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Editorial

# The new Brazilian legislation on access to the biodiversity (Law 13,123/15 and Decree 8772/16)☆

The Provisional Act (Medida Provisória – MP) 2,186-16, of August 23, 2001, was the first legal framework to regulate access to Genetic Heritage (GH)[1] and Associated Traditional Knowledge (ATK)[2] in Brazil for purposes of scientific research, bioprospecting, and technological development. This MP was also responsible for the creation of the Genetic Heritage Management Council (CGen). However, this MP had very negative impact on scientific research, displeasing the academic community, which felt obstructed by bureaucratization and criminalized by administrative penalties, discouraging Research & Development (R&D) of Brazilian biodiversity resources.

The construction of a new legislation was complex, considering the different interests and visions among diverse sectors of civil society, represented by the academia, business sector, and holders of associated traditional knowledge, as well as the different sectors of government. Thus, it was almost 15 years before the publication of the "New Law on Biodiversity", Law 13,123 of May 20, 2015, which came into force on November 17, 2016. However, regulation occurred only six months after the Law came into force, after extensive opposition, debates, and criticisms, through Decree No. 8772 of May 11, 2016. To facilitate compliance with the legislation and to assist the CGen, the Decree created the National System of Genetic Resource Management and Associated Traditional Knowledge (SisGen). Due to various bureaucratic and administrative issues, SisGen was made available to the public on November 6, 2017, which is almost one year after the Law came into force.

The new Law, whose scope is more comprehensive than previous legislation, involves research, technological development, and economic exploitation of finished product[3] and reproductive material[4] from access to GH and ATK. According to the new definitions of GH, access to GH,[5] and research,[6] the Law includes activities that were not contemplated by the MP, such as research related to molecular taxonomy, phylogeny, molecular epidemiology, and molecular ecology, as well as the use of information from public genetic sequence databases, such as GenBank.

It is important to emphasize that to comply with the legislation, an institution must first appoint a legal representative, who will be responsible for the institutional register and will alone have the power to represent it within SisGen. An

☆ This text is partly based on previous publications by the authors: Oliveira, D.R., da Silva, M., 2016. Regulamentada a Nova Lei da Biodiversidade: Desafios e perspectivas para P&D no Brasil. Jornal da Ciência Notícias – SBPC, 15/06/16. da Silva, M., 2017. A Lei da Biodiversidade: sua origem e seu impacto na pesquisa e no desenvolvimento tecnológico com patrimônio genético e conhecimento tradicional associado, em: Nader, H.B., de Oliveira,F., Mossri, B.B. (Orgs.), A ciência e o poder legislativo: relatos e experiências. SBPC, São Paulo, pp. 184–194. Oliveira, D.R., da Silva, M., Carmo, F., Angeli, R. 2017. Cumprindo as exigências da Nova Lei da Biodiversidade – Lei 13.123/2015. Chamada à comunidade científica para a regularização e cadastramento de atividades envolvendo patrimônio genético e conhecimento tradicional associado. Jornal da Ciência Notícias – SBPC, 27/10/17.

[1] Information on genetic origin of plant, animal, microbial, or species of other nature species, including substances derived from the metabolism of these living beings.

[2] Information or practice of indigenous population, traditional community, or traditional farmers on the properties or direct or indirect uses associated with genetic heritage.

[3] Product whose nature does not require any type of additional productive process, derived from access to genetic heritage or to associated traditional knowledge, in which the component of genetic heritage or associated traditional knowledge is one of the main elements that add value to the product, which is available for use by the final consumer, being either a person or company.

[4] Plant propagation or animal reproductive material of any genus, species, or crop derived from sexual or asexual reproduction.

[5] Research or technological development carried out on a sample of genetic heritage.

[6] Experimental or theoretical activity carried out on genetic heritage or associated traditional knowledge, with the objective of producing new knowledge, through a systematic process of knowledge construction that generates and tests hypotheses and theories, describes and interprets the fundamentals of phenomena and observable facts.

institution may appoint more than one legal representative. After the validation of the institutional register by the Executive Secretariat of CGEN, the researchers of this institution will be able to register as applicants, which will be validated by the legal representative. Only after these procedures will the researchers be able to register their activities covered by the Law.

The replacement of the previous authorization (MP 2,186-16) by the current registry, which can be carried out during the research and technological development with GH and ATK in SisGen, resulted in significantly reduced bureaucratization of R&D in Brazil and is consequently one of the most positive changes in the Law. Nevertheless, a researcher needs to be very attentive to some cases that require prior registration, such as shipment of genetic heritage; application for intellectual property rights; marketing of an intermediate product; dissemination of results (final or partial); or even notification of a finished product or reproductive material developed from an access. Prior authorization 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 forms, the registration receipt or notification will automatically be issued. This document demonstrates that the user has provided the required information. In addition, the user may request a Certificate of Access Regulatory from CGen.

There are two possibilities for transportation of genetic heritage abroad: shipment and sending. "Shipment" is considered more critical because it involves transferring a sample of GH to an institution located outside Brazil for the purpose of access. In this case, it is necessary to sign a Material Transfer Agreement (MTA) between sender and recipient of the shipment abroad. "Sending" consists of transporting a sample from GH to provide services abroad, as part of research or technological development, in which the responsibility for the sample remains with whoever performs the access in Brazil. It is mandatory that, upon completion of the laboratory analyzes, the samples sent are destroyed or returned. In place of MTA, a legal instrument signed between the national institution responsible for the access and the partner or contracted institution will be required. In case of sample submitted for genetic sequencing, a legal instrument will not be mandatory, only the formal communication to the partner institution or contractor about obligations and prohibitions defined in the Law.

Another novelty of this legislation is the single paragraph of the article referring to the definitions used in the Law (Article 2), which ensures that any microorganism isolated in Brazil is part of the Brazilian genetic heritage. The purpose, in this case, is to resolve uncertainties and questions relating to its origin, about whether the microorganism is native or exotic, which was very frequent during the term of the previous legislation. In this context, biomedical researchers should take into consideration that research involving pathogens obtained from human samples (e.g. blood, urine, tissues) must meet the requirements of the Law, considering that this pathogenic microorganism is a genetic heritage. Thus, this type of research must be in accordance with Law 13,123, as well as with Resolution 466/2012 of the National Health Council, which establishes the ethical and scientific foundations for research with human beings.

Regarding the shipment of microorganisms, the Law authorizes the transfer of the sample to third parties, with the condition that the MTA that accompanies the sample contains the same provisions as the original MTA, which should occur for all subsequent transfers. This was a major breakthrough, especially when the objective of the shipment is the deposit into international microbiological collections.

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. This requirement also applies to access samples of Brazilian genetic heritage deposited in *ex situ* collections or to genetic sequences obtained from samples of Brazilian genetic heritage deposited in public databases. Due to this requirement of association, foreign researchers, concerned about complying with Brazilian legislation, may give up to studying Brazilian biodiversity. To exemplify, the case of the description of a new species that needs the comparison with other Brazilian species deposited in biological collections, abroad or in Brazil, using molecular techniques. This situation would require the foreign researcher to have to look for a researcher in Brazil, who agrees to take the responsibility for registering the research (description of the new species), in order to get associated to him/her only for accessing this genetic heritage. Therefore, it is necessary to find alternatives and conduct adjustments in order to decrease the negative impacts that this requirement may cause.

In the current legislation, Associated Traditional Knowledge (ATK) encompasses all "information or practice of indigenous population, traditional community, or traditional farmers on the properties or direct or indirect uses associated with genetic heritage." In addition, ATK is characterized in two ways: of identifiable origin – in which it is possible to link its origin to at least one indigenous population, traditional community, or traditional farmer; and of unidentifiable origin - when this linkage is not possible. In the case of ATK with identifiable origin, no research can be initiated before obtaining Prior Informed Consent (PIC).

Considering that in the new legislation, the Federal Government is the recipient of the benefit sharing, the National Fund for Benefit Sharing (FNRB), of a financial nature, was established. This Fund will receive the money from benefit sharing (Monetary Benefit Sharing) and fines, and aims to support actions and activities that acknowledge the value of genetic heritage and associated traditional knowledge, and promote its use in a sustainable way. To manage the resources of the FNRB, a Management Committee was created, and a National Benefit Sharing Program was established to promote conservation of biological diversity; recovery, creation, and maintenance of *ex situ* collections of genetic heritage samples; prospecting and training of human resources associated with the use and conservation of genetic heritage or associated traditional knowledge; and gathering and inventory of genetic heritage; etc.

When the economic exploitation comes from GH or ATK with unidentifiable origin, the Federal Government is indicated as the recipient of the benefit sharing to be deposited in