REGULATION TO ACCESS TO GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE IN BRAZIL[1]

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Abstract

The nationwide enforcement of the Convention on Biological Diversity, particularly articles 8j and 15 which address respectively traditional knowledge and access to genetic resources and distribution of the benefits deriving from its utilization, has generated an intense debate regarding its impact on research.

Today, in Brazil, Provisional Measure 2.186-16/01 (MP), which established the rules for the access and sending of genetic heritage components and the access to associated traditional knowledge, is in effect. This norm foresaw the creation inside the Ministry of the Environment of a national competent authority – the Genetic Heritage Management Council (CGEN), whose activities began in April 2002.

In 2003, with the new government, enforcement of the MP tried to address, as far as possible, the demands of sectors of society, publishing acts that clarify concepts which are fundamental for its enforcement, reducing bureaucracy in the application of the norm and giving greater transparency to the actions of CGEN.

However, as these actions are limited by the legal text in force, a preliminary draft was made for a law to be sent by the Federal Executive Government to the National Congress, after being analyzed by the competent government department.

Taking up again the legislative process, begun in 1995 and interrupted in 2000 with the first edition of the MP mentioned above, society will have a new opportunity to participate in the discussion of this matter, with deeper understanding.

Key words: *Convention on Biological Diversity, Brazilian Provisional Measure 2.186-16/01 (MP), Brazilian Genetic Heritage Management Council (CGEN), Access to genetic resources, Traditinoal Knowledge, Benefit-Sharing.*

Resumo

A implementação, em nível nacional, da Convenção sobre Diversidade Biológica, especialmente dos artigos 8j e 15, que tratam respectivamente do conhecimento tradicional e do acesso aos recursos genéticos e da repartição dos benefícios provenientes da sua utilização, tem gerado intenso debate quanto ao seu impacto sobre a pesquisa.

No Brasil vigora atualmente a Medida Provisória 2.186-16/01 (MP) que instituiu as regras para o acesso a e a remessa de componentes do patrimônio genético e o acesso a conhecimentos tradicionais associados. Essa norma previu a criação da autoridade nacional competente – o Conselho de Gestão do Patrimônio Genético (CGEN) no âmbito do Ministério do Meio Ambiente, o qual iniciou suas atividades em abril de 2002.

Em 2003, com o novo governo, a implementação da MP buscou atender, na medida do possível, as demandas de setores da sociedade, editando atos que esclareceram conceitos básicos para sua implementação, diminuindo a burocracia para a aplicação da norma e dando maior transparência às ações do CGEN.

Entretanto essas ações estão limitadas pelo texto legal vigente, assim foi elaborado um anteprojeto de lei para, após sua análise pela casa Civil, ser encaminhado pelo Executivo Federal ao Congresso Nacional.

A retomada do processo legislativo, iniciado em 1995 e interrompido em 2000 com a primeira edição da referida MP, dará a sociedade uma nova chance para que participe da discussão dessa matéria, agora com mais conhecimento de causa.

Palavras Chave: *Convenção sobre a Diversidade Biológica, Medida Provisória 2.186-16/01 (MP), Conselho de Gestão do Patrimônio Genético (CGEN), Acesso a recursos genéticos, Conhecimento tradicional, Repartição de Benefícios.*

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Brief History[3]

Upon the ratification of the Convention on Biological Diversity (CBD) Brazil took on the responsibility to establish the rules for access to genetic resources under its jurisdiction and to protect traditional knowledge, of local communities and indigenous peoples, relevant to the conservation and sustainable use of biodiversity.

The Convention on Biological Diversity (CBD)[4], an international environmental treaty which is currently made up of 188 parts, has the following aims: conservation of biological diversity, sustainable use of its components and the fair, equitable benefits' sharing stemming from genetic resources.

This third objective stems from the demand of developing countries which possess a wealth of biodiversity and which have concluded that it is unfair to allow free access to genetic resources; the products obtained from these resources were an object of monopolistic appropriation, by means of patents, by companies whose headquarters, are in most cases, in developed countries.

With the inclusion of this aim in the CBD, the sovereignty of countries over their biological resources was recognized, thus access to genetic resources became subject to national legislation, and was no longer considered a heritage pertaining to humankind.

The first initiatives to regulate this matter in Brazil date back to 1995, with the presentation of a Bill by Marina Silva, Senator at the time, (PL 306/95). In spite of public lectures and seminars on the Bill, the involvement of the main sectors concerned with the matter was meager, such as the academic and entrepreneurial sectors and those providers of traditional knowledge.

This Bill was approved in the shape of a replacement proposed by Senator Osmar Dias in 1998 (PL 4.842/98).On this same year two other bills were presented to the Chamber of Deputies: one by the Deputy at the time, Jacques Wagner (PL 4.579/98) and the other by the Federal Executive Power (4.751/98), which was accompanied by a Constitutional Amendment Proposal N° 618/98.

The latter aims to alter clause 20 of the Federal Constitution in order to include genetic heritage amidst the heritage of the Union. At the time, the Executive Federal Power justified that this was the best option, as only this approach would allow an adequate control over access and benefits' sharing (Azevedo et al., to be published).

The bill approved by the Senate and presented by Deputy Jaques Wagner was inspired by Decision N° 391, of the Nations Andes Community, establishing contracts, also for scientific purposes, as a prerequisite for obtaining authorization to access to genetic resources. On the other hand, the Bill by the Federal Executive power coined the term "genetic heritage", used by the Federal Constitution, and established contracts only for access to genetic heritage and to associated traditional knowledge only in cases where there is economic potential. This was the embryo of the current legislation in effect, the Provisional Measure 2.186-16/2001.

In 2000 all these Bills were still being handled in the Chamber of Deputies, as well as others presented after 1998. It was at that point that the press announced with great commotion the Contract between the Social Organization "Bioamazonia" and the pharmaceutical company Novartis Pharma AG. Due to countless issues with it, many of which concerning the lack of existence of national legislation which would adequately protect the genetic resources extant within national territory, this Contract was not carried out.

Nonetheless the negative aftermath of the fact led to the edition of Provisional Measure 2.052, on June 29th, 2000 (in effect currently under N° 2.186-16/01). Like all Provisional Measures, this one was re-edited until the supervening of Constitutional Amendment N°32/2001, culminating with the version in effect.

Provisional Measure 2.186-16/01 (Provisional Measure) determines that access to associated traditional knowledge[5]and to genetic heritage extant in the Country[6], as well as its shipment abroad[7], should only be carried out with the consent of the Union[8], and instituted the Genetic Heritage Management Council (CGEN) as the competent authority for this purpose. Notwithstanding, this Council only began its activities in April 2002, which produced a state of uncertainty as to the possibility to carry out research in the country and difficulties concerning the exchange of biological matter for scientific purposes (from June 2000 to April 2002).The terminology used by the Provisional Measure which does not define clearly what "access and shipment of genetic heritage" is, was one aggravating factor in this scenario.

[3] In order to know the whole history: Azevedo & Azevedo, 2000; Azevedo, Lavratti & Moreira, Environmental Law Magazine: 2005, n. 37.

[4] CBD came into effect on December 29, 1993.

[5] Associated Traditional knowledge: individual or collective information or practice, associated to genetic heritage (Provisional Measure 2.186-16/01, clause 7º,11).

[6] Genetic Heritage: information of genetic origin, contained in the whole or part of vegetation specimen, fungus, microbian or animal, in the shape of molecules and substances stemming from the metabolism of livings beings and of extracts obtained from these live or dead organisms, found in in situ conditions, including those domesticated, or kept in collections ex situ, provided that they are collected in in situ conditions in national territory, on the continental platform or exclusive economic zone (Provisional Measure 2.186-16/01, clause 7º.1)

[7] Clause 9 of Provisional Measure 2.186-16/01.

[8] Clause 2º of Provisional Measure 2.186-16/01.

In 2002 CGEN received motions from various sectors of the academy which questioned the demand of obtaining authorization for scientific research involving access to genetic heritage, since this would only generate economic benefits eligible to be shared in a remote manner. Some provisions of the Provisional Measure which hindered research in the country were identified: the interpretation difficulty of the concept of "access and shipment of samples of components of genetic heritage"; the need to present beforehand the consent of the holder of the area where the samples would be collected and to indicate in advance the places for sample collecting as prerequisites to gaining access authorization; the obligation to deposit subsamples of components of the genetic heritage in an institution accredited as a loyal recipient; and in cases of bioprospecting, the need to present a Contract of Use of Genetic Heritage and Benefits' Sharing.

During this year also, questions were raised regarding the institutional jurisdiction - who authorized what? (CGEN, IBAMA[9], CNPq[10])

In the beginning of 2003, upon taking office at the Environment Ministry, Minister Marina Silva requested CGEN to prepare, by means of a process giving participation to society, a draft bill to be sent by the Executive Federal Power to the Congress, in order to reactivate the legislative process interrupted by the edition of the Provisional Measure. She also asked for goodwill in the resolution, inasmuch as possible, of issues identified by the academic sector.

Today, at the end of 2004, there is already a draft bill done with the participation of society, currently under evaluation by the Civil Cabinet, to be sent afterwards to the National Congress. In this draft bill, the application of various points of the Provisional Measure, have been either explained or altered, in order to facilitate the acquisition of access authorizations and shipment. Meanwhile, the debate over this issue has widened, with frequent meetings, seminars and panels over the issue in events in the country.

The application of Provisional Measure 2.186-16/01

Who may request authorization?

Currently, in Brazil it is necessary to obtain specific authorization to access traditional associated knowledge and/or components of genetic heritage for scientific research, bioprospecting and technological development purposes. Individuals, institutionally unaffiliated researchers, are not allowed to request such authorizations; this is also the case for foreign institutions, which must become associated with national research and development institutions in the biological and correlated fields in order to participate in research, involving access.

This prerequisite: the demand of being a national research institution in order to request authorization, has not so far, produced any great difficulties, except for the fact that some institutions, such as universities, have made arrangements in their daily activities to avoid overburdening the University Dean, for instance, with form signatures. The procedure which has been used is to assign faculty and institution directors to represent the university, before the public power, in research authorization requests.

Are collection and access to genetic heritage equivalent concepts?

As mentioned previously, the text of the Provisional Measure does not make the concept of "access" clear and so CGEN issued the Technical Guideline N° 01[11] which clarifies that "the access to the component of genetic heritage" is "the activity undertaken over genetic heritage with a view to isolating, identifying or utilizing information stemming from genetic origin or molecules and substances originating from the metabolism of living beings and of extracts obtained from these organisms". After the clarification of this concept, it was established definitely that access is different from collecting. While the former regards access at the molecular level of an organism or of substances stemming from its metabolism, collecting refers to the removal of an organism, integrally or partially, from *in situ* conditions.

This Technical Guideline and the application of the Provisional Measure have led to different interpretations from those defended by some authors. Although Péret de Sant'ana (2004) states that the use of the term "genetic heritage" refers to genetic resources as an asset belonging to humankind, this is not the interpretation provided by the Provisional Measure, whose clause 2º determines: "the access to genetic heritage extant in the Country shall only be carried out upon authorization of the Union(...)", reassuring therefore the sovereignty of the Country over resources extant in its territory, as prescribed by CBD. As for the definition of "genetic heritage" used by the Provisional Measure; in spite of its extensive length, contrary to what is stated by the aforementioned author, it is not restricted to the immaterial character of the genetic resource, as it refers to information of genetic origin **in the shape**[12] of molecules and substances, in accordance to subsection 1 of clause 7.

[9] IBAMA – Brazilian Institute for the Environment and Renewable Natural Resources, linked to the Ministry of Environment.
[10] CNPq – National Council for Scientific and Technological development, linked to the Ministry of Science and Technology.
[11] Available at the electronic address <http:// www.mma.gov.br/port/cgen>
[12] Our highlight.

Does any shipment of material abroad require authorization from CGEN?

The same Technical Guidelines also clarified that the shipment, ruled by the Provisional Measure, is only the temporary or permanent shipment of samples of genetic heritage components aimed at access to scientific research, bioprospecting or technological development. Thus, for instance, the shipment of exsiccations for morphological analysis does not have to go through the rulings established in the Provisional Measure.

In the cases of shipment of material to be submitted to activities of access to genetic heritage, CGEN has established Resolutions which institute models of "Material Transference Agreement (MTA)".The signature of these MTAs by the addressee institutions aims to promote security not only for the State, but also to the sending institutions. This prerequisite also produces complaints by research institutions which traditionally only used the shipment guides to manage the exchange of biological material. Some of the critiques have provided changes which have already been incorporated into CGEN in the revision of these Resolutions[13].

Prior Informed Consent

One of the most highly criticized prerequisites of the Provisional Measure by the academic sector is the demand to present the prior informed consent of the holder of the private area; of the indigenous or local community involved; of the legal entity, whenever protected areas are involved; and of the marine authority or National Defense Council.

The three most frequent arguments are: first, the fact that it is not always possible to know in advance where the material will be collected, and upon which genetic heritage access activities will be carried out; second an increase in research costs as it becomes necessary to travel back and forth to the field twice; once to obtain prior informed consent and another time to carry out the field work, which can only be done after consent is obtained; and last, the difficulty to locate and identify with certainty the holder of the area.

The justifications for the existence of this prerequisite regard the legal nature of genetic heritage and incentives to the conservation of biodiversity.

Although the Provisional Measure did not define clearly the legal nature of genetic heritage, it assured the holder of the area where the material is collected, which is an object of access; the right to have an integral part of the Contract of Use of Genetic Heritage and Benefits' Sharing[14]. However, this Contract only becomes effective after its consent by the Genetic Heritage Management Council[15], thus clearly showing that public interest besides the private interest of the holder of the area befall genetic heritage.

Until this heritage is clearly defined in legal terms by Law, it will remain as an object of dispute among legal scholars. Still, the notion which has prevailed is that this heritage is an asset of relevant public interest or of common use by the people, therefore implying that it belongs to collectivity, and that as such, Public Administration should only be in charge of its safekeeping and management, without taking away the holders' rights over the areas on which organisms lie (Varella, 2004; Meirelles, 2003).

The right of holders gains momentum whenever collection entailing access to genetic heritage with economic potential, such as bioprospecting or technological development is concerned. In such cases, though more remotely in the former, there are chances of obtaining profit derived from the access, and according to the Provisional Measure, it is required to forecast the benefits' sharing with the holder of the area. The incentive for biodiversity conservation would take place, exactly, by means of sharing the benefits with the holder of the area, which is the second justification for the need to adopt prior informed consent. The holder, by preserving biodiversity and allowing exploration of genetic heritage therein extant, becomes equal to the benefits' sharing.

As scientific research is not considered by the Provisional Measure as an activity entailing previously identifiable potential economic use, CGEN approved Resolution N°8, which dismisses the presentation of prior informed consent of the holder of a private area in order to gain access authorization to genetic heritage for scientific purposes, which may contribute to the advancement of knowledge about biodiversity in the country, thus characterizing it as an instance of relevant public interest[16].

Notwithstanding, the prerequisite of presenting prior informed consent in other cases which do not involve private property has been kept. The demand for presentation of prior informed consent in cases of research in Protected Areas has not produced complaints, as it was already a prerequisite needed for gaining a license for collection. Conversely, the need to present prior informed consent from indigenous and local communities has not been well tolerated by many researchers.

[13] Resolutions nos 13, 14 and, which substituted Resolutions nos 1, 2 ad 4, respectively and the recently published Resolution nº 16. They are all available at: <http//www.mma.gov.br/port/cgen>

[14] Clause 27 of Provisional Measure 2.186-16/01.

[15] Clause 29 of Provisional Measure 2.186-16/01.

[16] The provision in this resolution does not exempt the researcher from obtaining consent from the holder or his/her representative to enter and collect in the private area where the collecting will be done. (Resolution 8, clause 4º - available at http://www.mma.gov/br/port/cgen

This point merits consideration, as it may reveal a need for new ethics in research. This need was pointed out in a recent editorial of "Nature" Magazine (2004), in this instance exemplified by a dispute between researchers and a small tribe of Native Americans in the USA; the Havaupai, over samples of their DNA.

Research projects done in areas occupied by indigenous peoples and traditional communities should include, in their schedules, stages for the development of contact with the communities in order to build up mutual confidence, which would facilitate the process of acquisition of prior informed consent.

CGEN has established guidelines for the acquisition of prior informed consent from these communities[17], establishing explicitly that they should understand what the research is about, what the collected samples and/or assessed traditional knowledge will be used for, the field research method, etc.

Currently the presentation of prior informed consent of the private holder is a prerequisite for the acquisition of authorization for access to genetic heritage for bioprospecting and technological development; and it is also a prerequisite for the acquisition of authorization to genetic heritage and/or to traditional knowledge, when the providers are indigenous peoples or local communities, for scientific research, bioprospecting and technological development.

Thus, the statement by Varella (2004:120): "As one can see, Brazil is one of the few countries which accepts ignoring respect to the will of indigenous peoples, in the same way that other countries..." is not supported by the Provisional Measure, as its clause. 16, § 9°, I, instituted that "the authorization for access and shipment would only occur following the prior informed consent of the indigenous community entailed, according to the Official Indigenous Organization, whenever the access takes place in indigenous lands". Thus the community is the one who consents and FUNAI is heard, not the opposite, as the aforementioned author implies. The criteria for the application of this prerequisite are specified in the relevant Resolutions aforementioned[18].

This demand has required a revision of the manner in which field research is carried out. It is not enough, for instance, to come to an indigenous community or place and simply request authorization to collect some leaves of some species, or to ask how the community exploits certain resources; it is necessary to explain the reasons for the research, to tell in explicit terms what product is expected from the research. If it is simply for the purpose of writing a thesis , for example, the final text must identify the origin of the material collected (not only by providing geographic information, but also by identifying the providing community), as well as the origin of the information concerning associated traditional knowledge.

The thorough and highlighted reference of this information in publications has gained increasing significance. It is known that pharmaceutical, cosmetic and nutritional companies among others, rely on bibliographies and data banks as their main source of information (Ten Kate & Laird, 1999). It is necessary for the researcher to be concerned about what may be done with the product of his/her research.

Especial Authorization

The Provisional Measure prescribed a category known as "especial authorization" to gather in one single authorization the group of research projects, entailing access to genetic heritage and/or access to associated traditional knowledge, developed by a certain institution. In such cases, the applicant simply presents a 'portfolio' of the institution's projects. Albeit Decree n° 3.945-01, in its original version, demanded such a specific account about the research, as for instance, the detailed itinerary of the expedition in national territory, that it prevented the simplification of demands already prescribed in simple authorizations, specific for each research project.

By the end of 2003 CGEN made a proposal to the Executive power to modify Decree 3.945/01[19], explaining in which cases institutions could request especial authorizations and making the prerequisites for especial authorizations aimed at scientific research more flexible. Therefore, today an institution in possession of a special authorization may include new projects in its scope, without having to request authorizations for each case.

The alteration of Decree 3.945/01 also prescribed especial authorization to conduct access to genetic heritage aiming to constitute or integrate collections *ex situ*, which target activities bearing potential economic use, such as bioprospecting or technological development. Thus, DNA banks, extract collections, which are made to be object of bioprospecting, may obtain especial authorization. For this purpose they should, however, fulfill different prerequisites from those required in the case of scientific research.

[17] Resolution 05: Prior informed consent for access to associated traditional knowledge for scientific research purposes. Resolution 06: Prior informed consent access to associated traditional knowledge for bioprospecting or technological development; Resolution 09: Prior informed consent from local and indigenous communities for access to genetic heritage and scientific research; Resolution 12: Prior informed consent for access to genetic heritage for bioprospecting or technological development. Available at < http://www.mma.gov.port/cgen>.

[18] It must be highlighted that in cases of access for bioprospecting or technological development the prior informed consent must be accompained by an anthropological report. (Resolution 12).

[19] Modified by Decree nº 4.946/03.

Who authorizes what?

CGEN is the national competent authority to deliberate on such access requests to associated traditional knowledge and access to and shipment of components of genetic heritage for any of the three purposes prescribed by the Provisional Measure: scientific research, bioprospecting or technological development.

After having established that collection is different from access, the jurisdiction to issue a license for collections was assigned to the competent environmental organization, member of the National System for the Environment- SISNAMA.

In order to expedite the handling of requests for access to genetic heritage for scientific research, CGEN accredited IBAMA[20]to deliberate over such requests. Thus, research entailing collection and access receives simultaneously, respectively , the license and authorization from IBAMA. As this sort of request is no longer required to undergo appraisal by CGEN, it should be sent directly to IBAMA.

The procedures for cases in which there was participation of foreigners with a predictable permanence on national territory were still pending.

As the Ministry of Science and Technology (MCT) also intervened in the control of collecting, done by foreigners, regarding data and Brazilian scientific materials[21] and also because the Provisional Measure dealt with the issue in its clause 12, CGEN issued Technical Guidance n°3. This one explains that clause 12 of the Provisional Measure establishes that the activity subject to authorization of the organization in charge for the national policy for scientific and technological research, is the participation of a foreign legal entity in collection activities or access to genetic heritage or associated traditional knowledge, undertaken in national territory, which contribute to the advancement of knowledge and are associated to bioprospecting

Thus, today the access to genetic resources for scientific purposes, without any potential for economic use such as bioprospecting, is authorized by IBAMA, and in cases where the presence of a foreign legal entity is scheduled on national territory, the request for authorization should be sent to CNPq, an organization linked to the Ministry of Science and Technology, which will send the request to IBAMA and which will afterwards deliver the deliberations of both organizations to the applicant.

CGEN took the assignment of deliberating over access to genetic heritage for bioprospecting or technological development, and also over access to traditional associated knowledge for the three previously mentioned purposes. In these cases the requests should be sent to the Department of Genetic Heritage (DPG) of the Ministry of Environment, which holds the position of Executive Secretariat of CGEN[22].

In order for the applicant not to need to make requests in IBAMA, in the case of a collection forecast, or in CNPq, in the case of a forecast of the presence of foreigners, CGEN has organized the creation of Process Evaluation Committees[23] made up of counselors and representatives of organizations sympathetic to the requests at stake. In this manner CGEN takes over other licenses and authorizations.

This is a new institutional arrangement which is still at an implementation and testing stage, and which aims to diminish the transaction costs, both for requesters and the government. Until then, in many cases, requests were sent to more than three governmental organizations, which dealt with independent processes.

The integration of the National Indigenous Foundation- FUNAI is still pending. This is the organization which authorizes the entrance and research in Indigenous Territories, to the system of “exclusive doors”.

Makeup of CGEN

The makeup of CGEN was defined by the Provisional Measure[24] and may only be altered by law. This is a feature of the genetic heritage administration system and of associated traditional knowledge, which displeases all sectors of society concerned with the issue.

Minister Marina Silva, at the beginning of her term, asked CGEN to institutionalize the condition of “Permanent Guests”[25] representing with the right to give opinions, various sectors sympathetic to the issue, until the legislative process was engendered again through a new Bill to be sent by the Federal Executive Power and finished with the enactment of the new Access Law and Benefits’ Sharing.

The opening of CGEN to society, though it is still insufficient, has widened debates and given greater transparency to the tasks of that Council.

[20] Deliberation 40, available at <http://www.mma.gov.br/port/cgen>.

[21] Decree nº 98.830, of 15 January 1990; Deliberates upon collection, done by foreigners, scientific data and materials in Brazil and provides other measures.

[22]Provisional Measure 2.186-16/01, clause 15; Decree 3.945/01, clause 7º.

[23] Deliberation nº 49, available at <http://www.mma.gov.br/port/cgen >.

[24] Provisional Measure 2.186-16/01, clause 10 “It is thus established, that within the Ministry of Environment – MMA, The Council for Administration of Genetic Heritage, has a deliberative and normative character, made up of representatives of organizations and entities of Federal Public Administration which bear competence over several actions covered in this Provisional Measure”.

[25] The following sectors have a representation in CGEN as permanent guests: academic, entrepreneurial, environmentalist, holders of traditional knowledge, the states, as well as the Public Ministry. For a complete list of contacts please refer to; www.mma.gov.br/port/cgen.

Bioprospecting

The rules for access aimed at bioprospecting have engendered questioning, mainly from the academic sector, which claims that as this is a risk activity - the probability of achieving an economically exploitable product is small - there should not be, as a prerequisite to obtain authorization, the demand of presenting a Contract of Use of Genetic Heritage and Benefits' Sharing.

Bioprospecting is beyond any doubt a potentially economically useful activity. It is so much so that financing agencies and the agreements among institutions have increasingly adopted provisions which prescribe the rights and duties over possible products liable to economic exploitation and protection by intellectual property rights (DPIs).

One must also acknowledge that there are not many research and incentive institutions that have constituted intellectual property nuclei to support researchers in these agreements. This is one of the reasons appointed by specialists for the small percentage of patents obtained by national institutions.

In spite of a noticeable change in this scenario, with a widening of awareness on the side of researchers in what regards the economic potential of their research, there is still a grudging reluctance to extend these agreements to the providers of samples of genetic heritage and traditional associated knowledge.

Albeit, the Provisional Measure does not demand that the Contract of Use of Genetic Heritage and Benefits' Sharing present the detailed provisions related to intellectual property rights or benefits' sharing. This detailed account may be left aside for an additional contract to be signed if the generation of a product or process liable to economic exploitation arises. The signing of the Contract following the prior informed consent acquisition is tantamount to closing a deal after a negotiation process. The issue is that this activity demands time, resources and skills which are not always available to the researchers.

Notwithstanding, as this is a legal requirement, research and incentive institutions should form groups to raise awareness and support researchers, by adopting possibly contract models, in the same manner as they have been doing with intellectual property rights.

Furthermore, it is commonplace to allege that only the Brazilian researcher is being penalized. To ponder upon this statement one should first bear in mind the fact that Brazilian Legislation has territorial application, although the Material Transference Agreements and the Contracts of Use of Genetic Heritage and Benefits' Sharing, may in some instances involve foreign institutions, allowing greater security mainly to national institutions. Lastly, it is often forgotten that any company with headquarters in national territory, regardless of the origin of its capital, is considered a national company by the Federal Constitution.

The Law draft (APL) conceived by CGEN[26]

As previously mentioned, upon a request by Minister Marina Silva, CGEN formed a Thematic Chamber, equally composed by government and society, to draft a law to be sent to the Congress by the Federal Power, aiming to conclude the legislative process upon the theme with the enactment of an Access and Benefits' Sharing Law.

The result of this endeavor reflects not only the experience acquired with the implementation and ruling of the issue, by means of the application of Provisional Measure 2.18616/01, but also the interest of various sectors of society that participated in the process.

The text produced within the scope of CGEN shows remarkable differences from the Provisional Measure, such as:

- It readopts the terminology of CBD (genetic material), though it includes in the definition of "genetic material products" the "information of genetic origin";

- It considers genetic material and its by-products as of common use by the people;

- It dismisses the authorization for access activities to genetic material and its by-products, for scientific research purposes, stipulating a registration with the competent authority and the making of internal commissions for follow up on institutions;

- The access authorization to genetic material and its by-products for scientific research purposes is kept whenever the research project forecasts the participation of a foreign institution or an institution bearing profit purposes and the material stems from lands occupied by indigenous peoples, local communities in territories liable to measurement, or formerly runaway slave havens: "Afro-Americans".

- It renders the signing of the Contract of Benefits' Sharing optional, in cases where access to genetic material and its by-products for bioprospecting purposes, is for non-profit institutions;

- It gives a detailed account of the means of protection of traditional knowledge, specifying that the moral and heritage rights of its holders are inalienable, unremitting, imprescriptible and not liable to mortgage;

- It prescribes a benefits' sharing system which warrants that a percentage will always be allotted to the Funds for Benefits' Sharing, which would have two "signatures": one to warrant public interest incident on genetic material and its by-products; and the other, to benefit communities not taking part in the Benefits' Sharing Contract, which may have a share in the associated traditional knowledge;

[26] Available at <http://www.mma.gov.br/port/cgen >

- It prescribes penal and administrative sanctions[27].

This law draft was sent to the Civil Cabinet, which is carrying out consultation with the Ministries sympathetic to the theme in order to send the Bill to the Congress.

Conclusion

The implementation of the Convention on Biological Diversity, specifically in clauses 8j and 15, which deal, respectively, with the protection of traditional knowledge and access to genetic resources, as well as benefits' sharing stemming from its use, has been a challenge for all the members of this Treaty, especially for those providing genetic resources and traditional knowledge, such as Brazil.

Both the principle of sovereignty of the States over their genetic resources, and the need for benefits' sharing among providers and users are questioned very little[28], however one can not say the same concerning the instruments that have been adopted by countries to make their rights prevail.

The ruling of this issue has prescribed control measures at the moment of sample collection, either in *in situ* or *ex situ*, at the moment of shipment of samples - when the responsibility over their care is transferred from one institution to another, quite often foreign ones, and at the moment when a product or process is generated, which may be liable to economic exploitation. This moment is often identified whenever a patent is requested, which is considered a product of access to genetic resources or to traditional knowledge (Dutfield, 2004).

Thus control falls on both the beginning of the productive chain - research done by public and private institutions, and on the development of products, mostly in the cases done by private companies[29].

Clauses regarding the impact of this ruling on scientific and research exchange are frequent, both nationally and internationally. Still, Brazil is the country which responded fastest to the critique which targeted the current legislation, possibly for the very reason that this is a Provisional Measure.

Whereas in other countries, such as those which are members of the Nations of the Andine Community, it is necessary to establish a Contract for access activities for any purpose, including scientific research[30], Brazil has managed to minimize, within the conditions imposed by the legislation in effect, bureaucracy not only for research, but also for technological development[31].

It is important to acknowledge that researchers have been increasingly required to act and ponder beyond their restricted field of expertise. Some examples of this demand are the rulings which affect the practice of their profession, such as the Innovation Bill; Provisional Measure 2.186-16/02 and the Industrial Property Law, with the proposals for its alteration.

It is necessary to realize, however, that the challenge to act in unknown fields is present and is still greater in other sectors of society, such as local communities and the indigenous peoples.

Is it necessary to improve the legislation in effect in Brazil concerning access and benefits' sharing? The answer to this question is unanimously positive. Albeit, in order for this improvement to fulfill public interest - biodiversity conservation, protection of associated traditional knowledge, promotion of research and the sustainable use of biodiversity - it is paramount to practice citizenship by means of the representation of certain sectors of society, by seeking to build comprehension links among all the parties entailed and not by defending specific interests corporatively.

The remittal by the Executive Federal Power of the Bill concerning the issue to the Congress represents a new chance for society to discuss, give opinions about the matter; presently in a more effective manner and with more critical bulk, than in 1998.

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[27] The legislation in effect only prescribes administrative sanctions, because penal sanctions can not be established by a Provisional Measure, such as Provisional Measure 2.186-16/01.

[28] Those who question these points advocate a reversion to the principle that genetic resources belong to humankind, and that, therefore one should forbid all and any kind of private appropriation over these resources or products stemming from their use.

[29] Countries using genetic resources, such as the United States, are already warning their researchers about the rules implemented as a result of CBD. The State Department of the USA inserted information about obtaining biological material in *in situ* conditions abroad in its electronic address: http://www.state.gov/g/oes/rls/or/25962.htm

[30] Decision 391 of the Andine Community of The Nations of June 2, 1996 Common Regime of Access to Genetic Heritage. (Régimen Común sobre Acceso a los Recursos Genéticos),

[31] CGEN Resolution nº 17, published on October 25,2004, available at: http://www.mma.gov.br/port/cgen

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