THE BRAZILIAN LEGISLATION ON ACCESS AND BENEFIT SHARING

MANUELA DA SILVA

Coordinator of the Sectoral Chamber of Academia of the Genetic Heritage Management Council (Brazilian ABS Competent Authority)
THE NEW BRAZILIAN ABS LEGISLATION

The Law is based on the Federal Constitution and on the Convention on Biological Diversity, provides for access to genetic heritage, on the protection and access to associated traditional knowledge and the benefit sharing for conservation and sustainable use of biodiversity; revokes the Provisional Act 2.186/2001, and creates the ABS NATIONAL COMPETENT AUTHORITY, the Genetic Heritage Management Council - CGen.

20th May 2015
Publication of Law 13,123
THE NEW BRAZILIAN ABS LEGISLATION

20th May 2015
Publication of Law 13,123

17th November, 2015
Entry into force of Law 13,123

Provisional Act 2,186-16 / 2001 is revoked
THE NEW BRAZILIAN ABS LEGISLATION

- 20th May 2015
  Publication of Law 13,123

- 17th November, 2015
  Entry into force of Law 13,123

- 11th May 2016
  Publication of Decree 8.772 that regulates the Law

- 28th July 2016
  1ª Meeting of CGen

CGen consists of representatives of 9 Ministries and 9 representatives of civil society, 3 of each of the following sectors: Business sector; Indigenous peoples, traditional communities and traditional farmers; Academia (SBPC – Brazilian Society for the Science Progress; ABC - Brazilian Academy of Science, ABA - Brazilian Association of Anthropology)
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6th November 2017
SisGen Becomes available

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National System for the Management of Genetic Heritage and Associated Traditional Knowledge, the SisGen, instrument that allows law compliance
CGEN WORKS BY MEANS OF:

I. Plenary
II. Thematic Chambers
III. **Sectoral Chambers**
IV. Executive Secretary

Deliberação nº 5
Data: 21/03/2017

Sectoral Chamber of Academia is responsible for conducting technical discussions and presenting proposals of interest to the academic sector related to access and benefit-sharing legislation under the terms of Law 13,123 and Decree No. 8,772. The first meeting was in August 2017
<table>
<thead>
<tr>
<th>CGEN member who indicated</th>
<th>Name and Institution</th>
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<tr>
<td>SBPC, ABC</td>
<td>André Luis de Gasper – Universidade Regional de Blumenau Coordenador da Rede de Herbários da Sociedade Botânica do Brasil</td>
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<tr>
<td>SBPC, ABC</td>
<td>Manuela da Silva - Fundação Oswaldo Cruz/RJ Sociedade Brasileira de Microbiologia Coordinator</td>
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<td>SBPC, ABC</td>
<td>Luciane Marinoni - Universidade Federal do Paraná Presidente da Sociedade Brasileira de Zoologia Deputy Coordinator</td>
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<td>Marcelo H. A. Freitas - Secretaria de Relações Internacionais - Coordenadoria de Políticas Globais/Embrapa</td>
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<td>Elaine Moreira ABA</td>
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<td>Claudia Magioli – INPI/MDIC</td>
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<td>Nínieve Aguiar Colonello Frattini</td>
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<td>MMA</td>
<td>Thiago Zeidan Araujo</td>
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This chamber is the means by which researchers can expose problems with the legislation and its compliance and propose the necessary adjustments.
Câmara Setorial da Academia

PRÓXIMA REUNIÃO

16ª Reunião Ordinária da Câmara Setorial da Academia

A reunião poderá ser acompanhada on-line através do sistema de webconferência Zoom conforme detalhes abaixo:

Link da reunião: Em breve

Data: 03/07/2020
- Horário: 10 às 12h
- Local: Internet (Zoom)
- Pauta: Em breve.

1. Associação de instituição estrangeira com instituição brasileira:
   - IBICT/ICMBio como parceiro brasileiro para a associação;
   - Avaliação da CONJUR/MMA sobre o momento que a parceria/cadastro deve ser realizada pelo estrangeiro;
   - Desenvolvimento no SisGen 2 do formulário que será preenchido pelos estrangeiros para o cadastramento das atividades.

2. Problema com relação aos depósitos de linhagens de espécies novas de bactérias/fungos em coleções de culturas internacionais e o consequente impedimento da descrição destas espécies.
## Câmara Setorial da Academia

Pautas, Memórias, Atas e outros documentos das reuniões anteriores dessa Câmara Setorial.

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Câmara Setorial da Academia

Histórico  Composição  Calendário  Reuniões anteriores  Link/Documentos

Prazos para regularização

1. Lei nº 13.123, de 20 de maio de 2015 - versão em inglês
2. Acesso e repartição de benefícios no cenário mundial: A lei brasileira em comparação com normas internacionais
3. Parecer nº 169/2017/CONJUR-MMA/CGU/AGU
4. Manual SisGen
5. Manual Acesso ao Patrimônio Genético Brasileiro e ao Conhecimento Tradicional Associado - ABIFINA
6. Marcos regulatórios aplicáveis às atividades de pesquisa e desenvolvimento - EMBRAPA
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11. English version of Resolution 12 that approves the MTA
12. English version of MTA with additional clauses for Microbial Collections
13. Instrução Normativa nº3, de 20 de março de 2019
14. Lista de espécies introduzidas no território nacional (exóticas)
15. Instrução Normativa nº 16, de 4 de junho de 2019
ACCESS = UTILIZATION

There is no state authorization or benefit sharing for R & D; PIC and MAT for R & D using GH is already authorized by the National Congress

ORIGINATED FROM THE ACCESS OF GENETIC HERITAGE

ORIGINATED FROM THE ACCESS OF ASSOCIATED TRADITIONAL KNOWLEDGE

THE LAW COVERS THE ACTIVITY OF

- RESEARCH
- TECHNOLOGICAL DEVELOPMENT

- ECONOMIC EXPLOITATION
- FINISHED PRODUCT OR
- REPRODUCTIVE MATERIAL

THIS IS THE MOMENT WHEN THERE IS BENEFIT SHARING
INSTITUTO CHICO MENDES OF CONSERVATION OF BIODIVERSITY (ICMBio/MMA)

Through the Authorization and Information System in Biodiversity (SISBio), ICMBio is responsible for authorizing the following activities:

I. collection of biological material;
II. capturing or marking wild animals in situ;
III. temporary maintenance of specimens of wild fauna in captivity;
IV. transport of biological material; and
V. conducting research in a federal conservation unit or in an underground natural cavity.

Obs: The collection of plant, fungal or microbial material outside of a conservation unit or natural underground cavity, does not require authorization.
ECONOMIC EXPLOITATION

FINISHED PRODUCT

Product whose nature does not require any additional production process, arising from access to genetic heritage or associated traditional knowledge, in which the component of the genetic heritage or associated traditional knowledge is a key element of added value to the product, being able to be used by the final consumer, whether natural or legal person.

REPRODUCTIVE MATERIAL

It refers to plant propagation material or animal reproduction of any genus, species or cultivation from sexual or asexual reproduction.
SCOPE OF THE LAW 13.123/15

REACHES ALL RESEARCH (EXPERIMENTAL OR THEORETICAL) CONDUCTED WITH THE BRAZILIAN GENETIC HERITAGE

DEFINITION

information of genetic origin from plants, animals, microorganisms or species of other nature, including substances derived from the metabolism of these living beings

BASIC RESEARCH SUCH AS:

• EPIDEMIOLOGY
• MOLECULAR ECOLOGY
• MOLECULAR TAXONOMY
• PHYLOGENY
SCOPE OF THE LAW 13.123/15

REACHES ALL RESEARCH (EXPERIMENTAL OR THEORETICAL) CONDUCTED WITH THE BRAZILIAN GENETIC HERITAGE

DEFINITION

USE OF INFORMATION FROM GENETIC SEQUENCES PUBLISHED IN PUBLIC DATA BASES (GenBank)

information of genetic origin from plants, animals, microorganisms or species of other nature, including substances derived from the metabolism of these living beings
The microorganism that has been isolated from:

- National territory substrates
- Territorial sea
- Exclusive economic zone
- Continental shelf

is considered Brazilian genetic resource for the purposes of this law.
ACTIVITIES THAT ARE SUBJECT TO THE LAW

I. Access to genetic heritage and associated traditional knowledge;

II. Shipment abroad of genetic heritage

III. Economic exploitation of finished product or reproductive material from access to genetic heritage and associated traditional knowledge
FOR COMPLYING WITH THE LAW

REGISTRATION

- RESEARCH
- TECHNOLOGICAL DEVELOPMENT

THE REGISTRATION SHOULD BE CONDUCTED PRIOR TO:

- Shipment abroad
- Request of any intellectual property right
- Commercialization of any intermediate product
- Release of results, final or partial, in scientific or communication circles
- Notification of finished product or reproductive material developed as a result of the access
FOR COMPLYING WITH THE LAW

REGISTRATION

- RESEARCH
- TECHNOLOGICAL DEVELOPMENT

NOTIFICATION BEFORE

- ECONOMIC EXPLOITATION
NOTIFICATION

For economic exploitation will be required:

I. prior notification of the finished product or the reproductive material to CGen

II. presentation of the benefit-sharing agreement (BSA) within 1 year from the time of notification, except in the case of finished product or reproductive material from access to ATK of identifiable origin. In this case, the agreement must be presented at the time of notification.
AUTHORIZATION

THE AUTHORIZATION SHALL BE CARRIED OUT PRIOR TO:

- Access to GH or ATK in area indispensable to national security
- Access to GH or ATK in Brazilian territorial waters, continental shelf and exclusive economic zone

The authorization will be required only in cases where there is some involvement of foreigners:

I - National legal entity whose controlling shareholders or members who are natural or legal foreign persons

II - National institution of scientific research and technology, public or private, when access is made in association with legal entity based abroad

III - Brazilian natural person associated, funded or contracted by a legal entity based abroad
THE TRADITIONAL KNOWLEDGE ASSOCIATED TO GENETIC HERITAGE CAN BE RECOGNIZED IN SCIENTIFIC PUBLICATIONS, RECORDS IN REGISTERS OR DATABASES AND CULTURAL INVENTORIES.

THE POSSIBILITY OF LINKING ITS SOURCE TO AT LEAST AN INDIGENOUS POPULATION, TRADITIONAL COMMUNITY OR TRADITIONAL FARMER

ACCESS TO ASSOCIATED TRADITIONAL KNOWLEDGE

OF IDENTIFIABLE SOURCE

WHEN THERE IS

OF UNIDENTIFIABLE SOURCE

WHEN THERE IS NOT
ACCESS TO ASSOCIATED TRADITIONAL KNOWLEDGE

ANY INDIGENOUS POPULATION, TRADITIONAL COMMUNITY OR TRADITIONAL FARMER WHO CREATES, DEVELOPS, HOLDS OR PRESERVES CERTAIN TRADITIONAL KNOWLEDGE IS AN IDENTIFIABLE SOURCE OF SUCH KNOWLEDGE

ASSOCIATED TRADITIONAL KNOWLEDGE

OF IDENTIFIABLE SOURCE

WHEN THERE IS

THE POSSIBILITY OF LINKING ITS SOURCE TO AT LEAST AN INDIGENOUS POPULATION, TRADITIONAL COMMUNITY OR TRADITIONAL FARMER

OF UNIDENTIFIABLE SOURCE

WHEN THERE IS NOT
ACCESS TO ASSOCIATED TRADITIONAL KNOWLEDGE

THE ACCESS TO THIS KNOWLEDGE IS SUBJECT TO OBTAINING **PREVIOUS INFORMED CONSENT - PIC**

**ASSOCIATED TRADITIONAL KNOWLEDGE**

- **OF IDENTIFIABLE SOURCE**
  - WHEN THERE IS
  - THE POSSIBILITY OF LINKING ITS SOURCE TO AT LEAST AN INDIGENOUS POPULATION, TRADITIONAL COMMUNITY OR TRADITIONAL FARMER

- **OF UNIDENTIFIABLE SOURCE**
  - WHEN THERE IS NOT
**SHIPMENT ABROAD OF GENETIC HERITAGE**

**DEFINITION:** TRANSFERRENCE OF GENETIC HERITAGE TO AN INSTITUTION LOCATED IN ANOTHER COUNTRY WITH THE PURPOSE OF ACCESS, IN WHICH THE RESPONSABILITY OF THE GH IS TRANSFERRED TO THE RECEPIENT INSTITUTION

**SHIPMENT ABROAD WILL HAVE TO BE REGISTERED IN CASES WHERE ACCESS TO GENETIC RESOURCES ARE CONDUCTED BY:**

- LEGAL ENTITY LOCATED ABROAD THAT IS ASSOCIATED TO NATIONAL INSTITUTION (PUBLIC OR PRIVATE)
- NATIONAL INDIVIDUAL OR LEGAL ENTITY (PUBLIC OR PRIVATE) THAT IS ABROAD
SHIPMENT ABROAD OF GENETIC HERITAGE

DEFINITION: TRANSFERENCE OF GENETIC HERITAGE TO AN INSTITUTION LOCATED IN ANOTHER COUNTRY WITH THE PURPOSE OF ACCESS, IN WHICH THE RESPONSABILITY OF THE GH IS TRANSFERRED TO THE RECEPIENT INSTITUTION

REGISTRATION FOR SHIPMENT ABROAD MUST BE PERFORMED PRIOR SHIPMENT AND DEPENDS ON:

- THE SIGNATURE OF MATERIAL TRANSFER AGREEMENT – MTA
- THE SUPPLY OF INFORMATION ABOUT THE PROVIDER AND RECEPIENT INSTITUTIONS, GENETIC HERITAGE AND INTENDED USE
The MTA formalizes the shipment abroad of samples of genetic heritage accessed or available for access

It will predict that:
• It shall be interpreted in accordance with Brazilian law
• The recipient institution will not be considered provider of the GH

It will contain clauses that:
• Inform on access to ATK when applicable
• Authorizes or prohibits the transfer of the GH to third parties
The MTA formalizes the shipment abroad of samples of genetic heritage accessed or available for access.

It will predict that:
- It shall be interpreted in accordance with Brazilian law.
- The recipient institution will not be considered provider of the GH.

It will contain clauses that:
- Inform on access to ATK when applicable.
- **Authorizes** or prohibits the transfer of the GH to third parties.

In the case of authorization, the transfer of genetic heritage to third parties will also depend on a MTA containing the above requirements. This obligation will be applied to all subsequent transfers.
Resolution CGen Nº 12 ratifies and updates the MTA, making important changes in it:

- It will allow to sign a single MTA between the Brazilian institution and the foreign institution, with a validity period of a maximum of 10 renewable years, which may comprise all shipments to the same recipient.
- At each shipment, the researcher will register in SisGen, attach a copy of the signed MTA with the foreign institution and a sequentially numbered shipment invoice, with a description of the samples to be sent.

**ATTACHMENT 1**

MATERIAL TRANSFER AGREEMENT – MTA

This MATERIAL TRANSFER AGREEMENT – MTA, a legal document defined in the item III of the art. 25 of the Decree no. 8.772, of 2016, is signed by:

If the sender is a Legal Entity:

- **[NAME OF THE INSTITUTION AS INFORMED IN THE NATIONAL REGISTRY OF LEGAL ENTITIES - CNPJ]**, a legal entity registered with the CNPJ/MF under no. [CNPJ number], having its main headquarters located at [NAME OF THE STREET], number [NUMBER], [ADDITIONAL ADDRESS INFORMATION], neighborhood [NEIGHBORHOOD], in the municipality of [MUNICIPALITY], [STATE], postal code - CEP [NUMBER OF THE POSTAL CODE], herein represented in the form of ENTITY INCORPORATION INFORMATION through EMPOWERMENT DOCUMENT by COMPLETE NAME OF LEGAL REPRESENTATIVE, [NATIONALITY], [MARITAL STATUS], [PROFESSION]. Tax Number - CPF no. [CPF no.], identity card no. [IDENTITY CARD NUMBER], identity card issue office [NAME OF OFFICE], State [STATE], hereinafter referred to simply as the "SENDER".

If the sender is a Natural Person:

- **[FULL NAME]**, nationality [NATIONALITY], [MARITAL STATUS], [PROFESSION]. Tax Number - CPF no. [CPF no.], identity card no. [IDENTITY CARD NUMBER], identity card issue office [NAME OF OFFICE], State [STATE], residing at [NAME OF THE STREET], number [NUMBER], [ADDITIONAL ADDRESS INFORMATION], neighborhood [NEIGHBORHOOD], in the municipality of [MUNICIPALITY], [STATE], postal code - CEP [NUMBER OF THE POSTAL CODE], hereinafter referred to simply as the "SENDER".

**ATTACHMENT 2**

SHIPMENT INVOICE

- "Shipper Invoice No [ ] of the Material Transfer Agreement - MTA signed by and between [SENDER] and [RECIPIENT] on [DATE], valid until [DATE]."

1. Identifying information on the genetic heritage samples to be shipped, to the most specific taxonomic rank possible:

2. Origin of the samples to be shipped, indicating the municipality of the place of attainment in 2016, even if it has been obtained from an ex situ source:

3. Information on the kind of sample and method of storage:
MATERIAL TRANSFER AGREEMENT

1. English version of Resolution 12 that approves the MTA

MINISTRY OF THE ENVIRONMENT
Genetic Heritage Management Council

CGEN RESOLUTION No. 12, OF 18 SEPTEMBER 2018

Ratifies the standard Material Transfer Agreement - MTA document

Genetic Heritage Management Council (CGEN) - CGen as part of its attributions established by the Law no. 13.123, of 20 May 2015, and the Decrease no. 8.772, of 11 May 2016, and considering the provisions of its Bylaws, attached to the MMA [Ministry of the Environment] Ordinance no. 427, of 29 September 2016, decides upon the following:

Article 1 - To approve the standard Material Transfer Agreement - MTA document, in the form of the Attachment 1 of this Resolution.

Article 2 - As provided in the Article 25 of the Decrease no. 8.772, of 11 May 2016, the clauses presented in this standard MTA model are mandatory.

Sole Paragraph. Additional clauses of specific interest to the sender or to the recipient, may be included as attachments to the MTA, provided they do not conflict with the provisions of this Resolution or any other applicable law.
MATERIAL TRANSFER AGREEMENT

Prazos para regularização

1. Lei nº 13.123, de 20 de maio de 2015 - versão em inglês
2. Acesso e repartição de benefícios no cenário mundial: A lei brasileira em comparação com normas internacionais
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SENDING OF GENETIC HERITAGE

DEFINITION: SENDING OF GH FOR SERVICES PROVIDED ABROAD, AS PART OF A RESEARCH OR TECHNOLOGICAL DEVELOPMENT, IN WHICH THE RESPONSIBILITY FOR THE GH IS NOT TRANSFERED
DEFINITION: SENDING OF GH FOR SERVICES PROVIDED ABROAD, AS PART OF A RESEARCH OR TECHNOLOGICAL DEVELOPMENT, IN WHICH THE RESPONSIBILITY FOR THE GH IS NOT TRANSFERRED.

SERVICES PROVIDED ABROAD ARE CONSIDERED PERFORMED BY AN INSTITUTION COLABORATING WITH THE NATIONAL INSTITUTION RESPONSIBLE BY THE ACCESS OR BY WHICH IT WAS HIRED.
MAIN DIFFERENCES BETWEEN SHIPPING AND SENDING IN THE CASE OF SCIENTIFIC PARTNERSHIP

Sending:
• No need of a previous registration
• There is no transfer of responsibility on the sample
• The sample is accompanied by a legal instrument
• The sample must be destroyed or returned

Shipping:
• Previous registration needed
• There is transfer of responsibility on the sample
• The sample is accompanied by Material Transfer Agreement - MTA
• The sample can remain in the recipient
RESEARCH BY FOREIGNERS

BRAZILIAN BIODIVERSITY CAN ONLY BE ACCESSED BY

FOREIGN INSTITUTION
(LEGAL ENTITY LOCATED ABROAD)

in partnership with

BRAZILIAN INSTITUTION
(PUBLIC OR PRIVATE)

THAT WILL BE RESPONSIBLE FOR THE REGISTRATION AND UPDATING SisGen (REGISTRY, NOTIFICATION, BENEFIT SHARING PAYMENT)

If access occurs in Brazil, an Authorization's Request for Collecting and Research (Scientific Expeditions) has to be obtained from the Brazilian Institution for the Foreign Institution before the Registration in SisGen.

NATIONAL COUNCIL FOR SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENT

www.fiocruz.br
The requirement of the foreign researcher to have to associate with a Brazilian institution to research the Brazilian biodiversity has caused some difficulties.

The solution proposed:

- Pre-defined Brazilian Scientific and Technological Research Institution
- Brazilian partner for foreigners who want to research Brazilian biodiversity but have no collaboration in Brazil

To make this new procedure feasible, a pre-registration in version 2 of SisGen (English / Portuguese) will be made available for the foreigner to provide the necessary information about the research project to be developed. The pre-registration will be accessed by the pre-defined research institution, acting as a Brazilian partner, who will evaluate the pre-registration. If the institution agrees, it will validate the pre-registration that becomes the registration with a number and then follow the normal flow defined by law.
CLEAR AND FIXED RULES FOR BENEFIT SHARING WERE ESTABLISHED

THAT CAN BE:
- MONETARY, WITH THE PERCENTAGE OF 1% OF ANNUAL NET REVENUE OR UP TO 0.1% BY SECTORIAL AGREEMENT, OR
- NON MONETARY

ONLY THE MANUFACTURER OF THE FINISHED PRODUCT OR THE PRODUCER OF THE REPRODUCTIVE MATERIAL WILL BE SUBJECT TO BENEFIT-SHARING, REGARDLESS OF WHO PREVIOUSLY PERFORMED THE ACCESS.
CLEAR AND FIXED RULES FOR BENEFIT SHARING WERE ESTABLISHED

THAT CAN BE:

• MONETARY, WITH THE PERCENTAGE OF 1% OF ANNUAL NET REVENUE OR UP TO 0.1% BY SECTORIAL AGREEMENT, OR

• NON MONETARY

a. projects for conservation, sustainable use of biodiversity, protection and maintenance of knowledge, innovations and practices of populations holders of traditional knowledge
b. technology transfer
c. training of human resources on issues related to conservation and sustainable use of genetic heritage or associated traditional knowledge
d. free distribution of products in programs of social interest, etc...
BENEFIT SHARING

IN THE CASE OF ACCESS TO:

Genetic Heritage and Associated TK of unidentifiable source

Is the Government, represented by the Ministry of the Environment

Associated TK of identifiable source

Are the indigenous people, traditional communities and traditional farmers

The beneficiary of benefit sharing:
THE PAYMENTS FROM THE BENEFIT SHARING AND FINES DUE TO NON-COMPLIANCE OF THE LAW SHALL BE DEPOSITED IN THE NATIONAL FUND FOR BENEFIT SHARING - NFBS

ESTABLISHED FOR VALORIZING GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE AS WELL AS TO PROMOTE THEIR USE IN A SUSTAINABLE WAY
BENEFIT SHARING

WHEN THE BENEFIT SHARING COMES FROM:

- Genetic Heritage
  - The payments will go entirely to the FNRB

- Associated Traditional Knowledge of unidentifiable source
  - The payments will go entirely to the FNRB

- Associated Traditional Knowledge of identifiable source
  - The TK holders negotiate freely the benefit sharing and additional 0.5% of annual net revenue from the economic exploitation of the knowledge will go to the FNRB and will be administered by providers
THE MONETARY FUNDS DEPOSITED IN THE NATIONAL FUND OF BENEFIT SHARING (FNRB) ARISING FROM ECONOMIC EXPLOITATION OF FINISHED PRODUCT OR REPRODUCTIVE MATERIAL OBTAINED FROM THE ACCESS TO:

- Genetic Heritage from ex situ Collections
  - Will be partially (60 to 80%) intended for the benefit of these collections

- Associated Traditional Knowledge
  - Will be used exclusively for the benefit of traditional knowledge holders
**BENEFIT SHARING**

The monetary funds deposited in the National Fund of Benefit Sharing (FNRB) arising from economic exploitation of finished product or reproductive material obtained from the access to:

**Genetic Heritage from *ex situ* Collections**

Will be partially (60 to 80%) intended for the benefit of these collections.

*Ex situ* collections will only be eligible to receive this resources from the fund if they are accredited in SISGEN.
THE MONETARY FUNDS DEPOSITED IN THE NATIONAL FUND OF BENEFIT SHARING (FNRB) ARISING FROM ECONOMIC EXPLOITATION OF FINISHED PRODUCT OR REPRODUCTIVE MATERIAL OBTAINED FROM THE ACCESS TO:

Genetic Heritage from *ex situ* Collections

Will be partially (60 to 80%) intended for the benefit of these collections

**EX SITU COLLECTIONS CAN ALSO TRADE DIRECTLY WITH COMPANIES THROUGH NON-MONETARY BENEFIT SHARING**
BENEFIT SHARING

Through the National Fund of Benefit Sharing the National Program of Benefit Sharing – PNRB will be established in order to promote, among others:

- Conservation of biological diversity
- Survey and inventory of genetic resources
- Recovery, creation and maintenance of *ex situ* collections
- Training of human resources associated with the use and conservation of genetic heritage and associated traditional knowledge
- Promotion of research and technological development associated with genetic heritage and associated traditional knowledge
BENEFIT SHARING AGREEMENT

The modality of benefit sharing (monetary or non-monetary) will be established in the Benefit Sharing Agreement.

The Benefit-Sharing Agreement will be required in cases of:
- Non-monetary benefits
- Monetary benefits with holders of associated traditional knowledge of identifiable origin

In the case of monetary benefits regarding access:
- Genetic heritage and / or
- Associated traditional knowledge of unidentifiable origin

Benefit Sharing Agreement will not be necessary, the benefit can be deposited directly in the NFBS.
The National System for Genetic Heritage and Associated Traditional Knowledge Management (SisGen) was created to manage:

- **Registration**
  - Access to Genetic Heritage
  - Access to Associated Traditional Knowledge
  - Shipping Genetic Heritage
  - Sending Genetic Heritage

- **Notification**
  - Finished Product
  - Reproductive Material

- **Authorization**
  - Access to Genetic Heritage
  - Access to Associated Traditional Knowledge
  - Shipping Genetic Heritage

- **Accreditation**
  - National Institutions Maintaining ex situ Collections that Hold Genetic Heritage
Access through login (CPF - Social Security Number) and password

Security of the information:
- Digital certificate
- Shielding System - Security Module

Communication with user via electronic message (e-mail)

Training Environment (http://treina.sisgen.gov.br)

Manual available at SisGen

Elaboration of version 2
AFTER FINALIZING THE REGISTRATION OR NOTIFICATION

A RECEIPT WILL BE ISSUED AUTOMATICALLY

DOCUMENT THAT PROVES THAT THE USER PROVIDED THE REQUESTED INFORMATION AND PRODUCES THE FOLLOWING EFFECTS:

ESTABLISHES THE VERIFICATION PROCEDURE

ENABLES

THE USER DO NOT NEED TO WAIT FOR THE VERIFICATION CONCLUSION TO PERFORM THE ABOVE ACTIVITIES

- REGISTRATION OF ACCESS TO GH
- REGISTRATION OF ACCESS TO ATK
- REGISTRATION OF GH SHIPMENT
- NOTIFICATION

- request of any intellectual property right
- commercialization of the intermediate product
- dissemination of results from research or TD
- notification
- shipment abroad
- economic exploitation

NATIONAL SYSTEM FOR GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE MANAGEMENT
CERTIFICATE OF ACCESS REGULARITY

Upon request of the user and after determination of CGEN will be issued.

Administrative act by which the competent authority declares that.

Certificate of access regularity

Access to genetic heritage

Access to associated traditional knowledge

Prevents application of administrative penalties specifically regarding access activities undertaken until issuing the certificate.

Comply with the requirements of the law.
FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT

RESEARCH AND TD WITH THE BRAZILIAN GH

REGISTRATION

INDICATE THE SOURCE OF THE GH: IN SITU; EX SITU OR/AND IN SILICO

RECEIPT AUTOMATICALLY ISSUED
FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT

RESEARCH AND TD WITH THE BRAZILIAN GH → REGISTRATION → INDICATE THE SOURCE OF THE GH: IN SITU; EX SITU OR/AND IN SILICO → RECEIPT AUTOMATICALLY ISSUED

RESEARCH AND TD WITH THE BRAZILIAN GH

REGISTRATION

INDICATE THE SOURCE OF THE GH: IN SITU; EX SITU OR/AND IN SILICO

RECEIPT AUTOMATICALLY ISSUED

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FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT

- RESEARCH AND TD WITH THE BRAZILIAN GH
- REGISTRATION
  - INDICATE THE SOURCE OF THE GH: IN SITU; EX SITU AND IN SILICO
- RECEIPT AUTOMATICALLY ISSUED

- SHIPPING GH ABROAD
- REGISTRATION PRIOR SHIPPING GH ABROAD
- SIGNATURE OF A MATERIAL TRANSFER AGREEMENT
- RECEIPT AUTOMATICALLY ISSUED
  - DEPOSIT IN COLLECTION IS RECOMMENDED
  - BOTH DOCUMENTS GO ALONG WITH THE GH
FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT

RESEARCH AND TD WITH THE BRAZILIAN GH → REGISTRATION → INDICATE THE SOURCE OF THE GH: IN SITU; EX SITU AND IN SILICO → RECEIPT AUTOMATICALLY ISSUED

SENDING GH → REGISTRATION FOR SENDING THE GH ABROAD → SIGNATURE OF A LEGAL INSTRUMENT → THIS DOCUMENT GOES ALONG WITH THE GH
FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT

RESEARCH AND TD WITH THE BRAZILIAN GH → REGISTRATION → INDICATE THE SOURCE OF THE GH: IN SITU; EX SITU AND IN SILICO → RECEIPT AUTOMATICALLY ISSUED

SENDING GH → REGISTRATION FOR SENDING THE GH ABROAD → WHEN THE SENDING IS FOR GENETIC SEQUENCING → THERE IS NO NEED OF A LEGAL INSTRUMENT, JUST A FORMAL COMMUNICATION OF THE INSTITUTION ABOUT THE OBLIGATIONS AND PROHIBITIONS
FOR COMPLYING WITH THE LAW: ACCESS TO GR AND ATK

RESEARCH AND TD WITH THE BRAZILIAN GH ➔ REGISTRATION ➔ INDICATE THE SOURCE OF THE GH: IN SITU; EX SITU AND IN SILICO ➔ RECEIPT AUTOMATICALLY ISSUED

ACCESS TO ASSOCIATED TRADITIONAL KNOWLED ➔ OBTAINING PREVIOUS INFORMED CONSENT – PIC (identifiable ATK) BEFORE ACCESS ➔ REGISTRATION ➔ RECEIPT AUTOMATICALLY ISSUED
FOR COMPLYING WITH THE LAW: ECONOMICAL EXPLORATION

1. RESEARCH AND TD WITH THE BRAZILIAN GH
2. REGISTRATION
3. INDICATE THE SOURCE OF THE GH: IN SITU; EX SITU AND IN SILICO
4. RECEIPT AUTOMATICALLY ISSUED

FINISHED PRODUCTS DEVELOPED FROM BRAZILIAN GH

1. NOTIFICATION PRIOR ECONOMIC EXPLORATION
2. RECEIPT AUTOMATICALLY ISSUED
3. ECONOMIC EXPLORATION
4. SIGNATURE OF A BENEFIT SHARING AGREEMENT
5. BENEFIT SHARING CAN BE MONETARY OR NON-MONETARY

- WHEN MONETARY IS WITH THE GOVERNMENT AND TRADITIONAL COMMUNITY IF THERE IS IDENTIFIABLE ATK
- MONETARY OR NON-MONETARY
REGULARIZATION REGARDING THE PROVISIONAL MEASURE 2.186/2001

Establishment of more flexible rules for the regularization of liabilities arising from non-compliance with the Provisional Measure 2.186 / 2001. All sanctions were extinguished, with the exception of fines.

The regularization is conditional upon signature of a commitment term, but only for development. In the case of research, the user will be regularized by means of registration.

100% exemption from payment of a fine in case of access to Gh; in the case of ATK, 100% exemption for research and 90% for bioprospecting and TD.

RESEARCH
BIOPROSPECTING
TECHNOCLOGICAL DEVELOPMENT
VIOLATIONS AGAINST GH AND ATK

THOSE WHO FAIL TO MEET THE REQUIREMENTS OF THE LAW REGARDING ACCESS TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE, INCLUDING, AMONG OTHERS:

• Explore economically finished product or reproductive material from access to GH or ATK without notification
• Shipping GH abroad without prior registration or in disagreement with this
• Disseminate results, final or partial, in scientific or communication circles without prior registration
• Access ATK of identifiable source without obtaining prior informed consent or in disagreement with this
• Failing to indicate the origin of ATK of identifiable source in publications, utilizations, explorations and disclosures of results from the access

CAN BE PUNISHED WITH PENALTIES SUCH AS:

• Warning
• Fine
• Suspension of certificate
• Cancellation of certificate
• Embargo on the specific activity related to the offense
• Apprehension of materials
• Temporary suspension of the manufacture and sale of the finished product or reproductive materials
• Partial or total prohibition of the establishment, activity or enterprise
VIOLATIONS AGAINST GH AND ATK

THOSE WHO FAIL TO MEET THE REQUIREMENTS OF THE LAW REGARDING ACCESS TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE, INCLUDING, AMONG OTHERS:

• Explore economically finished product or reproductive material from access to GH or ATK without notification
• Shipping GH abroad without prior registration or in disagreement with this
• Disseminate results, final or partial, in scientific or communication circles without prior registration
• Access ATK of identifiable source without obtaining prior informed consent or in disagreement with this
• Failing to indicate the origin of ATK of identifiable source in publications, utilizations, explorations and disclosures of results from the access

CAN BE PUNISHED WITH PENALTIES SUCH AS:

• Fines
  ▪ From R $ 1,000.00 to R $ 100,000.00, when the infraction is committed by an individual
  ▪ From R $ 10,000.00 to R $ 10,000,000.00, when the infraction is committed by a legal entity
Access to genetic resources and associated traditional knowledge

Since 2015, Brazil has a new legislation which provides for the use of Brazilian biodiversity by science and production chain. It is the Law 13,123, known as the Biodiversity Law. Its rules define, in the bargain of the area, "access to genetic resources, protection, access to associated traditional knowledge and benefit sharing for the conservation and sustainable use of biodiversity". The new legal framework was regulated by Decree 8.772/15, on May 12, 2016.

In the scientist’s routine, it is very common to have to use biodiversity resources. It means that, in their research, they will isolate and study the genome of plants, animals, microorganisms and fungi. Observing the genetic information from these different forms of life, it is possible to better understand phenomena related to cell and molecular biology, allowing that biological and chemical structures are reproduced in the creation of numerous products and technologies.

In the law, the genetic resource is defined as "the genetic information of plant, animal, microbial species or species of other nature, including substances derived from the metabolism of these living beings". In the other hand, the access to associated traditional knowledge is "research or technological development (RTD) performed on traditional knowledge associated with genetic resources that enable or facilitate access to genetic resources".

Brazil was one of the first countries to regulate access to genetic resources, and to associate traditional knowledge and benefit sharing through Provisonal Act 2166-16 of 23 August 2001 for purposes of scientific research, bioprospecting, and technological development. After almost 15 years of many criticisms and demands from civil society and other sectors, Law 13,123 was sanctioned on 20 May 2015 and entered into force on 17 November 2015, replacing Provisonal Act 2.166.

The Law, known as the Biodiversity Law, regulates Article 1, Article 8(A), Article 10, Article 16, Article 18, Article 20, Article 21, Article 22, Article 23, Article 24, Article 25 and Article 27 of the Constitution of the Federal Republic of Brazil. It provides for access to genetic resource (known in Brazil as genetic heritage), for protection and access to associated traditional knowledge, and for benefit-sharing for conservation and sustainable use of biodiversity and the creation of the Genetic Heritage Management Council (GHMC). Therefore, despite the fact that Brazil has not yet ratified the Nagoya Protocol (NP) on Access to Genetic Resources and the Fair and Equitable Distribution of Benefits Arising from the利用 of Genetic Resources and Associated Traditional Knowledge (ATK), Brazil encourages the negotiation towards accession to the Nagoya Protocol and the implementation of the TRIPS Agreement's provisions.
THANK YOU!

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HEALTH MINISTRY