http://dx.doi.org/10.18623/rvd.v15i32.1268

THE LEGAL FRAMEWORK OF BIODIVERSITY AND ITS APPLICATION IN REGULARIZATION OF ACTIVITIES WITH THE USE OF BRAZILIAN GENETIC HERITAGE

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ABSTRACT

The Brazilian genetic heritage, object of world-renowned interest, had its use and protection regulated by Provisional Measure (MP) nº 2. 186-16/2001. After more than 15 years of validity, the MP was repealed by Law 13,123/2015, which, together with Decree No. 8,772/2016, presented new procedures for the economic use and exploitation of the national genetic heritage and associated traditional knowledge. The Legal Framework for Biodiversity (MLB), as the existing legal system became known, brought in its transitional provisions mandatory activity adjustment procedures for those who used the national biota under the PM without observing the procedures imposed at the time. The transitional provisions must be complied with by national and international users, within a period of one

year, as of November 6, 2017, under penalty of applying penalties to the researcher and institution to which he is bound and also to the importer of products manufactured abroad with the use of genetic heritage and traditional Brazilian knowledge. Faced with this new legislative demand, this study aimed to interpret the legal norms and systematically present the procedures to be adopted by the users, in order to comply with the transitional norms of the MLB.

Keywords: Genetic heritage; Law nº 13,123/2015; Biodiversity; Legal Framework for Biodiversity.

THE BIODIVERSITY LEGAL FRAMEWORK AND THE ENFORCEMENT TO REGULARIZE ACTIVITIES WITH BRAZILIAN GENETIC HERITAGE

ABSTRACT

The Brazilian genetic heritage, object of world-renowned interest, had its use and protection regulated by the Provisional Measure (PM) nº 2. 186-16/2001. After nearly 15 years of validity, this PM was substituted by the Law number 13,123 of 2015, which, together with the Decree 8,772/2016, introduced new procedures for the use and the economic exploitation of the national genetic heritage and the traditional knowledge associated to the genetic heritage. The Legal Framework for Biodiversity (LFB), this legal set of instruments became known, brought into its transitional provisions mandatory activity adjustment procedures for those who have accessed the national biota by the time of the validity of MP 2. 186-16/2001 and have failed observing its procedures. The transitional provisions must be complied with by national and international users, within a period of one year from November 6, 2017, only to avoid penalties to the researcher, the institution and even to the importer of manufactured products made abroad with the use of genetic heritage and traditional Brazilian knowledge. In view of this new regulation, the present study has interpreted the norms and systematically presented the procedures to be adopted by the users, in order to comply with the transitional norms of the LFB.

Keywords: *Genetic heritage; Law #13,123/2015; Biodiversity; Legal Framework for Biodiversity.*

INTRODUCTION

The protection and regulation of the use of Brazilian genetic heritage has been the subject of debate in the national and international scientific community (FERREIRA and SAMPAIO, 2013, FERRO *et al.,* 2006; SACCARO, 2011). Brazil, as the largest holder of the world's genetic patrimony, is home to approximately 13% of the world's available biodiversity (LEWINSOHN, TM & PRADO, PI, 2006; VASCONCELOS, 2012), with species richness and a high degree of endemism both in the elvel of species and the higher taxonomic categories (FERREIRA E SAMPAIO, 2013; MITTERMEIER, 1997; GERRA et al., 2015).

The Brazilian Constitution of 1988 recognized the intrinsic value of natural resources existing in the country by expressly inserting in its Article 225 the guarantee to an ecologically balanced environment and the collective duty to preserve and defend the national environmental patrimony (BRASIL, 1988). Notwithstanding the constitutional provision, the regulation of the use and protection of national biota came only years later, following the ratification of the Convention on Biological Diversity (CBD), which increased the genetic resources and traditional knowledge of communities when associated with them to goods of sovereign use and disposition of States, respecting the Charter of the United Nations and the principles of International Law (BRAZIL, 1994).

After incorporation into the national legal framework of the CBD, through Decree No. 2,519 (BRAZIL, 1998), several bills and a proposed amendment to the Constitution were processed in the National Congress with the objective of regulating access to and protection of genetic heritage Brazilian. However, in spite of the proposition of these projects, some authors consider that these were not properly discussed and processed, generating legal loopholes that hindered the protection of the national biodiversity and the distribution of benefits obtained with the use of biota (BRAZIL, 1998; AZEVEDO, 2005; GODINHO and MACHADO, 2011).

The case of the agreement between Novartis Pharma AG (a multinational drug company based in Switzerland) and the Bioamazonia Social Organization, responsible for the Brazilian Program of Molecular Ecology for the Sustainable Use of the Amazon, stands out. In this agreement, it was anticipated that Novartis would have the right to access and exclusive use of existing genetic material in the Amazonian territory,

in exchange for derisory benefits (BENSUSAN, 2003; GODINHO E MACHADO, 2011; MENUCHI et al., 2016). The national commotion and legal gaps, which existed due to the lack of CBD regulation, led to the annulment of the agreement (BENSUSAN, 2003).

In this context, the absence of both national regulations for the use of national genetic patrimony and of popular pressure contrary to the agreement between Bioamazonia and Novastis led to the issuance of Provisional Measure (MP) nº 2. 186, which came into force on the 29th June 2000, regulating access to genetic heritage (PG) and associated traditional knowledge (CTA) (BRASIL, 2001).

However, the MP, edited in this scenario, ignored draft laws and constitutional amendment in process, as well as debates in the academic and social milieu (MENUCHI et al., 2016), creating bureaucratic difficulties and conceptual inaccuracies that prevented (NADER et al., 2017, AZEVEDO, 2005, SACCARO, 2011, TÁVORA et al., 2015).

In view of the inability of the Public Prosecutor's Office (16 times before 2001) to meet its objectives, and in the face of the numerous criticisms presented, mainly by the scientific community, the Executive was led to present Bill 7,735/2014, resulting in May 20 (Law No. 13,123), which repealed Provisional Measure No. 2,186-16/2001 and was later regulated by Decree No. 8. 772/2016 (BRASIL, 2015, BRAZIL, 2016, MOREIRA et al., 2017). This new set of legislation is considered today as the Legal Framework for Biodiversity (MLB), as it presents new procedures to be observed in the use of the Brazilian biota (FERREIRA and SAMPABIO, 2013; FERRO et al., 2006; NADER et al, 2017).

The MLB is not restricted to new procedures initiated after its entry into force. In its text, there is a one-year period for the reformulation, regularization and adaptation of several activities developed irregularly during the MP's term. This period was started on November 6, 2017, when the National Genetic Heritage and Associated Traditional Knowledge Management System (SISGEN) (BRAZIL, 2017d) was made available. As a consequence of the noncompliance with this deadline, the application of a pecuniary fine to the institution or company and also to the natural person linked to it, in the variable amount of R$ 1,000. 00 (ten thousand reais) to R$10,000,000,00 (ten million reais) (BRAZIL, 2015; BRAZIL, 2016).

Due to the new provisions and the reduced term for regularization of activities, it is essential to understand the procedures and activities that

involve the genetic heritage of Brazil. Thus, the purpose of this study is to present, in a systematic way, the activities to be adjusted (reformulated, adequate or regularized) and the procedures to be adopted by the users, in order to comply with the MLB transitional norms. This article is organized according to the concepts and delimitations of the activities and procedures described in MLB.

1 OF THE SCOPE AND OF THE TRANSITIONAL RULES

The transition rules, provided for in Chapter VIII of Law 13,123/2015 and also in Decree No. 8,772/2016, should be applied to the activities carried out in force of the provisional measure (06. 30. 2000 to 16. 11. 2015), which, at the time of its accomplishment, did not fulfill or only partially fulfilled the requirements set forth in the MP (BRAZIL, 2015, 2016).

Figure 1 shows the time frames that define the activities subject to the application of the transitional rules.

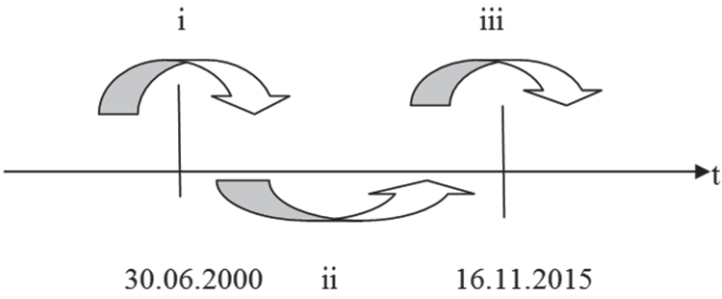

Figure 1. Temporal frameworks that define the activities subject to the application of the transitional provisions of Chapter VIII of Law 13,123/2015 and Decree No. 8. 772/2016.

According to figure 1, the transition rules cover: i) activities initiated prior to the effective date of the MP, as of 06. 30. 2000, but still in progress irregularly, as of this date; ii) activities initiated and finalized

irregularly during the term of the MP (06. 30. 2000 to 16. 11. 2015); and iii) activities initiated regularly during the Public Prosecutor's Office and in progress after the beginning of the Law, on November 17, 2015 (BRAZIL, 2015, 2016).

The MLB brings a distinction as to the adjustment procedure for the activities to be reformulated, regularized and those to be appropriate. Are considered, for adjustment purposes, the activities that were planned in the Provisional Measure. The actions that were not included in the PM's forecast list and were the result of innovation in the new legislative set are not included in the transition rule and therefore do not need to be repaired. Accordingly, the activities listed in **item ii**, regulated in **items i** and **iii** of figure 1, and reformulated, should comply with the activities set forth in **item iii** that awaited the processing of the application for registration or authorization to carry out activities (BRASIL, 2015; 2016).

In a broad sense, Decree No. 8,772/16 lists in article 3, paragraph 2, the means by which an activity would be considered finished, allowing the Genetic Heritage Management Council (CGEN) to define other means of closure. This delimitation becomes important for the temporal framework of activities and for the identification of the procedure to be adopted (BRAZIL, 2016).

Two legal principles guide the interpretation of the MLB transitional provisions. The first is that of legal certainty, which guarantees social stability and protects citizens from sudden changes in their legal system. According to this principle, supervening changes in legal norms can not retroact to reach already consolidated situations, thus ensuring confidence in current norms (MEIRELLES, 2016). The second is the constitutional principle of non-retroactivity of the law, which establishes in article 5, item XXXVI of the Federal Constitution, that the law can not retroactively harm the acquired right and the perfect juridical act (BRAZIL, 1988; MEIRELLES, 2016). Respect for the perfect legal act means prohibiting a new law from requiring new requirements, definitions and consequences that are different from those existing at the time of the act that fulfilled all the elements necessary for its formation (BRASIL, 1988).

The principle of non-retroactivity of the law makes it impossible to apply a later law that is more beneficial, when administrative sanction has already been applied under the repealed law (JUSTEM FILHO,

2005). Thus, those who received sanctions at the time of the MP will not be amnestied because the MLB fails to frame certain conduct as an administrative infraction.

Based on both principles, activities initiated and finalized during the period of MP and that were in accordance with this, should not be adjusted, administrative sanctions applied can not be changed and, also, the concepts used to define an activity should be the ones that were in force at the time of its accomplishment (BRASIL, 1942).

2 ACTIVITIES TO BE ADJUSTED

Chapter VIII of the Law and the Decree describe the transition rules and relate the activities that should be reformulated, appropriate or regularized, providing for different procedures for each form of adjustment. Specifically, Articles 35, 37 and 38 of Law 13,123/2015 relate to which activities must be adjusted. These are: i) access to genetic heritage; ii) access to associated traditional knowledge; iii) economic access and exploitation of product or process resulting from access to PG or CTA; iv) the shipment abroad of PG; (v) the dissemination, transmission or retransmission of data or information that are or constitute a CTA; and (vi) requests for authorization and regularization that were in progress at the entry into force of the MLB (BRAZIL, 2015).

The activities and their definitions recognized and accepted at the time of the MP's validity are presented below, interpreting and relating the adequacy and regularization procedures for each individual action.

2.1 Access to Genetic Heritage

The first activity foreseen in the MLB as of obligatory adjustment is the one of access to the genetic patrimony. Article 7, I of the MP defined genetic patrimony as:

> Information of genetic origin contained in samples of all or part of a plant, fungal, microbial or animal specimen in the form of molecules and substances derived from the metabolism of these living beings and of extracts obtained from these

> living or dead organisms found in **in situ**, including domesticated, or kept in **ex situ** collections, provided that they are collected in **in situ** conditions **in** the national territory, on the continental shelf or in the exclusive economic zone (BRASIL, 2001).

The good to be protected by MP and MLB is the native good, derived from Brazilian or exotic biodiversity, provided that it has acquired its own characteristics in the national territory, be it animal, fungal, microbial or vegetal (BRASIL, 2001; VASCONCELOS, 2012).

The delimitation of the scope of this expression was the object of many doubts during the validity of the MP.

In the definition of 'genetic heritage', the word 'information' deserves to be highlighted. This is to relate the activity of *access* to an immaterial activity, that is, the biological information to be used can be accessed by means other than just directly from the genetic material itself. As an example, one can consider reproducing the design of a molecule in a scientific article. This design would make it possible, in theory, to reconstruct the molecule, avoiding obtaining the genetic material directly. In this sense, the use of information of genetic origin extracted from a scientific article should have obeyed the rules set forth in the MP, that is, it should have obtained authorization from the competent authorities to perform access, since the place of sample collection/information is irrelevant (BRASIL, 2001; LAVRATTI, 2007; VASCONCELOS, 2012). It is important to emphasize that "information" incorporates not only DNA and RNA, but also all material that contains information of genetic origin, such as biomolecules, a frequent target of bioprospecting (LAVRATTI, 2007).

Other expressions contained in the concept that may raise doubts are those referring to "[...] *national territory, continental shelf and in the exclusive economic zone* " (article 7, I of the MP). However, for these, the interested party may consult Law No. 8,617/1993, which provides a precise definition of the mentioned expressions (BRAZIL, 1993).

In addition, to understand the term "access", it is necessary to jointly interpret item IV of article 7 of the MP and Technical Guidance (OT) nº 01/2003 of CGEN (BRAZIL, 2003). The word "access" should be understood as: obtaining a sample of genetic heritage with the purpose of isolating, identifying or using information of genetic origin or substances and molecules derived from the metabolism of living organisms or extracts

of these organisms (VASCONCELOS, 2012; BRASIL, 2003; BRASIL, 2001). Thus, the simple collection of the material, that is, the removal of a biological sample from its natural habitat, is not considered as access because it lacks the use for the purpose of isolating, identifying or using the information contained in this collected sample. That is, simple collection does not generate the adjustment obligation imposed by the transition rule.

For adjustment purposes, the date of the activity to be considered is the date on which the access was made and not the date on which the collection occurred. For example, if the sample was collected before the start of MP (30. 06. 2000), but its access - that is, the isolation, identification or use of the genetic information contained in this sample - only came after MP activity, this activity should be adjusted according to the MLB.

2.1.1 Activities not framed as access to genetic patrimony

During the term of the MP, several activities were not considered as access to the genetic heritage and, therefore, should not comply with the transition norms imposed in the MLB. Some because the MP, the Technical Guidelines (OT) and the Resolutions issued by the CGEN expressly excluded them, others because international agreements ratified by Brazil prevented the MP from reaching the scope (LENZA, 2015).

We highlight below the activities that were not considered access to the genetic patrimony:

(a) Activities of access and remittance of samples of **plant genetic resources**, held *ex situ*, when carried out exclusively for research, conservation, training and breeding, provided they are linked to food and agriculture governed by the International Treaty on Plant Genetic Resources for Food and Feed. Agriculture - TIRFAA (BRAZIL, 2008, BRAZIL, 2013).

Annex I of Decree 6. 476/2008, which incorporated the TIRFAA into the Brazilian legal system, lists the species that are included in the Treaty (BRAZIL, 2008). It is noted that the activities provided for in the ITPGRFA, when carried out from materials maintained in *in situ* conditions or, when they are intended for chemical, pharmaceutical or other industrial uses not related to animal or human food, should have complied with the rules of the MP and, therefore, are covered by the transition rules of MLB

(FERREIRA and CLEMENTINO, 2010; BRAZIL, 2013).

International treaties, other than those of human rights, when incorporated into the legal order of the country, have the character of an infraconstitutional norm equivalent to that of ordinary law, which is hierarchically superior to the Provisional Measures. Therefore, the norms contained in a treaty assimilated to ordinary law can not be restricted by a Provisional Measure (LENZA, 2015).

b) Research and tests to measure the mortality rate, growth or multiplication of parasites, pests or vectors of diseases, when they were exclusively aimed at investigating the properties of natural or synthetic molecules or chemical compounds (BRASIL, 2014a).

c) Use of information contained in national and international public domain databases, such as GenBank, Genome, UniGene and others (https://www.ncbi.nlm.nih.gov/) (BRAZIL, 2014b).

(d) Essential or fixed oils and commercial extracts are exempt from adjustment where isolation, extraction or purification result in a final product having a characteristic substantially equivalent to the raw material that gave rise to it (RESOLUTION No. 29/07; FERREIRA E CLEMENTINO, 2010; GODINHO and MACHADO, 2011).

e) In breeding programs, the pre-breeding and selection stages (eg progeny and mass selection tests) are classified as scientific research and were excluded from the hypothesis of MP incidence (FERREIRA and CLEMENTINO, 2010).

f) Research aimed at assessing and elucidating the historical evolution of a species or taxonomic group, the relationships between the living beings themselves or between them and the environment or the genetic variety of populations, as provided for in Resolution 28/07 of CGEN (BRASIL, 2007c).

It is observed that the exclusion provided for in the Resolution is restricted to the research activity (BRASIL, 2007c). In this way, the other

activities that derive from this, such as the generation of products and processes, would not be covered by exclusion and, therefore, should be adjusted according to the transitional provisions of the MLB.

g) *Scientific* activity *for affiliation tests, sexing techniques, and karyotype or DNA analyzes* aimed at the identification of a specimen or species (BRASIL, 2007c).

h) Epidemiological researches or those that sought to identify etiological agents of diseases, as well as the measurement of the concentration of known substance that indicated disease or physiological state depending on the concentration in the organism (BRASIL, 2006).

i) Research aimed at the composition of collections of germplasm, DNA, blood, tissues and serum (BRASIL, 2006).

j) Human genetic heritage, expressly excluded by Article 3 of the MP (BRASIL, 2001).

k) Plant and animal species that were introduced in Brazil, found in *in situ* conditions that form spontaneous populations, but which, however, did not acquire their own distinctive characteristics in Brazil (BRAZIL, 2016).

The Ministry of Agriculture, Livestock and Supply will periodically publish a list indicating the species that form spontaneous populations and varieties that have acquired characteristic properties in Brazil (BRAZIL, 2016). The first list can be found in normative instruction nº 23 (BRAZIL, 2017a).

Although this exclusion came from the MLB and not from the MP, its application is immediate, since it is a regulatory rule with a technical meaning that delimits the scope of the nationality of genetic heritage and, therefore, the coverage of Brazilian standards (GAGLIANO and STOLZE, 2012).

l) The use of genetic heritage as an excipient in personal hygiene

products, perfumery and cosmetics (BRASIL, 2017c).

Technical Guideline No. 02/2017 defined that, in the hypothesis described above, the PATGE used exclusively in the formula structure, which is responsible for the physical appearance, consistency and stability, and which does not determine the functionality of the product is considered as excipient (BRASIL, 2017c).

m) Activities developed in relation to cultivated varieties of sugarcane (Saccharum spp), because these varieties are not considered Brazilian genetic heritage (BRASIL, 2007b).

Finally, all genetic heritage access activities not listed in the exclusion scenarios described above, which were not carried out according to MP determinations or that were in progress at the time of MLB entry into force, should be adjusted as determined by the legislation in force.

2. 1. 2 Adjustment procedure

For the regularization of the activity of access to the genetic patrimony, the date of its accomplishment and the place where the access occurred must be observed (BRAZIL, 2016).

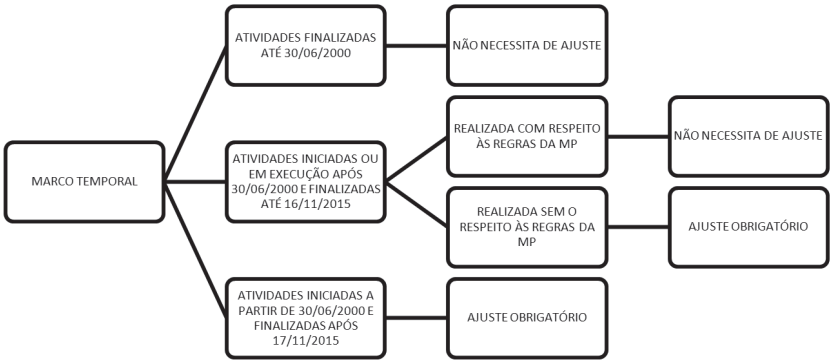

Figure 2. Schematic description of the hypotheses of Temporal Markings on the obligation to regularize activities with the use of Brazilian biodiversity

If access to genetic patrimony occurred between 06/30/2000 and 16/11/2015 in disagreement with the rules of the MP, the user will need to register the activity in SisGen and sign the Term of Commitment (TC) with the Union, represented in this act by the Minister of State and Environment, or to whom this delegation (BRAZIL, 2015).

The TC available on the website of the Ministry of the Environment (MMA) must be completed by the user or his legal representative and sent to the Ministry of Environment's Biodiversity Secretariat (BRAZIL, 2017b). In the event that the activity of access to the genetic patrimony was carried out solely for the purpose of scientific research, the user will be exempt from the signature of the TC, with the registration form being sufficient in SisGen (BRAZIL, 2015, 2016).

For the activities of access with the participation of foreign individuals or legal entities, carried out on a continental shelf, Brazilian jurisdictional waters, exclusive economic zone and areas indispensable to national security, including boundary bands and oceanic islands, the user is obliged to authorization from SisGen. However, if access to PATGEN started between 06/30/2000 and 16/11/2015 and was only finalized after 11/17/2015, this activity should be adequate only by performing the registration in SisGen, provided that the activity has fulfilled all the requirements of the MP until 16. 11. 2015. If the activity described here is in disagreement with the MP, the rule is to adopt the regularization procedure described above (BRAZIL, 2015, 2016).

Requests for authorization or regularization of access and remittance carried out under the MP should be reformulated with SisGen within one year, starting on November 6, 2017 (BRAZIL, 2015). Any application for a patent filing made until November 16, 2015, based on activities carried out during the term of the MP and in disagreement with it, shall be regularized with the National Intellectual Property Institute, by means of the presentation of proof of registration or authorization, obtained through the regularization procedure described here (BRAZIL, 2015, 2016).

2.2 Access to traditional associated knowledge

Another important concept is that concerning access to associated

traditional knowledge. Article 7, V of the MP defines access to traditional associated knowledge as:

> Obtaining information on individual or collective knowledge or practice associated with the genetic heritage, indigenous community or local community for purposes of scientific research, technological development or bioprospecting, aiming at its industrial or other application (BRASIL, 2001).

The term "indigenous community" has always been considered easy to understand. However, there is no precise conceptualization of "local communities". Several authors consider them as communities that maintain a close relationship with nature and are dependent on local natural resources for their subsistence and maintenance of their way of life (DIEGUES, 1993; MORTUREUX, 2000; SANTILLI, 2002). In this way, the characterization of a local community would not be in its geographical location, since it could be found even in urban environments, but in the way of life and in the symbiosis with the environment, where social, economic, cultural, spiritual and other (MOREIRA, 2007).

Article 7, item III of the MP, defines a local community as:

> Human group, including remnants of quilombos communities, distinguished by their cultural conditions, which is traditionally organized by successive generations and customs, and which preserves its social and economic institutions (BRASIL, 2001).

The MP's definition, apparently, excluded traditional farmers and riverine communities from protection (GODINHO and MACHADO, 2011).

It is important to emphasize that Decree No. 6,040/2007, which instituted the National Policy for the Sustainable Development of Traditional Peoples and Communities, and in item I of article 3, conceptualized a traditional community, here equated with the local community, such as: "[...] groups consciously culturally different that have their own social structure, that occupy and use lans and natural resources as conditions for their cultural, social, religious, ancestral and economic reproduction, using knowledge, innovations and practices generated and transmitted by the tradition. "(BRASIL, 2007a).

Based on the concept brought by the Decree of 2007 (BRASIL, 2007a), it is possible to consider quilombolas, extractivists, riverine fishermen, artisanal fishermen, coconut- babaçu, seringueiros, pantaneiros, geraizeiros, ebb, pasture, faxinalenses and caiçaras communities (VASCONCELOS, 2012).

As a general rule, small producers and settlers would not fit within the concept of local community for the protection granted by the MP, due to the absence of the requirements of distinct cultural conditions, traditional organization passed on by successive generations and customs (VASCONCELOS, 2012).

For the purpose of adjusting activities, the traditional knowledge to be considered is that which provided or facilitated access to genetic material or the making of its products (LAVRATTI, 2007). As examples of access to the traditional knowledge associated, one can mention knowledge about the pharmaceutical, alimentary and agricultural properties of flora and fauna species, management techniques, among others (DERANI, 2012; SANTILLI, 2005).

Given the conceptual imprecision of the MP, the analysis of the community framework in the concept of local community should be carried out in a thorough way, in order not to exclude a certain population from the scope of MP protection, since there is no defines which communities were considered local or traditional.

Having defined the profile of communities protected by the MP, it remains to know what actions were considered access to the associated traditional knowledge.

Considering the delimitation brought by the MP and making use of the abstract concept imbued with the word “access”, one can conclude that obtaining information would not need to be extracted directly from a given community. The information could also be taken from a newspaper article or other sources, provided it is able to facilitate or enable access to the genetic material. As an example, we can cite a newspaper article that reports on the life of a particular indigenous community in the state of Roraima, and inserts in its text that the seeds of a fruit have been used for centuries by the community as a contraceptive method. With this information, a laboratory collects a sample of the seed, isolates and identifies the molecule that holds the active principle of this sample, develops and patents contraceptive medicine (BOFF, 2015).

In this example, it can be seen that the laboratory accessed the traditional knowledge of the indigenous community of the state of Roraima, which provided a shortcut of many years and a high cost in research for the development of the drug and, therefore, should have followed the procedures provided in MP, including the allocation of benefits resulting from the economic exploitation of the product.

However, the regularization of the activity is not restricted to the laboratory that used the published knowledge, but also focuses on the author of the publication regarding the indigenous community. According to the transition rule inserted in item IV of article 38 of Law 13,123/2015, the one who has disclosed, transmitted or retransmitted information that integrates or constitutes traditional associated knowledge (BRAZIL, 2015) would be required to be regularized.

2. 2. 1 Adjustment procedure

The form of adjustment of the activity of access to traditional associated knowledge is similar to that already described in topic 3. 1. 2, both in adequacy, regularization and reformulation.

Some differences, however, deserve attention. For the purpose of adjusting the activity, following the example above, both the laboratory and the author of the article should sign a Term of Commitment (TC) with the Union, whereby, depending on the case, the registration, access authorization or notification, of the finished product and the forecast of benefit distribution, as provided in articles 38, § 1 and 39 of Law 13,123/2015 (BRAZIL, 2015).

However, if the author of the publication on the indigenous community elaborated the article solely and exclusively for the purpose of scientific research, it will only be necessary to make the registration in SisGen, dispensing with the signature of TC (BRAZIL, 2015).

2.3 The economic access and exploitation of product or process originating from access to PG or CTA

The MLB enumerated the hypotheses in which the economic

exploitation of items originating from the national biota must be reformulated, regularized or adequate. As a rule, economic exploitation is materialized by the issuance of the invoice for the marketing of a certain item (BRAZIL, 2016). When issuing the invoice, the obligation to distribute the benefits received from the sale of items from the national genetic patrimony is born. In legal terms, the incidence hypothesis is economic exploitation ; the generating event is the issuance of the Nota Fiscal (NF), and the legal consequence is the obligation to distribute the benefits.

For the adjustment of economic exploration activity, the first point to consider is the date on which the generating event occurred: whether it was in the MP or MLB. This distinction is extremely relevant because there is a distinction between the activities that were considered as an incidence hypothesis for PM and MLB (FIGURE 2).

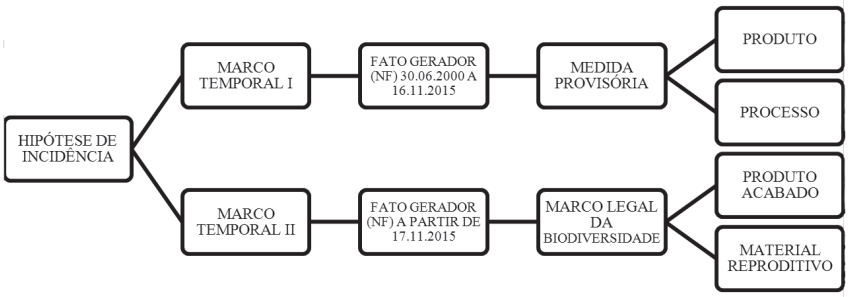

Figure 3. Schematic description of the hypotheses of economic exploitation in the two time frames.

In figure 3, time frame I comprises the generating facts that occurred during the period of validity of the MP (between 06. 30. 2000 and 16. 11. 2015). In this period, the hypotheses of incidence were the economic exploitation of product or process derived from the genetic patrimony or associated traditional knowledge (BRASIL, 2001).

MP No. 2,186/2000 did not delimit the concept of product and process, restricting itself to broadly protect the economic exploitation of product and process developed from the access of components of genetic heritage and traditional national knowledge (BRAZIL, 2001).

On the other hand, Time Frame II comprises the generating facts that occurred during the MLB (after November 17, 2015), only

for economic exploitation activities of finished product or reproductive material (BRAZIL, 2015).

For purposes of adjustment of activities, only the study of Temporal Framework I will be relevant at this moment.

Observing the Temporal Markings one can notice that there is no conflict between the application of MLB and PM. Based on the principles of legal certainty and non-retroactivity of the law, actions finalized under a given standard should be governed by it, not allowed to change later definitions and procedures for legal acts considered to be perfect, ie finalized (MEIRELLES, 2016).

Thus, the legal act of economic exploitation in the MP is considered perfect, that is, finalized, when the user, understood here as the economic explorer, issues the Nota Fiscal for the commercialization of the product and has a Contract for Utilization of Genetic Heritage and Benefit Sharing (CURB) registered and approved by CGEN (BRASIL, 2001). For this situation, no subsequent law can determine any change (MEIRELLES, 2016). On the other hand, actions pending finalization in this period will be governed by the transitional provisions of the MLB.

Note that the scope of the standard after the pending fact is not unlimited, since the consummate part of the action can not be changed. A new law could alter the consequences of a pending fact, but it could not change the fact itself (LEVADA, 2009).

Specifically in Time Frame I four scenarios unfold (FIGURE 4):

Figure 4. Schematic description of the hypothesis of incidence when there is economic exploitation of biodiversity

As summarized in figure 4, in the first scenario, the facts are considered perfect, since they were finalized according to the MP. On the other hand, in the second scenario, the facts are considered outstanding, since they were carried out during the MP, but in disagreement with the norm and, therefore, should be made according to MLB.

The third scenario comprises situations in which CURB has a validity higher than the date of November 17, 2015, that is, the validity of the MP. In this situation, Decree No. 8. 772/2016 provides, in paragraph 2 of article 103, that this contract will remain valid for the period established therein (BRAZIL, 2016). In this way, all marketing of product or process included in the events described in the agreement and, as long as it is valid, will not suffer the incidence of MLB. However, once the term of validity of the contract has expired, the continuity of the economic exploitation activity contemplated therein shall follow the rules of the MLB, both in relation to the registration procedure of the activity and in relation to the sharing of benefits.

Finally, the fourth scenario comprises the situations in which the activity started regularly during the term of the MP and lasted after its revocation; for example, when access to PG or CTA performed regularly during the MP period was the basis for the development of product or reproductive material after its revocation. In this scenario, there is a need not only for notification of the finished product or the reproductive material under MLB, as well as for the sharing of benefits. In the latter case, the generating fact (NF emission) occurred during the MLB and, therefore, should follow the procedures established in the MLB for cases of economic exploitation (BRASIL, 2016).

2.3.1 Adjustment procedure

The economic exploitation of the product or process described in scenarios II and IV should be regularized by signing the Term of Commitment, to be approved by the user and forwarded to the Biodiversity Secretariat of the Ministry of Environment (BRAZIL, 2016, BRAZIL, 2017b).

2.4 External sample delivery of the PG

In dealing with the transfer abroad of a sample of genetic heritage, the chapter of the transitional provisions of the MLB determined as a triggering factor of the irregular shipment occurred between 06/30/2000 and 17. 11. 2015 (i. e., occurred during the period of MP).

Technical Guidance No. 01/03 issued by CGEN defines consignment as the actual shipment or transport of a component of the genetic patrimony, permanent or temporary, in order to constitute access for scientific research, technological development or bioprospecting, with or without transferring responsibility for the sample from the sending institution to the receiving institution (BRASIL, 2003).

The new definition presented by the MLB for the remittance activity is more restricted, only considering remittance for legal purposes when the responsibility for the sample is transferred to the receiving institution located abroad. By the rules of legal hermeneutics, later rule can not extend the concept brought to a generating fact already occurred; however, may restrict the concept (GAGLIANO and STOLZE, 2012). In this way, the consignment covered by the transitional provisions is the one in which there is a transfer of responsibility to the recipient institution located abroad.

The transfer of a sample to provide services abroad, for the purpose of conducting research or technological development, without transferring responsibility to a foreign individual or legal entity, is configured in the MLB as a sending activity, which does not require adjustment.

2.4.1 Adjustment procedure

The user, as described in the transitional provisions of the MLB, must sign the Term of Commitment, in the manner of Ordinance No. 350/2017 issued by the MMA and register the shipping activity in SisGen, informing the intended use (BRAZIL, 2017b).

The shipment carried out by a national legal entity with the participation of a foreign natural or legal person, carried out on the continental shelf, Brazilian jurisdictional waters, exclusive economic zone and areas indispensable to national security (including the border strips

and the oceanic islands), requires authorization to be formulated in SisGen (BRAZIL, 2015, 2016).

2.5 Disclosure, transmission or retransmission of data or information that are or constitute CTA

One of the most sensitive points of the transitional provisions in MLB refers to the difficulty that the user has to identify with the action. This is because, when we talk about genetic heritage, as a rule, the theme is associated with the biological and agrarian sciences, completely removing the relation of the theme with other areas, such as applied human and social sciences. However, when the MP and the transitional provisions of the MLB deal with the dissemination, transmission and retransmission of traditional knowledge associated with genetic heritage, the scope of the standard is broadened, reaching all areas of knowledge.

Resuming the example of the indigenous community of Roraima, discussed in topic 3. 2, the associated traditional knowledge was accessed, disseminated and subsequently used. Suppose was found that the disclosure occurred in reporting the result of a study on the behavior of that indigenous community, where the mention of the use of seed was carried out without any pretense, just like an account of the peculiarities of that community. In this case, the researcher who published the study must perform the adjustment of its activity.

2.5.1 Adjustment procedure

In the event of disclosure, transmission or retransmission of information that constitutes a CTA to genetic heritage, the only form of adjustment is the regularization, that is, when that activity was performed between June 30, 2000 and November 16, 2015, in violation of the rules of MP.

The regularization, as said before, must be done by registering in SisGen and signing the Term of Commitment. However, when the activity is only developed for the purpose of scientific research, the user will be exempt from the signature of the TC, being sufficient for the regularization the registration in SisGen.

2.6 Applications for authorization and regularization that were in progress at the entry into force of the MLB

The MLB is clear as to the situations in which the user had requested, during the validity of the MP, the authorization to carry out their access and remittance activities of the PG and CTA or the regularization of the activities already developed, but still awaited the completion when the MLB came into force. For such cases, Article 35 of Law 13,123 requires the user to restate requests to SisGen, within a period of one year from the date of availability of the system (BRAZIL, 2015).

CONCLUSION

This article describes the activities to be adjusted and the procedures for compliance with the MLB transitional rules. Although apparently simple, the concepts and delimitations of the activities and procedures described in MLB present several details that lead to different forms of reformulation, adequacy and regularization. Failure to comply with such specificities may lead to misunderstandings, since the actions to be adjusted under the new legislation should be limited to the definitions related to them at the time of the PM's validity. Thus, by understanding and identifying the activities covered by the MLB and its timeframes described in this article, the biodiversity user is allowed to see, among their activities already completed, which ones should be adjusted and which are not covered by the transition.

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