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Biographies

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Brazil, example of a non-Nagoya Protocol country



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Brazil was one of the first countries to regulate access to genetic resources, and to associate traditional knowledge and benefit sharing through Provisional Act 2186-16 of 23 August 2001 for purposes of scientific research, bioprospecting, and technological development. After almost 15 years of many criticisms and demands from civil society and other sectors, Law 13,123 was sanctioned on 20 May 2015¹ and entered into force on 17 November 2015, revoking Provisional Act 2.186.

The Law, known as the Biodiversity Law, regulates Article 1, Article 8(j), Article 10(c), Article 15, and Article 16, items 3 and 4 of the Convention on Biological Diversity (CBD), besides regulating part of Article 225 of the Brazilian Federal Constitution. It provides for access to genetic resource (known in Brazil as genetic heritage), for protection and access to associated traditional knowledge, and for benefit-sharing for conservation and sustainable use of biodiversity and creates the Genetic Heritage Management Council (CGen), the Brazilian National Competent Authority for ABS. Therefore, despite the fact that Brazil has not yet ratified the Nagoya Protocol (NP) on Access to Genetic Resources and the Fair and Equitable Distribution of Access and

Benefit Sharing (ABS), the Law 13,123 is aligned with this international agreement.

The construction process of this new legislation was complex, considering the different interests and points of view of the various sectors of civil society, represented by academia, business sector, and holders of associated traditional knowledge, as well as those of the different ministries. The Law is regulated through Decree No. 8,772 of 11 May 2016 and to enable compliance with the legislation, the National System of Genetic Resource Management and Associated Traditional Knowledge (SisGen) was developed by the Ministry of Environment.

The Law 13,123 has a broader scope than the previous legislation and involves research, technological development, and economic exploitation of products arising from access to genetic resources (GR) and associated traditional knowledge (ATK). Due to the new definitions of GR [genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms], access to GR [research or technological development carried out on genetic heritage samples] and research [experimental or theoretical activity carried out on genetic heritage or associated traditional knowledge with the objective of building new knowledge by means of a systematic process that creates and tests hypothesis, describes and interprets fundamentals of observed phenomena and facts], the Law includes activities such as basic research related to taxonomy, phylogeny, epidemiology, and ecology, among others, as well as the obtention of genetic sequence from GR and their use.

Brazil set a precedent when it included genetic information in the scope of its ABS legislation, taking into account that in the last two meetings of the Conference of the Parties to the CBD (COP 13 and COP 14) and of the Parties to the NP (COP-MOP 2 and COP-MOP 3) the issue of Digital Sequence Information (DSI) was discussed

regarding its potential implications on the three objectives of CBD and the objective of the NP, which will be resumed at the next COP meeting. Brazil's position is to defend that if there is a product resulting from the use of DSI that benefit-sharing with the countries of origin of the genetic resource from which the DSI was generated is required. In cases of DSI originating from genetic resources coming from several countries, the proposal is for the monetary benefits to be deposited in a multilateral fund.

Based on the experience with the former legislation and to avoid uncertainties and questions relating to microorganism's origin, about whether they are native or exotic, the Law brings the determination that any microorganism isolated in Brazil is a Brazilian genetic resource. In this context, medical researchers should take into consideration that research involving pathogenic microorganisms, isolated or not isolated, present in human samples (e.g. blood, urine, tissues), shall also meet the requirements of the Law.

The prior informed consent (PIC) for accessing genetic resources was replaced by a self-declaratory registration in SisGen, which may occur during the phase of research and technological development. However, the registration must be conducted prior to shipment of the genetic heritage; application for intellectual property rights; marketing of intermediate product; dissemination of results (final or partial); or even notification of product developed from an access. Prior authorisation will also be required for cases involving foreigners, in which access takes place in the border area and Brazilian jurisdictional waters, on the continental shelf, and in the exclusive economic zone. Upon completing the SisGen electronic form, the registration receipt will automatically be issued. This document demonstrates that the user has provided the required information.

When there is a product derived from access to GR or ATK, notification in SisGen prior to economic exploitation is required. Benefit sharing only occurs when there is a product to be marketed and beneficiaries are the Federal Government or the ATK holders. Thus, the National Benefit Sharing Fund (FNRB) was established to receive money from the monetary benefit sharing and fines resulting from non-compliance with the legislation. These financial resources will be used to promote the conservation of biological diversity; recovery, creation and maintenance of *ex situ* collections; prospecting and training of human resources associated with the use and conservation of GR or ATK; among other initiatives. In the case of access to ATK the holders of this knowledge will be the beneficiaries and negotiate with the user. The Law also establishes that when monetary resources deposited in the FNRB are derived from the economic exploitation of products obtained from access to GR coming from the *ex situ* collections that are registered in

SisGen, part of this resource will be shared with them. Another option of benefit sharing is the non-monetary benefit sharing, which can be by means of implementing projects for conservation and protection of biodiversity and ATK. Non-monetary benefit sharing may be more advantageous in some cases than the transfer of resources to the FNRB.

Regarding shipment of genetic resources abroad, it is necessary to sign a Material Transfer Agreement (MTA) between sender and recipient and to register the shipment in SisGen. A new resolution (CGen Resolution 12 of 09/18/2018), allows a single MTA to be used for all shipments with the same foreign institution, which may be valid for up to 10 years and can be renewed. Once the material under the MTA is shipped to an institution, it becomes its property for an indefinite period. Additionally, a shipment invoice is filled with the description of the GR to be transferred, which will be sent with a copy of the MTA and the shipment registration receipt together with the GR. The Law authorises the transfer of GR to third parties, provided that the accompanying MTA contains the same provisions of the original MTA, which should occur for all subsequent transfers. This is a breakthrough, especially when GR is a microorganism and has to be deposited in an international culture collection, considering that the former legislation required that the new users of the deposited microorganisms had to negotiate a new MTA with the original depositor, which made the process very difficult.

Foreign researchers will be able to access native biodiversity only if they are associated with public or private Brazilian scientific and technological research institutions, which must take responsibility for registering the activity in SisGen. This requirement also applies to access Brazilian GR deposited in *ex situ* collections or to genetic sequences deposited in public databases, which were obtained from Brazilian GR. Since this requirement of association is also for basic research, there is a discussion for facilitating the process in these cases.

In this context it should be considered that the term access is interpreted in different ways by different countries. For Brazil, access is the same as the use of GR, that is, research and technological development involving these resources. While for the vast majority of other countries access is the collection or isolation of GR. Therefore, when using Brazilian GR deposited in *ex situ* collections, even before 2014 when Nagoya Protocol came into force, the Brazilian legislation must be complied with.

There were improvements regarding the former legislation, however many adjustments are still needed regarding the operational rules and SisGen. Within CGen, the Sectorial Chamber of the

Academy, which is an open forum and the main entities representing the Brazilian academy take part, was created to debate, elaborate and propose solutions to be further submitted for approval at CGen. The Chamber has been very active and have already proposed many resolutions and technical orientations which have been approved by CGen that have improved the process. The Chamber is also involved with discussions and proposals for the new version of SisGen that is being proposed to ameliorate and correct the problems identified during the use of the current system since the end of 2017. The expectation is that the process will be improved and will allow the compliance of the legislation in a more optimised and efficient way.

Conflicts of interest

The author declares no conflicts of interest.

Acknowledgements

This research did not receive any specific funding.

Reference

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Biography

Dr Manuela da Silva received her PhD degree in Food Science (Microbiology) at the State University of Campinas (UNICAMP) in 2002, part of which was conducted at the Food and Drug Administration (FDA-NCTR) in USA. In 2002 Dr da Silva joined the Oswaldo Cruz Foundation (Fiocruz), institution of science and technology under the Brazilian Ministry of Health, and currently works as Director of the Biological Collections from Fiocruz. She is a member of the Executive Board of the World Federation of Culture Collection (WFCC) and of the Executive Committee of the Global Genome Biodiversity Network (GGBN). She was member of the Brazilian National Competent Authority for ABS (CGen), from 2011 until 2015. At the moment she is the Coordinator of the Sectorial Chamber of the Academy of CGen.

DSMZ: the European Union's first Registered Collection under the Nagoya Protocol



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The Convention on Biological Diversity and the Nagoya Protocol have created new challenges for international microbiological research. With the implementation of the Nagoya Protocol in 2014, the European Union created a new voluntary legal mechanism, the Register of Collections, to

help users of collections, including culture collections, have an easier path to Nagoya Protocol compliance by using a so-called 'registered collection'. The Leibniz Institute DSMZ is the first, and so far only, collection to successfully be entered into the Register. The challenges and lessons