THE BRAZILIAN LEGISLATION ON ACCESS AND BENEFIT SHARING

MANUELA DA SILVA - FIOCRUZ – FUNDAÇÃO OSWALDO CRUZ
VICE-PRESIDENCY OF RESEARCH AND BIOLOGICAL COLLECTIONS
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.
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
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 11 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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- 11th May 2016
  - Publication of Decree 8.772 that regulates the Law
- 28th July 2016
  - 1ª Meeting of CGen
- 6th November 2017
  - SisGen Becomes available

National System for the Management of Genetic Resources and Associated Traditional Knowledge, the SisGen

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The Brazilian ABS National Competent Authority is the Genetic Heritage Management Council - CGen

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.

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• Business sector
• Academia
• Indigenous peoples, traditional communities and traditional farmers
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- Business sector
- **Academia** SBPC – Brazilian Society for the Science Progress; ABC - Brazilian Academy of Science, ABA - Brazilian Association of Anthropology
- Indigenous peoples, traditional communities and traditional farmers
CGEN WORKS BY MEANS OF:

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

Deliberação nº 5
Data: 21/03/2017

Sectorial Chamber of Academy 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>
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<tr>
<th>CGEN member who indicated</th>
<th>Name and Institution</th>
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<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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<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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<td>André Fábio De Souza – MDIC</td>
<td>André Fábio de Souza – MDIC</td>
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<tr>
<td>Maira Smith – MJSP</td>
<td>Maira Smith – MJSP</td>
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<tr>
<td>Fabrício - MAPA</td>
<td>Rosa Míriam Rosa Miranda</td>
</tr>
<tr>
<td>Bruno César Prodocími Nunes - MCTIC</td>
<td>Ricardo Henrique Kruger - Instituto de Biologia da Universidade de Brasília</td>
</tr>
<tr>
<td>Bruno César Prodocími Nunes - MCTIC</td>
<td>Kátia Regina Torres - Departamento de Assistência Farmacêutica e Insumos Estratégicos, Ministério da Saúde</td>
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<tr>
<td>Rafael Marques – MMA</td>
<td>Henry Philippe Ibanez de Novion – MMA</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.
The first major achievement of SCA was the proposition of 5 resolutions approved by CGen that facilitate various aspects regarding the legislation compliance.
SCOPE OF THE LAW 13.123/15

THE LAW COVERS THE ACTIVITY OF

• RESEARCH
• TECHNOLOGICAL DEVELOPMENT

ACCESS = UTILIZATION

• ECONOMIC EXPLOITATION

ORIGINATED FROM THE ACCESS OF GENETIC HERITAGE

• FINISHED PRODUCT OR
• REPRODUCTIVE MATERIAL

ORIGINATED FROM THE ACCESS OF ASSOCIATED TRADITIONAL KNOWLEDGE

THIS IS THE MOMENT WHEN THERE IS BENEFIT SHARING
**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.
DIFERENTELY 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)**
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

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
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.
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.
ANY INDIGENOUS POPULATION, TRADITIONAL COMMUNITY OR TRADITIONAL FARMER WHO CREATES, DEVELOPS, HOLDS OR PRESERVES CERTAIN TRADITIONAL KNOWLEDGE IS AN IDENTIFIABLE SOURCE OF SUCH 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
    - THE POSSIBILITY OF LINKING ITS SOURCE TO AT LEAST AN INDIGENOUS POPULATION, TRADITIONAL COMMUNITY OR TRADITIONAL FARMER
DEFINITION: TRANSFERERENCE 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 OFGENETIC 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 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.
- 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.
One of the approved resolutions was the one that 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**

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 under no. (CNPJ number), having its main headquarters located at (NAME OF THE STREET), number (NUMBER), [ADDITIONAL ADDRESS INFORMATION], neighborhood (NEIGHBORHOOD), in the municipality (MUNICIPALITY), (STATE), postal code - CEP (NUMBER OF THE POSTAL CODE), herein represented in the form of ENTITY INCORPORATION INFORMATION through [IMPROVEMENT 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), residence at (NAME OF THE STREET), number (NUMBER), [ADDITIONAL ADDRESS INFORMATION], neighborhood (NEIGHBORHOOD), in the municipality (MUNICIPALITY), (STATE), postal code - CEP [NUMBER OF THE POSTAL CODE], hereinafter referred to simply as the "SENDER".

**ATTACHMENT 2**

**SHIPMENT INVOICE**

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 obtaining in situ, even if it has been obtained from an in vitro culture:

[OR]

3. Information on the kind of sample and method of storage:
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 TRANSFERRED
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

TESTS

SPECILIZED TECHNIQUES

PERFORMED BY AN INSTITUTION COLLABORATING WITH THE NATIONAL INSTITUTION RESPONSIBLE BY THE ACCESS OR BY WHICH IT WAS HIRED
LEGAL OPINION: DIFFERENCES BETWEEN SHIPPING AND Sending

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
The SHIPPMENT is broader and can be used for practically all situations, except for the specific case of service supply, for instance genetic sequencing, which is classified as SENDING in the Law 13.123/15.

In the context of scientific partnership, the data is shared as well as the resulting scientific output. When the transport is classified as SENDING, the foreign partner institution would be prohibited from economically exploiting and filing any patent application.

There is no significant simplification regarding the procedures for SENDING in relation to SHIPPMENT, since in both cases a registration and a legal instrument or MTA are needed. The difference is the moment of the registration, in the case of SHIPPMENT the registration must be prior.
DIFFERENCES BETWEEN SHIPPING AND SENDING

• The Law and the Decree do not clarify or define what would mean transference of responsibility, so it can be more than transfer of ownership and so we can have the following understanding:

  ▪ Shipping: when there is a transfer of responsibility, which refers to compliance with applicable law, liability for damages in the use and disposal of material, etc.

  ▪ Sending: when there is no transfer of responsibility, therefore Fiocruz or another research institution will be responsible for the non-compliance with applicable law and for damages in the use and improper disposal of the biological material
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.
The requirement of the foreign researcher to have to associate with a Brazilian institution to research the Brazilian biodiversity has caused some difficulties.

To enable this new procedure, a simplified form will be developed in version 2 of SisGen in English to be completed by the foreign researcher. At the end of the form the IBICT, serving as a Brazilian partnership institution, will validate the information provided.
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...
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

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

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
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:

- **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
NATIONAL SYSTEM FOR GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE MANAGEMENT
NATIONAL SYSTEM FOR GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE MANAGEMENT

Cadastro de atividade de acesso

Tipo de Usuário:

Responsável pelo cadastro

Objeto do Acesso:

Finalidade do Acesso:

As atividades objeto deste cadastro são baseadas em outras atividades de acesso realizadas anteriormente?

Este cadastro está vinculado a cadastro anterior de remessa?
Patrimônio Genético

Título da Atividade:

Título da Atividade em inglês:

Resumo da atividade (incluindo objetivos e resultados esperados ou obtidos, conforme o caso):

Resumo não sigiloso da Atividade em Inglês:

Palavra(s)-chave:

Palavra(s)-chave em Inglês:

Período das Atividades:

Equipe

Adicionar +

Nome Completo | Documento | Instituição | Nacionalidade
--- | --- | --- | ---
FioCruz | | |
Sobre o Componente do Patrimônio Genético acessado

O acesso ao patrimônio genético será realizado em área indispensável à segurança nacional (faixa de fronteira ou ilhas oceânicas) ou águas jurisdicionais brasileiras, plataforma continental e zona econômica exclusiva:

Tipo de Componente: [Selecionar]

Nome científico:
- Gênero
- Epitélio específico

Clique aqui para pesquisar

Reino:

Filo/Divisão:

Classe:

Ordem:

Família:

Estirpe/Linhagem/Cepa

Nome(s) popular(es)

Trata-se de variedade tradicional local ou crioula ou raça localmente adaptada ou crioula?: [Selecionar]
NATIONAL SYSTEM FOR GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE MANAGEMENT

Sobre o Componente do Patrimônio Genético acessado

O acesso ao patrimônio genético será realizado em área indispensável à segurança nacional (faixa de fronteira ou ilhas oceânicas) ou águas jurisdicionais brasileiras, plataforma continental e zona econômica exclusiva:

Tipo de Componente: Fungos

Nome científico: Gênero Epitélo específico

Clique aqui para pesquisar

Reino:

Filo/Divisão:

Classe:

Ordem:

Família:

Espécie/Linhagem/Cepa

Nome(s) popular(es)

Trata-se de variedade tradicional local ou crioula ou raça localmente adaptada ou crioula?

Procedência da amostra:

Selecionado

In situ

Ex situ

In silico

Produto intermediário

Limpar

Salvar

Cancelar
REGISTRATION OF THE SENDING

NATIONAL SYSTEM FOR GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE MANAGEMENT
Cadastro de Remessa de Amostra de Patrimônio Genético

Tipo de Usuário: Independente

Responsável pelo cadastro

Esta remessa foi realizada em data anterior a 17/11/2015?: Não

Este cadastro está vinculado a cadastro anterior de acesso?: Não

Termo de Transferência de Material:
Anexar Documento

Escolher arquivos Nenhum arquivo selecionado *
Cadastro de Remessa de Amostra de Patrimônio Genético

Tipo de Usuário: Independente*

Responsável pelo cadastro

Adicionar +

CPF Habilitado

Sim

Esta remessa foi realizada em data anterior a 17/11/2015?: Não

Este cadastro está vinculado a cadastro anterior de acesso?: Não

Termo de Transferência de Material: Anexar Documento

Escolher arquivos Nenhum arquivo selecionado*

Atividades de acesso no exterior

Especificação das atividades a serem realizadas no exterior

Objetivos e uso pretendido

Setor de aplicação:

Seção

OUTRAS ATIVIDADES DE SERVIÇOS *

Divisão

Selecione*

Grupo

Selecione*

Classe

Selecione*

Subclasse

Selecione*
Sobre o componente do Patrimônio Genético a ser remetido

Adicionar +
Sobre o componente do Patrimônio Genético a ser remetido

Tipo de amostra a ser remetida:

Adicionar +

Forma de acondicionamento:

Adicionar +

Selecione

- Seleção
- Amostra vegetal, fúngica ou animal (organismos inteiros ou partes destes)
- Mudas ou Sementes
- Extratos vegetais, animais ou fúngicos
- Cultura de células animais ou vegetais
- Substratos (solo, água, sangue, urina, fezes, dente outros) contendo material biológico
- Micro-organismos isolados (exceto fungos e vírus)
- Fungos isolados / Cultura de fungos
- Virus
- Material Genético isolado (inclusive transposons, plasmídeos, dente outros)
- Informação in silico
- Outros

Limpar
Sobre o componente do Patrimônio Genético a ser remetido

Adicionar + 

Tipo de amostra a ser remetida: 
Selecione

Forma de acondicionamento: 
Selecione

Adicionar + 

Forma de acondicionamento:

Adicionar + 

Quantidade Recipiente

Volume a ser remetido

Método do envio:

Número do conhecimento de carga:

Selecionar:
- Amostra líquida em tubo de microcentrifuga (ependorf)
- Amostra sólida em tubo de microcentrifuga (ependorf)
- Material hibridado / exsicata
- Material entomológico fixado em caixas
- Material zoológico fixado em caixas
- Material zoológico fixado em frascos
- Material zoológico fixado em sacos plásticos
- Material zoológico fixado em lâminas (Lâminas de microscopia)
- Placas de cultivo, com substrato
- Tubos de centrífuga
- Garrafa/frasco com meio de cultivo
- Amostra líquida em recipientes diversos (garrafas, tambores, galões e bombonas)
- Outra

Limpar

ABOUT THE GENETIC HERITAGE TO BE SHIPPED ABROAD
NATIONAL SYSTEM FOR GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE MANAGEMENT

Sobre o componente do Patrimônio Genético a ser remetido

Tipo de amostra a ser remetida:

Forma de acondicionamento:

Adicionar +

Adicionar +

Forma de acondicionamento:

Quantidade Recipiente

Volume a ser remetido

Método do envio:

Número do conhecimento de carga:

Adicionar +

Adicionar +

Forma de acondicionamento:

Quantidade Recipiente

Volume a ser remetido

Método do envio:

Número do conhecimento de carga:

Selecionar

Em mãos

Correios

Remessa expressa

SISCOMEX

Limpar

Salvar

Cancelar

ABOUT THE GENETIC HERITAGE TO BE SHIPPED ABROAD
### Instituição Destinatária no Exterior

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<th>Código Postal:</th>
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### Representante Legal da Instituição Destinatária

Adicionar

* Campos Obrigatórios.

**Termos de uso do SisGen:**
# Cadastro de Notificação de Produto

<table>
<thead>
<tr>
<th>campo</th>
<th>descrição</th>
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<tbody>
<tr>
<td>Tipo de Usuário:</td>
<td>Independente</td>
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</table>

### Responsável pelo cadastro

<table>
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<tr>
<th>CPF</th>
<th>Habilitado</th>
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<td>Sim</td>
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### Número de Cadastro de Acesso/Remessa

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<tr>
<th>campo</th>
<th>descrição</th>
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### Tipo de Produto para Notificação:

- Selecionar

### Identificação Comercial do Produto:

- Produto Acabado (exceto para atividades agrícolas)
- Produto Acabado (para atividades agrícolas)
- Material Reprodutivo - Para Atividades Agrícolas (último elo da cadeia produtiva)
- Material Reprodutivo - De uso Exclusivo nas Cadeias Produtivas que não Envolvam Atividade Agrícolas
- Material Reprodutivo - Para atividades agrícolas (meio da cadeia produtiva)

### Classificação NCM do Produto:

- Seleccionar
NOTIFICATION OF PRODUCT

Cadastro de Notificação de Produto

Tipo de Usuário: Independente

Responsável pelo cadastro

Número de Cadastro de Acesso/Remessa

Tipo de Produto para Notificação:

Identificação Comercial do Produto:

Classificação NCM do Produto:

Setor de Aplicação:

Seção

Divisão

Grupo

Classe

Subclasse

O patrimônio Genético e/ou o Conhecimento Tradicional Associado Utilizado Contribui para a Formação do Apelo Mercadológico?

O Patrimônio Genético e/ou o Conhecimento Tradicional Associado Utilizado é Determinante para a Existência de Características Funcionais?

Abrangência da Comercialização do Produto Acabado ou Material Reprodutivo:

Nacional

Internacional
INFORMATION ON THE COLLECTION CURATOR
After finalizing the registration or notification, a receipt will be issued automatically, which is a document that proves that the user provided the requested information and produces the following effects:

- Enables registration of access to GH
- Enables registration of access to ATK
- Enables registration of GH shipment
- Enables notification
- Enables dissemination of results from research or TD
- Enables notification
- Enables shipment abroad
- Enables economic exploitation

The user do not need to wait for the verification conclusion to perform the above activities.
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

ACCESS TO GENETIC HERITAGE

ACCESS TO ASSOCIATED TRADITIONAL KNOWLEDGE

COMPLY WITH THE REQUIREMENTS OF THE LAW

PREVENTS APPLICATION OF ADMINISTRATIVE PENALTIES SPECIFICALLY REGARDING ACCESS ACTIVITIES UNDERTAKEN UNTIL ISSUING THE CERTIFICATE
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

1. RESEARCH AND TD WITH THE BRAZILIAN GH
2. REGISTRATION
3. **INDICATE THE SOURCE OF THE GH: IN SITU; EX SITU OR/AND IN SILICO**
4. 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

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 OR/AND IN SILICO

RECEIPT AUTOMATICALLY ISSUED

REGISTRATION

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

www.fiocruz.br
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 OR/ AND IN SILICO → RECEIPT AUTOMATICALLY ISSUED

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

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

FINISHED PRODUCTS DEVELOPED FROM BRAZILIAN GH → NOTIFICATION PRIOR ECONOMIC EXPLORATION → RECEIPT AUTOMATICALLY ISSUED → ECONOMIC EXPLORATION → BENEFIT SHARING CAN BE MONETARY OR NON-MONETARY

SIGNATURE OF A BENEFIT SHARING AGREEMENT → WHEN MONETARY IS WITH THE GOVERNMENT AND TRADITIONAL COMMUNITY IF THERE IS IDENTIFIABLE ATK
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.

- **RESEARCH**
- **BIOPROSPECTING**
- **TECHNOLOGICAL DEVELOPMENT**

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.

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 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.

THE PERIOD FOR REGULARIZATION IS ONE YEAR AFTER THE ELECTRONIC SYSTEM IS MADE AVAILABLE.
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
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- 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
The new Brazilian legislation on access to the biodiversity (Law 13,123/15 and Decree 8772/16)

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 and benefit sharing for the conservation and sustainable use of biodiversity’. The new legal framework was regulated by Decree 8.772/16, on May 12, 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 how life works and how it can be improved.
THANK YOU!

Manuela da Silva
manuela.dasilva@fiocruz.br
FIOCRUZ
FUNDAÇÃO OSWALDO CRUZ
HEALTH MINISTRY