traditional Knowledge". Online and free, the course was held in partnership with the Federal University of Amazonas (UFAM), the Federal Rural University of the Amazon (UFRA), the Federal University of the South and Southeast of Pará (Unifesspa) and the Federal Institute of Pará (IFPA) and is available in full on Instituto Escolhas' YouTube:
< https://www.youtube.com/playlist?list=PLzasBNcIWEx8HRq5GZdGYUSBqc9_dxABB>.

studied highlight the need to provide technical legal advice to holders and greater transparency regarding the commercial exploitation of products with ATK.

Most of the time, Traditional Peoples and Communities holding ATK do not have all the information necessary to negotiate Benefit Sharing values. For example, in some cases, there is no sharing of information about the volume of the finished product sold and how much the ATK represents in adding value to the finished product, which could be identified through comparative studies with other (conventional) products available in the market.

Quantitative indicators of finished products sold and added value concerning conventional products are information that can increase the commercial appreciation of bioeconomy products by ATK holders. Furthermore, this information can enable the development of an ATK valuation method.

CGen can guide users on methods of sharing indicators of final economic results between both parties. On the other hand, offering technical legal assistance to holders is very important. Negotiating Benefit Sharing agreements requires technical knowledge about what can or cannot be required and under what terms. This repertoire could be developed with the support of an experienced professional trained in the subject.

Data related to profit margins arising from economic explorations are confidential under legislation[20], which does not prevent them from being shared with ATK holders, as is the case with data relating to monetary volumes shared, which are also confidential.

The sharing of this information may be provided for in the ARB executed between the ATK provider and the user company, obliging the user company to declare annually to the relevant Traditional Peoples and Communities the sales volume of each product and the respective value-adding indicators, in addition to the annual net revenue, as provided for by Law 13,123/2015.

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The way to calculate net revenue is established by law. The user is obliged to declare, via SisGen, the annual net revenue resulting from the sale of finished products.

6. Conclusion

The bioeconomy is a recurring theme in Brazil's various levels of government, companies, and civil society. There is an undeniable concern to promote an economy combined with the conservation and restoration of ecosystems, ensuring income generation and social inclusion.

There is no way to achieve these goals without respecting and guaranteeing the rights of traditional peoples and communities.

Therefore, Law 13,123/15, which regulates access to Genetic Heritage and Associated Traditional Knowledge, should not be seen as an obstacle to the development of the bioeconomy, as some researchers and companies that deal with the legal framework think.

The opinion that this type of regulation is complicated and requires work is limited, as it underestimates the importance of the legal framework to promote biodiversity conservation and ensure that the economic benefits arising from the use of Genetic Heritage and Associated Traditional Knowledge are appropriately shared and remain in the country and the territory of origin.

As seen here, improvements in the Law's implementation environment are possible and necessary to ensure that the rights of Traditional Peoples and Communities holding Associated Traditional Knowledge are respected.

The proposal for an ATK database would significantly improve the identification of Traditional Peoples and Communities with knowledge when accessing GH and ATK by users and would expand the capacity of public bodies responsible for monitoring the use of GH and ATK. Furthermore, concrete measures could improve the still unequal relationship between Traditional Peoples and Communities and users, such as: (i) offering training to Traditional Peoples and Communities concerning the legal framework; (ii) offering technical legal assistance to Traditional Peoples and Communities; and (iii) promoting transparency of commercial information in ARBs.

This set of measures should be a priority for the current government (2023-2027), represented by the Ministry of the Environment and Climate Change, which aims to promote the bioeconomy more inclusively, with income generation and local development.

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how can Brazil push this agenda?

realization

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