Workshop Biodiversity and Biobank

BIOLOGICAL COLLECTIONS AND THE BRAZILIAN LEGISLATION ON ACCESS BENEFIT SHARING (LAW OF BIODIVERSITY)

MANUELA DA SILVA - FIOCRUZ – FUNDAÇÃO OSWALDO CRUZ
COORDINATOR OF FIOCRUZ BIOLOGICAL COLLECTIONS
THE NEW BRAZILIAN ABS LEGISLATION
The New Brazilian ABS Legislation

The law was published on May 21, 2015 and entered into force on November 17, 2015.

LAW Nº 13.123, FROM 20 OF MAI 2015

Regulates the section II of § 1 and § 4 of article 225 of the Federal Constitution, Article 1, point j of Article 8, point c of Article 10, Article 15 and §§ 3 and 4 of Article 16 of the Convention on Biological Diversity, promulgated by Decree No. 2519 of 16 March 1998, 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, 23 August 2001, and takes other measures.
The law was published on May 21, 2015 and entered into force on November 17, 2015.

After almost 6 months since the law came into force, the Decree regulating it was published. Thus, we had a scenario in which there was a law in force without regulation, which prevented its implementation.

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Regulates Law No. 13,123, of May 20, 2015, which provides for access to genetic resources, the protection and access to associated traditional knowledge and the sharing of benefits for conservation and sustainable use of biodiversity.
The law was published on May 21, 2015 and entered into force on November 17, 2015. After almost 6 months since the law came into force, the Decree regulating it was published. Thus, we had a scenario in which there was a law in force without regulation, which prevented its implementation.

Now we have law and regulation, but after 2 years of the publication of the new law, we are still waiting for SisGen, which 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.
The law was published on May 21, 2015 and entered into force on November 17, 2015.

After almost 6 months since the law came into force, the Decree regulating it was published. Thus, we had a scenario in which there was a law in force without regulation, which prevented its implementation.
The Brazilian ABS National Competent Authority is the Genetic Heritage Management Council - CGen
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CGen consists of representatives from bodies and entities of the federal public administration that are competent on the various actions of this law and the representation of civil society.

There are 11 Ministries and 9 representatives of civil society, 3 of each of the following sectors:

- Business sector
- Academia
- Indigenous peoples, traditional communities and traditional farmers
CGEN WORKS BY MEANS OF:

I. Plenary
II. Thematic Chambers
III. Sectorial Chambers
IV. Executive Secretary
CGEN WORKS BY MEANS OF:

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

Deliberação nº 5

Data: 21/03/2017

Assunto: Cria a Câmara Setorial da Academia, em caráter permanente, para conduzir discussões técnicas e apresentar propostas de interesse do setor acadêmico relacionadas à legislação de acesso e repartição de benefícios nos termos da Lei nº 13.123, de 20 de maio de 2015 e do Decreto nº 8.772, de 11 de maio de 2016.

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<thead>
<tr>
<th>CGEN member who indicated</th>
<th>Name and Institution</th>
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</thead>
<tbody>
<tr>
<td>SBPC, ABC e ABA</td>
<td>André Luis de Gasper – Universidade Regional de Blumenau Coordenador da Rede de Herbários da Sociedade Botânica do Brasil</td>
</tr>
<tr>
<td>SBPC, ABC e ABA</td>
<td>Manuela da Silva - Fundação Oswaldo Cruz/RJ Coordenadora das Coleções Biológicas da Fiocruz/ Sociedade Brasileira de Microbiologia</td>
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<tr>
<td>SBPC, ABC e ABA</td>
<td>Luciane Marinoni - Universidade Federal do Paraná Presidente da Sociedade Brasileira de Zoologia</td>
</tr>
<tr>
<td>SBPC, ABC e ABA</td>
<td>Marcelo H. A. Freitas - Secretaria de Relações Internacionais - Coordenadoria de Políticas Globais/Embrapa</td>
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<tr>
<td>SBPC, ABC e ABA</td>
<td>Laura Rodrigues Santonieri</td>
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<tr>
<td>SBPC, ABC e ABA</td>
<td>Diego Soares da Silveira - Instituto de Ciências Sociais da Universidade Federal de Uberlândia</td>
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<tr>
<td>André Fábio De Souza – MDIC</td>
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<td>Maira Smith – MJSP</td>
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<tr>
<td>Fabrício - MAPA</td>
<td>Rosa Míriam - Embrapa</td>
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<tr>
<td>Bruno César Prosdocími Nunes - MCTIC</td>
<td>Ricardo Henrique Kruger - Instituto de Biologia da Universidade de Brasília</td>
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<tr>
<td>Bruno César Prosdocími Nunes - MCTIC</td>
<td>Kátia Regina Torres - Departamento de Assistência Farmacêutica e Insumos Estratégicos, Ministério da Saúde</td>
</tr>
<tr>
<td>Rafael Marques – MMA</td>
<td>Henry Philippe Ibanez de Novion – MMA</td>
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</table>
SCOPE OF THE LAW 13.123/15
THE LAW COVERS THE ACTIVITY OF

- RESEARCH
- TECHNOLOGICAL DEVELOPMENT
- ECONOMIC EXPLOITATION
THE LAW COVERS THE ACTIVITY OF:
- RESEARCH
- TECHNOLOGICAL DEVELOPMENT
- ECONOMIC EXPLOITATION

- FINISHED PRODUCT OR
- REPRODUCTIVE MATERIAL

ORIGINATED FROM THE ACCESS OF GENETIC HERITAGE
ORIGINATED FROM THE ACCESS OF ASSOCIATED TRADITIONAL KNOWLEDGE
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THIS IS THE MOMENT WHEN THERE IS BENEFIT SHARING
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ORIGINATED FROM THE ACCESS OF GENETIC HERITAGE

ORIGINATED FROM THE ACCESS OF ASSOCIATED TRADITIONAL KNOWLEDGE

ACCESS = UTILIZATION

THIS IS THE MOMENT WHEN THERE IS BENEFIT SHARING

SCOPE OF THE LAW 13.123/15
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REACHES ALL RESEARCH (EXPERIMENTAL OR THEORETICAL) CONDUCTED WITH THE BRAZILIAN GENETIC HERITAGE
DIFFERENTLY FROM THE PREVIOUS LEGISLATION, THE NEW LAW:

- 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.
SCOPE OF THE LAW 13.123/15

**DIFERENTLY FROM THE PREVIOUS LEGISLATION, THE NEW LAW:**

- 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
Differently from the previous legislation, the new Law:

- 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.
- Use of information from genetic sequences published in public data bases (GenBank).
OTHER NOVELTY IN THE LAW IS THE PARAGRAPHS ON MICROORGANISMS
The microorganism that has been isolated from:

- National territory substrates
- Territorial sea
- Exclusive economic zone
- Continental shelf
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
FOR COMPLYING WITH THE LAW
FOR COMPLYING WITH THE LAW

REGISTRATION

RESEARCH

TECHNOLOGICAL DEVELOPMENT
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
SHIPMENT ABROAD OF GENETIC HERITAGE
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DEFINITION: TRANSFERENCE OF GENETIC HERITAGE TO AN INSTITUTION LOCA TED IN ANOTHER COUNTRY WITH THE PURPOSE OF ACCESS, IN WHICH THE RESPONSABILITY OF THE GH IS TRANSFERRED TO THE RECEPIENT INSTITUTION
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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 RECEPTIVE 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
SHIEMENT 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 SHIEMENT ABROAD MUST BE PERFORMED PRIOR SHIEMENT AND DEPENDS ON:

• THE SIGNATURE OF MATERIAL TRANSFER AGREEMENT – MTA

• THE SUPLY OF INFORMATION ABOUT THE PROVIDER AND RECEIPIENT 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.
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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.
CONSELHO DE GESTÃO DO PATRIMÔNIO GENÉTICO

RESOLUÇÃO N° 1. DE 5 DE OUTUBRO DE 2016

Aprova o modelo de Termo de Transferência de Material - TTM

O CONSELHO DE GESTÃO DO PATRIMÔNIO GENÉTICO - CGen, no uso das atribuições que lhe conferem a Lei nº 13.123, de 20 de maio de 2015, e o Decreto nº 8.772, de 11 de maio de 2016, e tendo em vista o disposto no seu Regimento Interno, anexo à Portaria MMA nº 427, de 29 de setembro de 2016, resolve:

Art. 1º Aprovar o modelo de Termo de Transferência de Material - TTM, na forma do anexo a esta Resolução.

Art. 2º Conformar disposto no artigo 25 do Decreto nº 8.772, de 11 de maio de 2016, as cláusulas apresentadas neste modelo de TTM são obrigatórias.

Parágrafo único. Cláusulas adicionais, de interesse específico do remetente ou do destinatário, poderão ser incluídas em anexo ao TTM, desde que não conflitem com o disposto nesta Resolução ou na legislação pertinente.

Art. 3º Esta Resolução entra em vigor na data de sua publicação.

3. O DESTINATÁRIO declara que utilizará as amostras de patrimônio genético recebidas para:

<table>
<thead>
<tr>
<th>OBJETIVO</th>
<th>USO PRETENDIDO E SETOR DE APLICAÇÃO</th>
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<tbody>
<tr>
<td>Pesquisa</td>
<td>Usos pretendidos:</td>
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<td>Setor de aplicação do projeto / atividade de pesquisa:</td>
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<tr>
<td>Desenvolvimento tecnológico</td>
<td>Usos pretendidos:</td>
</tr>
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<td></td>
<td>Setor de aplicação do projeto / atividade de desenvolvimento tecnológico:</td>
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<td>Deipo em coleção ex situ</td>
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3.1. a) O DESTINATÁRIO deverá informar ao CGen (cgen@mma.gov.br) qualquer alteração nas informações indicadas no item 3.

[OU]

3.1. b) As amostras objeto do presente TTM deverão ser utilizadas exclusivamente para os objetivos, uso pretendido e setor de aplicação indicados no item 3.

[OU]

3.1. c) O DESTINATÁRIO depende de autorização do(a) REMETENTE para qualquer alteração nos objetivos, uso pretendido e setor de aplicação indicados no item 3.

4. Trata-se de variedade tradicional local ou crícula ou de raça localmente adaptada ou crícula?

[ ] Sim.
[ ] Não.

5. O DESTINATÁRIO reconhece que não é provedor das amostras de patrimônio genético objeto deste TTM.

6. Fica vedado o repasse a terceiros de amostras de patrimônio genético objeto dessa remessa.

[OU]

6. As amostras do patrimônio genético poderão ser repassadas a terceiros.

6.1. Para o repasse, o DESTINATÁRIO exigirá do destinatário subsequente a assinatura de novo TTM contendo todas as cláusulas deste TTM, podendo alterar os objetivos, uso pretendido e setor de aplicação previstos no item 3, deste documento.

6.2. O DESTINATÁRIO é responsável por informar qualquer repasse subsequente do material objeto deste TTM ao CGen (cgen@mma.gov.br).

6.3. O disposto nos itens 6.1 e 6.2 aplica-se a todos os repasses subsequentes.
SENDING OF GENETIC HERITAGE
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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
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SERVICES PROVIDED
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SERVICES PROVIDED ABROAD ARE CONSIDERED

TESTS
SPECILIZED TECHNIQUES

PERFORMED BY AN INSTITUTION COLLABORATING WITH THE NATIONAL INSTITUTION RESPONSIBLE BY THE ACCESS OR BY WHICH IT WAS HIRED
RESEARCH BY FOREIGNERS

BRAZILIAN BIODIVERSITY CAN ONLY BE ACCESSED BY
RESEARCH BY FOREIGNERS

BRAZILIAN BIODIVERSITY CAN ONLY BE ACCESSED BY

FOREIGN INSTITUTION
(LEGAL ENTITY LOCATED ABROAD)

in partnership with

BRAZILIAN INSTITUTION
(PUBLIC OR PRIVATE)
RESEARCH BY FOREIGNERS

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in partnership with

BRAZILIAN INSTITUTION
(PUBLIC OR PRIVATE)

THAT WILL BE RESPONSIBLE FOR THE REGISTRATION AND UPDATING SisGen (REGISTRY, NOTIFICATION, BENEFIT SHARING PAYMENT)
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.
CLEAR AND FIXED RULES FOR BENEFIT SHARING WERE ESTABLISHED
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THAT CAN BE:

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

• NON MONETARY
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.
BENEFIT SHARING

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...
GENETIC HERITAGE AND ASSOCIATED TK OF UNIDENTIFIABLE SOURCE

IN THE CASE OF ACCESS TO:

IS THE GOVERNMENT, REPRESENTED BY THE MINISTRY OF THE ENVIRONMENT

The beneficiary of benefit sharing:
**BENEFIT SHARING**

**IN THE CASE OF ACCESS TO:**

- Genetic Heritage and Associated TK of unidentifiable source
  - The beneficiary of benefit sharing: Is the Government, represented by the Ministry of the Environment

- Associated TK of identifiable source
  - The beneficiary of benefit sharing: Are the indigenous people, traditional communities and traditional farmers
THE PAYMENTS FROM THE BENEFIT SHARING AND FINES DUE TO NON-COMPLIANCE OF THE LAW SHALL BE DEPOSITED IN
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THE NATIONAL FUND FOR BENEFIT SHARING - FNRB
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 - FNRB

ESTABLISHED FOR VALORIZING GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE AS WELL AS TO PROMOTE THEIR USE IN A SUSTAINABLE WAY
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.
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
Through the National Fund of Benefit Sharing the National Program of Benefit Sharing – PNRB will be established in order to promote, among others:
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
The National System for Genetic Heritage and Associated Traditional Knowledge Management (SisGen) was created to manage:
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- Registration
- Access to Genetic Heritage
- Access to Associated Traditional Knowledge
- Shipping Genetic Heritage
- Sending Genetic Heritage
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- Registration
  - Access to Genetic Heritage
  - Access to Associated Traditional Knowledge
  - Shipping Genetic Heritage
  - Sending Genetic Heritage

- Notification
  - Finished Product
  - Reproductive Material
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

- **ACCREDITATION**
  - NATIONAL INSTITUTIONS MAINTAINING *ex situ* COLLECTIONS THAT HOLD GENETIC HERITAGE
ELECTRONIC SYSTEM FOR REGISTRATION AND NOTIFICATION
AFTER FINALIZING THE REGISTRATION OR NOTIFICATION
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A RECEIPT WILL BE ISSUED AUTOMATICALLY
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REGISTRATION OF ACCESS TO GH
REGISTRATION OF ACCESS TO ATK
REGISTRATION OF GH SHIPMENT
NOTIFICATION
DOCUMENT THAT PROVES THAT THE USER PROVIDED THE REQUESTED INFORMATION AND PRODUCES THE FOLLOWING EFFECTS:

AFTER FINALIZING THE REGISTRATION OR NOTIFICATION

A RECEIPT WILL BE ISSUED AUTOMATICALLY

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AFTER FINALIZING THE REGISTRATION OR NOTIFICATION

A RECEIPT WILL BE ISSUED AUTOMATICALLY

ESTABLISHES THE VERIFICATION PROCEDURE

ENABLES

REQUESTS OF ANY INTELLECTUAL PROPERTY RIGHT

COMMERCIALIZATION OF THE INTERMEDIATE PRODUCT

DISSEMINATION OF RESULTS FROM RESEARCH OR TD

NOTIFICATION

SHIPMENT ABROAD

ECONOMIC EXPLOITATION

REGISTRATION OF ACCESS TO GH

REGISTRATION OF ACCESS TO ATK

REGISTRATION OF GH SHIPMENT

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

- AFTER FINALIZING THE REGISTRATION OR NOTIFICATION
- A RECEIPT WILL BE ISSUED AUTOMATICALLY
- ENABLES
- ESTABLISHES THE VERIFICATION PROCEDURE
- 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
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.

REGULARIZATION REGARDING THE PROVISIONAL MEASURE 2.186/2001

RESEARCH

TECHNOLOGICAL DEVELOPMENT

100% exemption from fine payment

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.
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.

100% exemption from fine payment

The period for regularization is one year after the electronic system is made available.
Administrative infringements against the genetic heritage or associated traditional knowledge are any action or omission that violates the norms of the Law.

Administrative offenses shall be punishable by the following penalties:

- Warning
- 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
- Apprehension
- Temporary suspension of the manufacture and sale of the product
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 jargon of the area, "access to genetic resources, protection, access to associated traditional knowledge, benefit sharing for the conservation and sustainable use of biodiversity". The new legal framework was regulated by Decree 8,772/16, on May 17, 2016.

In the scientist’s routine, it is very common to have to use to biodiversity resources. It means that, in their research, they will isolate and study the genome of plants, animals, micro-organisms 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...
Access to genetic resources and associated traditional knowledge

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THANK YOU!

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FIOCRUZ
FUNDAÇÃO OSWALDO CRUZ
HEALTH MINISTRY