

Article

Access to Genetic Resources and Associated Traditional Knowledge with Federal Science and Technology Institutions in Brazil: A Systematic Review of Regulatory Challenges

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RESUMO

A biodiversidade brasileira e o conhecimento tradicional associado são recursos estratégicos para o desenvolvimento científico, tecnológico e socioeconômico do país. Este estudo teve como objetivo analisar como as Instituições de Ciência e Tecnologia (ICTs) públicas federais brasileiras cumprem a Lei nº 13123/2015, com foco nos desafios regulatórios relacionados ao acesso ao patrimônio genético e ao conhecimento tradicional associado. Para isso, foi realizada uma revisão sistemática da literatura em bases como Periódicos Capes, Scopus e SciELO, abrangendo publicações entre 2015 e 2024. Os resultados destacam a obrigatoriedade de registro no Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado (SisGen) como requisito central para as atividades de pesquisa e inovação. Apesar de avanços, como o aumento do número de registros e da transparência das atividades, os desafios regulatórios persistem. As principais dificuldades incluem a complexidade do cadastramento no SisGen, a adaptação institucional às exigências legais e a ausência de estudos práticos que detalhem a aplicação da lei nas ICTs públicas federais. Conclui-se que, embora a Lei nº 13123/2015 represente um marco regulatório relevante, são necessários ajustes para garantir sua efetividade. A simplificação de processos administrativos, a capacitação das ICTs e a realização de estudos mais aprofundados são recomendados para fortalecer a conformidade regulatória e promover o equilíbrio entre a conservação da biodiversidade, a proteção dos direitos das comunidades tradicionais e o avanço científico e tecnológico.

Palavras-chave: biodiversidade, conhecimento tradicional, lei nº 13123/2015, SisGen.

ABSTRACT

The Brazilian biodiversity and associated traditional knowledge are strategic resources for the country's scientific, technological, and socioeconomic development. This study aimed to analyze how Brazilian federal Science and Technology Institutions (ICTs) comply with Law nº 13123/2015, focusing on regulatory challenges related to accessing genetic resources and associated traditional knowledge. A systematic literature review was conducted using databases such as Periódicos Capes, Scopus, and SciELO, covering publications from 2015 to 2024. The results highlight the mandatory registration in the National System for the Management of Genetic Heritage and Associated Traditional Knowledge (SisGen) as a central requirement for research and innovation activities. Despite advances, such as the increase in registrations and greater transparency in activities, regulatory challenges persist. The main



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difficulties include the complexity of the SisGen registration process, institutional adaptation to legal requirements, and the lack of practical studies detailing the application of the law in federal public ICTs. It is concluded that, while Law n° 13123/2015 represents an important regulatory framework, adjustments are necessary to ensure its effectiveness. Simplifying administrative processes, providing training for ICTs, and conducting more in-depth studies are recommended to strengthen regulatory compliance and promote a balance between biodiversity conservation, the protection of traditional community rights, and scientific and technological progress.

Keywords: biodiversity, traditional knowledge, law n° 13123/2015, SisGen.

Introduction

Biodiversity and associated traditional knowledge are essential for scientific advancement and technological innovation, particularly in countries with high biological diversity, such as Brazil (Bermudez *et al.*, 2022). The conservation and sustainable use of these resources are strategic for scientific development, socioeconomic strengthening, and cultural preservation. In Brazil, scientific research and technological development activities are governed by specific policies and legislation, including mechanisms to regulate the use of genetic resources and associated traditional knowledge (Mozini, 2022).

The primary legal framework regulating this use is Federal Law No. 13123 (Brasil, 2015), known as the Biodiversity Law, which came into effect on November 17, 2015, repealing Provisional Measure No. 2186-16 of 2001. This law establishes rules and conditions for using samples of Brazil's genetic heritage and associated traditional knowledge in research and technological development activities (Da Silva *et al.*, 2020; Dos Santos *et al.*, 2023; Ferreira *et al.*, 2021).

Vasconcelos (2016) highlights that the law applies to institutions in science, technology, and innovation, as well as to manufacturers and producers researching or exploiting products or materials derived from genetic resources or associated traditional knowledge. The legislation covers both scientific research agents and the final stages of the production chain, such as technology transfer and innovation, including individuals and legal entities (Folgoosi *et al.*, 2021).

The main concepts and definitions outlined in this law, according to Article 2 (Brasil, 2015), are:

- I - Genetic heritage: Genetic information of plant, animal, microbial species, or other organisms, including substances derived from their metabolism of these living organisms;
- II - Associated traditional knowledge: Information or practices of indigenous populations, traditional communities, or traditional farmers regarding the properties or uses, direct or indirect, associated with genetic heritage;
- III - Associated traditional knowledge of unidentified origin: Associated traditional knowledge where it is not possible to link its origin to at least one indigenous population, traditional community, or traditional farmer;
- IV - Traditional community: A culturally differentiated group that self-identifies as such, possesses a unique form of social organization, and occupies and uses territories and natural resources essential for their cultural, social, religious, ancestral, and economic reproduction, employing knowledge, innovations, and practices generated and transmitted through tradition;
- [...]
- VIII - Access to genetic heritage: Research or technological development conducted on a sample of genetic heritage;
- IX - Access to associated traditional knowledge: Research or technological development conducted on associated traditional knowledge linked to genetic heritage that enables or facilitates access to it, even if obtained from secondary sources such as fairs, publications, inventories, films, scientific articles, registries, and other forms of systematized records of associated traditional knowledge;



X - Research: Experimental or theoretical activity conducted on genetic heritage or associated traditional knowledge with the aim of producing new knowledge through a systematic process of constructing knowledge that generates and tests hypotheses and theories, describing and interpreting the foundations of observable phenomena and facts;

XI - Technological development: Systematic work on genetic heritage or associated traditional knowledge, based on existing procedures obtained through research or practical experience, aimed at developing new materials, products, or devices, improving or developing new processes for economic exploitation.

To ensure regulatory compliance for activities involving the use of genetic resources and associated traditional knowledge, Law No. 13123/2015 requires the registration of activities in the National Management System for Genetic Heritage and Associated Traditional Knowledge (SisGen) or prior authorization from the Genetic Heritage Management Council (CGen). During the economic exploitation phase, CGen must be notified to review the submitted registrations and notifications (Amarante Segundo *et al.*, 2018).

In Brazil, Science, Technology, and Innovation Institutions (ICTs) play a central role in knowledge generation and innovation (Brasil, 2022). In terms of scientific output, measured by the number of published articles, universities and public research institutes are the primary contributors, accounting for most of the country's scientific production (Brasil, 2023). Escobar (2019) notes that 15 public universities produced over 60% of Brazil's scientific knowledge from 2013 to 2018 and that collaboration with industry has grown exponentially since 2000, predominantly involving public universities. As key producers of research, public ICTs are also the main entities subject to Law No. 13123/2015 for using genetic heritage and associated traditional knowledge.

The Brazilian Federal Constitution (Art. 37) reinforces the principle of legality for public administration (Brasil, 1988). Research and publications falling under the scope of Law No. 13123/2015 must comply with its legal requirements, as non-compliance may result in fines ranging from R\$1,000 to R\$100,000 for individuals and R\$10,000 to R\$10,000,000 for legal entities (Brasil, 2015). Regarding industrial protection, the National Institute of Industrial Property (INPI) requires compliance with Law No. 13123/2015 as a prerequisite for registering technologies within its scope (Brasil, 2013).

Given the central role of public ICTs in research and innovation, this article conducts a systematic literature review to examine how these institutions address regulatory challenges and comply with Law No. 13123/2015, with a focus on accessing genetic heritage and associated traditional knowledge.

Following this introduction, which contextualizes the study and highlights the importance of Law No. 13123/2015 for ICTs, the article outlines the methodological procedures, explaining the systematic literature review and source selection criteria. The results are then discussed, emphasizing the impacts and challenges ICTs face in implementing the law. The final section presents the conclusions, summarizing the main findings and reflecting on regulatory compliance and its implications for research and innovation.

Material and methods

This study was conducted through a systematic literature review with a qualitative approach, following the method described by Galvão and Ricarte (2019). This method characterizes systematic reviews as structured research with reproducible and transparent steps, including the delimitation of the research question, selection of databases, formulation of search strategies, definition of inclusion and exclusion criteria, and systematization of results, ensuring methodological rigor and a high level of scientific evidence.



The purpose of this approach is to synthesize qualitative studies on the topic, providing information and interpretations that enhance the understanding of the application of Law No. 13123/2015 in Brazilian federal public ICTs. The methodological steps undertaken included delimiting the research question, selecting databases, formulating search strategies, establishing inclusion and exclusion criteria, and systematizing the collected data.

Data source selection and searches were performed using the Periódicos Capes, Scopus, and SciELO databases. Only articles and editorials in Portuguese were considered in this review. This choice was justified by the objective of prioritizing texts directly aligned with the Brazilian legal and institutional context, as Law No. 13123/2015 is a national legislation regulating specific practices in Brazil and requires analysis within its sociopolitical and legal framework. Additionally, this linguistic restriction aims to ensure a more precise analysis of local nuances and facilitate the inclusion of studies most relevant to discussions about federal public ICTs. Table 1 presents the descriptors used in the database searches.

Table 1. Descriptors used for database searches

Category	Descriptors
Law 13123	Law 13123; Law 13123 AND public ICTs; Law 13123 AND federal public ICTs; Law 13123 AND public Science and Technology Institutions; Law 13123 AND federal public Science and Technology Institutions
SisGen	SisGen; SisGen AND public ICTs; SisGen AND federal public ICTs; SisGen AND public Science and Technology Institutions; SisGen AND federal public Science and Technology Institutions
Access to Genetic Heritage	Access to genetic heritage AND public ICTs; Access to genetic heritage AND federal public ICTs; Access to genetic heritage AND public Science and Technology Institutions; Access to genetic heritage AND federal public Science and Technology Institutions
Associated Traditional Knowledge	Associated traditional knowledge AND public ICTs; Associated traditional knowledge AND federal public ICTs; Associated traditional knowledge AND public Science and Technology Institutions; Associated traditional knowledge AND federal public Science and Technology Institutions
Legal and Regulatory Framework	Legal framework AND public ICTs; Legal framework AND federal public ICTs; Legal framework AND public Science and Technology Institutions; Legal framework AND federal public Science and Technology Institutions; Regulatory framework AND public ICTs; Regulatory framework AND federal public ICTs; Regulatory framework AND public Science and Technology Institutions; Regulatory framework AND federal public Science and Technology Institutions
Biodiversity Law and Innovation	Biodiversity Law AND public ICTs; Biodiversity Law AND federal public ICTs; Biodiversity Law AND public Science and Technology Institutions; Biodiversity Law AND federal public Science and Technology Institutions; Biodiversity AND Technological Innovation
Genetic Heritage	Genetic heritage AND 13123

Source: Authors (2024).



For the selection of bibliographies, the following inclusion criteria were adopted: (i) open-access articles, (ii) Articles published from 2015, when Law No. 13,123/2015 (Biodiversity Law) came into effect, to 2024, (iii) studies addressing the application of Law No. 13123/2015 and related regulations in accessing genetic heritage and associated traditional knowledge within federal public ICTs, and (iv) articles written in Portuguese. The exclusion criteria were: (i) articles unavailable in full text in the consulted databases, (ii) duplicate articles, (iii) studies not addressing regulatory aspects of Law No. 13123/2015 and related regulations, and (iv) studies not focusing on federal public ICTs.

The process of selecting primary studies began with reading the abstracts of the articles, followed by a full-text review of those meeting the inclusion criteria. After this screening, each selected study was analyzed in detail. Relevant information was extracted and organized in a spreadsheet, categorizing the data by database, descriptor, title, authors, year of publication, and main contribution, with an emphasis on the application of Law No. 13123/2015 in federal public ICTs.

Results And Discussion

The results of this outline the challenges faced by federal public ICTs in implementing Law No. 13123/2015. Although this law established an important regulatory framework for the protection of genetic heritage and associated traditional knowledge, its application within ICTs still encounters significant obstacles, particularly regarding the complexity of registration and notification processes in SisGen, as well as the need for institutional adaptation to regulatory requirements. Below, we present a summary of the analyzed studies, highlighting the most recurrent aspects in the literature concerning the application of the Biodiversity Law in ICTs' research and innovation activities.

Initially, as shown in Figure 1, 101 articles were identified in the Periódicos Capes, SciELO, and Scopus databases. After applying inclusion and exclusion criteria, the number of studies was reduced to 10, focusing only on works directly relevant to the analysis of the application of Law No. 13123/2015 in federal public ICTs.

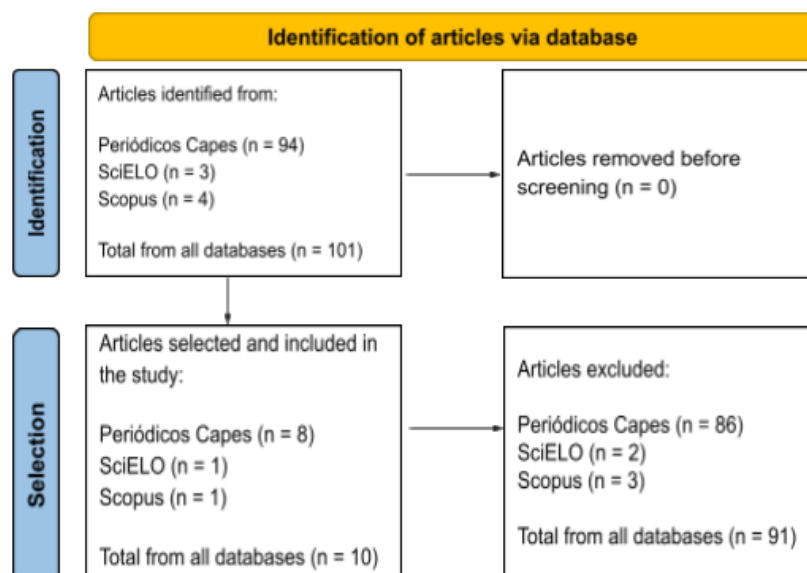


Figure 1. Flowchart of article identification and selection. Source: Authors (2024).

The Periódicos Capes database yielded the highest number of results, with 94 articles identified, of which 8 were selected. Only one article was extracted from the SciELO database and one from Scopus, suggesting



lower representativeness of these databases for this specific topic. Table 2 summarizes the excluded, included, and total articles by database and descriptor.

Table 2. Distribution of excluded and included articles by database and descriptor used

Descritores	Base de dados: Periódicos Capes			Base de dados: SciELO			Base de dados: Scopus			Total das 3 bases de dados		
	Total de artigos	Artigos excluídos	Artigos incluídos	Total de artigos	Artigos excluídos	Artigos incluídos	Total de artigos	Artigos excluídos	Artigos incluídos	Total de artigos	Artigos excluídos	Artigos incluídos
Lei 13.123	17	15	2	1	1	0	1	0	1	19	16	3
SisGen	10	7	3	1	0	1	1	1	0	12	8	4
Marco legal AND ICTs públicas	8	8	0	0	0	0	0	0	0	8	8	0
Marco legal AND Instituições de Ciência e Tecnologia públicas	14	14	0	0	0	0	1	1	0	15	15	0
Marco legal AND Instituições de Ciência e Tecnologia públicas federais	2	2	0	0	0	0	0	0	0	2	2	0
Marco regulatório AND ICTs públicas	2	2	0	0	0	0	0	0	0	2	2	0
Marco regulatório AND Instituições de Ciência e Tecnologia públicas	6	6	0	0	0	0	0	0	0	6	6	0
Marco regulatório AND Instituições de Ciência e	2	2	0	0	0	0	0	0	0	2	2	0



Descritores	Base de dados: Periódicos Capes			Base de dados: SciELO			Base de dados: Scopus			Total das 3 bases de dados		
	Total de artigos	Artigos excluídos	Artigos incluídos	Total de artigos	Artigos excluídos	Artigos incluídos	Total de artigos	Artigos excluídos	Artigos incluídos	Total de artigos	Artigos excluídos	Artigos incluídos
Tecnologia públicas federais												
Lei da Biodiversidade AND Instituições de Ciência e Tecnologia públicas	1	1	0	0	0	0	0	0	0	1	1	0
Biodiversidade AND Inovação Tecnológica	19	18	1	0	0	0	0	0	0	19	18	1
Patrimônio genético AND 13.123	13	11	2	1	1	0	1	1	0	15	13	2
Total de artigos	94	86	8	3	2	1	4	3	1	101	91	10

Source: Authors (2024).

Of the 10 articles selected for the final analysis, the majority (eight articles) were obtained from the Periódicos Capes database, reflecting the extensive coverage and relevance of this database for Brazilian scientific research, particularly on regulatory topics such as Law No. 13123/2015. Only one article was extracted from the SciELO database and one from Scopus, suggesting lower representativeness of these databases for this specific topic. This discrepancy may be attributed to the fact that the Periódicos Capes database includes a broader range of national academic publications, often focused on the implementation of Brazilian laws and public policies. Table 3 provides a detailed overview of the selected articles and their main contributions to the discussion on compliance with the Biodiversity Law in federal public ICTs.

Teixeira and Silva (2021) analyzed access to genetic heritage and traditional knowledge, as well as benefit-sharing between companies and traditional communities in Brazil, from Provisional Measure No. 2,186-16/2001 to the approval of Law No. 13123/2015. The authors highlight that between 2009 and 2011, Brazilian Institute of the Environment and Renewable Natural Resources (IBAMA) conducted rigorous inspections of research institutions, universities, and companies that were conducting research and developing products using Brazilian biodiversity resources without CGen authorization. Fines imposed during this period prompted these institutions to comply with existing regulations. The authors suggest that adherence to these norms could foster a more equitable and sustainable relationship among stakeholders.



Table 3. Description and main contributions of the selected articles

Database	Descriptor	Title	Authors	Year	Main Contribution
Periódicos Capes	Law 13123	Repartição de benefícios à luz da Lei nº 13123/2015: casos de empresas com acesso ao patrimônio genético e ao conhecimento tradicional associado	Patrícia Conceição Costa Teixeira, Lívia Maria da Costa Silva	2021	Emphasizes penalties for non-compliance and the need for benefit-sharing with traditional communities.
Periódicos Capes	Law 13123	Implementação da Lei Federal nº 13123/15 e da Convenção sobre Diversidade Biológica (CDB) no Brasil: com foco na promoção de conservação do uso sustentável da biodiversidade	Kassya Evellyn Nunes Araujo	2023	Highlights advances in implementing Law No. 13123/2015 and challenges to effective protection.
Periódicos Capes	SisGen	Legislação brasileira sobre o patrimônio genético e o conhecimento tradicional associado: muitas dúvidas para os pesquisadores de todas as áreas	Andreas Hörner, Tiango Aguiar Ribeiro, Rosmari Hörner	2018	Provides a critical view of the potential negative impacts of Law No. 13123/2015.
Periódicos Capes	SisGen	Acesso legal ao conhecimento tradicional associado à biodiversidade no Brasil: Novas perspectivas nacionais	André Luiz Gomes de Souza, Gabriel Francisco da Silva	2021	Explores the evolution and challenges of accessing genetic heritage and traditional knowledge with SisGen.
Periódicos Capes	SisGen	Prospecção Tecnológica em Sistemas de Informação: estratégias para regularização do acesso ao patrimônio genético de uma instituição de pesquisa agropecuária	Fábio Lima Cordeiro, Adelina do Socorro Serrão Belém, Alessandra Rodrigues da Silva	2019	Shows how technology aids in the regularization of genetic heritage access.
Periódicos Capes	Biodiversity AND Technological Innovation	A lei de inovação e a proteção do conhecimento tradicional	Sabrina Carvalho Verzola	2015	Suggests Technological Innovation Center (NIT) as a tool for integrating the protection of traditional knowledge with other organizations.
Periódicos Capes	Genetic Heritage AND 13123	Lei de Acesso ao Patrimônio Genético e seu impacto na pesquisa científica brasileira	Alexandro Cagliariari	2019	Identifies bureaucratic hurdles and SisGen's complexity in safeguarding traditional knowledge.
Periódicos Capes	Genetic Heritage AND 13123	A Lei N. 13123/2015 e o retrocesso na proteção dos conhecimentos tradicionais	Eliane Cristina Pinto Moreira, Leandro Barbalho Conde	2017	Critiques the reduced protection for traditional



Database	Descriptor	Title	Authors	Year	Main Contribution
					knowledge compared to earlier legislation.
SciELO	SisGen	Tecnologias e produtos decorrentes do acesso ao patrimônio genético brasileiro e aos conhecimentos tradicionais associados: estudo dos recursos informacionais relativos à Mata Atlântica	Celise Villa dos Santos, Fábio Mascarenhas e Silva	2023	Points to the need for improved data access and patent analysis to protect traditional communities.
Scopus	Law 13123	Marco regulatório do acesso ao patrimônio genético e aos conhecimentos tradicionais associados no Brasil: da MP 2186-16 à Lei Federal Nº 13123/2015	Caroline Bastos do Amarante, Maria de Lourdes Pinheiro Ruivo	2017	Assesses legislative developments and recommends adjustments to enhance the law's effectiveness.

Source: Authors (2024).

Araújo (2023) examined the implementation of Law No. 13123/2015 and the Convention on Biological Diversity (CBD) in Brazil, with a focus on biodiversity conservation and sustainable use. The author identifies gaps in the protection of traditional knowledge, noting that although the law recognizes the rights of traditional peoples and communities, these rights do not yet guarantee effective legal protection against the misuse of such knowledge. Araújo argues that the law, which prioritizes economic aspects over environmental ones, may compromise conservation goals and recommends revisions to strengthen the protection of genetic heritage and associated traditional knowledge.

Horner *et al.* (2018) discuss that, despite its environmental protection intent, Law No. 13123/2015 and Decree No. 8772/2016 introduce controversial elements that could hinder scientific research, international cooperation, and the rights of traditional communities. Bureaucratic hurdles and access restrictions to traditional knowledge are viewed as barriers to scientific and technological development. The authors point out that fines and warnings have already begun impacting research activities and question whether this legal structure will effectively contribute to the conservation and sustainable use of Brazil's biodiversity.

Souza and Silva (2021) analyzed the evolution of access to genetic heritage and associated traditional knowledge in Brazil, focusing on changes following the enactment of Law No. 13123/2015 and the creation of the SisGen system. They report a significant increase in SisGen registrations, which has facilitated the regularization and transparency of related activities. Universities and research centers, particularly in the North, where biodiversity and indigenous populations are prominent, emerged as key stakeholders. Between 2017 and 2020, 54.32% of SisGen registrations were from universities, 30.31% from individuals, with other institutions, such as public agencies and private companies, completing the distribution. The study emphasizes the need for enhanced monitoring to strengthen transparency and combat biopiracy.

Cordeiro *et al.* (2019) provide a comprehensive analysis of how technological prospecting, using the Ainfo information system at an agricultural research institution, supported the identification and regularization of liabilities associated with accessing genetic heritage in research conducted prior to the implementation of Law No. 13123/2015. The Ainfo system facilitated the inventory of past research activities, enabling researchers to comply with SisGen registration requirements by efficiently consolidating relevant publications and data. This



streamlined approach not only enhanced the transparency and traceability of genetic resource usage but also ensured adherence to the legal framework, highlighting the critical role of integrated information management systems in addressing regulatory challenges while fostering compliance.

Verzola (2015) discusses the need to integrate the Innovation Law, Industrial Property Law, and biodiversity legislation to promote justice and equity in the protection of traditional knowledge and genetic resources, particularly in the Amazon. The study highlights conflicts over ownership of traditional knowledge, which is often collective and non-identifiable, complicating the attribution of specific rights. Verzola proposes strengthening Technological Innovation Centers (NITs) to empower and protect traditional communities, encouraging their autonomy and citizenship.

Cagliari (2019) discusses how Law No. 13123/2015 seeks to regularize access to Brazilian genetic heritage and protect traditional knowledge by establishing rules for economic exploitation. The legislation requires all research projects to be registered with SisGen, prompting universities and institutions to adapt to avoid fines. Despite challenges, such as registering composite samples, the growing number of SisGen registrations indicates that the scientific community is adapting to the new law. The study highlights the importance of sustainably and responsibly utilizing Brazil's biodiversity, stressing that regulation should not impede research and scientific development.

Moreira and Conde (2017) critically analyze Law No. 13123/2015, arguing that it represents a setback in protecting the rights of traditional peoples and communities by limiting their participation in benefit-sharing. The authors advocate revising the law to ensure more effective protection of traditional knowledge and alignment with international law, suggesting amendments to safeguard these rights and fulfill Brazil's international obligations.

Santos and Silva (2023) analyze information sources on genetic heritage (GH) and associated traditional knowledge in Brazil, investigating their use for developing technologies and products. They identify gaps in available information and recommend methodologies to monitor biodiversity's economic use while safeguarding traditional communities' rights. The study highlights resources such as REFLORA, REFAUNA, and SpeciesLink, emphasizing patent analysis as a tool to combat biopiracy. Scientific publications are also cited as valuable sources on genetic heritage and associated traditional knowledge use. The authors conclude that integrating data on genetic heritage and traditional knowledge is essential for promoting sustainable development and technological innovation, stressing the need for standardized data collection and analysis to evaluate public policies and ensure biodiversity conservation.

Amarante and Ruivo (2017) examine the evolution of Brazilian legislation on access to genetic heritage and associated traditional knowledge, highlighting the central role of Law No. 13123/2015 as a regulatory milestone. The study demonstrates progress brought by the new law compared to the repealed Provisional Measure No. 2186-16, particularly in clarifying benefit-sharing mechanisms and expanding regulatory coverage for research, technological development, and economic exploitation activities. However, it also points out gaps and challenges in the practical implementation of the law, especially in ensuring the rights of traditional communities and achieving fair and equitable benefit-sharing, critical aspects for fulfilling the objectives of the Convention on Biological Diversity.

The reviewed articles converge on emphasizing the importance of Law No. 13123/2015 for managing genetic heritage and traditional knowledge in Brazil. Souza and Silva (2021) highlight SisGen's role in monitoring these activities, evidencing increased transparency and registrations. However, Horner *et al.* (2018) identify challenges such as bureaucracy, capacity building needs, and inconsistent information that hinder effective implementation. Traditional knowledge protection and community rights are widely discussed, with



authors like Araújo (2023) and Moreira and Conde (2017) pointing out gaps in legal guarantees and equitable benefit-sharing.

Despite differing evaluations of the law's effectiveness, with some authors noting progress (Souza & Silva, 2021; Cagliari, 2019) and others criticizing setbacks (Moreira & Conde, 2017), the findings suggest that implementing Law No. 13123/2015 remains a complex process. Adjustments such as simplifying administrative procedures (Cagliari, 2019) and strengthening rights protection (Araújo, 2023) could improve its applicability, fostering scientific research, sustainable development, and traditional community rights.

Conclusion

The analysis of the application of Law No. 13123/2015 in federal public Science and Technology Institutions (ICTs) revealed significant challenges and progress related to regulatory compliance and the management of genetic heritage and associated traditional knowledge. Key findings include the mandatory SisGen registration as a central element of research and innovation activities and the need for institutional adaptation to meet legal requirements. While acknowledging the importance of Brazilian biodiversity and the balance between regulation and research, the studies highlight the complexity of SisGen's registration and notification processes, as well as the lack of specific practical case studies within federal public ICTs.

Although most studies focus on the legal and regulatory analysis of the legislation, a gap was identified in the practical and detailed exploration of its application. This gap limits the understanding of how the law directly impacts research and innovation activities in these institutions. Thus, the study's objective was partially met, providing valuable insights into the general challenges and limitations of the law but lacking a more in-depth approach to the practical context of federal public ICTs.

Future studies are recommended to address the specific impacts of Law No. 13123/2015 on federal public ICTs through case studies and quantitative analyses detailing the volume and quality of SisGen records. Additionally, it is suggested to identify strategies to overcome regulatory barriers, such as simplifying administrative processes and enhancing institutional capacity, contributing to strengthened regulatory compliance and the sustainable use of genetic heritage and associated traditional knowledge.

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