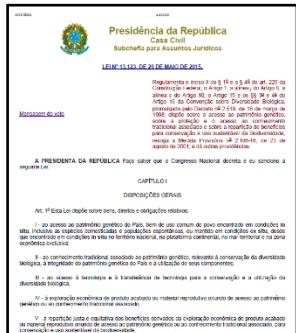


# **THE BRAZILIAN LEGISLATION ON ACCESS AND BENEFIT SHARING**

**MANUELA DA SILVA - FIOCRUZ – FUNDAÇÃO OSWALDO CRUZ  
VICE-PRESIDENCY OF RESEARCH AND BIOLOGICAL COLLECTIONS**



# THE NEW BRAZILIAN ABS LEGISLATION

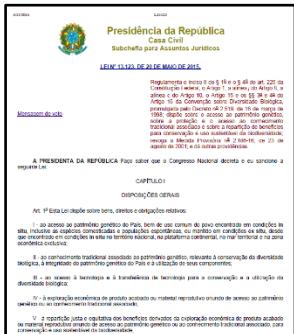


The Law is based on the Federal Constitution and on the Convention on Biological Diversity, provides for access to genetic heritage, on the protection and access to associated traditional knowledge and the benefit sharing for conservation and sustainable use of biodiversity; revokes the Provisional Act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

20<sup>th</sup> May 2015  
Publication of  
Law 13,123

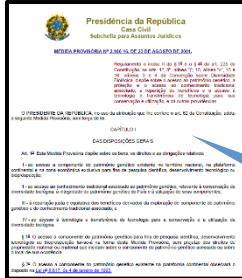


# THE NEW BRAZILIAN ABS LEGISLATION



20<sup>th</sup> May 2015  
Publication of  
Law 13,123

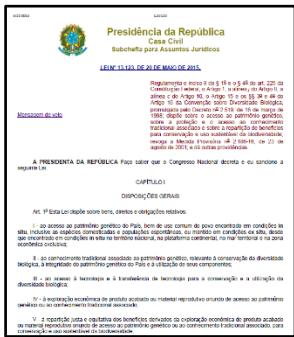
17<sup>th</sup> November,  
2015  
Entry into force  
of Law 13,123



Provisional Act 2,186-16 / 2001  
is revoked



# THE NEW BRAZILIAN ABS LEGISLATION

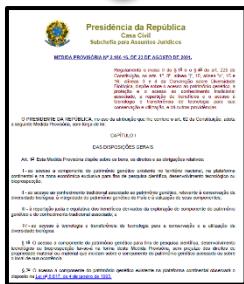


20<sup>th</sup> May 2015  
Publication of  
Law 13,123

17<sup>th</sup> November,  
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11th May 2016  
Publication of  
Decree 8.772  
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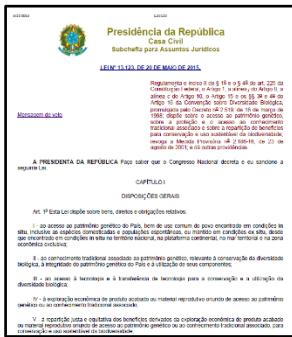
28th July 2016  
1<sup>ª</sup> Meeting of  
CGen



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)



# THE NEW BRAZILIAN ABS LEGISLATION



20<sup>th</sup> May 2015  
Publication of  
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Entry into force  
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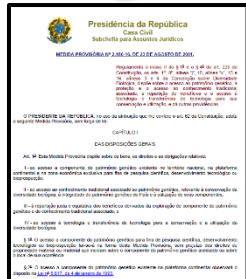
28th July 2016  
1<sup>st</sup> Meeting of  
CGen

6th November  
2017  
SisGen Becomes  
available

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



Sistema Nacional de Gestão do  
Patrimônio Genético e do Conhecimento Tradicional  
Associado



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)



# ABS NATIONAL COMPETENT AUTHORITY

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.

**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



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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



# ABS NATIONAL COMPETENT AUTHORITY

## 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



# PARTICIPANTS OF THE SECTORIAL CHAMBER OF ACADEMY

CGEN member who indicated	Name and Institution
SBPC, ABC e ABA	André Luis de Gasper – Universidade Regional de Blumenau Coordenador da Rede de Herbários da Sociedade Botânica do Brasil
SBPC, ABC e ABA	Manuela da Silva - Fundação Oswaldo Cruz/RJ Coordenadora das Coleções Biológicas da Fiocruz/ Sociedade Brasileira de Microbiologia
SBPC, ABC e ABA	Luciane Marinoni - Universidade Federal do Paraná Presidente da Sociedade Brasileira de Zoologia
SBPC, ABC e ABA	Marcelo H. A. Freitas - Secretaria de Relações Internacionais - Coordenadoria de Políticas Globais/ Embrapa
SBPC, ABC e ABA	Laura Rocca - MCTI
SBPC, ABC e ABA	Diego Soárez - MCTI
André Fábio De Souza – MDIC	André Fábio De Souza – MDIC
Maira Smith – MJSP	Maira Smith – MJSP
Fabrício - MAPA	Rosa Míriam - MAPA
Bruno César Prosdocimi Nunes - MCTIC	Ricardo Henrique Kruger - Instituto de Biologia da Universidade de Brasília
Bruno César Prosdocimi Nunes - MCTIC	Kátia Regina Torres - Departamento de Assistência Farmacêutica e Insumos Estratégicos, Ministério da Saúde
Rafael Marques – MMA	Henry Philippe Ibanez de Novion – MMA

This chamber is the means by which  
researchers can expose problems  
with the legislation and its  
compliance and propose the  
necessary adjustments



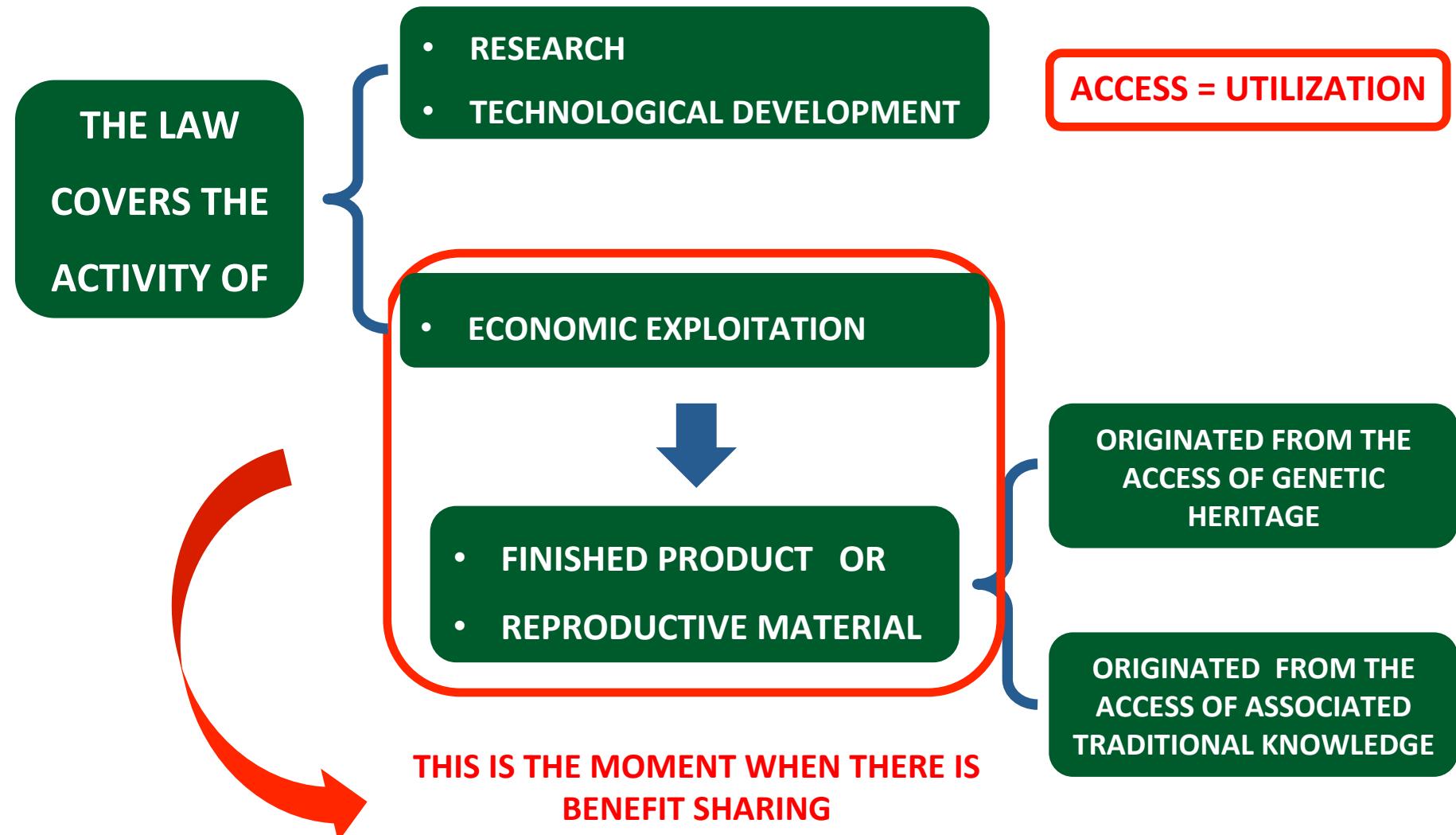
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Bruno César Prosdocimi Nunes - MCTIC	Kátia Regina Torres - Departamento de Assistência Farmacêutica e Insumos Estratégicos, Ministério da Saúde
Rafael Marques – MMA	Henry Philippe Ibanez de Novion – MMA

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



# 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



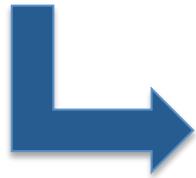
# SCOPE OF THE LAW 13.123/15

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



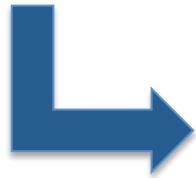
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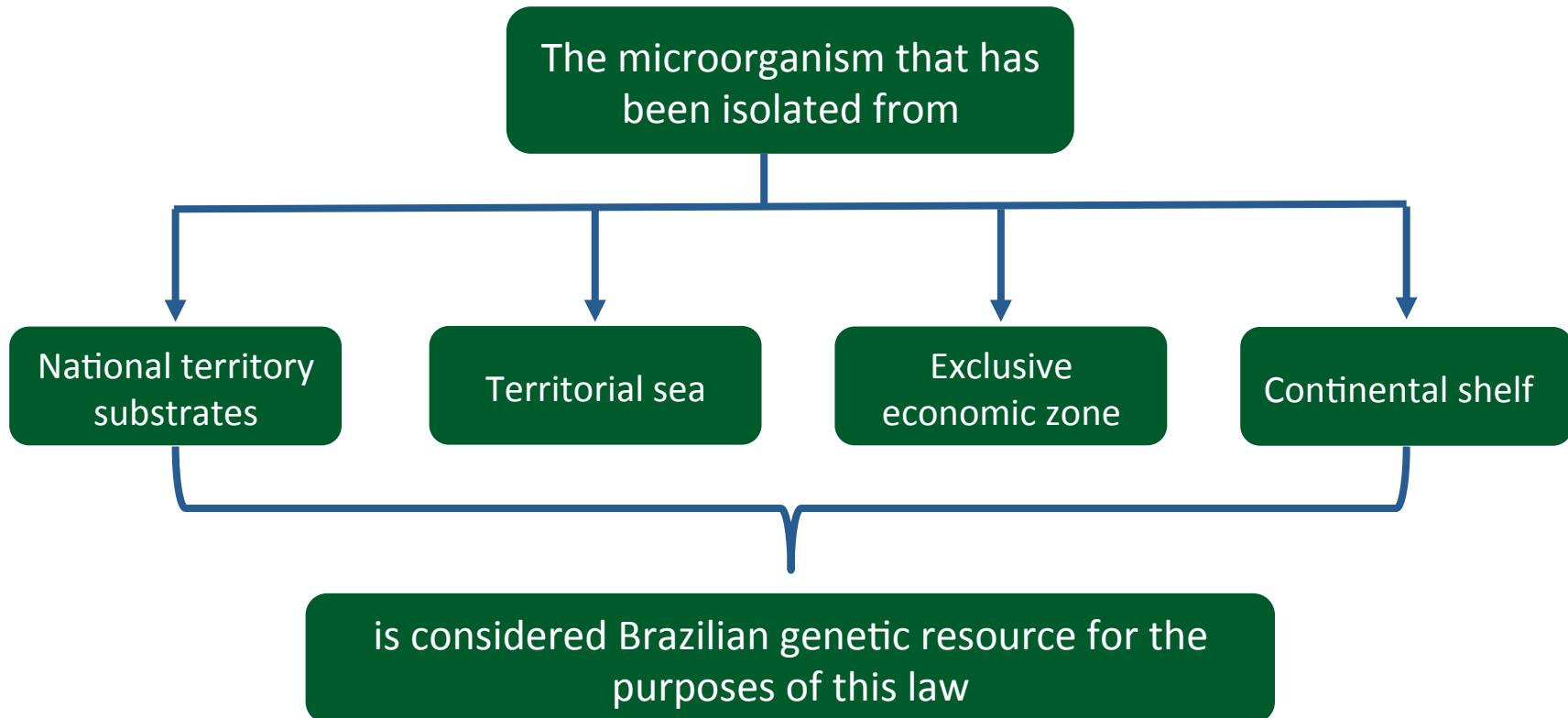


USE OF INFORMATION FROM  
GENETIC SEQUENCES PUBLISHED IN  
PUBLIC DATA BASES (GenBank)



# SCOPE OF THE LAW 13.123/15

## OTHER NOVELTY IN THE LAW IS THE PARAGRAPH ON MICROORGANISMS



## 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**

**NOTIFICATION BEFORE**

**TECHNOLOGICAL DEVELOPMENT**

**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



# ACCESS TO ASSOCIATED TRADITIONAL KNOWLEDGE

THE TRADITIONAL KNOWLEDGE ASSOCIATED TO GENETIC HERITAGE CAN BE RECOGNIZED IN SCIENTIFIC PUBLICATIONS, RECORDS IN REGISTERS OR DATABASES AND CULTURAL INVENTORIES

ASSOCIATED TRADITIONAL  
KNOWLEDGE

OF IDENTIFIABLE  
SOURCE

WHEN THERE IS

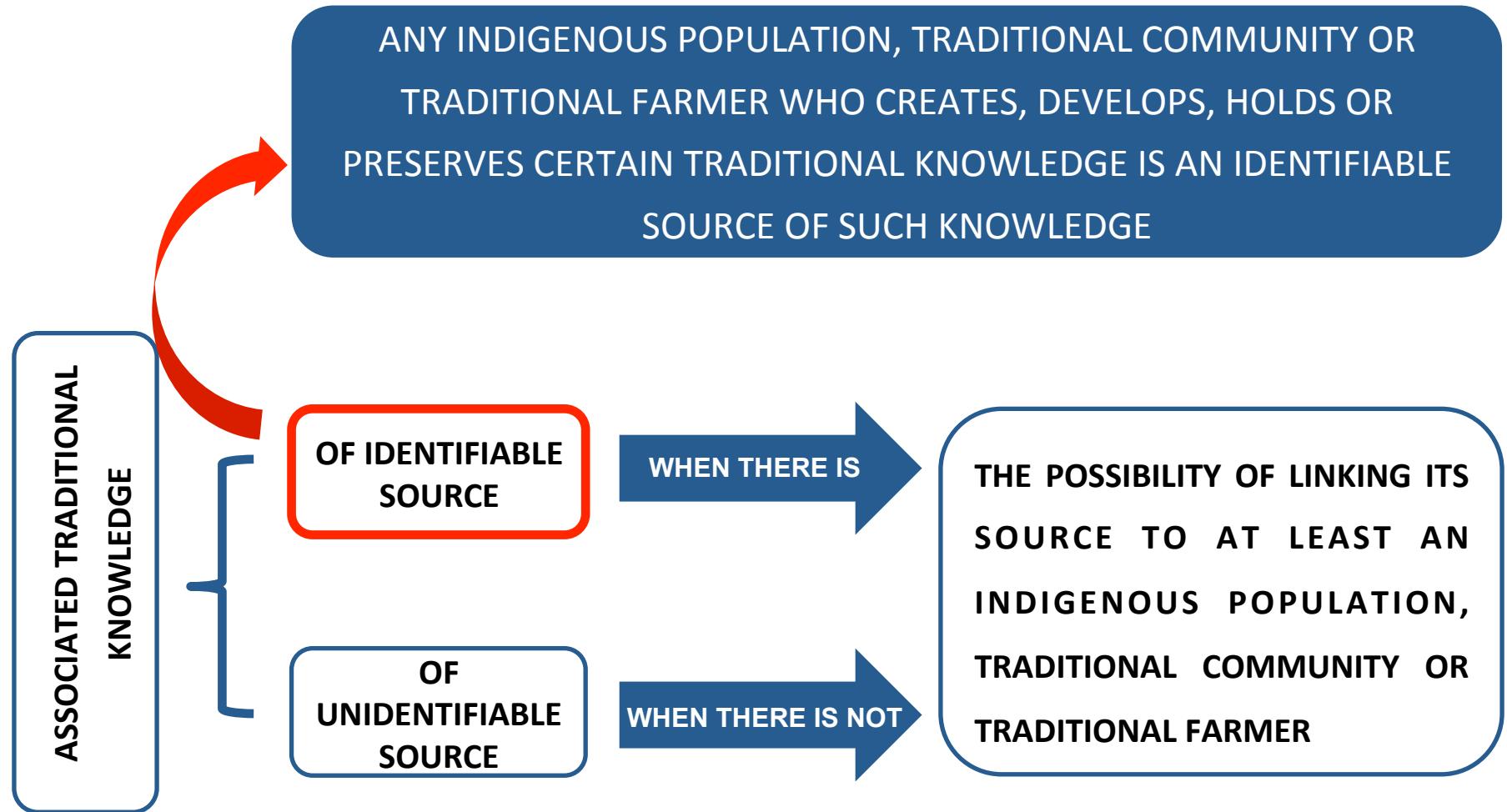
THE POSSIBILITY OF LINKING ITS SOURCE TO AT LEAST AN INDIGENOUS POPULATION, TRADITIONAL COMMUNITY OR TRADITIONAL FARMER

OF  
UNIDENTIFIABLE  
SOURCE

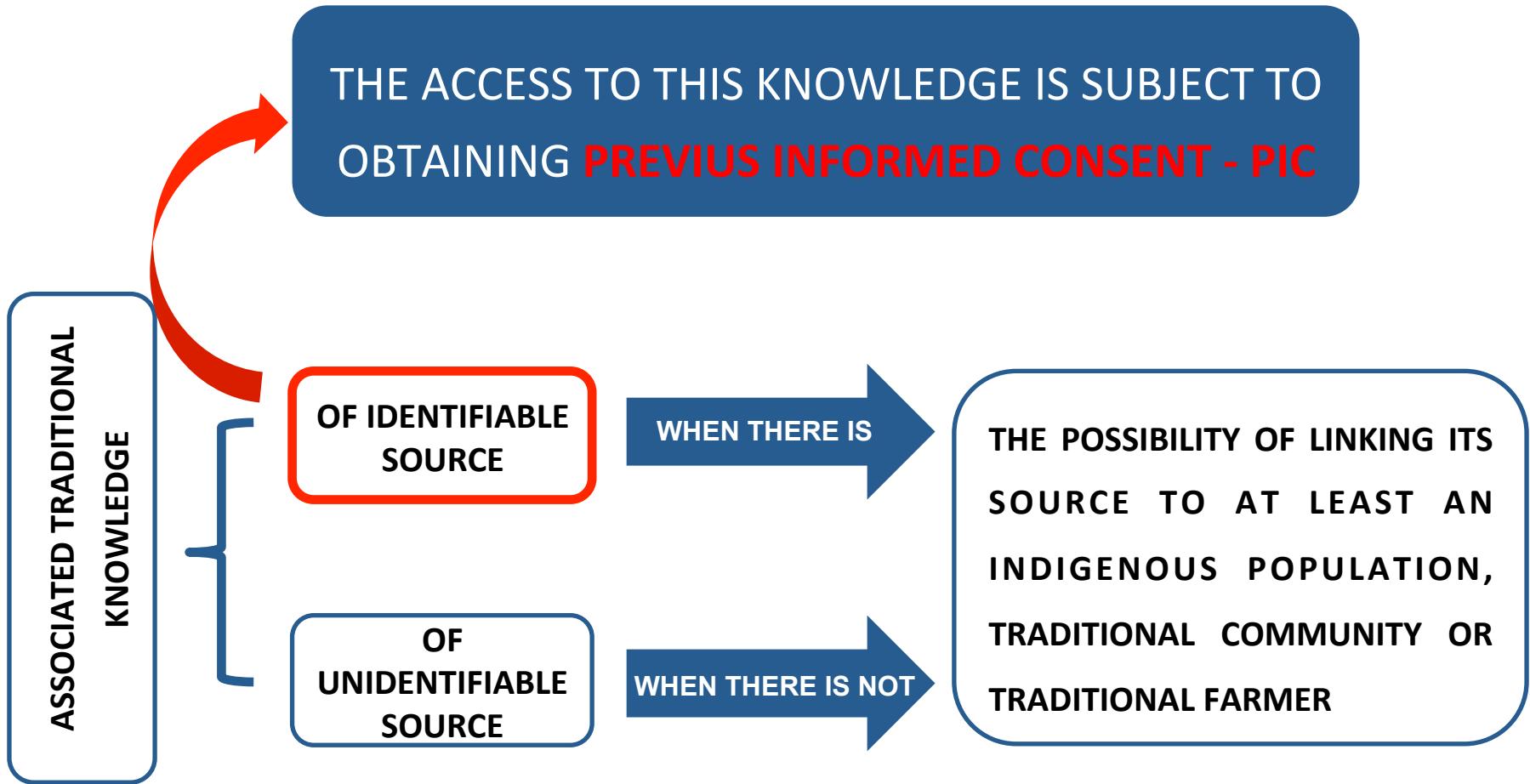
WHEN THERE IS NOT



# ACCESS TO ASSOCIATED TRADITIONAL KNOWLEDGE



# ACCESS TO ASSOCIATED TRADITIONAL KNOWLEDGE



# 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 RECIPIENT 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 RECIPIENT 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 RECIPIENT INSTITUTIONS, GENETIC HERITAGE AND INTENDED USE



# MATERIAL TRANSFER AGREEMENT

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



# MATERIAL TRANSFER AGREEMENT

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



# MATERIAL TRANSFER AGREEMENT

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.

  
MINISTRY OF THE ENVIRONMENT  
Genetic Heritage Management Council  
  
CGEN RESOLUTION No. 05, OF 20 MARCH 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 Decree no. 8.772, of 11 May 2016, and in light of 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 per the provisions of the Article 25 of the Decree no. 8.772, of 11 May 2016, the clauses presented in the standard MTA document 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.

Article 3 - The sender and the recipient may sign, at their sole discretion, one or several MTAs, which will remain valid for the maximum period of 10 (ten) years and which may be renewed.

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<sup>1</sup>:

[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 Natural Person<sup>2</sup>:

[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**

"Shipment Invoice No. [ ] of the Material Transfer Agreement - MTA signed by and between [SENDER] and [RECIPIENT] on [MTA 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 obtainment *in situ*, even if it has been obtained from *ex situ* sources:  
 OR  
 2. Origin of the samples to be shipped, indicating the municipality of the place of obtainment *in situ*, even if it has been obtained from *ex situ* sources:

3. Identifying information on the *ex situ* source of the genetic heritage, with the information contained in the deposit record, if it comes from an *ex situ* collection as determined in §1 of the article 22 of the Decree no. 8.772, of 2016:

3. Information on the kind of sample and method of stowage:



## 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**



# 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**

SERVICES PROVIDED  
ABROAD ARE CONSIDERED

TESTS

SPECIALIZED 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

PARECER n. 00037/2017/CONJUR-MMA/CGU/AGU

NUP: 02000.000358/2016-33

INTERESSADOS: SECRETARIA DE BIODIVERSIDADE E FLORESTAS DO MINISTÉRIO DO MEIO AMBIENTE

ASSUNTOS: CONSULTA E ORIENTAÇÃO DE ATUAÇÃO - OUTROS ASSUNTOS

EMENTA: CGAJ. CONSULTA. DEPARTAMENTO DE PATRIMÔNIO GENÉTICO. NOVA CONCEPÇÃO DE ATUAÇÃO DO ESTADO DIANTE DA LEI N° 13.123/15. PONDERAÇÃO DE INTERESSES CONSTITUCIONAIS. INCENTIVO AO DESENVOLVIMENTO CIENTÍFICO. OMISSÃO JURÍDICO-NORMATIVA DE DECRETO REGULAMENTADOR (JÁ SUPRIDA PELO DECRETO N° 8772/2016) NORMA DE APLICABILIDADE PLENA. HIPÓTESES. VIABILIDADE DE PESQUISA. DIFERENCIAMENTO ENTRE ENVIO E REMESSA DE COMPONENTE DO PATRIMÔNIO GENÉTICO. LIMITES. POSSIBILIDADE DO ENVIO MESMO SEM DECRETO REGULAMENTADOR. SEGURANÇA JURÍDICA.

## I- RELATÓRIO

1. Trata-se de consulta formulada pela área técnica especializada deste Ministério do Meio Ambiente, Departamento de Patrimônio Genético, provocada por constantes dúvidas de usuários/administrados em face do advento da lei nº 13.123/2015. A dúvida ocorre em face da possibilidade de realizar pesquisa científica em virtude da ausência momentânea de Decreto que regulamente a referida lei.

2.

3. Em que pese a referida regulamentação tenha sido publicada, o Decreto nº 8772/2016, a área técnica manteve o interesse na presente consulta, que segue como meio de sanar dúvidas porventura remanescentes.

4. Diante da situação em tela, propõe o Departamento de Patrimônio Genético os seguintes pontos para análise desta CONJUR:

- (i) há diferença entre “envio” e “remessa”, nos termos da Lei nº 13.123, de 20 de maio de 2015, merecendo os referidos institutos tratamento normativo diverso?
- (ii) existe a possibilidade de mero envio, considerando-se seu conceito definido no referido diploma legal, como “envio de amostra para prestação de serviços no exterior como parte de pesquisa ou desenvolvimento tecnológico (...); e
- (iii) como dar cumprimento à exigência de cadastramento das atividades previstas no caput do art. 12, quando a finalidade do acesso ao patrimônio genético é pesquisa, em face da ausência de Decreto regulamentador da Lei nº 13.123, de 20 de maio de 2015.

## 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



# DIFFERENCES BETWEEN SHIPPING AND SENDING

## EVALUATION BY FIOCRUZ REGARDING MMA LEGAL OPINION

- 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 SHIPMENT, 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)**

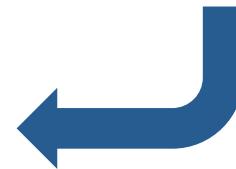
in partnership with

**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



NATIONAL COUNCIL FOR  
SCIENTIFIC AND TECHNOLOGICAL  
DEVELOPMENT



**The requirement of the foreign researcher to have to associate with a Brazilian institution to research the Brazilian biodiversity has caused some difficulties**

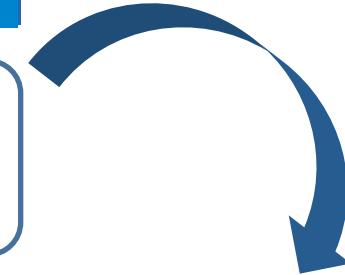
**The solution proposed**



Brazilian Institute of  
Information in Science and  
Technology

**Ministry of Science, Technology,  
Innovation and Communication**

**Brazilian partner for foreigners  
who want to study Brazilian  
biodiversity**



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



# 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**

**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...



# 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



# 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 - 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 unidentified 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



# 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

**Associated Traditional Knowledge**



Will be used **exclusively** for the benefit of traditional knowledge holders



## 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



# CGEN CREATED ELECTRONIC SYSTEM

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



Conselho de Gestão do  
**Patrimônio Genético**

Login:

Senha:

**Entrar**

 Esqueceu sua  
Senha?

 Cadastre-se

Sistema Nacional de Gestão do  
Patrimônio Genético e do Conhecimento Tradicional  
Associado



## SisGen

Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado

Tempo Restante: 59:54

PÁGINA INICIAL > ATIVIDADE DE ACESSO > CADASTRO DE ATIVIDADE DE ACESSO

### Cadastro de atividade de acesso

Tipo de Usuário:

Independente \*

#### ATIVIDADE DE ACESSO

[Novo Cadastro](#)

[Atualizar  
Cadastro](#)

#### REMESSA

[Novo Cadastro](#)

[Atualizar  
Remessa](#)

#### NOTIFICAÇÃO DE PRODUTO

[Novo Cadastro](#)

[Atualizar](#)

Responsável pelo cadastro

[Adicionar + \\*](#)

CPF	Habilitado		
	Sim		

Objeto do Acesso:

Selecione \*

O acesso foi realizado antes de 17/11/2015 ou  
obteve autorização de acesso antes de  
17/11/2015?

Selecione \*

Finalidade do Acesso:

Selecione \*

Estas atividades são baseadas em acesso  
realizado anteriormente?

Selecione \*

Não

Este cadastro está vinculado a cadastro  
anterior de remessa?

Selecione \*

Não

## ACTIVITY



## SisGen

Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado

Tempo Restante: 59:54

PÁGINA INICIAL > ATIVIDADE DE ACESSO > CADASTRO DE ATIVIDADE DE ACESSO

- ATIVIDADE DE ACESSO**
- [Novo Cadastro](#)
- [Atualizar Cadastro](#)
  
- REMESSA**
- [Novo Cadastro](#)
- [Atualizar Remessa](#)
  
- NOTIFICAÇÃO DE PRODUTO**
- [Novo Cadastro](#)
- [Atualizar](#)
  
- NOTIFICAÇÃO DE PRODUTO**
- [Novo Cadastro](#)
- [Notificações Cadastradas](#)

## ACTIVITY

## SisGen

Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado

Tempo Restante: 14:46

PÁGINA INICIAL > ATIVIDADE DE ACESSO > CADASTRO DE ATIVIDADE DE ACESSO

### Cadastro de atividade de acesso

ATIVIDADE DE ACESSO	<p><b>Tipo de Usuário:</b> <input type="text" value="Independente"/> *</p> <p><b>Responsável pelo cadastro:</b></p> <p><b>Adicionar +</b></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <th>CPF</th> <th>Habilitado</th> </tr> <tr> <td></td> <td>Sim</td> </tr> </table> <p><b>Objeto do Acesso:</b></p> <p>O acesso foi realizado antes de 17/11/2015 ou obteve autorização de acesso antes de 17/11/2015?</p> <p><b>Finalidade do Acesso:</b></p> <p>As atividades objeto deste cadastro são baseadas em outras atividades de acesso realizadas anteriormente?</p> <p>Este cadastro está vinculado a cadastro anterior de remessa?</p>	CPF	Habilitado		Sim
CPF	Habilitado				
	Sim				



## SisGen

Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado

Tempo Restante: 59:54

PÁGINA INICIAL > ATIVIDADE DE ACESSO

- ATIVIDADE DE ACESSO**
- [Novo Cadastro](#)
- [Atualizar Cadastro](#)
  
- REMESSA**
- [Novo Cadastro](#)
- [Atualizar Remessa](#)
  
- NOTIFICAÇÃO DE PRODUTO**
- [Novo Cadastro](#)
- [Atualizar](#)

## SisGen

Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado

Tempo Restante: 14:46

PÁGINA INICIAL > ATIVIDADE DE ACESSO

- ATIVIDADE DE ACESSO**
- [Novo Cadastro](#)
- [Acessos Cadastrados](#)
  
- REMESSA**
- [Novo Cadastro](#)
- [Remessas Cadastradas](#)
  
- NOTIFICAÇÃO DE PRODUTO**
- [Novo Cadastro](#)
- [Notificações Cadastradas](#)

## ACTIVITY

## SisGen

Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado

Tempo Restante: 13:53

PÁGINA INICIAL > ATIVIDADE DE ACESSO > CADASTRO DE ATIVIDADE DE ACESSO

### Cadastro de atividade de acesso

CPF	Habilitado	*
	Sim	

**Tipo de Usuário:**  \*

**Responsável pelo cadastro:**

**Adicionar + \***

**Objeto do Acesso:**  \*

O acesso foi realizado antes de 17/11/2015 ou obteve autorização de acesso antes de 17/11/2015?

**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?

**Selecionar Pesquisa** \*

**Desenvolvimento Tecnológico**

**Pesquisa e Desenvolvimento Tecnológico**

**Não** \*



## Patrimônio Genético

Título da Atividade:

 500 \*

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:

 fungos, degradação, corantes textéis

Palavra(s)-chave em inglês:

Período das Atividades:

Data  
Início:  
mm/aaaa

Data  
término:  
mm/aaaa

\*

Ainda não iniciado ou  
em execução

Equipe

Adicionar + \*

Nome Completo	Documento	Instituição	Nacionalidade		
		Fiocruz			

## RESEARCH INFORMATION



## Sobre o Componente do Patrimônio Genético acessado

Adicionar + \*

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 \*

Fungos \*

Nome científico:

Gênero Epíteto 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 \*

## ABOUT THE GENETIC HERITAGE ACCESSED



## Sobre o Componente do Patrimônio Genético acessado

**Adicionar + \***

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 \*

Fungos \*

**Nome científico:**

Gênero Epíteto 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?

## ABOUT THE GENETIC HERITAGE SOURCE

### Sobre a Procedência Do Patrimônio Genético

**Adicionar + \***

**Procedência da amostra:**

Selecionar \*

**Selecionar**

- In situ
- Ex situ
- In silico
- Produto intermediário

**Limpar**

**Limpar**

**Salvar**

**Cancelar**



## Envio de Amostra que Contenha Patrimônio Genético ao Exterior

Adicionar +

### Sobre o Patrimônio Genético

Patrimônio Genético:

 \*

Tipo de PG enviado ou a ser enviado:

 \*

Forma de acondicionamento:

Adicionar +

### Informações do Projeto

Especificação das atividades a serem realizadas no exterior

 \* 

O envio de amostra tem por finalidade o sequenciamento genético?

 \*

REGISTRATION OF THE  
SENDING



Envio de Amostra que Contenha Patrimônio Genético ao Exterior

[Adicionar +](#)

Sobre o Patrimônio Genético

Patrimônio Genético:

Tipo de PG enviado ou a ser enviado:

Selecionar

Forma de acondicionamento:

[Adicionar +](#)

Informações do Projeto

Especificação das atividades a serem realizadas no exterior

O envio de amostra tem por finalidade o sequenciamento genético?

Não

REGISTRATION OF THE  
SENDING

Instituição Destinatária no Exterior

Nome Institucional

 \* 

País:

Selecionar \*

Região:

 \*

Município:

 \*

Código Postal:

 \*

Endereço:

 \*

Contato:

 \* 

Telefone:

 \* 

Email:

 \* 

Representante Legal:

 \*

Contrato de prestação de serviços ou outro instrumento jurídico firmado entre o remetente nacional e a destinatária:

Anexar Documento:

[Escolher arquivos](#) Nenhum arquivo selecionado



[Limpar](#)

[Salvar](#)

[Cancelar](#)



## 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 \*

REGISTRATION OF THE  
SHIPMENT ABROAD



**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 \*

**REGISTRATION OF THE  
SHIPMENT ABROAD****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**

Selecionar \*

**Grupo**

Selecionar \*

**Classe**

Selecionar \*

**Subclasse**

Selecionar \*



Sobre o componente do Patrimônio Genético a ser remetido

Adicionar + \*

ABOUT THE GENETIC HERITAGE  
TO BE SHIPPED ABROAD



## Sobre o componente do Patrimônio Genético a ser remetido

Adicionar + \*

## ABOUT THE GENETIC HERITAGE TO BE SHIPPED ABROAD

**Tipo de amostra a ser remetida:**

Selecionar \*

Selecionar

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, dentre outros) contendo material biológico

Micro-organismos isolados (exceto fungos e vírus)

Fungos isolados / Cultura de fungos

Vírus

Material Genético isolado (inclusive transposons, plasmídeos, dentre outros)

Informação in silico

Outros

Limpar



## Sobre o componente do Patrimônio Genético a ser remetido

Adicionar + \*

## ABOUT THE GENETIC HERITAGE TO BE SHIPPED ABROAD

Tipo de amostra a ser remetida:

Selezione \*

Forma de acondicionamento:

Selezione \*

Adicionar + \*

Forma de acondicionamento:

Adicionar + \*

Forma de acondicionamento:

Quantidade Recipiente

Volume a ser remetido

Método do envio:

Número do conhecimento de carga:

Limpar

Selezione \*



Selezione

- Amostra líquida em tubo de microcentrifuga (eppendorf)
- Amostra sólida em tubo de microcentrifuga (eppendorf)
- Material herborizado / 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 lâmina (Lâminas de microscopia)
- Placas de cultivo, com substrato
- Tubos de centrifuga
- Garrafa/frasco com meio de cultivo
- Amostra líquida em recipientes diversos (garrafas, tambores, galões e bombonas)
- Outra



## Sobre o componente do Patrimônio Genético a ser remetido

Adicionar + \*

## ABOUT THE GENETIC HERITAGE TO BE SHIPPED ABROAD

Tipo de amostra a ser remetida:

Selezione \*

Forma de acondicionamento:

Adicionar + \*

Forma de acondicionamento:

Adicionar + \*

Forma de acondicionamento:

Quantidade Recipiente

Volume a ser remetido

Método do envio:

Número do conhecimento de carga:

Limpar

Forma de acondicionamento:

Adicionar + \*

Forma de acondicionamento:

Selezione \*

Selezione \*

Selezione \*

Quantidade Recipiente

Volume a ser remetido

Método do envio:

Número do conhecimento de carga:

Limpar

Salvar Cancelar



## Instituição Destinatária no Exterior

Nome Institucional

 \*

País:

 Seleccione \*

Região:

 \*

Município:

 \*

Código Postal:

 \*

Endereço:

 \*

Telefone:

Email:

## Representante Legal da Instituição Destinatária

Adicionar + \*

\* Campos Obrigatórios.

Termos de uso do SisGen:

RECIPIENT INSTITUTION



## Cadastro de Notificação de Produto

Tipo de Usuário:

Independente \*

Responsável pelo cadastro

Adicionar + \*

CPF	Habilitado	
	Sim	

Número de Cadastro de Acesso/Remessa

Adicionar + \*

Tipo de Produto para Notificação:

Selecionar \*

Selecionar

- 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)

Identificação Comercial do Produto:

Classificação NCM do Produto:

NOTIFICATION  
OF PRODUCT



## Cadastro de Notificação de Produto

NOTIFICATION  
OF PRODUCT

Tipo de Usuário:

Independente \*

Responsável pelo cadastro

Adicionar + \*

CPF	Habilitado		
	Sim		

Número de Cadastro de Acesso/Remessa

Adicionar + \*

Tipo de Produto para Notificação:

Selecionar  
Selecionar  
Produto  
Produto  
Material  
Material  
Material

Identificação Comercial do Produto:

Classificação NCM do Produto:

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

Selecionar \*

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

Selecionar \*

Abrangência da Comercialização do Produto  
Acabado ou Material Reprodutivo:

Nacional

Internacional \*



## Novo Credenciamento

Tipo de Usuário:

Independente \*

Coleção Ex Situ:

Grupos Taxonômicos Colecionados:

REGISTRATION OF EX SITU  
COLLECTION



## Novo Credenciamento

Tipo de Usuário:

Independente \*

Coleção Ex Situ:

Grupos Taxonômicos Cole

INFORMATION ON THE SAMPLE  
PRESERVED IN THE COLLECTION

Adicionar Tipo de Amostra Conservada: \*

Adicionar +

Tipo de Amostras Conservadas:

\*

Capacidade Total para o Armazenamento de  
Amostras:

\*

Métodos de Armazenamento e Conservação:

\*

Limpar

Salvar

Cancelar



## Novo Credenciamento

Tipo de Usuário:

Independente \*

Coleção Ex Situ:

Grupos Taxonômicos Cole

INFORMATION ON THE  
COLLECTION CURATOR

Adicionar Tipo de Amostra Conservada: \*

Adicionar +

Tipo de Amostras Conservadas:

\*

Capacidade Total para o Armazenamento de  
Amostras:

\*

Métodos de Armazenamento e Conservação:

\*

Adicionar Curador: \*

Adicionar +

CPF:

\*

Nome:

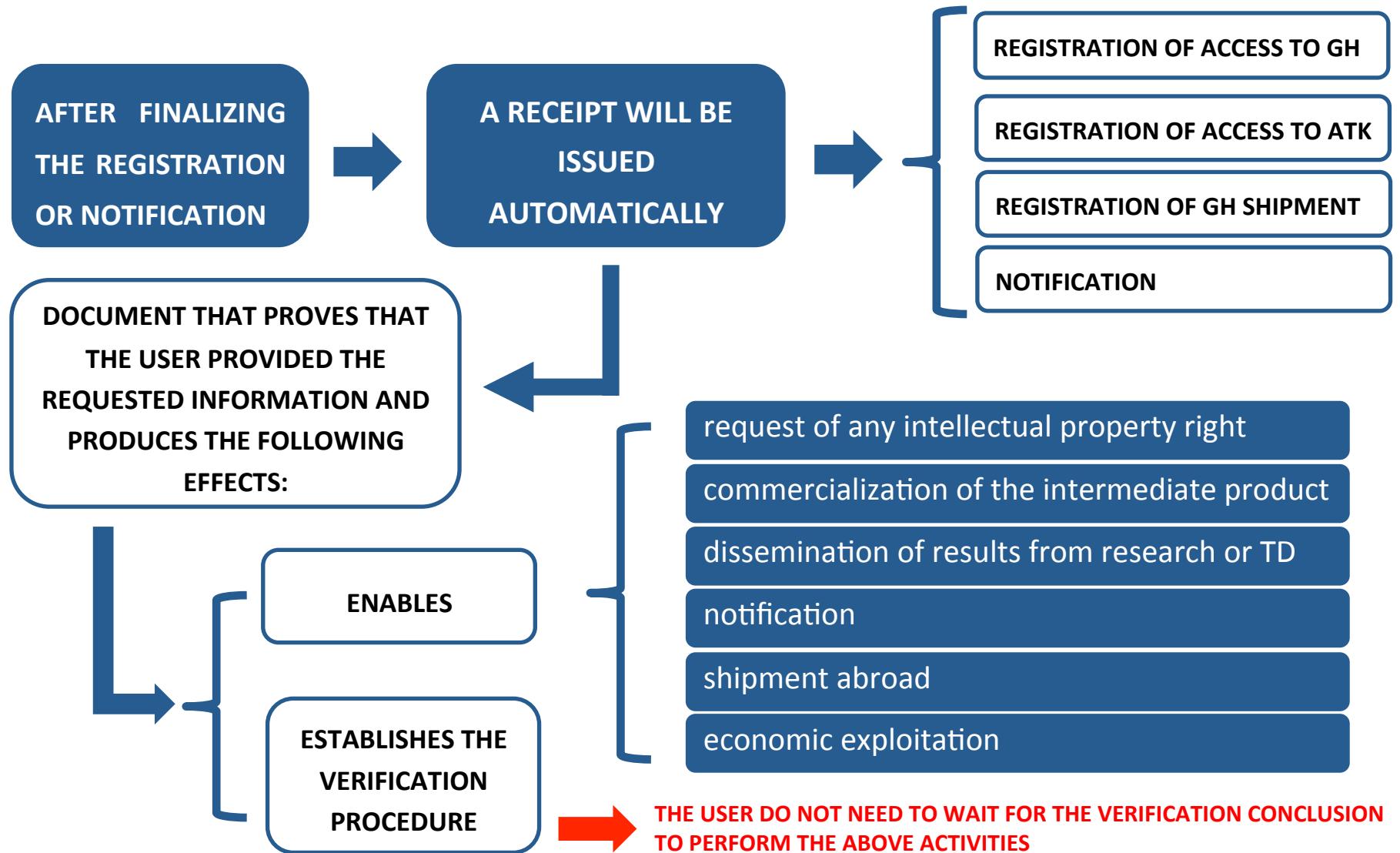
\*

Limpar

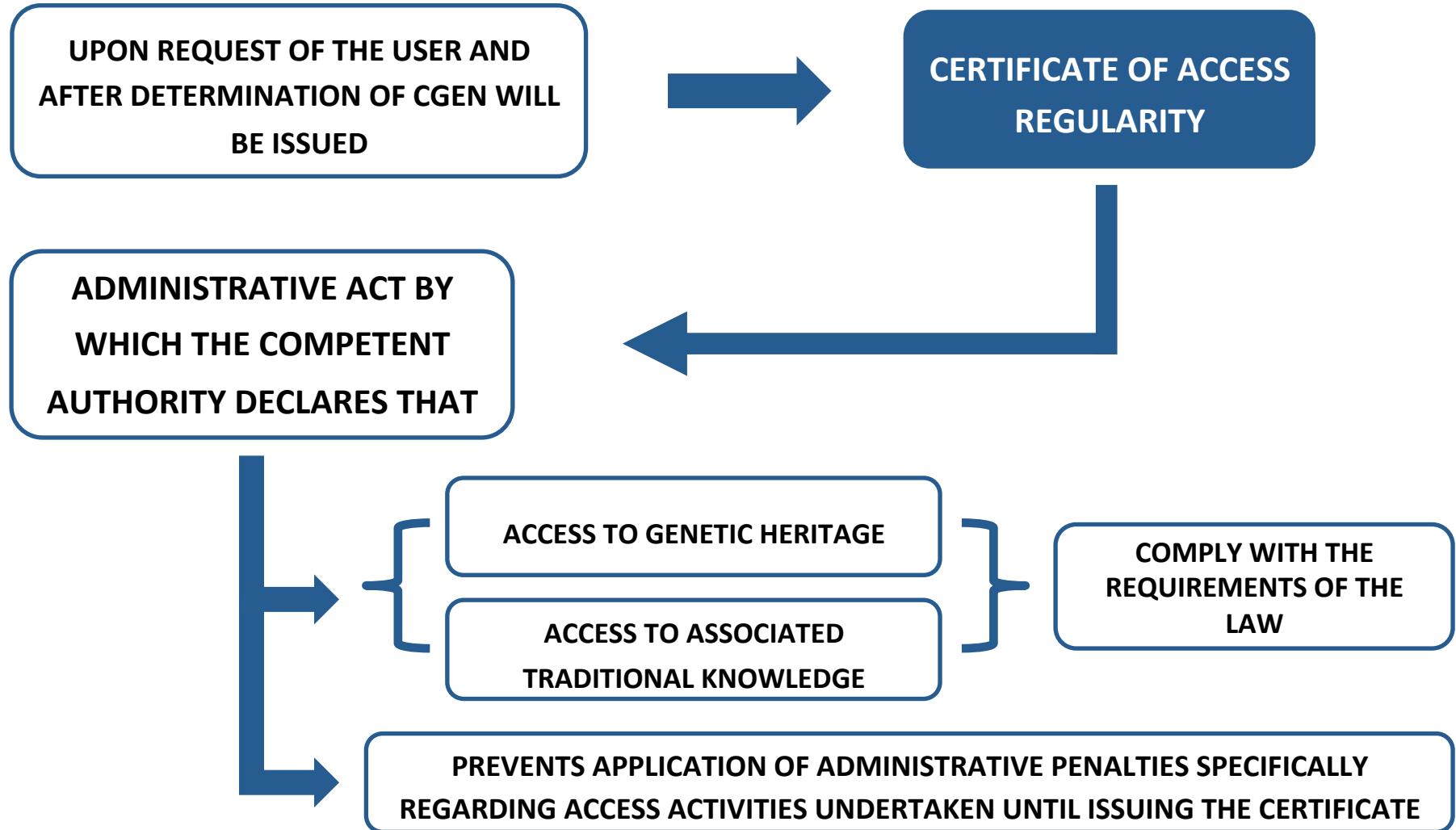
Salvar

Cancelar

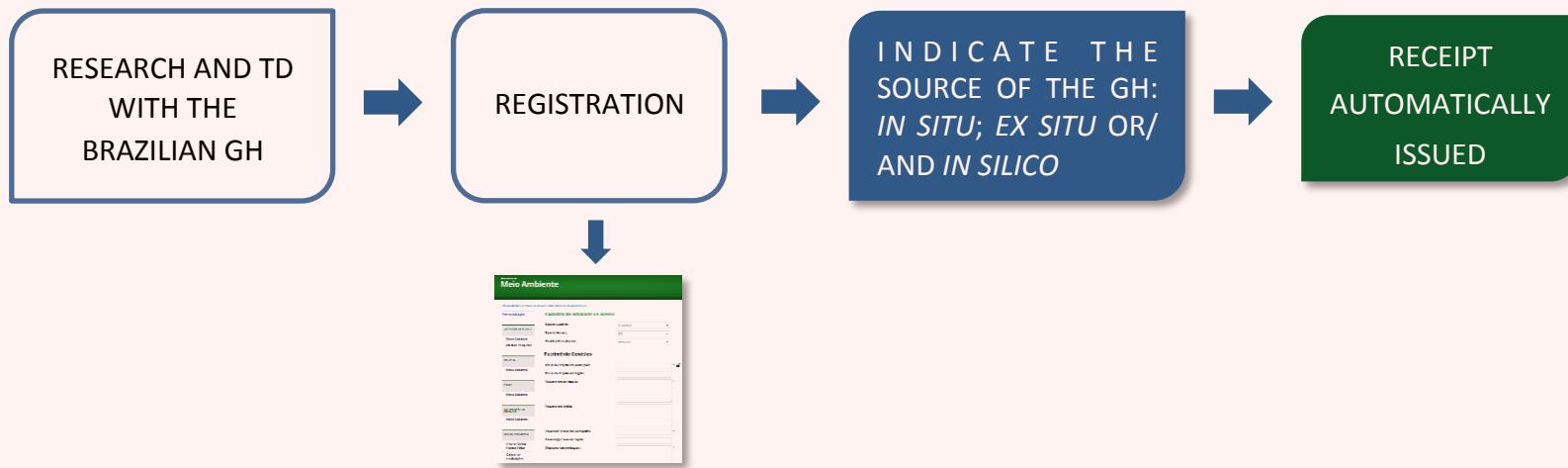




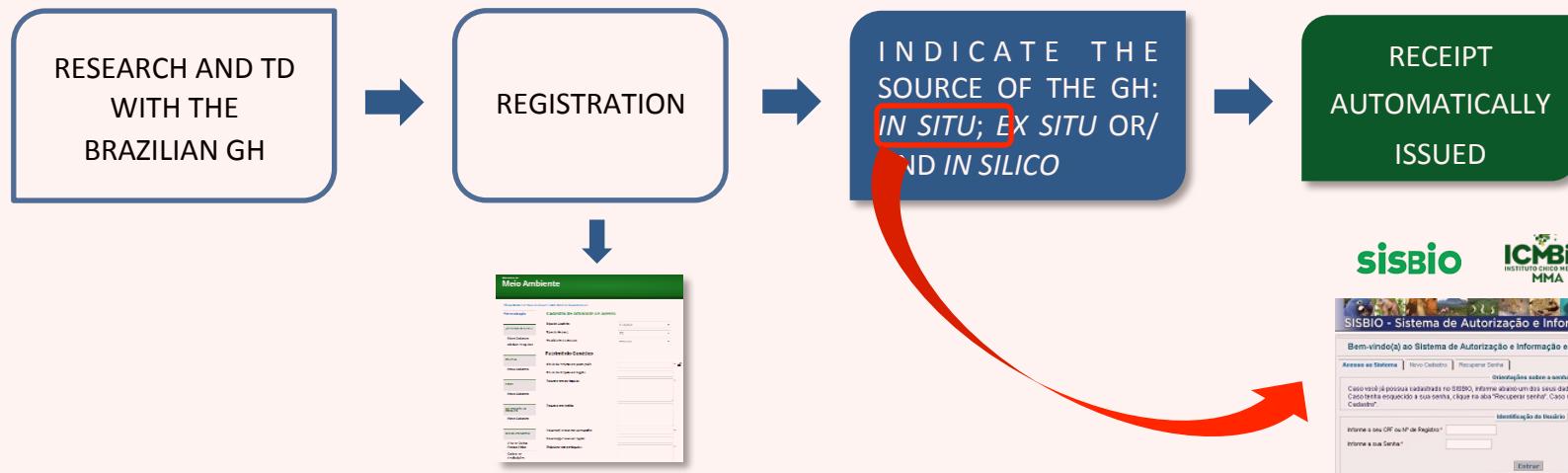
# CERTIFICATE OF ACCESS REGULARITY



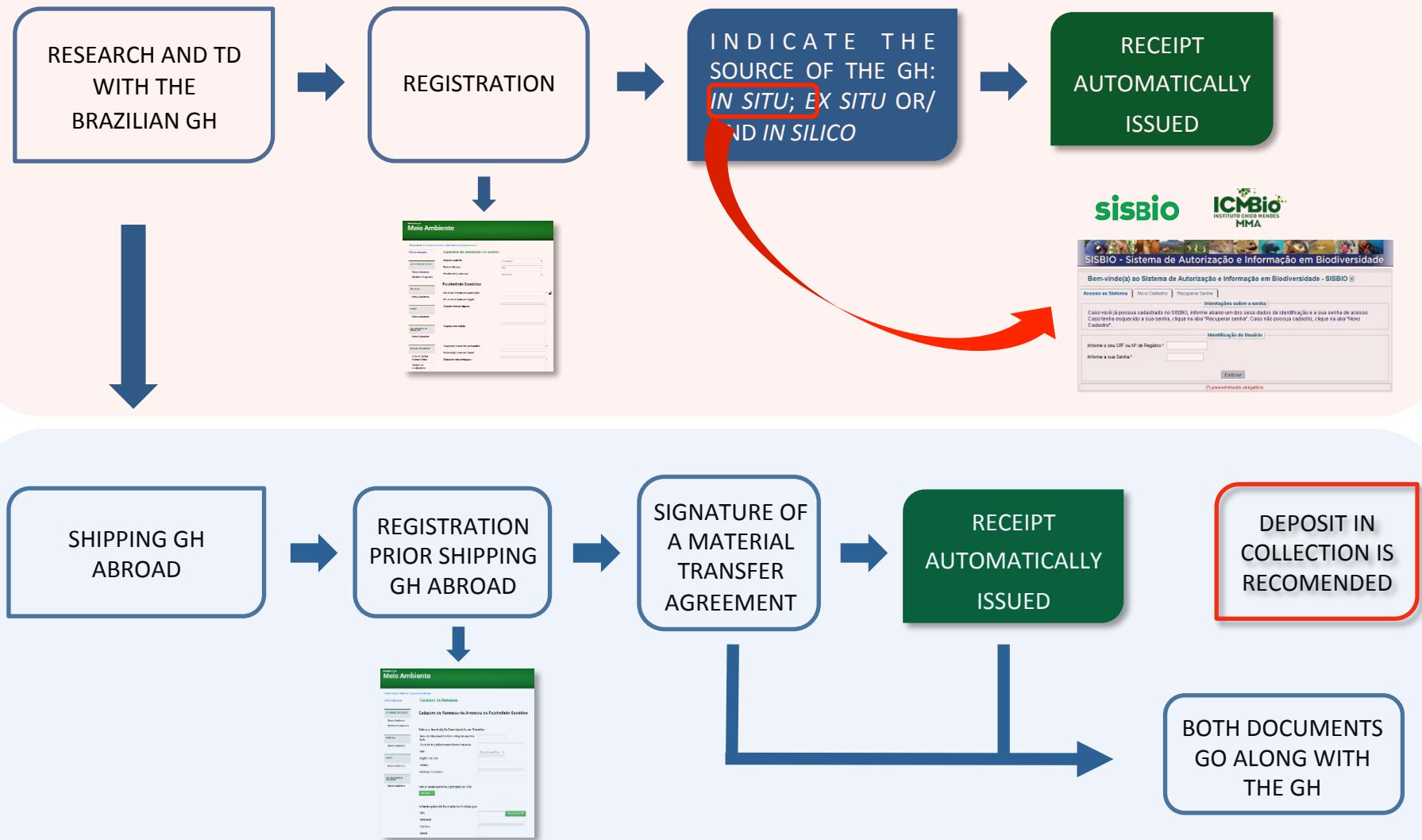
# FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT



# FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT



# FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT



# FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT

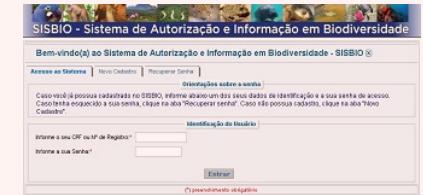
RESEARCH AND TD  
WITH THE  
BRAZILIAN GH

REGISTRATION

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

RECEIPT  
AUTOMATICALLY  
ISSUED

**sisbio** 



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

**sisbio** ICMBio  
Instituto Chico Mendes  
MMA



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 OR/  
AND IN SILICO*

RECEIPT  
AUTOMATICALLY  
ISSUED

**sisbio** ICMBio  
Instituto Chico Mendes  
MMA



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



## 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

**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



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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



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## 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

- Biodiversity Law
- Fiocruz and Law 13.123
- Nagoya Protocol



Arte: Bruno de Oliveira/Fiocruz

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

### Read More

- New ABS Brazilian legislation Law: presentation (Portuguese)
- New ABS Brazilian legislation Law: presentation (English)
- The new institutional procedures (Portuguese)
- Material Transfer Agreement
- Manual on the

### Legislation

- Read, in the whole, the new Brazilian ABS legislation

- Know the Decree 8.772, which regulates the Biodiversity Law
- CGen Academy Sectorial Chamber
- Rules of the CGen Academy Sectorial Chamber
- Fulfilling the requirements of the New

### Reference Documents - Nagoya Protocol

- Explanation of the Nagoya Protocol on ABS and its implication for microbiology
- The U.S. Culture Collection Network

### News (Portuguese)

- Fiocruz debate gestão do patrimônio genético brasileiro
- Palestra aborda responsabilidade e uso racional da biodiversidade brasileira
- Evento discute lei da biodiversidade na perspectiva da sociedade civil
- Mais notícias

### Reference Documents - Biodiversity Law

- The new Brazilian legislation on access to the biodiversity (English)



### Editorial

## The new Brazilian legislation on access to the biodiversity (Law 13,123/15 and Decree 8772/16)<sup>☆</sup>



The Provisional Act (Medida Provisória – MP) 2,186-16, of August 23, 2001, was the first legal framework to regulate access to Genetic Heritage (GH)<sup>1</sup> and Associated Traditional Knowledge (ATK)<sup>2</sup> in Brazil for purposes of scientific research, bioprospecting, and technological development. This MP was also responsible for the creation of the Genetic Heritage Management Council (CGen). However, this MP had very negative impact on scientific research, displeasing the academic community, which felt obstructed by bureaucratization and criminalized by administrative penalties, discouraging Research & Development (R&D) of Brazilian biodiversity resources.

The construction of a new legislation was complex, considering the different interests and visions among diverse sectors of civil society, represented by the academia, business sector, and holders of associated traditional knowledge, as well as the different sectors of government. Thus, it was almost 15 years before the publication of the "New Law on Biodiversity", Law 13,123 of May 20, 2015, which came into force on November 17, 2016. However, regulation occurred only six months after the

law came into force, after extensive opposition, debates, and criticisms, through Decree No. 8772 of May 11, 2016. To facilitate compliance with the legislation and to assist the CGen, the Decree created the National System of Genetic Resource Management and Associated Traditional Knowledge (SisGen). Due to various bureaucratic and administrative issues, SisGen was made available to the public on November 6, 2017, which is almost one year after the law came into force.

The new law, whose scope is more comprehensive than previous legislation, involves research, technological development, and economic exploitation of finished product<sup>3</sup> and reproductive material<sup>4</sup> from access to GH and ATK. According to the new definitions of GH, access to GH,<sup>5</sup> and research,<sup>6</sup> the law includes activities that were not contemplated by the MP, such as research related to molecular taxonomy, phylogeny, molecular epidemiology, and molecular ecology, as well as the use of information from public genetic sequence databases, such as GenBank.

It is important to emphasize that to comply with the legislation, an institution must first appoint a legal representative, who will be responsible for the institutional register and will alone have the power to represent it within SisGen. An

<sup>1</sup> This text is partly based on previous publications by the authors: Oliveira, D.R., da Silva, M., 2016. Regulamentada a Nova Lei da Biodiversidade: Desafios e perspectivas para P&D no Brasil. *Jornal da Ciéncia Noticias*. SBPC, 15/06/16. da Silva, M., 2017. A Lei da Biodiversidade: origem e seu impacto na pesquisa científica e no desenvolvimento tecnológico comunitário genético e conhecimento tradicional associado, em: Nader, H.B., de Oliveira, F., Mossi, B.B. (Orgs.), *A ciéncia e o poder legislativo: relatos e experiéncias*. SBPC, São Paulo, pp. 184-194. Oliveira, D.R., da Silva, M., Carmona, F., Angeli, R. 2017. Cumprindo as exigências da Nova Lei da Biodiversidade - Lei 13.123/2015. Chamada à comunidade científica para a regularização e cadastramento de atividades envolvendo patrimônio genético e conhecimento tradicional associado. *Jornal*.

<sup>2</sup> Product whose nature does not require any type of additional protective process, derived from access to genetic heritage or to associated traditional knowledge, in which the component of genetic heritage or associated traditional knowledge is one of the main elements that add value to the product, which is available for use by the final consumer, being either a person or company.

<sup>3</sup> Plant propagation or animal reproductive material of any genus, species, or crop derived from sexual or asexual reproduction.

<sup>4</sup> Research or technological development carried out on a sample



# **THANK YOU!**

**Manuela da Silva**  
**[manuela.dasilva@fiocruz.br](mailto:manuela.dasilva@fiocruz.br)**  
**FIOCRUZ**  
**FUNDAÇÃO OSWALDO CRUZ**  
**HEALTH MINISTRY**

