# THE IMPACTS OF BIODIVERSITY LAW ON RESEARCH

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## Abstract

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Brazil in the year 2015 approved the law 13123/2015 which provides for access to genetic heritage, protection and access to associated traditional knowledge, as well as the sharing of benefits for conservation and sustainable use of biodiversity. Law 13123/2015 revoked Provisional Measure 2,186-16 of August 23, 2001, which for fifteen years was the legal framework of the matter. The law appears as an attempt to simplify procedures for research and development of technologies using biodiversity in the country. In this sense, the scope of this article is the analysis of the Brazilian biodiversity law, particularly with regard to the bureaucratic obstacles created to science by SisGen, which is the National System for the Management of Genetic Heritage and Associated Traditional Knowledge. Some alternatives to mitigate the impacts caused to science and technological development by the new legislation are being discussed in the political, business and academic spheres, and it is certain that the discussions in the thematic chambers are undoubtedly the most efficient way of interpreting the concepts, as well as constituting a true body for approximation and conciliation of the proposals of the sectors involved. The methodology to be used is descriptive and exploratory research, based on literature, case studies, historical analysis, interviews with researchers and other users of the System who are knowledgeable on the subject. The balanced and parity construction of the interpretation referring to the law 13.123/2015, duly articulated for a greater effectiveness to the protection of the genetic patrimony and for a greater legal security of the users should be the main focus of the actors involved in the effectiveness of this legal framework of biodiversity.

**Keywords:** Biodiversity. Impacts of law 13.123/2015; SisGen. Cadastre. law Lacunae. Sector chambers. CGen standard.

**Resumo**

O Brasil no ano de 2015 aprovou a lei 13123/2015 que dispõe sobre o acesso ao patrimônio genético, a proteção e o acesso ao conhecimento tradicional associado, bem como a repartição de benefícios para conservação e uso sustentável da biodiversidade. A lei 13123/2015 revogou a Medida Provisória nº 2.186-16 de 23 de agosto de 2001 que, durante quinze anos, foi o marco legal da matéria. A lei surge como uma tentativa de simplificar os procedimentos para pesquisa e desenvolvimento de tecnologias utilizando biodiversidade do país. Nesse sentido, o presente artigo tem como escopo a análise da lei da biodiversidade brasileira, notadamente quanto aos entraves burocráticos criados à ciência pelo SisGen, que é o Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado. Algumas alternativas para se mitigar os impactos causados à ciência e ao desenvolvimento tecnológico pela nova legislação estão sendo discutidas no âmbito político, empresarial e acadêmico, sendo certo que as discussões nas câmaras temáticas, indubitavelmente, constituem a forma mais eficiente de interpretação dos conceitos, bem como se mostra como verdadeiro órgão de aproximação e conciliação das propostas dos setores envolvidos. A metodologia a ser utilizada é a pesquisa descritiva e exploratória, baseadas n literatura, em estudos de casos, análise histórica,

entrevistas com os pesquisadores e demais usuários do Sistema que detenham conhecimento sobre o tema. A construção equilibrada e paritária da interpretação referente à lei 13.123/2015, devidamente articulada para uma maior efetividade à proteção do patrimônio genético e para uma maior segurança jurídica dos usuários deve ser o foco principal dos atores envolvidos na efetivação deste marco legal da biodiversidade.
**Palavras-chave:** Biodiversidade. Impactos da lei 13.123/2015. SisGen. Cadastro. Lacunas da lei. Câmaras setoriais. Normas CGen.

**Resumen**

En el 2015, Brasil aprobó la Ley13123/2015, que establece el acceso al patrimonio genético, a la protección y al conocimiento tradicional asociado, así como a la distribución de beneficios para la conservación y uso sostenible de la biodiversidad. Esta Ley revocó la Medida Provisional N° 2.186-16 del 23 de agosto del 2001, la cual, durante quince años fue el marco legal del asunto. La ley surge como un intento de simplificar los procedimientos de investigación y de desarrollo de tecnologías que utilizan la biodiversidad del país. En este contexto, este artículo tiene como objetivo analizar la ley brasileña de biodiversidad, particularmente en lo que se refiere a su "primera obligación", la cual está determinada por el registro y por la regularización de las actividades desarrolladas a partir del 30 de junio del año 2000, para los usuarios que realizaron acceso al patrimonio genético. La fecha límite para dicha regularización es un año, a partir de la fecha de disponibilidad propuesta por el SisGen, que es el Sistema Nacional para la Gestión del Patrimonio Genético y los Conocimientos Tradicionales Asociados.

Algunas alternativas para mitigar los impactos causados a la ciencia y el desarrollo tecnológico por la nueva legislación son discutdos en las esferas política, empresarial y académica, garantizando que las discusiones en las cámaras temáticas constituyan um modo más eficiente de interpretacion de los conceptos; además de exibirse como un verdadero órgano de aproximación y conciliación de las propuestas de todos los sectores involucrados. La metodología empleada em la investigación descriptiva y exploratória fue basada en: estudios de casos, análisis históricos, entrevistas con investigadores y otros usuarios del sistema conocedores de la temática propuesta. La construcción equilibrada e igualitaria de la interpretación que hace referencia a la Ley Nº 13.123 / 2015, articulada adecuadamente para una mayor efectividad en la protección del patrimonio genético y para una mayor seguridad jurídica para los usuarios, o cual debería ser el foco principal de los actores involucrados en la implementación de este marco legal para la biodiversidad.
**Palabras clave:** Biodiversidad. Impactos de la ley 13.123 / 2015. SisGen. Registro. Lagunas presentes em la actual ley. Cámaras sectoriales. Resoluciones

## 1. INTRODUCTION

The Brazilian biodiversity due to the immensity of exploited and unexploited riches is a highlight in the national and international scenario and has been attracting the attention of researchers, companies and the political class that intend to permeate the exploitation of these resources, aiming at the economic and social growth of the country.

By becoming a signatory of the Convention on Biological Diversity, Eco-92, which is a multilateral international treaty that deals with the protection and use of biological diversity in each signatory country, Brazil published the Legislative Decree No. 2 of 1994 that regulated this matter.

The convention established three main objectives, which are: the conservation of biological diversity (or biodiversity), its sustainable use and the fair and equitable distribution of the benefits arising from the economic use of genetic resources, respecting the sovereignty of each nation over the existing heritage in its territory.

The debates on the care of Brazilian biomes are of extreme importance today and fundamental to demonstrate that the country's greatest losses occur due to the illegal use of genetic resources, resources that are of unique importance for the country's development.

After a famous case of biopiracy (BioAmazonia x Novartis Pharma) the provisional measure 2052/2000 was enacted and then the provisional measure – MP no. 2186-01/2001 which became the legal framework on the matter until the publication of law 13.123/2015, which provides for access to genetic heritage, protection and access to associated traditional knowledge and the sharing of benefits for conservation and sustainable use of biodiversity.

On May 12, 2016, Decree no. 8,772/2016, which regulates Law no. 13,123/2015, was published. Among other provisions, in its article 20 provides electronic and on-line registration of declaratory nature, of the activities of access and remittance of the genetic heritage and of access to the associated traditional knowledge in the National System of Genetic Heritage Management - Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado (SisGen).

Intense discussion had prevailed in the academic environment regarding the bureaucratic obstacles created by law 13.123/2015 and its respective decree 8.772/2016, in its various aspects, and as inserted in the legislation, the research institutions may experience a retrograde step in Brazilian research.

The used methodology is descriptive and exploratory research, based on literature research, case studies, resolutions and technical guidelines from the competent bodies.

The main sources of research were the website of the Ministry of the Environment, SisGen, CGen, Fundação Oswaldo Cruz - Fiocruz and articles on the subject, the key words were Biodiversity Law, Law 13123/2015, Decree 8772/16.

## 2. BIODIVERSITY LAW.

The new legal framework for biodiversity, constituted by Law 13.123/2015, has the mission of promoting the sustainable use of Brazilian biodiversity and bringing legal security to its users.

This law provides for access to genetic heritage, the protection of and access to associated traditional knowledge and the sharing of benefits for conservation and sustainable use of biodiversity.

The sustainable use of biodiversity is now considered the foundation of the bioeconomy. The absence of public policies for the sustainable use of biodiversity implies neglecting Brazilian research, making its institutions obsolete and renouncing an asset with high economic potential.

It is a public and notorious fact that the industry is increasingly interested in expanding investments in the use of biodiversity.

According to an article published by the National Confederation of Industry (CNI) in 2018, the Industry recommendations for investment in biodiversity are based on three simultaneously developed pillars :

1) Ecosystems of innovation: production of knowledge and conditions for the use of this knowledge for the development of goods based on biodiversity.
2) Aggregation and appropriation of value: productive development, by the industry, of goods based on biodiversity in segments such as food, pharmaceutical, cosmetics, home care, energy, among others.
3) Legal and operational security: improvement of the legal and infralegal framework, offering favorable conditions for productive investment.

In the same report, it sets out the recommendations, whatever they may be to:

1) Develop financing lines and instruments and stimulate venture capital for enterprises that make sustainable use of biodiversity.
2) Foster R&D at various stages of development of new goods and services based on biodiversity resources.
3) Create and strengthen the Brazilian Biodiversity brand.
4) Prepare standardizing and guiding documents for companies and Scientific and Technological Research Institutions (STIs), in order to disseminate rules that guide investments in research and innovation and productive development.
5) Train and align oversight agencies and users of biodiversity resources (corporations, ICTs and international users).
6) Establish methodologies and criteria for recognition of Traditional Associated Knowledge - CTA.
7) Disseminate methods of valuing biodiversity to facilitate economic measurement of these resources to support investment decisions. Align national and international regulatory frameworks - particularly the Nagoya Protocol, which places rules on access to and use of biodiversity resources between countries - and improve the channel of communication between stakeholders. (source: CNI 2018)

In this regard, in a concrete hypothesis, it is essential to define the risks and consequences that Law 13123/2015 may cause to scientific production and public research institutions in Brazil and to the technological development of the country in general.

The academy, companies and public managers in Brazil have been discussing the various points of view, legal, environmental, political and economic, about the preservation of the genetic heritage of the country and the sustainable way to better develop it and create a favorable environment for its growth.

Therefore, the reasons that justify this research go through the necessary conceptualization and delimitation of the addressed topics, as well as the ways to solve and or minimize the negative impacts of biodiversity legislation on the evolution of Brazilian science.

**2.1 - The encountered obstacles in the registration activities of access to genetic heritage in SisGen - the national system of genetic heritage management and associated traditional knowledge.**

Under the terms of Article 3 of Law No. 13,123/2015, access to the genetic heritage for purposes of research or technological development and the economic exploitation thereof shall be preceded by registration, authorization or notification and shall be subject to inspection, restrictions and distribution of benefits under the terms and conditions established in this Law and its regulations.

Article 11 of the Law 13.123/2015 provides that access to the genetic heritage or associated traditional knowledge, the shipment abroad of samples of genetic heritage and the economic exploitation of finished product or reproductive material originating from access to the genetic heritage or associated traditional knowledge carried out after this Law is in force are subject to this law.

According to article 12 of law 13.123/2015, the following activities are subject to registration, thus:

> Art. 12. The following activities must be registered:
>
> I - access to the genetic patrimony or associated traditional knowledge within the country by a national, public or private natural person or legal entity;
>
> II - access to the genetic heritage or associated traditional knowledge by a legal entity based abroad associated to a national public or private scientific and technological research institution;
>
> III - access to the genetic patrimony or associated traditional knowledge carried out abroad by a national, public or private natural person or legal entity;
>
> IV - sending a sample of genetic heritage abroad for the purpose of access, in the hypotheses of clauses II and III of this caput; and
>
> V - sending a sample containing genetic heritage by a national legal entity, public or private, to provide services abroad as part of research or technological development.
>
> § The register referred to in this article shall have its operation defined in regulations.
>
> § Paragraph 2 The registration shall be made prior to the shipment, or the application for any intellectual property right, or the commercialization of the intermediate product, or the disclosure of the results, final or partial, in scientific or communication media, or the notification of the finished product or reproductive material developed as a result of access.

§ (3) The information contained in the database referred to in subsection IX of Article 6(1) shall be public, except for information that may jeopardize scientific or technological research or development activities or the commercial activities of third parties, which information may be made available upon authorization by the user.

Law 13.123/2015, in its articles 35 to 38, brings in its framework the procedures for adequacy and regularization of activities in disagreement with MP 2186-16/2001. (law 13.123 planalto site), which are:

Art. 35. The request for authorization or regularization of access and remittance of genetic heritage or associated traditional knowledge still in process on the date this Law comes into force shall be reformulated by the user as a request for registration or authorization of access or remittance, as the case may be.

Art. 36 The period for the user to reformulate the request for authorization or regularization dealt with in art. 35 shall be one (1) year, as of the date of availability of the registration by the CGen.

Art. 37. The user who carried out the following activities as of June 30, 2000, in accordance with Provisional Measure no. 2,186-16, of August 23, 2001, must comply with the terms of this Law within one (1) year from the date the registration was made available by the CGen:

I - access to genetic heritage or associated traditional knowledge;

II - economic exploitation of finished product or reproductive material from access to genetic heritage or associated traditional knowledge.

Single paragraph. For the purposes of the caption sentence, the user, in compliance with art. 44, shall adopt one or more of the following measures, as the case may be:

I - register the access to the genetic heritage or associated traditional knowledge;

II - to notify the finished product or reproductive material object of economic exploitation, pursuant to this Law; and

III - to distribute the benefits related to the economic exploitation performed as from the date this Law is enforced, pursuant to Chapter V, except when it has done so pursuant to Provisional Measure no. 2,186-16, of August 23, 2001.

Art. 38. The user who, between June 30, 2000 and the date of entry into force of this Law, carried out the following activities in disagreement with the enforced legislation at the time, shall be regularized under the terms of this Law, within one (1) year, counted from the date of availability of the Cadastre by the CGen:

I - access to genetic heritage or associated traditional knowledge;

II - access and economic exploitation of a product or process derived from access to genetic heritage or associated traditional knowledge, dealt with in Provisional Measure No. 2.186-16, of August 23, 2001;

III - sending abroad a sample of genetic heritage; or

IV - dissemination, transmission or retransmission of data or information that integrate or constitute associated traditional knowledge.

§ Paragraph (1) The regularization referred to in the caput is conditioned to the signing of a Term of Commitment.

> § Paragraph 2 In the event of access to the genetic heritage or the associated traditional knowledge solely for the purposes of scientific research, the user shall be exempted from signing the Term of Commitment, being regularized by means of registration or authorization of the activity, as the case may be.
>
> § Paragraph 3 The registration and authorization referred to in Paragraph 2 extinguish the enforceability of the administrative sanctions provided for in Provisional Measure no. 2,186-16, of August 23, 2001, and specified in art. 15 and 20 of Decree no. 5,459, of June 7, 2005, provided that the infraction was committed up to the day prior to the date on which this Law came into force.
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> § Paragraph 4 For the purpose of regularization at the National Institute of Industrial Property - INPI of patent applications filed during the term of Provisional Measure no. 2,186-16, of August 23, 2001, the applicant shall submit the proof of registration or authorization referred to in this article.

The SisGen, created with the purpose of assisting the Genetic Heritage Management Council - CGen - in the management of genetic heritage and associated traditional knowledge, currently constitutes one of the most controversial points of the legislation, facing many fierce discussions in academic, business and political circles.

The system was instituted by Decree 8772/16 and implemented by SECEX/CGEN Ordinance No. 1, of October 3, 2017, and began operating on November 6, 2017, thus allowing its users the following situations:

> a) the register of access to genetic heritage or associated traditional knowledge, as well as the register of sending a sample that contains genetic heritage for rendering services abroad;
>
> b) the register of genetic heritage sample delivery and the Material Transfer Agreement;
>
> c) authorizations for access to the genetic heritage or associated traditional knowledge and for remittance abroad, for the cases dealt with in Article 13 of Law No. 13 123, of 2015;
>
> d) the accreditation of institutions maintaining ex situ collections that contain samples of genetic heritage;
>
> (e) notifications of finished products or reproductive material and benefit-sharing agreements; and
>
> (f) certificates of regularity of access.

The registration also foresees the obligation of prior information to the system for the shipment of genetic heritage, the application for any intellectual property right, the marketing of the intermediate product, the disclosure of the results, final or partial, in scientific or communication media or the notification of finished product or reproductive material developed as a result of access.

Between June 30, 2000 and November 16, 2015, those who developed scientific research or technological development originating from access to Brazilian genetic heritage and/or associated traditional knowledge, accessed and economically exploited product or process originating from access to Brazilian genetic heritage and/or associated traditional knowledge, sent abroad a sample of Brazilian genetic heritage or disseminated, transmitted or retransmitted data or information that integrate or constitute associated traditional knowledge in disagreement with the legislation enforced at the time (provisional measure 2.186-16, of August 23, 2001), has a period of one (1) year, counted from the date of availability of the SisGen to regularize itself.

This is the term provided for in the new Brazilian biodiversity law, the law 13,123, in force since November 17, 2015, and regulated by decree 8,772, of May 11, 2016, which conditioned the deadline for regularization to the date of availability of SisGen, the National System for Management of Genetic Heritage and Associated Traditional Knowledge, under the control of CGen (Council for Management of Genetic Heritage).

It is noteworthy to point out that those who carried out the activities subject to the scope of the law between 17/11/2015 (the law's enforcement entry) and 05/11/2017 (day before the implementation and availability of SisGen) should also promote the regularization of their research.

The registration, of access activities, shipment, product notification, etc. is now mandatory, therefore, with the current law and the SisGen implemented. After November 6, 2017, it is fully obligatory before the precepts of the law and the decree.

The obligation to register, the difficulty of interpreting the concepts of the law and the lack of effective implementation of the system (SisGen II which is still being developed) have been delaying research and in many cases causing researchers to give up such research.

This, of course, becomes a discouragement and detriment not only to the researchers, but to the Universities and especially to the country, since there are several bottlenecks and dark spots that only bring unnecessary animosities and fear of punishment to researchers who prefer to interrupt their research.

An important alternative to ease this bureaucratic burden on researchers would be the integration of systems related to biodiversity, which should be the focus of the work to be carried out by the responsible actors (government), and for dialogue with academia and the private sector to be effective.

The relevance of this subject is notorious, since the construction of an integrated, functional and less bureaucratic system is essential for the development of the country.

Therefore, the discussion with all the sectors involved is extremely important for the country to advance in the balanced construction of legislation that can give greater effectiveness to the protection of biodiversity, research, security in legal relations, as well as applied technological advance.

Finally, it is important to mention that researches have always been and continues to be the hope of growth of a nation, being certain that the right, as a social fact that it is, must follow the development of the society and not induce its delay.

2.2 Interference in research, the UFMG example.

The obligation imposed by the biodiversity law to promote the adequacy/regularization/adjustment of the activities practiced by researchers from the year 2000 to the present given, i.e., to adapt/regularize/adjust 20 years of research, is totally unreasonable, as well as imposing absolutely onerous obligations on researchers and research institutions.

The Federal University of Minas Gerais - UFMG, as well as other institutions, first began studies on the legislation, promoting actions to disseminate knowledge about the regulatory instrument so that they could then initiate the procedures for the regularization of activities practiced in disagreement with the Provisional Measure 2186-16/2001 and then as recommended by articles 35 to 38 of Law 13123/15.

Especially for the regularization of research that generated technologies that were filed as patent applications at the National Institute of Industrial Property - INPI, there was a great effort to mobilize inventors first to declare whether or not, in their research, there was access to genetic heritage or associated traditional knowledge and then a second effort to promote registration on SisGen. (source: CTIT -UFMG)

Despite the great work involved, there are cases in which the researcher has not kept a record of all research/activities, or does not remember the details requested. It is also noted that researchers still have many doubts about the framing of their activities in the concepts provided for in the previous legislation and about how to insert the data in the new system made available (SisGen), and there is no clarity in the MP or help in clarifying doubts by the Ministry of the Environment.

In other cases, it was found that many researchers had already passed away and or had retired and could no longer assist, in view of the large time gap.

It is important to highlight that access information, in accordance with the biodiversity law, is a requirement for the maintenance of the patent, implying nullity, therefore the absence of registration.

Thus, it is asserted that the legal insecurity created by the law and its respective decree constitutes a clear violation of rights and principles provided for in the constitution, to the extent that they bring an unreasonable and disproportionate bureaucratic burden, violates a fundamental right not only of those directly affected, but of society as a whole, to the extent that the delay causes a setback in Brazilian research.

## 3. GENETIC HERITAGE MANAGEMENT BOARD (CGEN) AND ITS SECTORIAL CHAMBERS

The CGen is a deliberative, normative, advisory and appeal body of the Ministry of the Environment, created by Law no. 13.123/2015. It is a representative body made up of twenty board members, eleven representing federal public administration bodies and nine representing civil society, as provided for in Article 7 of Decree No. 8772/2016.

Responsible for coordinating the development and implementation of policies for the management of access to genetic heritage and associated traditional knowledge and benefit sharing.

With the entry into force of the Biodiversity Law, several demands have been made by sectors of civil society that have demanded a more equal distribution of representation in the CGen, thus giving the business sector, the academic sector, and the indigenous populations, traditional communities and traditional farmers their respective representatives in the body.

The board has Thematic Chambers and Sector Chambers that subsidize the plenary in making its decisions. These Chambers are composed of various experts, from various areas of knowledge, responsible for debates on issues brought by society and related to biodiversity law.

The main objective of the CGen is to make the national system of access and benefit sharing an instrument of social and environmental development, promoting the conservation of biodiversity alongside economic development.

As already exposed, one of the ways to mitigate the negative impacts of law 13.123/2015 is precisely through the debate with the sectorial Chambers, in order to be one of the entrances, with meetings open to the public, to the demands brought by various sectors.

For example, the Academy's Sectorial Chamber is responsible for conducting technical discussions and presenting proposals of interest to the academic sector.

3.1 - CGen standards (resolutions, normative instructions, technical guidelines, ordinances)

According to the manual for the preparation of normative acts in the ministry of justice and public security, normative acts are defined as being:

> A normative act is a legal norm that establishes or suggests conduct in a general and abstract manner, that is, without specific addressees and dealing with hypotheses. A normative act, as its name suggests, has a normative value, that is, it establishes norms, rules, standards or obligations. Unlike, for example, an ordinance appointing a servant in a commission position, an act of concrete effect which, although essential to ensure the necessary formality and publicity of the administrative act, has no normative load.

According to the same manual Resolutions, Normative Instructions and Ordinances are defined as follows:

> Resolution is the normative act issued by a collegiate with deliberative competence established in a legal or casual act. Depending on the attributions defined in the act of constitution of the collegium, the scope of this type of a Resolution may extend to external actors to the Ministry. Resolutions are typically signed by its highest authority (for example, the president of a council).
>
> Normative Instruction is a normative act issued by an authority to its subordinates, based on established or delegated competence, in order to discipline the execution of law, decree or regulation, without, however, transposing or innovating in relation to the norm it complements. The Normative Instruction typically aims to provide guidance to sectors, sections or decentralized units.
>
> Ordinance is the instrument by which the Minister of State or, by virtue of regimental or delegated competence, other authorities establish instructions and procedures of a general nature necessary for the execution of laws, decrees and regulations, and perform other acts within their competence. The effects of an ordinance may extend beyond the Ministry itself. ”

In turn, the technical guidelines are normative that aims to consolidate the understanding of technicians by avoiding positioning or discrepant judgments.

All these CGen rules have as content to establish procedures, clarify points of legislation, consolidate understanding on a certain theme, define concepts and most of them evidenced by legislation failure.

We realize today that the CGEN should be praised as it recognizes that, in certain situations, legislation is inapplicable and teratological and causes delays in economic development and the protection of biodiversity.

It is emphasized here that during the 3rd Extraordinary Meeting, held on October 31st, 2018, Resolution no. 19 was approved, which establishes an alternative form for the regularization of users who have carried out activities of access to genetic heritage or associated traditional knowledge, solely for the purposes of scientific research, pursuant to article 38, paragraph 2 of Law no. 13,123/2015.

The purpose of this resolution is to resolve the situation of users who intend to regularize, pursuant to article 38, paragraph 2 of law 13,123/2015, establishing that, by signing the Term of Commitment set forth in Annex VII of MMA Ordinance No. 378, of 10/01/2018, users will have a period of one (1) year, as of the date of signing of the aforementioned term, to specify the activities to be regularized. After the deadline for the description of the activities, users will have one (1) more year to register the activities to be regularized.

However, despite the intention to impose better criteria on biodiversity legislation, the resolution eventually created a "rework" by requiring users to first specify activities.

Recently the resolution CGEN 23/19 was published, in this normative the CGen ends up recognizing that the SISGEN, for certain circumstances, is not able to fully meet the needs of users regarding the registration of their activities, establishing expressly that the deadlines for regularization of the activities described therein have not begun.

Another important point among the several other gaps found in the legislation is the problem of lack of foresight as to the users who did not request the signature of the Term of Commitment and who intend to regularize their activities of access to genetic heritage between June 30, 2000 and November 17, 15, being at hand of the next demands and or the punishments already foreseen.

In order to solve this impasse, the Ministry of Environment is in the process of proposing a Resolution to the CGen, whose purpose is to create a new procedure for those users who have not complied with the legislation in time and now want to regularize their activities.

In this regard, it is important to understand that the law is influenced by our reality, it is a social fact. The dynamics of events demands a change of attitude in the very conception of law and the way it should be interpreted. We live in the third era, the digital era, the biotechnology era, and for that we must be prepared for this complex system of human iterations and for that reason we cannot be hostages of legislation that slows down this evolutionary process.

It is science, economic, cultural and social relations that must be complex and not the law.

## 4. THE LAW OF BIODIVERSITY IN TIMES OF COVID-19

In the midst of the Covid-19 pandemic with the worldwide determination of social isolation, with the paralysis of non-core activities we are faced with an absolutely exceptional situation that demands a balance in today's decisions so that they can have a positive repercussion in the future.

Humanity has already experienced other challenges such as the black plague and the Spanish flu, which has decimated millions of people in the world.

As a result of advances in medicine and technology, humanity has come to a feeling that it is unattainable, causing many to fall into social isolation, but others to despise it.

While we have no answer from science, the only way to preserve us is to listen to the voice of experience that the aforementioned diseases, black death and Spanish flu, have taught us.

In this sense, the CGen doesn't lag behind as it promoted, in a way, the flexibility of measures imposed by legislation, having been published on 06/04/2020, the Inter-ministry Ordinance No. 155/2020, which establishes a simplified procedure for the remittance of genetic heritage related to the situation of Emergency in Public Health of National Importance - ESPIN, which is dealt with in Decree No. 7,616 of November 17, 2011, specifically for the confrontation of the state of ESPIN due to Human Infection by Coronavirus (COVID-19).

Thus, it must be affirmed that the preservation and balance of the ecosystem play, per se, a role in protecting human beings from infections, epidemics and pandemics diseases. A catastrophe is necessary for us to seek measures that will leverage science for the protection of biodiversity.

## 5. CONCLUSION

To ensure its sustainable use, the new legal framework of biodiversity constituted by Law 13.123/2015, which has the mission of bringing legal security to the users of the system and promoting the sustainable use of Brazilian biodiversity regulated by Decree No. 8.772/2016 is enforced.

After more than four years of the law's effectiveness, discussion is still reigning and uncertainty prevails in academia, in the public sphere and, also, in the industrial sectors, regarding the bureaucratic obstacles created by the legislation.

This subject is an expensive one for Brazilians, due to the fact that we are "owners" of one of the greatest biodiversity on the planet, so the construction of integrated legislation (academia-government-industry), which are functional and less bureaucratic, would be fundamental and indispensable for legislation to achieve its objectives.

The current legislation has brought advances in relation to the previous one (MP 2186-16/2001), but still needs adjustments, especially in the case of surveys without commercial objectives.

The liability (adequacy/regularization) created by law 13123/2015, besides encumbering the research, brought a sensation of insecurity to the researchers, in view of the imprecision of its concepts, in many cases making its effective advance impossible and in others making it completely impossible.

The obligation to adapt/regulate the activities practiced since the year 2000, that is, 20 years ago, is beyond reason, as well as imposing totally disproportionate bureaucratic obligations on researchers and research institutions.

With regard to the registration system (SisGen), it is important to emphasize, at this time, the imperative need for its interoperability with other existing systems, which would facilitate the work of researchers.

The new legal framework for biodiversity, however, is imbued in its hermeneutics a process of culture change of the actors who are being and will be influenced by this legislation.

It was observed that the exploitation of nature and its resources has always been, from the beginning, a source of development for societies, initially for survival, later for the exchange of goods for the benefit of a community until these exchanges exceeded the limit of human needs and became the object of exploitation for the accumulation of wealth.

Awareness of how we should use the natural resources so abundant in our country will define our position in a global context.

Biotechnology, derived from biodiversity, is an urgent need both to save the resources available today for the not too distant future and, above all, to use science and technology as determinants for the country's development process.

The mapping of gaps between biodiversity protection and economic development has become strategic and fundamental in this process, as failures (legislative, in processes, in research) have a direct impact on the speed and form, of our development. Will we stay behind, doubling up, or will we emerge as a world leader on this issue?

Finally, it is important to emphasize that the law as a social fact must meet the desires of a society, given the protection-development dichotomy, but, fundamentally, the legislation must protect those people directly involved with the spirit (researchers), with interaction, exchange of experiences, dialogue, under the penalty of making their profession impossible.

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