NATIONAL IMPLEMENTATION OF ACCESS & BENEFIT-SHARING FOR NON-COMMERCIAL ACADEMIC RESEARCH

BRAZIL

This form is an annex of the document "Access & Benefit-Sharing in Latin America & the Caribbean, a science-policy dialogue for academic research", Biber-Klemm et al. (2014) (Available at http://www.diversitas-international.org/activities/policy/cbd-1/access-and-benefits-sharing-abs).

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Note: **All the regulations mentioned in this document are available in Portuguese at http://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico/normas-sobre-acesso .**

DIVERSITAS an international programme of biodiversity science
ICSU International Council for Science Regional Office for Latin America and the Caribbean
sc | nat Swiss Academy of Sciences Akademie der Naturwissenschaften Accademia di scienze naturali Académie des sciences naturelles
IUBS

SECTION 1: LEGAL AND INSTITUTIONAL FRAMEWORK

1. LEGAL SOURCES

1.1. Title of regulation(s) on access[1] to genetic resources and traditional knowledge regarding:

1.1.1. The conditions and procedures for access

The National Authority for regulations on access to genetic resources and traditional knowledge in Brazil is Genetic Heritage Management Council (CGEN) and it is composed by several Ministries and federal organizations as listed below:

- Ministries: Environment Ministry, Agricultural Ministry, Ministry of Science, Technological and Innovation, Ministry of Culture, Defense Ministry, Ministry of Justice, Health Ministry, Foreign Affairs Ministry, Ministry of Development, Industry and Foreign Trade.
- Federal agencies: Federal Environment Agency - Ibama, the National Science Research Council – CNPq
- National Institute of Industrial Property (INPI) from the Ministry of Development, Industry and Foreign Trade
- Federal Research organizations: Fiocruz (Health Ministry), Embrapa (Agricultural Ministry), Botanical Garden of Rio de Janeiro (Environment Ministry), National Institute of Amazonian Research – INPA (Ministry of Science, Technological and Innovation) and Institute of Carlos Chagas (Health Ministry), also a health institute such as Fiocruz
- Groups representing traditional communities: Fundação Cultural Palmares (representing the African descendents) from the Ministry of Culture, Funai (National Indian Foundation) from the Ministry of Justice

To increase the capacity of CGEN to manage the ABS system, the council may accredit other institutions to concede access authorizations. The Federal Environment Agency (Ibama), the National Science Research Council (CNPq), and the National Institute of Historic and Artistic Heritage (IPHAN) of the Ministry of Culture have been accredited by CGEN.

Below the procedures and requirements for access for scientific research (non-commercial research) stated by the Federal Environment Agency (Ibama), that had it translated in English, considering that the requirements are the same for CGEN (i.e. information necessary for the issuance of authorization to the access and remittance of genetic patrimony for scientific research):

1. Filling out the Application Form to Request the Authorization of Access to and Remittance of a Component Sample of Genetic Patrimony for Scientific Research, without any potential economic use;
2. If the applicant prefers to request a special authorization, the Application Form to Request the Special Authorization of Access to and Remittance of a Component Sample of Genetic Patrimony for Scientific Research must be filled out. The difference of this authorization to the former is that, once authorized, the institution may include projects into its portfolio in a simplified way, avoiding to send documentation already included in previous processes;
3. Term of Commitment signed by the legal representative of the institution. This term is already inserted into the application form to be filled out by the applicant;
4. A document proving the competence of the institution's legal representative. The responsible of the

[1]Including legislation that regulates access to genetic resources but does not make explicit mention / use of the term "access" (e.g., "scientific collections", use for biotechnology purposes) when such legislation exists.

institution is that person who holds the legal competence to respond in the institution's name before the public authorities. For example, the case of an university whose representative is the rector and not institute or faculty directors composed by it, except in the case of an explicit delegation with the competence of that to these.

5. Proof that the requesting institution has been constituted under the Brazilian law. This proof may occur through informing the law, decree or act of creation of the institution.
6. Proof that the requesting institution carries out research activities and development in biological and similar areas.
7. Technical qualification to perform activities to the access and remittance of a sample component of genetic patrimony. Such a proof is given by means of the curriculum vitae of the researchers linked to the research project(s). In this case, we recommend using the curricula from lattes platform.
8. Presentation of the research project. In the case of a special authorization, the applicant shall present portfolio of the project(s) developed by the institution.
9. Presentation of authorizations or licenses for the projects that involve previous collections of biological material, when pertinent. Or, otherwise, indicate the origin of the biological material to be utilized to access the genetic patrimony.
10. Destination of the components' samples of the genetic patrimony to be accessed.
11. Deposit of a sub-sample of the genetic patrimony's component. The sub-sample of the genetic patrimony accessed must be deposited in a Brazilian institution accredited by CGEN as "trusted depository". For more information, access site www.mma.gov.br/cgen.

Provisional Act 2.186-16 establishes the ABS legal framework in Brazil. Its main provisions require:

- Previous authorization by CGEN in order to access genetic resources and associated traditional knowledge for research, bioprospecting and technological development.
- Prior Informed Consent from indigenous and local communities as a necessary condition for accessing their genetic resources and/or traditional knowledge associated to genetic resources.
- Benefit sharing with the providers when any product or process that results from the access to genetic resources or associated traditional knowledge arrives at the market.
- The signing of benefit sharing contracts and their submission for approval by CGEN.

Simultaneously, Decree 3.945/2001 provided overall complementary regulation. It designated the Council for Genetic Heritage Management (CGEN) as the ABS national competent authority and the Department of Genetic Heritage (DPG) to operate as Secretariat for CGEN. DPG functions within the Ministry of the Environment.

Subsequent Decrees have amended the requirements for obtaining authorization for access, regulated the application of administrative penalties and regulated the use of public funds for benefit sharing.

Since its establishment in April 2002, CGEN has approved a number of norms to clarify and promote the implementation of the legislation, including 40 Resolutions and 8 Technical Orientations. The Council has also certified around 360 public *ex situ* collections as Trusted Depository Collections.

1.1.2. The competences and procedures for issuing permits

- For scientific research (that does not involve taxonomy, epidemiology, etc, see the translation of the Resolution 21 attached): Ibama (Federal Environment Agency) from the Ministry of Environment, and CNPq (National Council for Scientific and Technological Development) from Ministry of Science, Technology and

Innovation

- For bioprospecting: CGEN (Genetic Heritage Management Council) from the Ministry of Environment and CNPq (National Council for Scientific and Technological Development) from Ministry of Science, Technology and Innovation
- For technological development (TD): CGEN (Genetic Heritage Management Council) from the Ministry of Environment and CNPq (National Council for Scientific and Technological Development) from Ministry of Science, Technology and Innovation
- When the scientific, bioprospecting or TD has traditional knowledge (TK) associated the permit is issued by CGEN.
- When the project refers to traditional knowledge associated but without considering genetic resources the permit is issued by National Institute of Historic and Artistic Heritage (IPHAN) from the Ministry of Culture

CNPq has an electronic form for the request of authorizations and it issues the permits online and electronically (http://www.cnpq.br/web/guest/acesso-ao-patrimonio-genetico). There is an electronic platform only for researchers (Plataforma Carlos Chagas) for all issues regarding research, including the authorizations for access of genetic resource (http://carloschagas.cnpq.br/).

The permits are issued through physical documents by Ibama (http://www.ibama.gov.br/servicos/acesso-e-remessa-ao-patrimonio-genetico) and CGEN (http://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico).

1.1.3. The issuing of research permits

- For scientific research (that does not involve taxonomy, epidemiology, etc, see parts of the Resolution 21 below): Ibama (Brazilian Institute of Environment and Renewable Natural Resources) from the Ministry of Environment, and CNPq (National Council for Scientific and Technological Development) from Ministry of Science, Technology and Innovation
- For bioprospecting and Technological Development: CNPq and CGEN

Part of the Resolution 21: the following research and scientific activities are not under the concept of access to genetic resources for the purposes Provisional Measure No. 2.186-16 of August 23, 2001, under the Brazilian ABS legislation:

I. research that aims to elucidate the evolutionary history of a species or taxonomic group from the identification of species or specimens; the evaluation of phylogenetic relationships; the assessment of the genetic diversity of the population or the relationship of living beings with each other or with the environment;

II. paternity tests, sexing techniques and karyotype analyses intended to identify a species or specimen;

III. epidemiological research or research that aims to identify the etiologic agents of diseases, as well as measurement of the concentration of known substances whose relative quantities in the body indicate disease or physiological state;

IV. research intended to build DNA, tissues, germplasm, blood or serum collections.

1.2. Content of the regulations

The ABS is regulated by the Provisional Act 2186-16, in accordance with the Convention on Biological Diversity, mainly its articles 8j and 15, and by the Decrees 3945, 5459 and 6915. Additionally, there are 40 Resolutions

and 8 Technical Orientations in order to deal with specific aspects, as well as clarify inconsistencies and poorly defined terms and promote the implementation of the legislation.

1.3. Specific norms

1.3.1. On monitoring and compliance

The Brazilian National Patent Office (INPI) has begun refusing patent requests which do not fulfil the requirements of Provisional Measure 2.186-16. This is an important step towards meeting the requirements of Article 17 of the Nagoya Protocol which requires Parties to designate one or more checkpoints to ensure compliance by monitoring and enhancing transparency about the utilization of genetic resources.

1.3.2. For research or non-commercial research

The norms for research and non-commercial research are provided by the General Provisions from the Provisional Act 2.186-16.

GENERAL PROVISIONS

- Article 1. This Provisional Act provides for assets, rights and obligations concerning:

  I. Access to components of genetic heritage existing within the Brazilian territory, on the continental shelf and in the exclusive economic zone for purposes of scientific research, technological development or bioprospecting;

  II. Access to traditional knowledge associated to genetic heritage, related to the conservation of biological diversity, to the integrity of the country's genetic heritage and to the use of its components;

  III. The fair and equitable sharing of the benefits arising from the use of the genetic heritage component and the associated traditional knowledge; and

  IV. Access to technology and transfer of technology for the conservation and use of biological diversity.

- Paragraph 1. Access to components of genetic heritage for the purpose of scientific research, technological development or bioprospecting shall be carried out under the terms of this Provisional Act, without prejudice to material or intangible property rights that are incident upon the accessed genetic heritage components or upon the site of its occurrence.
- Paragraph 2. Access to components of genetic heritage existing on the continental shelf shall comply with that provided for in Law No. 8,617, dated January 4, 1993.
- Article 2. Access to genetic heritage existing in the country shall only be take place with an authorization from the Federal Government and its use, commercialization and employment for any purpose shall be submitted to inspection, restrictions and sharing of benefits in the terms and conditions established in this Provisional Act and its complementary legislation.
- Article 3. This Provisional Act does not apply to human genetic heritage.
- Article 4. The exchange and dissemination of components of genetic heritage and of associated traditional knowledge practiced within indigenous communities and local communities for their own benefit and based on customary practices is hereby preserved.
- Article 5. Access to genetic heritage is hereby prohibited for practices that are harmful to the environment and to human health and for the development of biological and chemical weapons.
- Article 6. At any moment, in the light of scientific evidence denoting the risk of serious and irreparable

damage to biological diversity, arising from activities carried out in the terms of this Provisional Act, the Government, through the Genetic Heritage Management Council, provided for in Article 10, based on criteria and technical assessments, shall determine measures intended to prevent such damage and may even stop the activity, observing the mandate of the agency responsible for the biosafety of genetically modified organisms.

The norm for benefit sharing is provided only for commercial research in the Provisional Act 2.186-16:

BENEFIT- SHARING

- Article 24. The benefits arising from the economic use of the product or process developed from samples of genetic heritage components and associated traditional knowledge, obtained by a Brazilian or foreign institution, shall be shared in a fair and equitable manner among the contracting parties, as defined in complementary and relevant legislation.
- Sole Paragraph. When the Federal Government is not a party to the Contract for Use of Genetic Heritage and Benefit-Sharing, it shall be assured participation in these benefits, as provided for in the chapeau of this article, as appropriate, in accordance with complementary legislation.
- Article 25. The benefits arising from the economic use of the product or process developed from a sample of a genetic heritage component or from associated traditional knowledge, may be, among others:

  I. Sharing of profits;

  II. Payment of royalties;

  III. Access and transfer of technologies;

  IV. Licensing, without cost, of products and processes; and

  V. Capacity building of human resources;

- Article 26. The economic use of a product or process developed from samples of genetic heritage components or from associated traditional knowledge, accessed in a manner contrary to the provisions of this Provisional Act, shall subject the offender to payment of compensation corresponding to at least twenty percent of the gross income obtained in the commercialization of the product or of the royalties obtained from third parties by the offender, as a result of licensing the product or process or use of technology, whether or not they are protected by intellectual property, without prejudice to the administrative sanctions and appropriate penalties.
- Article 27. The Contract for Use of Genetic Heritage and Benefit-Sharing should clearly indicate and qualify the contracting parties, namely, on the one side the owner of the public or private area or the representative of the indigenous community and the official Indian Affairs body, or the representative of the local community and, on the other side, the Brazilian institution authorized to carry out the access and the recipient institution.
- Article 28. The clauses that are mandatory in the Contract for Use of Genetic Heritage and Benefit-Sharing, in accordance with complementary legislation, without prejudice to others, are those that provide for:

  I. The object, its elements, quantification of the sample and intended use;

  II. Period of duration;

  III. Manner of fair and equitable sharing of benefits, and when appropriate, access to and transfer of technology;

  IV. Rights and responsibilities of the parties;

  V. Intellectual property rights;

VI. Withdrawal;

VII. Penalties;

VIII. Court jurisdiction in Brazil.

- Sole Paragraph. When the Federal Government is a party, the contract mentioned in the chapeau of this Article shall be ruled by the public law.
- Article 29. The Contracts for Use of Genetic Heritage and Benefit-Sharing shall be submitted for registration with the Management Council and shall only enter into force after its consent.
- Sole Paragraph. The Contracts for Use of Genetic Heritage and Benefit-Sharing shall be considered null and void, without any legal standing, when they are signed contrary to the provisions of this Provisional Act and its complementary legislation.

1.3.3. For access to *ex-situ* collections (for non-commercial and for commercial purposes)

There are two resolutions, Resolution 32 and the new Resolution 40, that regulate the access to *ex-situ* collections. However, they are not translated. Below see the free translations of the content of these two resolutions.

Resolution 32 / CGEN - March, 2008

- Establishes specific rules on the access of genetic resources collected in *in-situ* conditions and maintained in *ex-situ* collections.
- Establishes specific rules for the preparation of benefit sharing contracts for the use of genetic resources obtained from *ex-situ* collections, which were deposited after the approval of MP 2.186-16, 2001.
- The applicant must present PIC and a Benefit Sharing Agreement with the provider indicated by the *Ex-situ* Collection supplying the sample. When the provider cannot be identified, the Council will decide on the need or not of these requirements.
- In all cases, the applicant will present a benefit sharing contract according with Article 25 of the Provisional Act 2.186-16, 2001.
- For the accession to samples obtained before the approval of Provisional Act 2.186-16, 2001, and maintained in *ex-situ* collections, the applicant shall interact with the institution, which is storing the samples. (For additional information see Resolution 40).
- The above rules do not apply to samples collected in Conservation Units, Indigenous peoples' land, territorial sea and continental platform. In these cases, the Council will decide on the need or not of PIC and the destination of benefits to be shared.

Resolution 40 / CGEN - February, 2013

- Establishes specific rules for the preparation of benefit sharing contracts for the use of genetic resources obtained from:

1. supermarkets and groceries or other commercial sources, when it is not possible to identify the provider
2. the land owned by the interested research institution itself
3. from providers that are not interested in the potential benefit sharing
4. from *ex-situ* collection maintained by the interested research institution itself, when the genetic resource was collected and deposited before the approval of Provisional Act 2.186-16, 2001.

- In this last case, the activity of *ex-situ* conservation may be considered as benefit shearing, only if the collection was accredited as Faithful Trustee (different from the European concept).
- In all cases, the applicant will present a project of benefit sharing according with Article 25 of Provisional Act 2.186-16, 2001.
- The project will have to present, preferably, proposals for the conservation and the sustainable use of the biodiversity, in benefit of the collective.
- The Council will decide, on a case by case analysis, about the need for PIC and the Benefit Sharing Agreement based on the information provided by the applicant.

Observation regarding Trusted Depository Collection based on the Provisional Act 2.186-16:

A representative sub-sample of the accessed genetic resource shall be deposited in *ex situ* condition at a Brazilian public institution accredited by CGEN as trustee, in accordance with Article 11 and Article 16 of the Provisional Act 2.186-16 and complementary legislation. Each collection must go through the accreditation process by CGEN to be recognized as Trusted Depository Collection.

The deposit of sub-samples has several objectives, among others, the conservation and the traceability of the biological material. The collection to be accredited must demonstrate that it has infrastructure, technical capacity and funding for the conservation activities.

1.3.4. About change of intent from non-commercial to commercial

It is in the Provisional Act 2186 as it follows:

- Paragraph 5o If potential for economic use is identified in a product or process, liable or not to intellectual property protection, originating in a sample of a genetic heritage component and in information arising from associated traditional knowledge, accessed with authorization in which this hypothesis was not established, the authorized institution commits itself to inform the Management Council or the institution where the process for access and shipment originated, to formalize a Contract for Use of Genetic Heritage and Benefit-Sharing.

and in the MTA from where there is the following statement:

- In cases of any subsequent wish to make use of the samples of the genetic heritage components transferred under this MTA for the purposes of bioprospecting, technological development, or the request of a patent, the Receiving Institution shall undertake to so inform the Sending Institution, which shall in turn inform the Genetic Heritage Management Council or an institution accredited under the terms of Article 11(IV)(e) of Provisional Act No. 2,186, dated August 23, 2001.

1.4. Definitions

1.4.1. Access

Acquisition of samples of a genetic heritage component for the purpose of scientific research, technological development, or bioprospecting, with a view to its industrial or other application

1.4.2. Change of intent (including indicators)

See above. There is no specific definition for this in the Brazilian system.

1.4.3. Non-commercial-commercial use

There are two groups of non-commercial research:

- the research that are listed in the Resolution 21 (see above)
- the research (defined in our legislation as scientific research) that seeks knowledge without economical objective but involves access in the Brazilian meaning (see above)

There are two other groups of commercial research:

- Bioprospecting: an exploratory activity that aims to identify genetic heritage components and information on associated traditional knowledge, with potential for commercial use (Provisional act 2186).
- Technological development: the systematic research, based on the already existing knowledge, that aims the production of specific innovation, the elaboration or modification of already existing products and processes, with economical application (Technical Orientation nº 4, CGEN, without English version).

1.4.4. Genetic resources

The Brazilian legislation uses the term genetic heritage instead of genetic resources. Genetic heritage: information of genetic origin, contained in samples of all or part of a plant, fungal, microbial or animal species, in the form of molecules and substances originating in the metabolism of these living beings, and in extracts obtained from *in situ* conditions, including domesticated, or kept in *ex situ* collections, if collected from *in situ* conditions, within the Brazilian territory, on the continental shelf or in the exclusive economic zone.

1.4.5. Traditional knowledge

Individual or collective information or practice of the indigenous community or local community, with real or potential value, associated to genetic heritage

1.4.6. Others

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2. MANAGEMENT/GOVERNANCE

Functions of different authorities in the ABS process:

2.1. Focal Point

Ministry of Foreign Affairs

2.2. Authority granting authorisation

The focal point does not grant authorization but has a representative in CGEN.

- For scientific research (that does not involve taxonomy, epidemiology, etc; see the translation of the

Resolution 21 attached): Ibama (Federal Environment Agency) from the Ministry of Environment, and CNPq (National Council for Scientific and Technological Development) from Ministry of Science, Technology and Innovation

- For bioprospecting: CGEN (Genetic Heritage Management Council) from the Ministry of Environment and CNPq (National Council for Scientific and Technological Development) from Ministry of Science, Technology and Innovation
- Technological development (TD): CGEN (Genetic Heritage Management Council) from the Ministry of Environment and CNPq (National Council for Scientific and Technological Development) from Ministry of Science, Technology and Innovation
- When the scientific, bioprospecting or TD has TK associated the permit is issued by CGEN.
- When the project refers to TK associated but without considering genetic resources is issued by National Institute of Historic and Artistic Heritage (IPHAN) from the Ministry of Culture.

2.3. Authorities (ministries, departments) involved in the evaluation process

The authorities involved in the evaluation process are exactly the same as the ones granting authorisations, see above.

2.4. External (non-governmental) entities involved (on the horizontal levels)

Representatives of scientific research are involved in the evaluation of the application: in CGEN from the 19 representatives there are 5 who are from research institutes. The research institutions involved are from the federal government: Fiocruz (Health Ministry), Embrapa (Agricultural Ministry), Botanical Garden of Rio de Janeiro (Environment Ministry), National Institute of Amazonian Research – INPA (Ministry of Science, Technological and Innovation) and Institute of Evandro Chagas (Health Ministry), also a health institute such as Fiocruz

Groups representing traditional communities are: Fundação Cultural Palmares (representing the African descendents) from the Ministry of Culture, Funai (National Indian Foundation) from the Ministry of Justice.

There are some invited people including the Brazilian Society for the Advancement of Science (SBPC) that represents all the scientific societies.

2.5. Organisation of evaluation (e.g. number of authorities involved; lead authority collecting assessments; meetings and procedures)

The evaluations are conducted by the monthly meetings of CGEN, from which CNPq and Ibama are also members. For how the evaluation of the application is organised, report to the power point presentation, the Brazilian ABS regulation documents and the English version of provisional act 2186.

SECTION 2: PROCEDURES

The procedure(s) for (i) application for and (ii) authorisation of access to genetic resources and / or associated traditional knowledge.

3. PROCEDURE FOR ACCESS/APPLICATION FOR PIC AND MAT

3.1. The requirements for application

The requirements for PIC is established in the Resolution 9 (see below parts of this regulation translated specifically for this document by Fiocruz):

RESOLUTION Nº 9, DECEMBER 18th, 2003

Establishes guidelines to obtain Prior Consent for access to genetic heritage components located on indigenous lands, in private areas, land tenure or property of local communities and in Conservation Units of Sustainable Use for purposes of scientific research without potential or perspective commercial use.

- Article 1. Establish guidelines to guide the process of obtaining prior approval with local or indigenous communities by national institutions interested in accessing the genetic heritage components existing in indigenous lands, private areas of tenure or property of local communities, as well as for prior approval of the competent environmental agency when the access occurs in Conservation Unit of Sustainable Use, for purposes of scientific without potential or perspective commercial use, in accordance with art. 16, § 9th, item I, II and III of Provisional Act #2.186-16/01.
- Sole Paragraph. For the purposes of this resolution apply the definitions set in the art. 7th of Provisional Act #2.186-16/01.
- Article 2. The process of obtaining prior consent which refers to art. 1st of this Resolution will be guided by the following guidelines, without prejudice of other requirements provided for in legislation:

  I. clarification to the consenting community, in an accessible speech to it, about the object of the research, the methodology, the duration, the budget, the possible benefits, sources of project financing, the use which is intended to give to the genetic heritage components to be accessed, the geographical area covered by the project and the involved communities;

  II. respect to the ways of social organization and of traditional political representation of the involved communities during the consultation process;

  III. clarification to the community about the social, cultural and environmental impacts from the project;

  IV. clarification to the community about the rights and the duties of each party in project execution and in its results;

  V. establishment, together with the community, of modalities and forms of consideration derived from the execution of the project;

  VI. ensuring respect for the right of the community to refuse the access to the genetic heritage components during the process of Prior Consent.

- Article 3. The official indigenous agency will adopt the administrative procedures necessary for the entry into indigenous land to obtaining the due prior consent by the interested party.
- Article 4. When the access to the genetic heritage component occurs in Conservation Unit of Sustainable Use provided by Article 14 and the followings of Law 9.985, from July, 2000, the prior consent mentioned in art.

16, §9th, II from the Provisional Act 2.186-16/01 should be issued by the competent environmental agency, the covered local communities should be heard by the Conservation Unit, through their representatives, directly or in the respective Advisory or Deliberative Board, when constituted.

The requirements for MAT is established in the Resolution 7 (see below parts of this regulation translated specifically for this document by Fiocruz):

RESOLUTION Nº 7, JUNE 26TH, 2013

Establishes guidelines for the preparation and analysis of the Use of Genetic Heritage and Sharing of Benefits Agreements signed between private and which do not involve associated traditional knowledge or component of wildlife.

- Article 1. Establishes guidelines for the preparation of Use of Genetic Heritage and Sharing of Benefits Agreements between private, which do not involve associated traditional knowledge or component of wildlife, and for the analysis of the applications for consent relative to these Agreements by the Genetic Heritage Management Council, in accordance with the articles 24 and 29 of the Provisional Act #2.186-16, from August 23rd, 2011.
- Sole paragraph. For the purposes of this resolution apply the definitions set in the art. 7th of Provisional Act #2.186-16, from 2001.
- Article 2. The preparation of Use of Genetic Heritage and Sharing of Benefit Agreements to which this Resolution refers will be guided by the following guidelines, without prejudice of other requirements provided in legislation:

I. presence of essential clauses required in the art. 28 of the Provisional Act #2.186, from 2001;

II. identification and qualification of all parties involved, including the samples receiving institution, when it is defined in the Agreement signature moment;

III. regularity of the power of attorney when the parties constitute prosecutors to represent them in any stage of the Agreement negotiation;

IV. proof of ownership of the area where the sample to be accessed will be collected;

V. with respect to the subject of the Agreement: a) identification of its elements; b) sample quantification; c) intended use description;

VI. the information contained in the Agreement should keep consistency with the Authorization for Access and Shipment granted separately;

VII. about deadlines: a) should be specified the periods provided for collection, bioprospecting, product development or process and the commercial exploitation, when such steps are contemplated in the project; b) unless different and expressly agreed between the parties, the deadline for receipt of benefits will be counted from the beginning of the exploitation of the developed product or process; c) the Agreement which contains exclusivity clause should have given period, established by the parties by mutual agreement, according to criteria of reasonableness to be assessed case by case;

VIII. with respect to the form of benefit sharing and, if applicable, access to the technology and the transfer of technology: a) the Agreement should keep consistency with the prior consent obtained, if it has specified clauses on benefit sharing; b) in case of pecuniary benefit calculated as a percentage, the Agreement should clarify the basis and the method of calculation and, if this occurs on the profit or income, gross or net, and still should, in this last case, clearly specify the deductions to be made; c) the forms of benefit sharing should be expressed and clear and they should be those already provided in art. 25 of the Provisional Act #2.186-16, from 2001, or other chosen by the parties; d) by electing the forms of benefit sharing the parties should seek a balance between the benefits of short, medium and long

term;

IX. the institution that will access the genetic heritage should commit to: a) periodically provide the holder of the genetic heritage component a report on the research progress, as well as on the product or process exploitation; b) allow monitoring by the holder or a third party indicated by him, during the achievement of the expedition to collect samples; c) keep at the disposal of the holder the results obtained in the expedition achieved within the area of his respective ownership; d) do not communicate to third parties any information or right arising from this agreement without prior consent of the holder;

X. the Agreement should define, when appropriate, the ownership of the rights of intellectual property or other rights related to its subject, as well as the duties arising from these rights;

XI. the Agreement shall clearly stipulate the forms of rescission, which, by no means, should harm right acquired before the rescission;

XII. the Agreement will fix the additional penalties to be applied to the parties in the case of noncompliance of its clauses, safeguarded, in any case, the application of penalties provided for in legislation;

XIII. the place of jurisdiction for the resolution of disputes arising from the Agreement will be rather the domicile of the holder of the area where the genetic heritage component will be obtained, unless when the circumstances point the self-sufficiency of this to defend himself in court in a jurisdiction other than his, an hypothesis that the forum can be freely chosen by the parties, subject to the provisions of Art.28, item VIII, of the Provisional Act #2.186-16, from 2001.

Regarding MAT, there is some information below from the Provisional Act 2186:

- Article 24. The benefits arising from the economic use of the product or process developed from samples of genetic heritage components and associated traditional knowledge, obtained by a Brazilian or foreign institution, shall be shared in a fair and equitable manner among the contracting parties, as defined in complementary and relevant legislation.
- Sole Paragraph. When the Federal Government is not a party to the Contract for Use of Genetic Heritage and Benefit-Sharing, it shall be assured participation in these benefits, as provided for in the chapeau of this article, as appropriate, in accordance with complementary legislation.
- Article 25. The benefits arising from the economic use of the product or process developed from a sample of a genetic heritage component or from associated traditional knowledge, may be, among others:

  I. Sharing of profits;

  II. Payment of royalties;

  III. Access and transfer of technologies;

  IV. Licensing, without cost, of products and processes; and

  V. Capacity building of human resources;

- Article 26. The economic use of a product or process developed from samples of genetic heritage components or from associated traditional knowledge, accessed in a manner contrary to the provisions of this Provisional Act, shall subject the offender to payment of compensation corresponding to at least twenty percent of the gross income obtained in the commercialization of the product or of the royalties obtained from third parties by the offender, as a result of licensing the product or process or use of technology, whether or not they are protected by intellectual property, without prejudice to the administrative sanctions and appropriate penalties.
- Article 27. The Contract for Use of Genetic Heritage and Benefit-Sharing should clearly indicate and qualify the contracting parties, namely, on the one side the owner of the public or private area or the representative

of the indigenous community and the official Indian Affairs body, or the representative of the local community and, on the other side, the Brazilian institution authorized to carry out the access and the recipient institution.

- Article 28. The clauses that are mandatory in the Contract for Use of Genetic Heritage and Benefit-Sharing, in accordance with complementary legislation, without prejudice to others, are those that provide for:

I. The object, its elements, quantification of the sample and intended use;

II. Period of duration;

III. Manner of fair and equitable sharing of benefits, and when appropriate, access to and transfer of technology;

IV. Rights and responsibilities of the parties;

V. Intellectual property rights;

VI. Withdrawal;

VII. Penalties;

VIII. Court jurisdiction in Brazil.

- Sole Paragraph. When the Federal Government is a party, the contract mentioned in the chapeau of this Article shall be ruled by the public law.
- Article 29. The Contracts for Use of Genetic Heritage and Benefit-Sharing shall be submitted for registration with the Management Council and shall only enter into force after its consent.
- Sole Paragraph. The Contracts for Use of Genetic Heritage and Benefit-Sharing shall be considered null and void, without any legal standing, when they are signed contrary to the provisions of this Provisional Act and its complementary legislation.

3.2. Procedural steps for applicant

The PIC from public and private providers is required in the case of bioprospecting and technological development, as well as the MAT that must be signed by provider and user. Both PIC and MAT, along with the detailed research project on access, must be submitted to CGEN to be evaluated and for the MAT to be endorsed.

For bioprospecting only the PIC is needed. For technological development, the MAT is also needed, besides PIC. B However in the majority of the cases the researchers apply for biorpospecting and technological development at the same time, therefore they submit both PIC and MAT together.

There are instructions for PIC and MAT but not a proper format for them, as it can be seen above.

Application is required only at national level.

When the scientific, bioprospecting or TD has TK associated to GR the permit is issued by CGEN as described in the Provisional Act 2186:

PROTECTION TO ASSOCIATED TRADITIONAL KNOWLEDGE

- Article 8. This Provisional Act protects the traditional knowledge of the indigenous communities and of the local communities, associated to genetic heritage, from illicit use and exploitation and other harmful actions or those actions not authorized by the Brazilian Council referred to in Article 10, or by an accredited institution.
- Paragraph 1. The State recognizes the right of the indigenous communities and of the local communities to

decide on the use of their traditional knowledge related to the genetic heritage of the country, in the terms of this Provisional Act and its complementary legislation.

- Paragraph 2. The traditional knowledge related to genetic heritage provided for by this Provisional Act is an integral part of the Brazilian cultural heritage and may be registered, as provided for the Brazilian Council or specific legislation.
- Paragraph 3. The protection conferred by this Provisional Act may not be interpreted so as to become an obstacle to the preservation, utilization and development of traditional knowledge of an indigenous community or a local community.
- Paragraph 4. The protection hereby established shall not affect, damage or limit rights related to intellectual property.
- Article 9. The indigenous communities and local communities that create, develop, hold or conserve traditional knowledge associated to genetic heritage are assured the right to:

I. Have acknowledged the origin of the access to the traditional knowledge in all publications, uses, exploitations and dissemination;

II. Prevent non-authorized third-parties to:

a. Use, test, research or make commercial use, in regard to associated traditional knowledge;

b. Disseminate, transmit or forward data or information that make up associated traditional knowledge, or part thereof;

III. Receive benefits from the economic use by third parties, directly or indirectly, of associated traditional knowledge to which they hold rights, in accordance with this Provisional Act.

- Sole Paragraph. For the purposes of this Provisional Act, any traditional knowledge related to genetic heritage may be deemed to be held by the community even if only one member of this community holds this knowledge.

4. PROCEDURE FOR ISSUING PIC/MAT – EVALUATION OF APPLICATION

4.1. Lead authority

Genetic Heritage Management Council (CGEN) from the Environment Ministry

4.2. Other authorities and agencies involved

This evaluation is conducted only by CGEN.

4.3. Procedures if several decentralised entities are involved

Regarding PIC/MAT the procedure is centralised.

4.4. Procedures if TK associated to GR is involved

The procedure is conducted by CGEN as stated above. When the TK has to be evaluated without considering the GR, it can be conducted by IPHAN

5. ADDITIONAL INFORMATION ON SPECIFIC POINTS

5.1. Difference in requirements and/or procedure between applications by national researchers/research institutions vs. application from outside the country/province

The institution from the foreign researchers has to be associated to a Brazilian institution, which, for all legal purposes, will be responsible for the activities of access to genetic resources.

Parts of the provisional act 2186 that deal with this issue:

- Paragraph 6o Participation of a foreign legal entity in an expedition to collect *in situ* samples of genetic heritage components and to access associated traditional knowledge shall only be authorized when it is joined by a Brazilian public institution, the latter with mandatory coordination of activities and if all participating institutions carry out research and development activities in biological and related areas.
- Article 22. The access to and transfer of technology between a Brazilian research and development institution, public or private, and a foreign-based institution, may be carried out through the following activities, among others:

I. Scientific research and technological development;

II. Training and capacity building of human resources;

III. Exchange of information;

IV. Exchange between a Brazilian research institution and a foreign-based research institution;

V. Consolidation of scientific research and technological development infrastructure;

VI. Economic use, in partnership, of process and product arising from the use of a genetic heritage component; and

VII. Establishment of joint technologically based undertaking.

5.2. Procedure for facilitation of access for research

The Resolution 21, which excluded some research and scientific activities from the concept of access to genetic resources, including taxonomy, phylogeny and epidemiology, and the simplified electronic system developed by CNPq as already described above.

The new legislation that hopefully will be clearer and have consistent rules associated to devices for stimulating scientific research, after 12 years of experience with the current framework.

5.3. Specific requirements or procedure for access in protected areas or when it involves a species listed as threatened under national legislation

In this case it is necessary to have a licence from the competent body, ICMBio (Chico Mendes Institute of Biodiversity Conservation). This is not under the responsibility of CGEN.

5.4. Number of permits issued per year

By CGEN only: 2003 – 14; 2004 – 4; 2005 – 12; 2006 – 20; 2007 – 18; 2008 – 14; 2009 – 7; 2010 – 9; 2011 – 10; 2012 – 33; 2013 – 59

5.5. Number of permits rejected per year

There were 42 rejected permits in 2012 and 50 in 2013. The majority of them were rejected because of the lapse of time (the interested institution did not reply to CGEN on time)

5.6. Taxonomic groups for which permits are issued

Animals, plants, algae, protozoa, fungi, bacteria, virus

6. ASSESSMENT (AUTHORS' PERSONAL EVALUATION OF THE ABS PROCESS)

6.1. Reflection of authors on the complexity/simplicity of the respective authorisation processes in regards to facilitating access for non-commercial research (including a potential change of intent)

In general the authorization process for non-commercial research is simple, since part of this research is not in the scope of our ABS legislation (resolution 21) and due to the online and electronic system of CNPq for scientific research involving access in the Brazilian meaning.

6.2. Perception from authors of specific problems (for ABS for non-commercial research) regarding both, researchers and involved governmental agencies

For all sectors, academia, government and productive sector, the Provisional Act 2186 is complex, ambiguous and difficult to comprehend, leading to legal uncertainty. The result of this situation is the discouragement of the scientific research.

6.3. Experiences and lessons learned deemed important by authors

Even though the regulatory system looks nice, in practical terms, it does not work properly. The system has been holding innovation regarding the use of Brazilian biodiversity and so far, very little benefit has been shared (12

years since approval of the law). This is the reason why there is an ongoing effort by many sectors to propose a new law to Parliament.

One positive aspect is the fact that researchers and social organizations are involved in all the steps for developing the ABS legislation framework together with the government representatives.

APPENDIX 1

Brazilian ABS system

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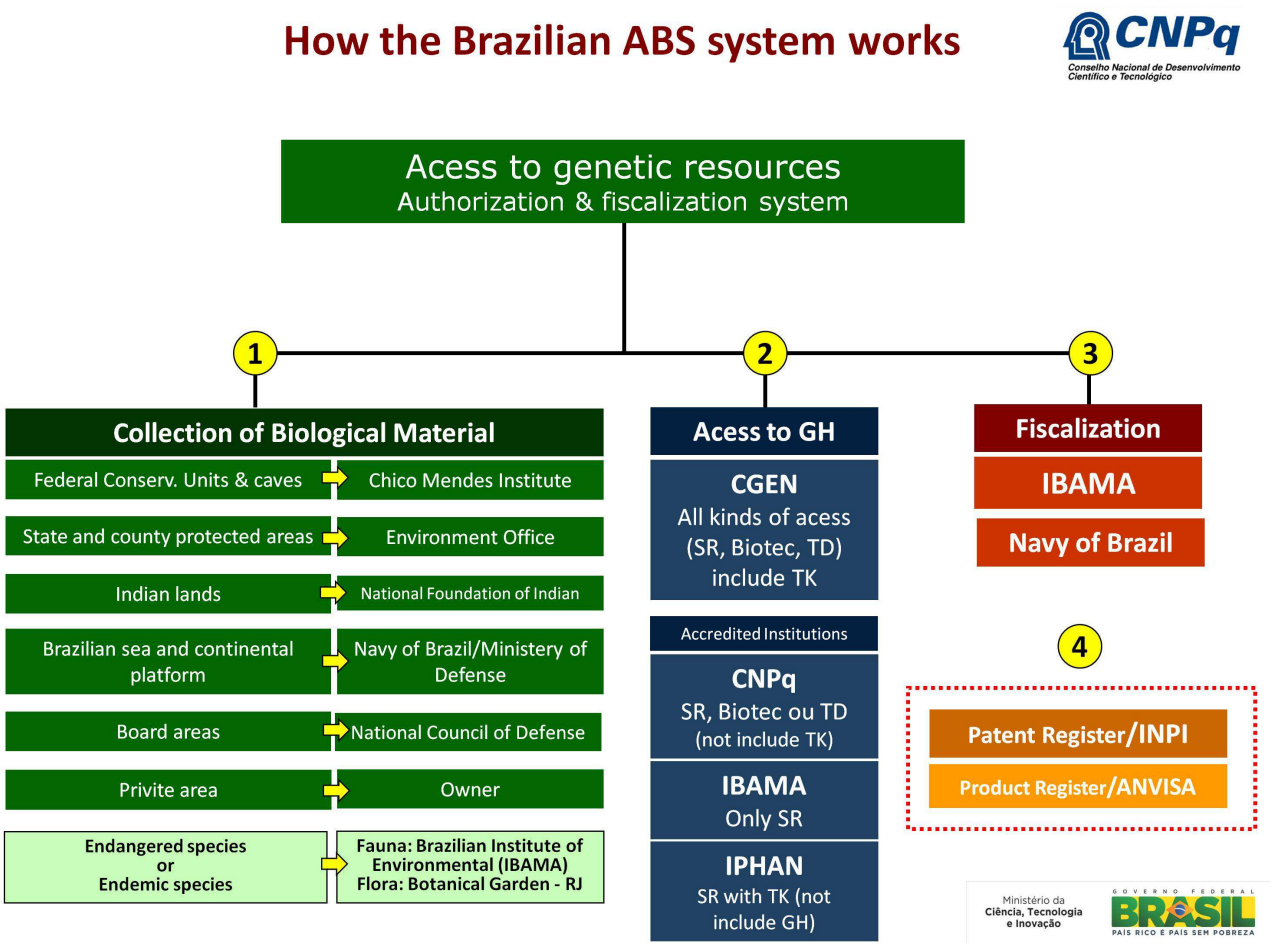

APPENDIX 2

Diagram representing the application process step by step

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