

# THE BRAZILIAN LEGISLATION ON ACCESS AND BENEFIT SHARING

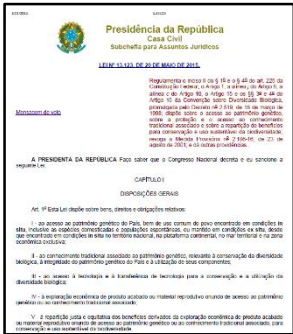
**MANUELA DA SILVA**

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



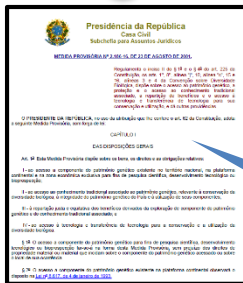


# THE NEW BRAZILIAN ABS LEGISLATION



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

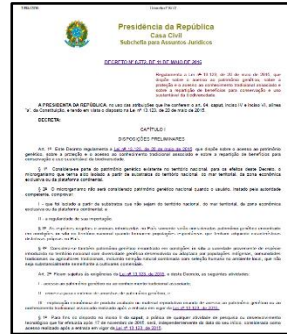
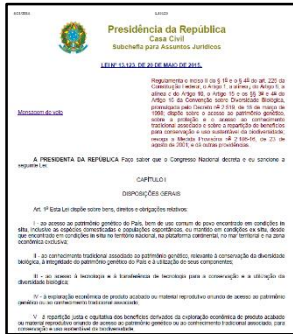
17<sup>th</sup> November,  
2015  
Entry into force  
of Law 13,123



Provisional Act 2,186-16 / 2001  
is revoked



# THE NEW BRAZILIAN ABS LEGISLATION

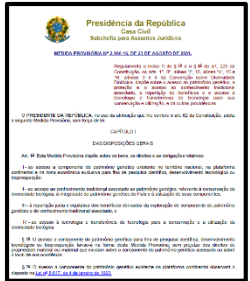


20<sup>th</sup> May 2015  
Publication of  
Law 13,123

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

11<sup>th</sup> May 2016  
Publication of  
Decree 8.772  
that regulates  
the Law

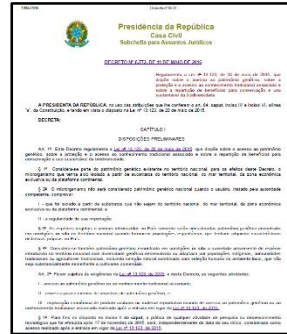
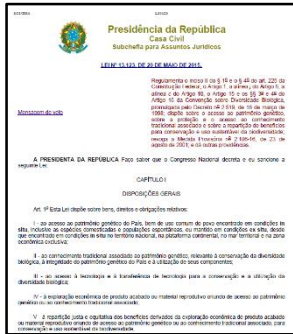
28<sup>th</sup> July 2016  
1<sup>st</sup> Meeting of  
CGen



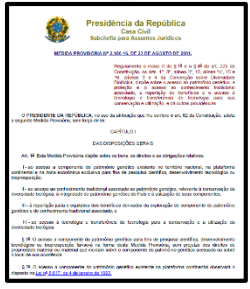
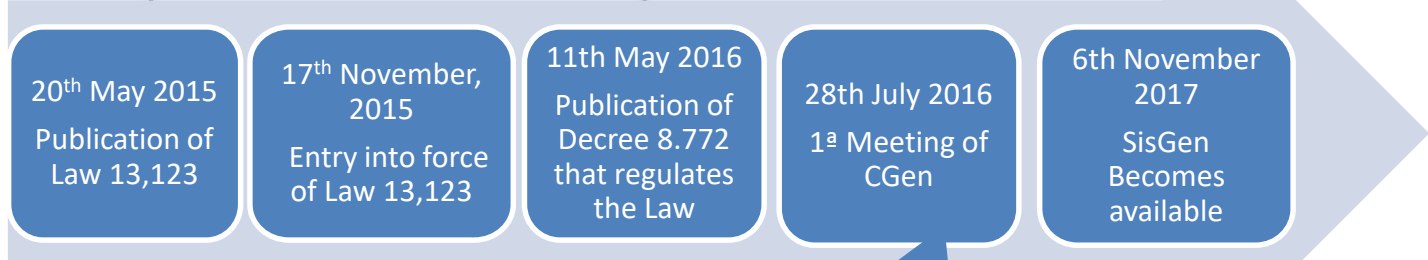
CGen consists of representatives of **9 Ministries** and **9 representatives of civil society**, **3 of each of the following sectors**: Business sector; Indigenous peoples, traditional communities and traditional farmers; **Academia** (SBPC – Brazilian Society for the Science Progress; ABC - Brazilian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



# THE NEW BRAZILIAN ABS LEGISLATION



National System for the Management of Genetic Heritage and Associated Traditional Knowledge, the SisGen, instrument that allows law compliance



CGen consists of representatives of 9 Ministries and 9 representatives of civil society, 3 of which are of the following sectors: Business sector; Academia (SBPC – Brazilian Society for the Science Progress; ABC - Brazilian Academy of Science, ABA - Brazilian Association of Anthropology)



# ABS NATIONAL COMPETENT AUTHORITY

## CGEN WORKS BY MEANS OF:

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

 [Deliberação nº 5](#)

Data: 21/03/2017

Sectoral Chamber of Academia is responsible for conducting technical discussions and presenting proposals of interest to the academic sector related to access and benefit-sharing legislation under the terms of Law 13,123 and Decree No. 8,772. The first meeting was in August 2017



# PARTICIPANTS OF THE SECTORIAL CHAMBER OF ACADEMY

CGEN member who indicated	Name and Institution	
SBPC, ABC	André Luis de Gasper – Universidade Regional de Blumenau Coordenador da Rede de Herbários da Sociedade Botânica do Brasil	
SBPC, ABC	Manuela da Silva - Fundação Oswaldo Cruz/RJ Sociedade Brasileira de Microbiologia	<b>Coordinator</b>
SBPC, ABC	Luciane Marinoni - Universidade Federal do Paraná Presidente da Sociedade Brasileira de Zoologia	<b>Deputy Coordinator</b>
SBPC, ABC	Marcelo H. A. Freitas - Secretaria de Relações Internacionais - Coordenadoria de Políticas Globais/Embrapa	
ABA	Nurit Rad	<p><b>This chamber is the means by which researchers can expose problems with the legislation and its compliance and propose the necessary adjustments</b></p>
ABA	Elaine M	
MDIC	Claudia M	
MJ	Maira Sm	
MAPA	Rosa Mir	
MCTI	Claudia Morosi Czarneski	
MS	Nínive Aguiar Colonello Frattini	
MMA	Thiago Zeidan Araujo	





## Câmara Setorial da Academia



4 Patrimônio Genético
Capacitação e Publicações
4 Conselho de Gestão do Patrimônio Genético
Reuniões
Composição
4 Câmaras Temáticas e Setoriais
Câmara Setorial das Populações Indígenas, Comunidades Tradicionais e Agricultores Tradicionais
<b>Câmara Setorial da Academia</b>
Câmara Temática sobre dosimetria das multas dos Autos de Infração
Câmara Temática sobre proposta de definição sobre características distintivas próprias
Câmara Temática sobre os conceitos de excipientes para setor de higiene pessoal, perfumaria e cosméticos
Normas do CGen

### PRÓXIMA REUNIÃO

#### 16ª Reunião Ordinária da Câmara Setorial da Academia

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

Link da reunião: Em breve

Data: 03/07/2020

- **Horário:** 10 às 12h
- **Local:** Internet (Zoom)
- **Pauta:** Em breve.

1. Associação de instituição estrangeira com instituição brasileira:

- IBICT/ICMBio como parceiro brasileiro para a associação;
- Avaliação da CONJUR/MMA sobre o momento que a parceria/cadastro deve ser realizada pelo estrangeir; e
- Desenvolvimento no SisGen 2 do formulário que será preenchido pelos estrangeiros para o cadastramento das atividades.

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







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Normas do CGen

Histórico

Composição

Calendário

Reuniões anteriores

Link/Documentos

Prazos para regularização

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

Reunião	Documentos	Pauta	Memória	Lista de Presença
1ª Reunião - 14/08/17	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	-
2ª Reunião - 25/09/17	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
3ª Reunião - 20/11/17	-	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
4ª Reunião - 26/02/18	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
5ª Reunião - 19/03/18	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
6ª Reunião - 29/05/18	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	-
7ª Reunião - 18/06/18	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
8ª Reunião - 20/08/18	-	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
9ª Reunião - 17/09/18	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
10ª Reunião - 18/03/19	-	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
11ª Reunião - 06/08/19		<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
12ª Reunião - 01/10/19		<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
13ª Reunião - 03/12/19	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
14ª Reunião - 18/02/20	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>
15ª Reunião - 03/07/20	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>	<a href="#">Clique aqui</a>





## Câmara Setorial da Academia



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Normas do CGen

1. [Lei nº 13.123, de 20 de maio de 2015 - versão em inglês](#)
2. [Acesso e repartição de benefícios no cenário mundial: A lei brasileira em comparação com normas internacionais](#)
3. [Parecer nº 169/2017/CONJUR-MMA/CGU/AGU](#)
4. [Manual SisGen](#)
5. [Manual Acesso ao Patrimônio Genético Brasileiro e ao Conhecimento Tradicional Associado - ABIFINA](#)
6. [Marcos regulatórios aplicáveis às atividades de pesquisa e desenvolvimento - EMBRAPA](#)
7. [Perguntas Frequentes - Patrimônio Genético e Conhecimento Tradicional Associado](#)
8. [Cartilha para a academia referente a lei nº 13.123, de 2015.](#)
9. [Instrução Normativa nº 19, de 16 de abril de 2018 - Lista de espécies animais introduzidas no território nacional](#)
10. [FAQ on Law 13.123 for foreign biological collections - 2019](#)
11. [English version of Resolution 12 that approves the MTA](#)
12. [English version of MTA with additional clauses for Microbial Collections](#)
13. [Instrução Normativa nº3, de 20 de março de 2019](#)
14. [Lista de espécies introduzidas no território nacional \(exóticas\)](#)
15. [Instrução Normativa nº 16, de 4 de junho de 2019](#)



# SCOPE OF THE LAW 13.123/15

THE LAW  
COVERS THE  
ACTIVITY OF

- RESEARCH
- TECHNOLOGICAL DEVELOPMENT

• ECONOMIC EXPLOITATION



- FINISHED PRODUCT OR
- REPRODUCTIVE MATERIAL

**ACCESS = UTILIZATION**

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

ORIGINATED FROM THE  
ACCESS OF GENETIC  
HERITAGE

ORIGINATED FROM THE  
ACCESS OF ASSOCIATED  
TRADITIONAL KNOWLEDGE

THIS IS THE MOMENT WHEN THERE IS  
BENEFIT SHARING



**sisBio**



Cachoeira do Veado

> Saiba Mais

> Dúvidas Frequentes

> Estatísticas

> Destaques

> Manual

> Legislação Específica

> Verificar Autenticidade

> Relatório de Atividades

> Dados de Licenciamento

## INSTITUTO CHICO MENDES OF CONSERVATION OF BIODIVERSITY (ICMBio/MMA)

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

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

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



# ECONOMIC EXPLOITATION

## FINISHED PRODUCT

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

## REPRODUCTIVE MATERIAL

It refers to plant propagation material or animal reproduction of any genus, species or cultivation from sexual or asexual reproduction



# SCOPE OF THE LAW 13.123/15

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

**DEFINITION**

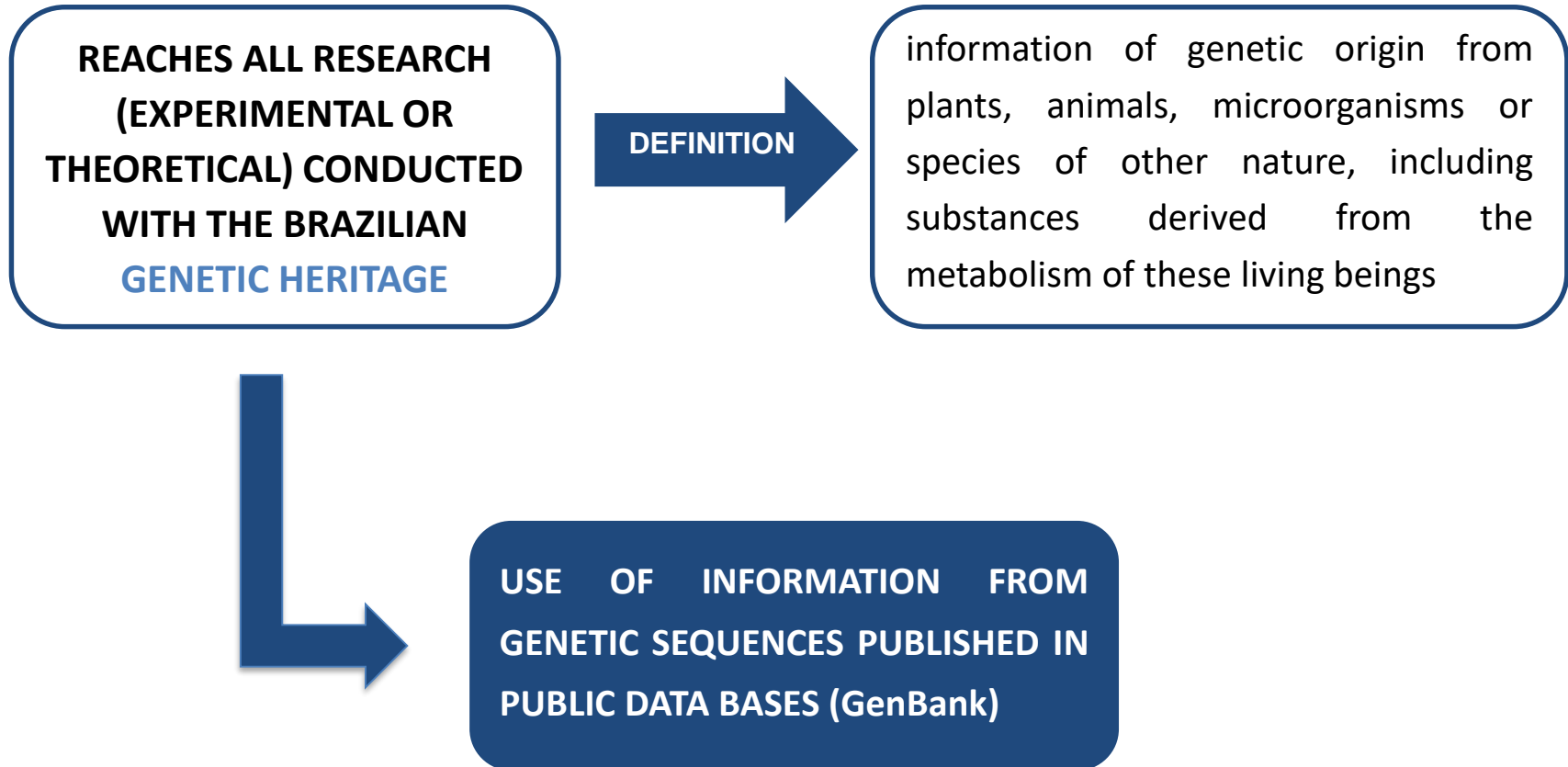
information of genetic origin from plants, animals, microorganisms or species of other nature, including substances derived from the metabolism of these living beings

**BASIC RESEARCH SUCH AS:**

- **EPIDEMIOLOGY**
- **MOLECULAR ECOLOGY**
- **MOLECULAR TAXONOMY**
- **PHYLOGENY**

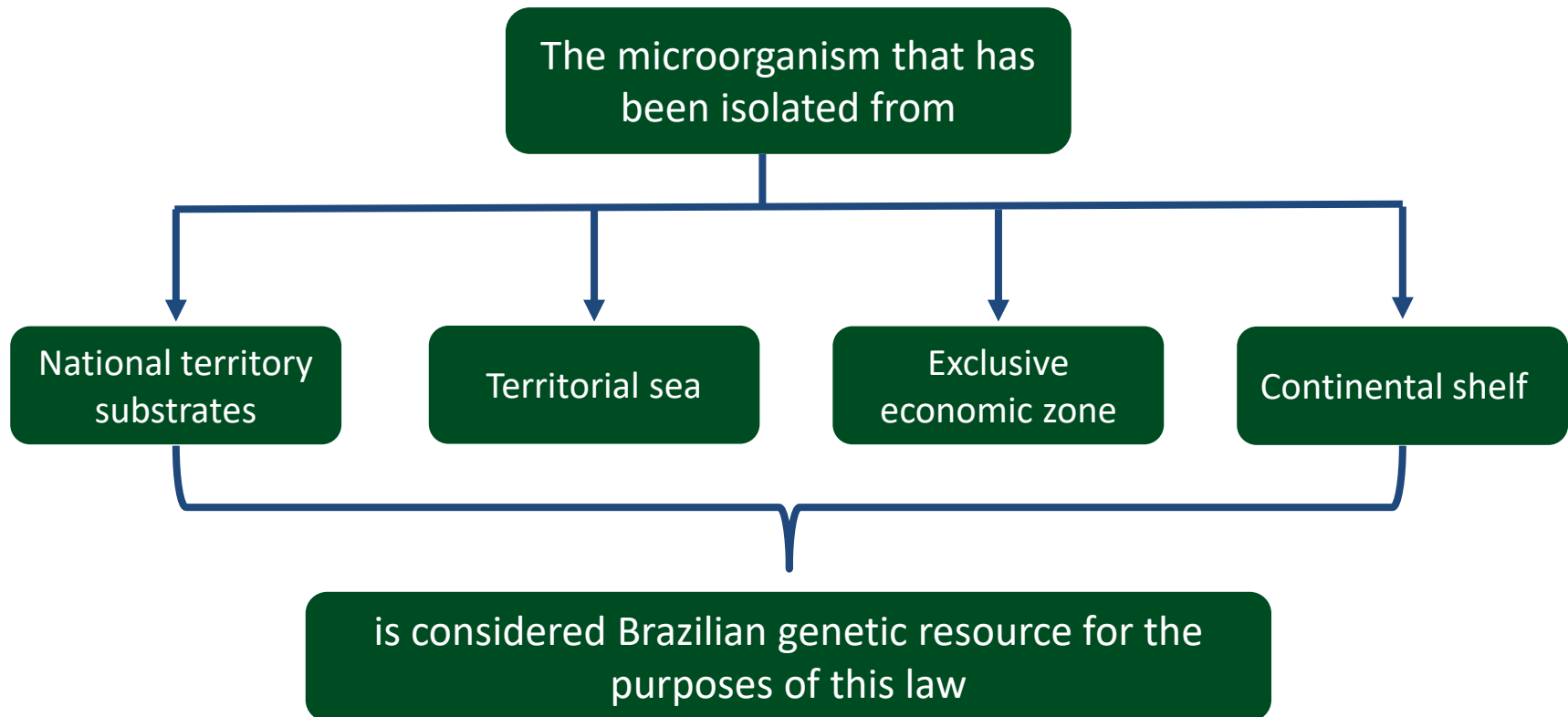


# SCOPE OF THE LAW 13.123/15



# 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**

**TECHNOLOGICAL DEVELOPMENT**

**NOTIFICATION BEFORE**

**ECONOMIC EXPLOITATION**



# NOTIFICATION

## **For economic exploitation will be required:**

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



# AUTHORIZATION

## THE AUTHORIZATION SHALL BE CARRIED OUT PRIOR TO:

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

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

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

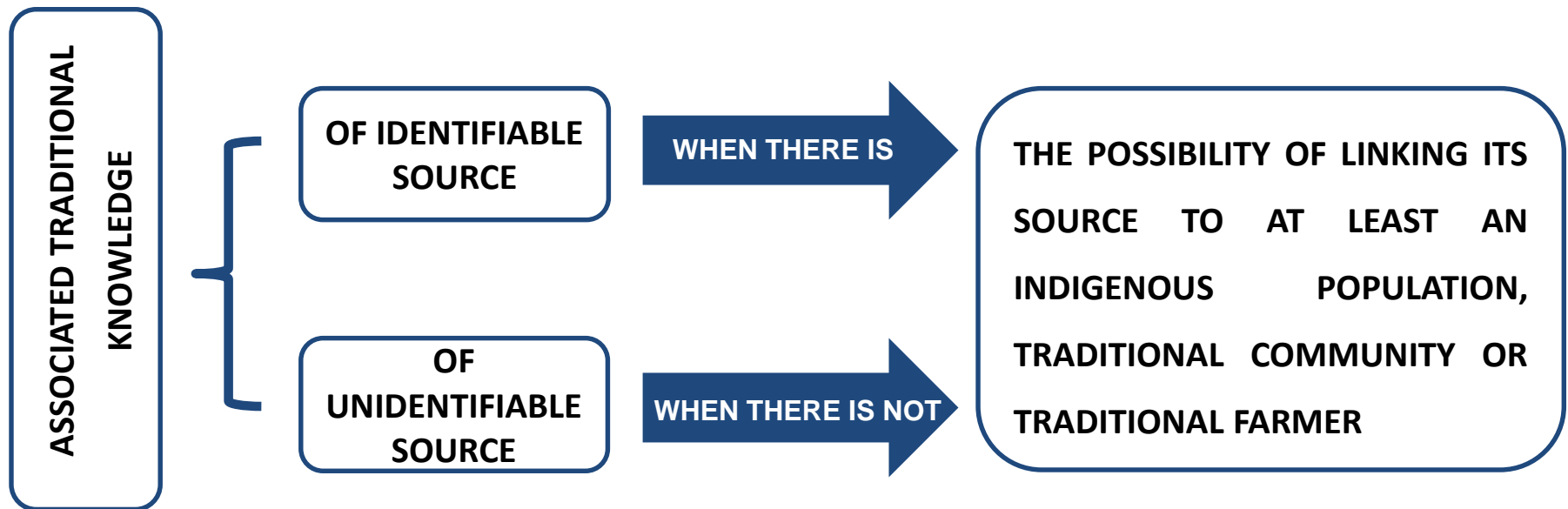
II - national institution of scientific research and technology, public or private, when access is made in association with legal entity based abroad

III - Brazilian natural person associated, funded or contracted by a legal entity based abroad



# 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



# ACCESS TO ASSOCIATED TRADITIONAL KNOWLEDGE

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

ASSOCIATED TRADITIONAL KNOWLEDGE

OF IDENTIFIABLE SOURCE

WHEN THERE IS

OF UNIDENTIFIABLE SOURCE

WHEN THERE IS NOT

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



# ACCESS TO ASSOCIATED TRADITIONAL KNOWLEDGE

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

ASSOCIATED TRADITIONAL KNOWLEDGE

OF IDENTIFIABLE SOURCE

WHEN THERE IS

OF UNIDENTIFIABLE SOURCE

WHEN THERE IS NOT

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





# SHIPMENT ABROAD OF GENETIC HERITAGE

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

**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 RECEIPT 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 RECEIPT 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

## Resolution CGen Nº 12 ratifies and updates the MTA, making important changes in it:

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

  
**MINISTÉRIO DO MEIO AMBIENTE**  
**CONSELHO DE GESTÃO DO PATRIMÔNIO GENÉTICO**  
**RESOLUÇÃO CGEN Nº 12, DE 18 DE SETEMBRO DE 2018**

*Approva 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 I desta Resolução.

Art. 2º Conforme 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 O remetente e o destinatário poderão firmar, a seu critério, um ou mais TTM s, que terão prazo de validade de, no máximo, 10 (dez) anos, renováveis.

§ 1º Para cada uma das remessas vinculadas ao TTM de que trata o caput, o remetente deverá fazer o cadastro prévio da remessa no Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado – SisGen, incluindo Guia de Remessa, numerada em ordem sequencial, com a descrição das amostras a serem remetidas, conforme o modelo do Anexo II desta Resolução.

§ 2º Para serem regularmente remetidas, as amostras de patrimônio genético deverão estar acompanhadas de três documentos:

**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. 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:



# MATERIAL TRANSFER AGREEMENT

Histórico	Composição	Calendário	Reuniões anteriores	Link/Documentos
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Prazos para regularização

1. Lei nº 13.123, de 20 de maio de 2015 - versão em inglês
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10. *FAQ on Law 13.123 for foreign biological collections - 2019*
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12. English version of MTA with additional clauses for Microbial Collections
13. Instrução Normativa nº3, de 20 de março de 2019
14. Lista de espécies introduzidas no território nacional (exóticas)
15. Instrução Normativa nº 16, de 4 de junho de 2019



**MINISTRY OF THE ENVIRONMENT**  
**Genetic Heritage Management Council**

**CGEN RESOLUTION No. 12, OF 18 SEPTEMBER 2018**

*Ratifies the standard Material Transfer Agreement - MTA document*

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

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

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

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



# MATERIAL TRANSFER AGREEMENT

<a href="#">Histórico</a>	<a href="#">Composição</a>	<a href="#">Calendário</a>	<a href="#">Reuniões anteriores</a>	<a href="#">Link/Documentos</a>
<a href="#">Prazos para regularização</a>				
<ol style="list-style-type: none"><li>1. Lei nº 13.123, de 20 de maio de 2015 - versão em inglês</li><li>2. Acesso e repartição de benefícios no cenário mundial: A lei brasileira em comparação com normas internacionais</li><li>3. Parecer nº 169/2017/CONJUR-MMA/CGU/AGU</li><li>4. Manual SisGen</li><li>5. Manual Acesso ao Patrimônio Genético Brasileiro e ao Conhecimento Tradicional Associado - ABIFINA</li><li>6. Marcos regulatórios aplicáveis às atividades de pesquisa e desenvolvimento - EMBRAPA</li><li>7. Perguntas Frequentes - Patrimônio Genético e Conhecimento Tradicional Associado</li><li>8. Cartilha para a academia referente a lei nº 13.123, de 2015.</li><li>9. Instrução Normativa nº 19, de 16 de abril de 2018 - Lista de espécies animais introduzidas no território nacional</li><li>10. <i>FAQ on Law 13.123 for foreign biological collections - 2019</i></li><li>11. <i>English version of Resolution 12 that approves the MTA</i></li><li>12. <b>English version of MTA with additional clauses for Microbial Collections</b></li><li>13. Instrução Normativa nº3, de 20 de março de 2019</li><li>14. Lista de espécies introduzidas no território nacional (exóticas)</li><li>15. Instrução Normativa nº 16, de 4 de junho de 2019</li></ol>				



## 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 TRASFERED**





# 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 TRASFERED**

**SERVICES PROVIDED  
ABROAD ARE CONSIDERED**

**TESTS**

**SPECILIZED TECHNIQUES**

**PERFORMED BY AN INSTITUTION COLABORATING WITH THE NATIONAL  
INSTITUTION RESPONSIBLE BY THE ACCESS OR BY WHICH IT WAS HIRED**



# SHIPPING AND SENDING

## MAIN DIFFERENCES BETWEEN SHIPPING AND SENDING IN THE CASE OF SCIENTIFIC PARTNERSHIP

### Sending:

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

### Shipping:

- Previous registration needed
- There is transfer of responsibility on the sample
- The sample is accompanied by Material Transfer Agreement - MTA
- The sample can remain in the recipient



# RESEARCH BY FOREIGNERS

## BRAZILIAN BIODIVERSITY CAN ONLY BE ACCESSED BY

**FOREIGN INSTITUTION  
(LEGAL ENTITY LOCATED  
ABROAD)**

in partnership with

**BRAZILIAN INSTITUTION  
(PUBLIC OR PRIVATE)**

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

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

### NATIONAL COUNCIL FOR SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENT



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

**The solution proposed**

**Pre-defined Brazilian Scientific and Technological Research Institution**

**Brazilian partner for foreigners who want to research Brazilian biodiversity but have no collaboration in Brazil**

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



# 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 - NFBS



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





# BENEFIT SHARING

## WHEN THE BENEFIT SHARING COMES FROM:

**Genetic Heritage**



**The payments will go entirely to the FNRB**

**Associated Traditional Knowledge of unidentifiable source**



**The payments will go entirely to the FNRB**

**Associated Traditional Knowledge of identifiable source**



**The TK holders negotiate freely the benefit sharing and additional 0.5% of annual net revenue from the economic exploitation of the knowledge will go to the FNRB and will be administered by providers**



# 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

THE MONETARY FUNDS DEPOSITED IN THE NATIONAL FUND OF BENEFIT SHARING (FNRB) ARISING FROM ECONOMIC EXPLOITATION OF FINISHED PRODUCT OR REPRODUCTIVE MATERIAL OBTAINED FROM THE ACCESS TO:

Genetic Heritage from *ex situ* Collections



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

**EX SITU COLLECTIONS WILL ONLY BE ELIGIBLE TO RECEIVE THIS RESOURCES FROM THE FUND IF THEY ARE ACCREDITED IN SISGEN**



# BENEFIT SHARING

THE MONETARY FUNDS DEPOSITED IN THE NATIONAL FUND OF BENEFIT SHARING (FNRB) ARISING FROM ECONOMIC EXPLOITATION OF FINISHED PRODUCT OR REPRODUCTIVE MATERIAL OBTAINED FROM THE ACCESS TO:

Genetic Heritage from *ex situ* Collections



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

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



# BENEFIT SHARING

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

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



# BENEFIT SHARING AGREEMENT

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

**The Benefit-Sharing Agreement will be required in cases of:**

- Non-monetary benefits
- Monetary benefits with holders of associated traditional knowledge of identifiable origin

**In the case of monetary benefits regarding access:**

- Genetic heritage and / or
- Associated traditional knowledge of unidentifiable origin

**Benefit Sharing Agreement will not be necessary, the benefit can be deposited directly in the NFBS**



# 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?

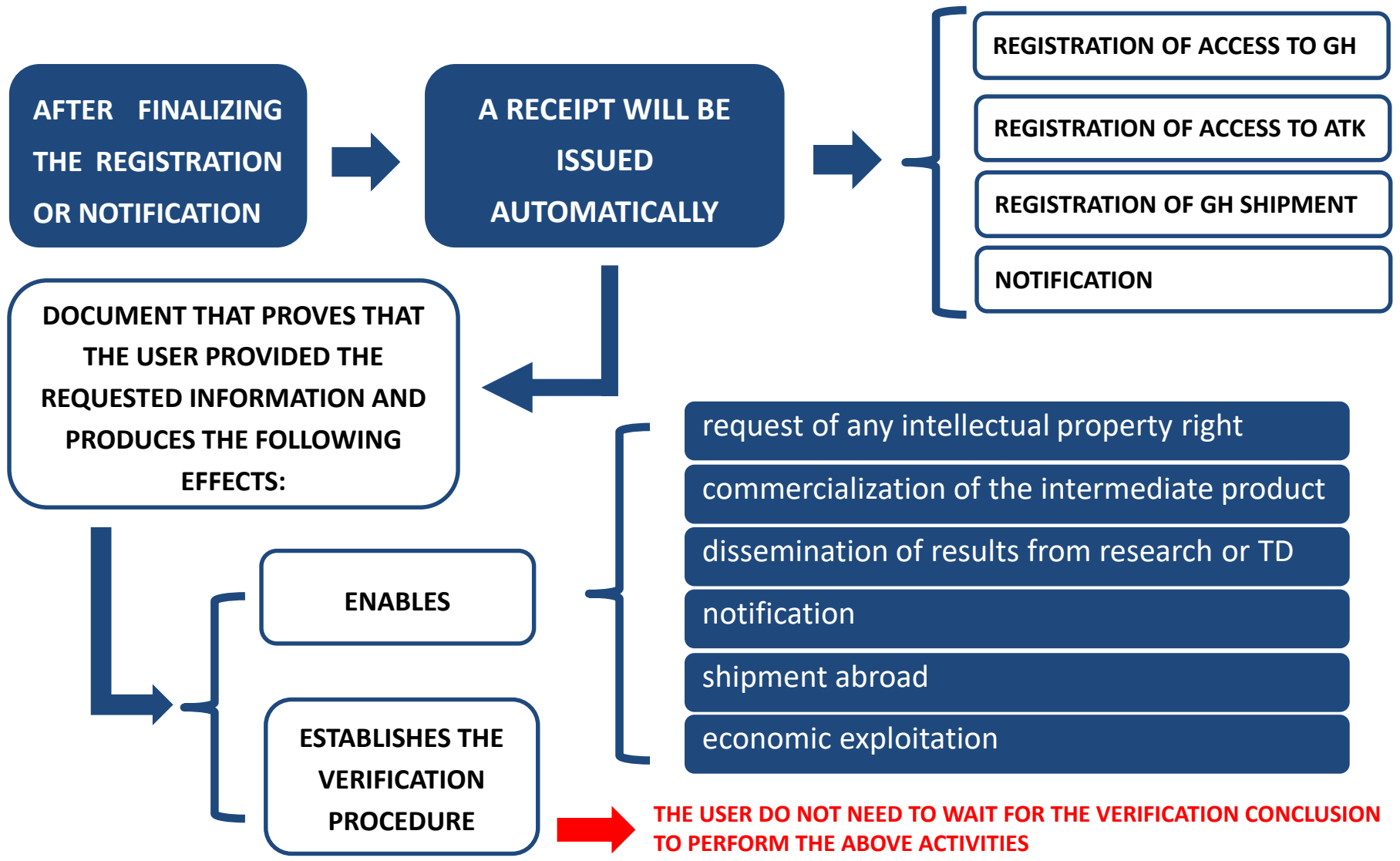
 Cadastre-se

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

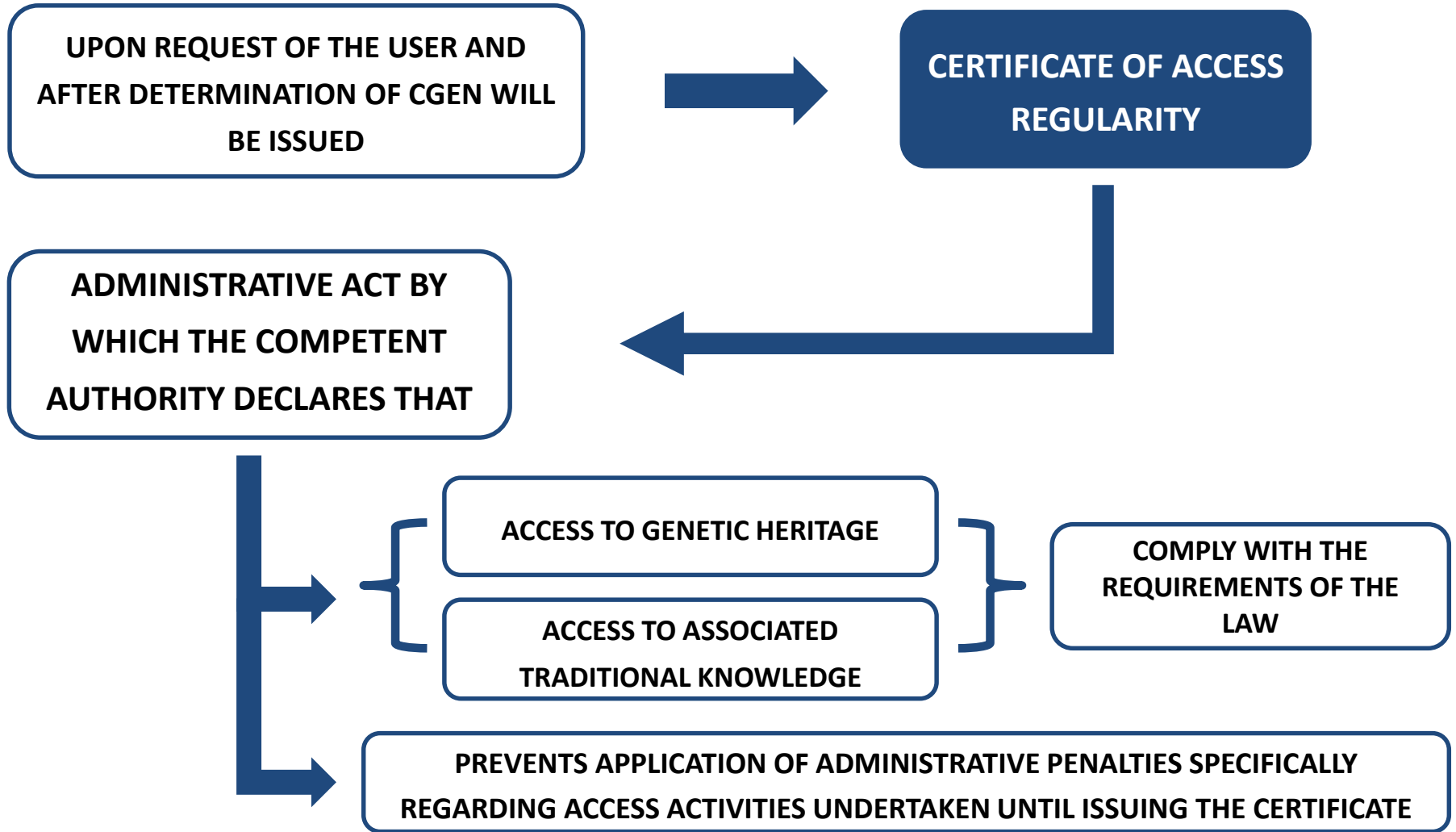
- Access through login (CPF - Social Security Number) and password
- Security of the information:
  - Digital certificate
  - Shielding System - Security Module
- Communication with user via electronic message (e-mail)
- Training Environment (<http://treina.sisgen.gov.br>)
- Manual available at SisGen
- Elaboration of version 2







# CERTIFICATE OF ACCESS REGULARITY





# 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

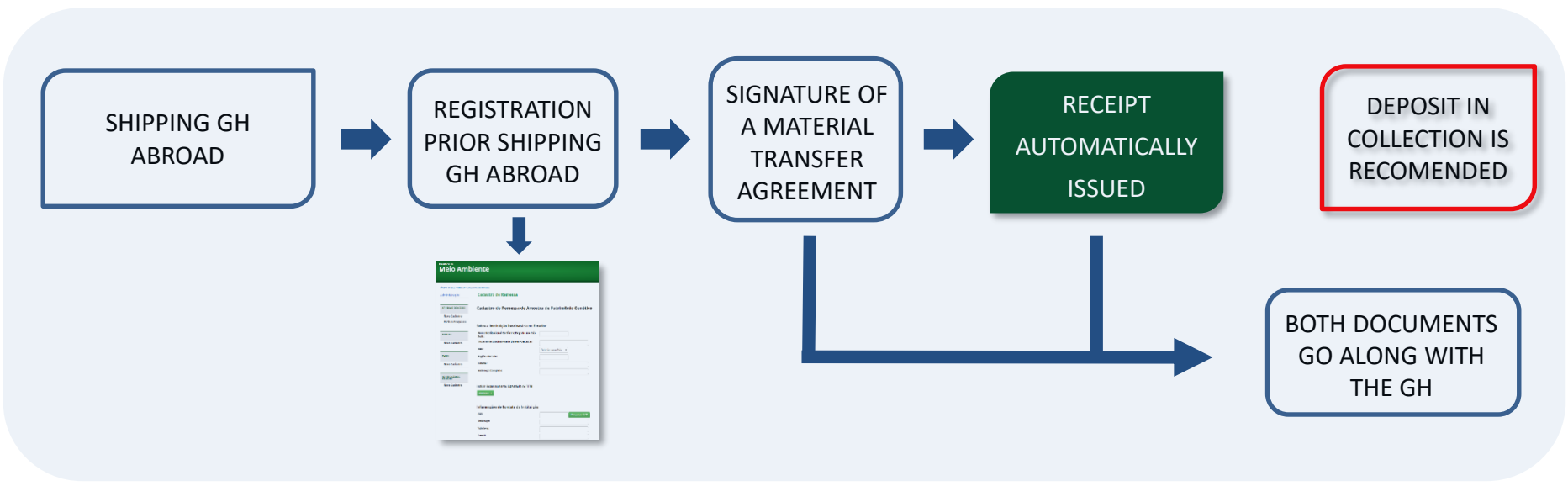
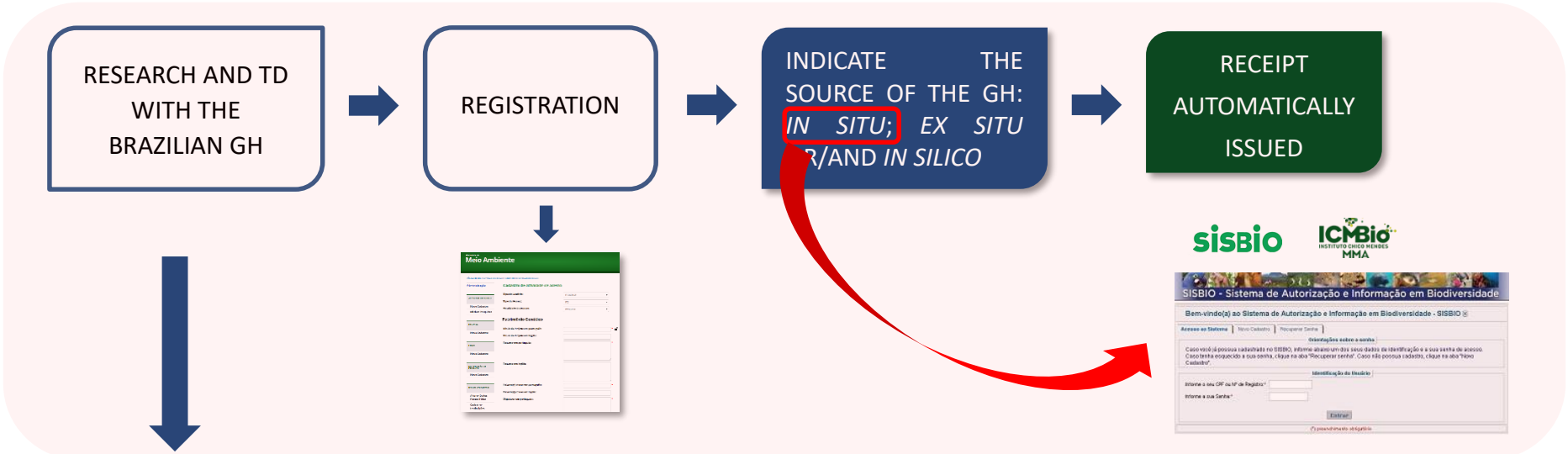
RECEIPT  
AUTOMATICALLY  
ISSUED

A screenshot of a web form titled 'Meio Ambiente'. It contains several sections with labels and input fields, including 'Dados do Registro do Produto', 'Dados do Produto', 'Finalidade Científica', 'Dados do Pesquisador', 'Dados do Laboratório', 'Dados do Financiador', and 'Dados do Patrocinador'. The form is partially filled out.

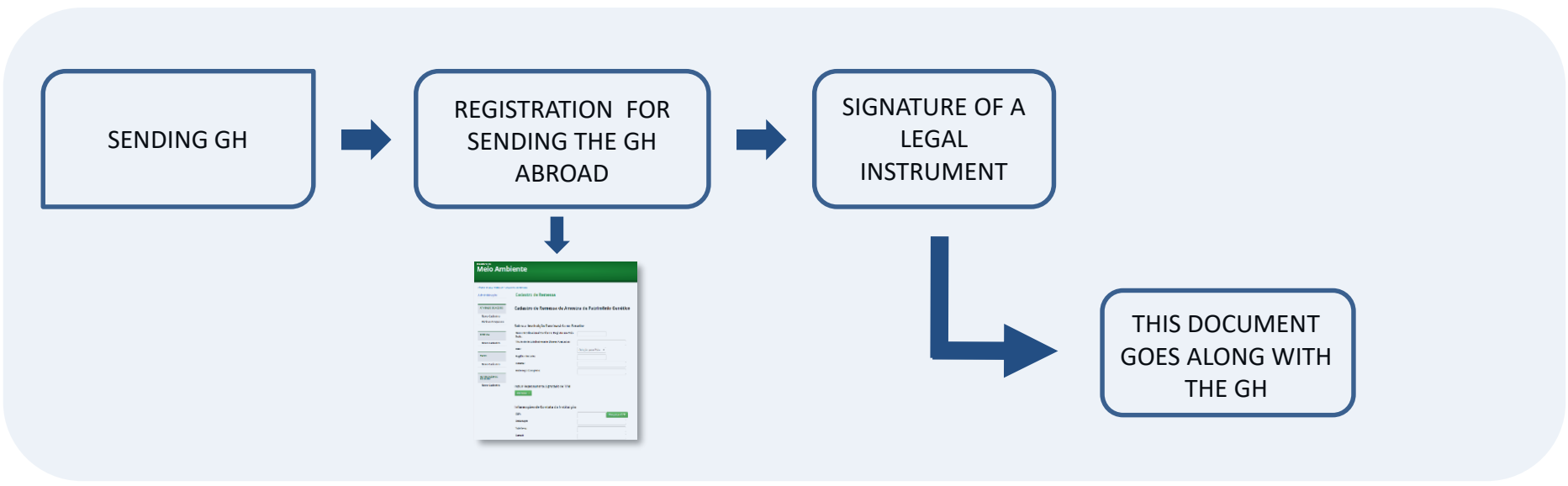
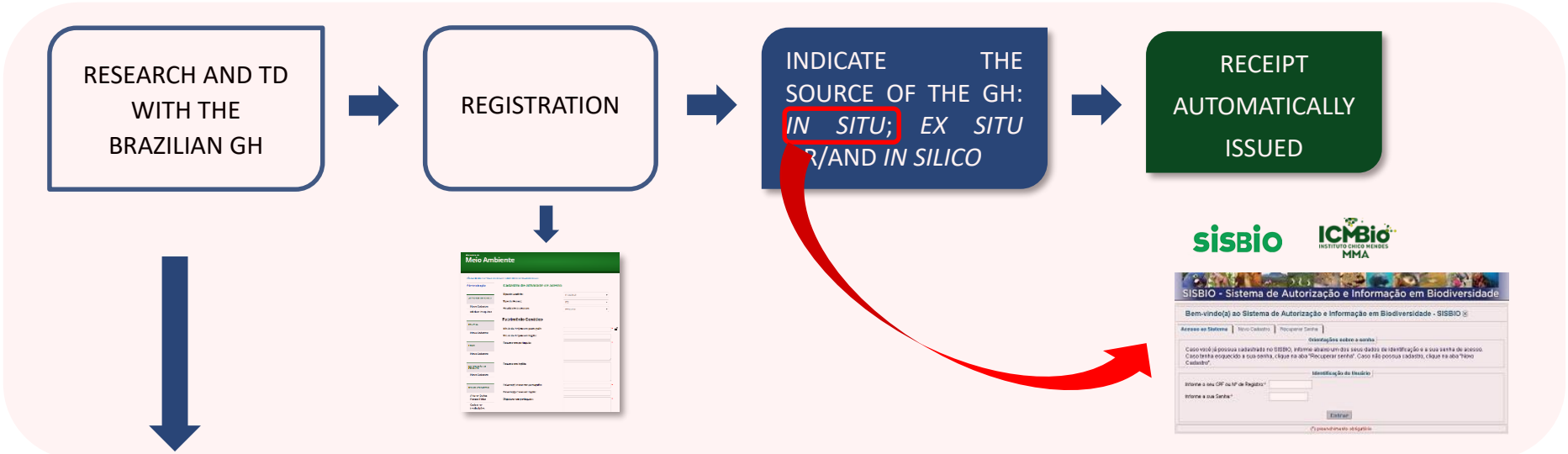
A screenshot of the SISBIO system interface. At the top, it displays the logos for 'sisbio' and 'ICMBio INSTITUTO CHICO MENDES MMA'. Below the logos, the text reads 'SISBIO - Sistema de Autorização e Informação em Biodiversidade'. The main content area shows a welcome message: 'Bem-vindo(a) ao Sistema de Autorização e Informação em Biodiversidade - SISBIO'. There are navigation links for 'Acessar ao Sistema', 'Novo Cadastro', and 'Recuperar Senha'. A paragraph of text explains the system's purpose: 'Este sistema possui todas as informações sobre a pesquisa e sua fonte de acesso. Caso tenha esquecido a sua senha, clique na aba "Recuperar senha". Caso não possua cadastro, clique na aba "Novo Cadastro".' Below this, there is a section for 'Identificação do Usuário' with input fields for 'Informe o seu CPF ou Nº de Registro' and 'Informe a sua Senha'. A 'Entrar' button is located at the bottom right of this section. A small link for 'Políticas de Privacidade' is visible at the very bottom.



# FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT

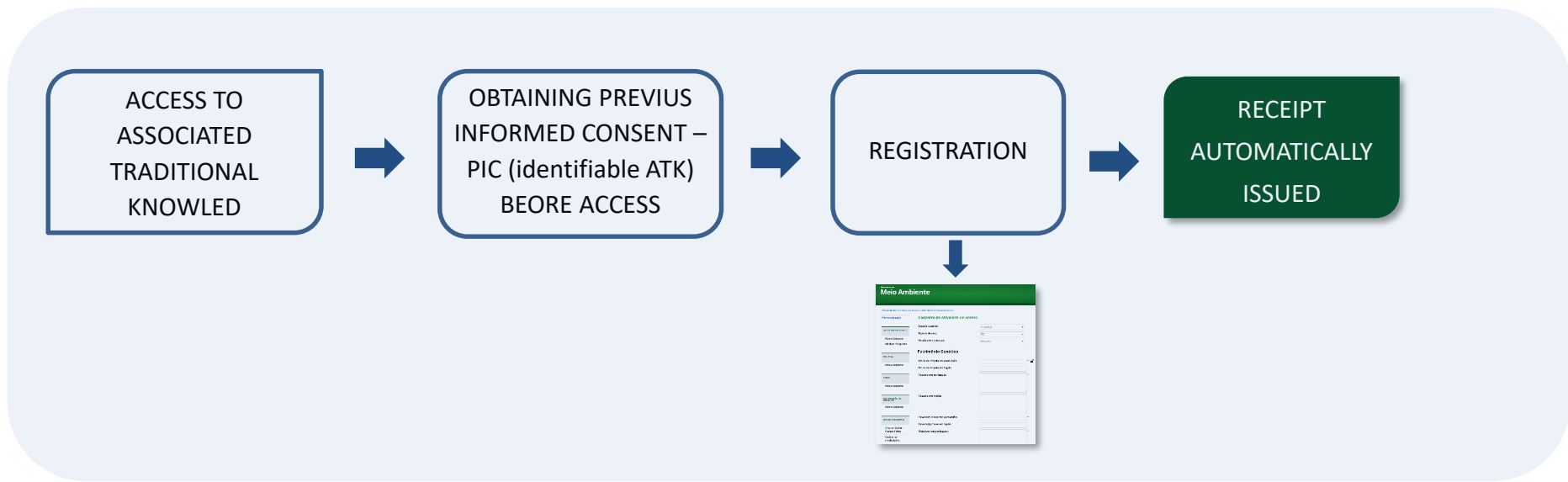
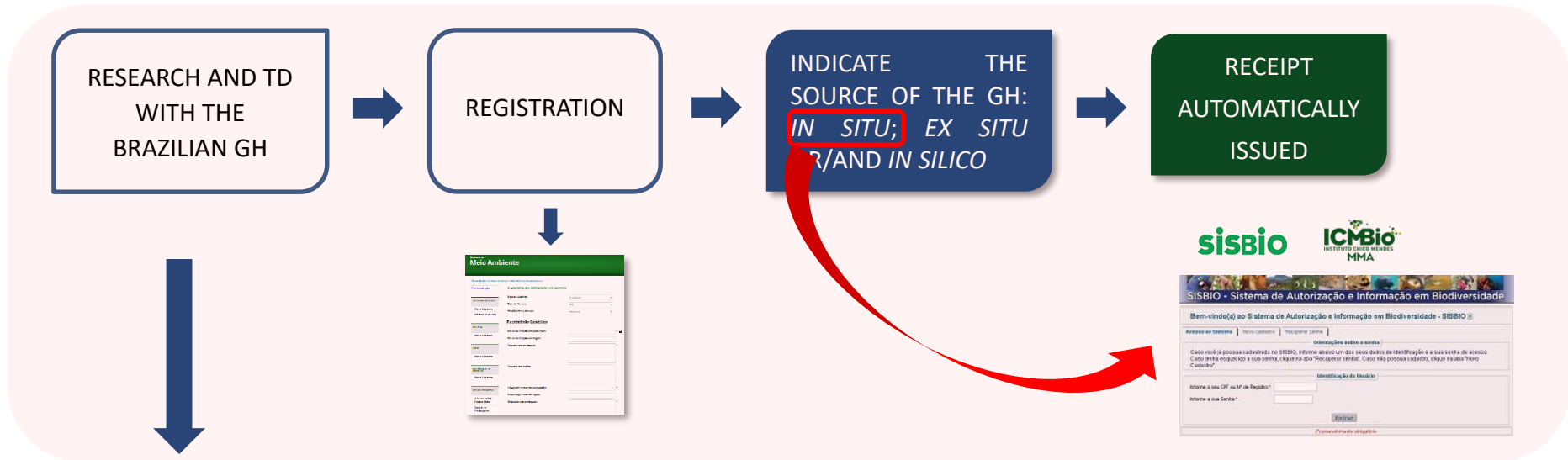


# FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT



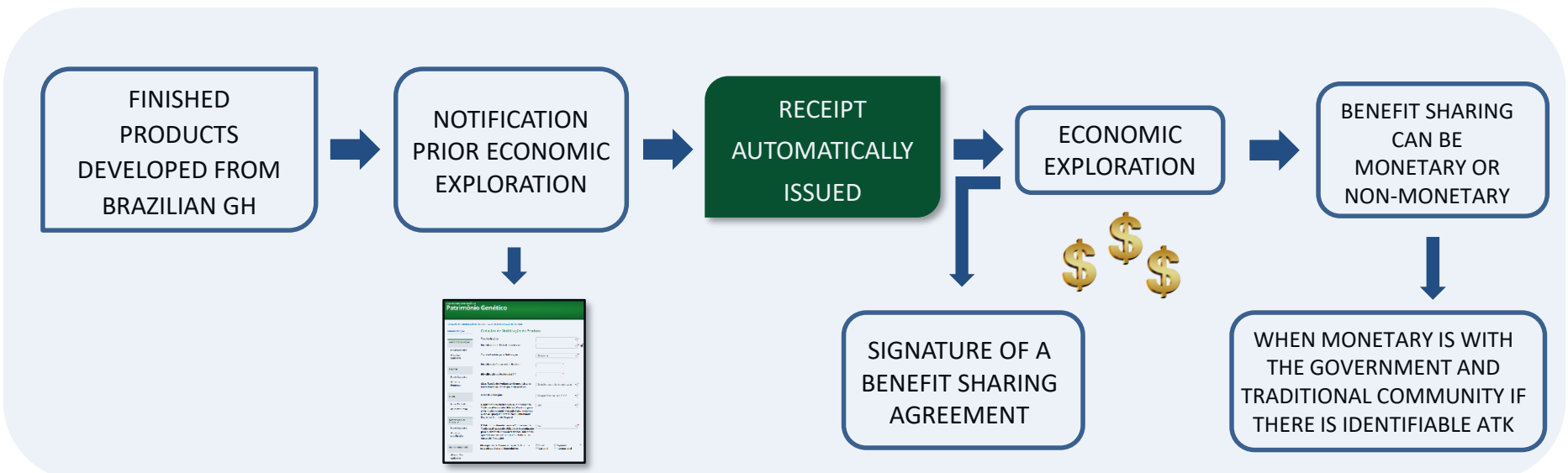
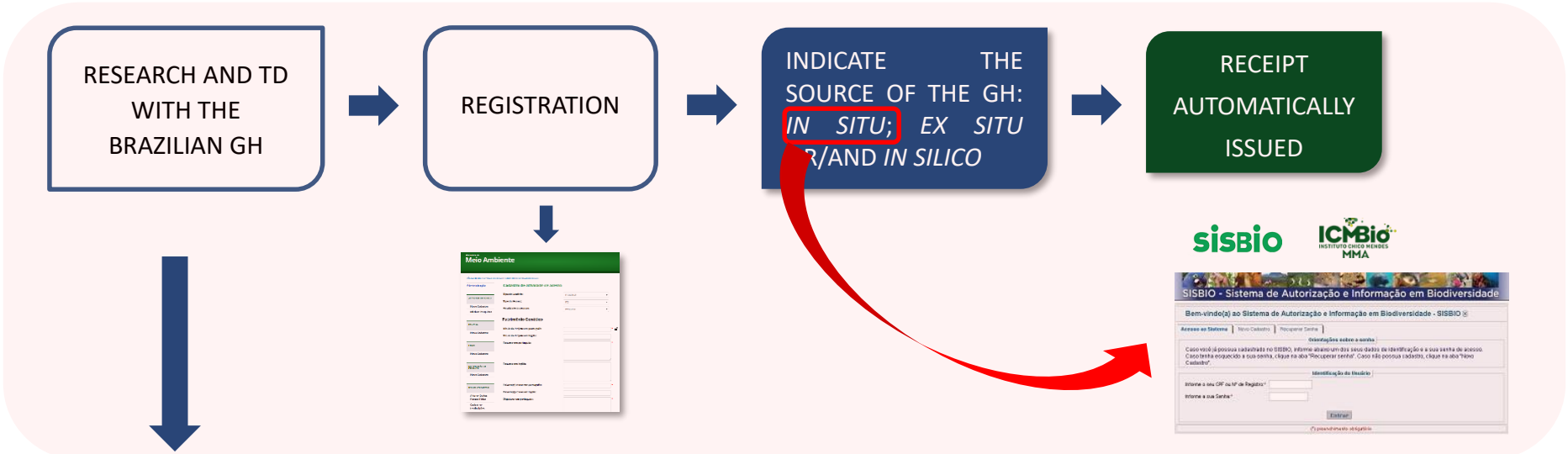


# FOR COMPLYING WITH THE LAW: ACCESS TO GR AND ATK





# FOR COMPLYING WITH THE LAW: ECONOMICAL EXPLORATION



## 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



# VIOLATIONS AGAINST GH AND ATK

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

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

## CAN BE PUNISHED WITH PENALTIES SUCH AS:

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



# VIOLATIONS AGAINST GH AND ATK

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

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

## CAN BE PUNISHED WITH PENALTIES SUCH AS:

- Fines
  - From R \$ 1,000.00 to R \$ 100,000.00, when the infraction is committed by an individual
  - From R \$ 10,000.00 to R \$ 10,000,000.00, when the infraction is committed by a legal entity





## Access to genetic resources and associated traditional knowledge

- Fiocruz and Law 13.123
- Biodiversity Law
- Nagoya Protocol



Air: 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 understand phenomena related to cell and molecular biology, allowing that biological and chemical structures are reproduced in the creation of numerous products and technologies.

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

### Read More

- ABS Brazilian legislation Law: presentation (Port)
- ABS Brazilian legislation Law: summary presentation (Eng)
- Brazilian legislation on access to the biodiversity paper (Eng)
- Brazil, example of a non-Nagoya Protocol country

### Legislation

- Read the Law 13.123 (Eng)
- Know the Decree 8.772 that regulates the Law 13.123 (Port)
- CGen Academy Sectorial Chamber (Port)
- Rules of CGen (Port)
- Material Transfer Agreement (Eng)

### Biological Collections



### News (Portuguese)

- Fiocruz integra workshop internacional

### Reference Documents

- Biodiversity Law
- Nagoya Protocol

### Manual de uso da biodiversidade



## Brazil, example of a non-Nagoya Protocol country



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**Brazil was one of the first countries to regulate access to genetic resources, and to associate traditional knowledge and benefit sharing through Provisional Act 2186-16 of 23 August 2001 for purposes of scientific research, bioprospecting, and technological development. After almost 15 years of many criticisms and demands from civil society and other sectors, Law 13,123 was sanctioned on 20 May 2015<sup>1</sup> and entered into force on 17 November 2015, revoking Provisional Act 2.186.**

The Law, known as the Biodiversity Law, regulates Article 1, Article 8(f), Article 10(c), Article 15, and Article 16, items 3 and 4 of the Convention on Biological Diversity (CBD), besides regulating part of Article 225 of the Brazilian Federal Constitution. It provides for access to genetic resource (known in Brazil as genetic heritage), for protection and access to associated traditional knowledge, for protection and access to associated traditional and sustainable use of biodiversity and creates the Genetic Heritage Management Council (CGen), the Brazilian National Competent Authority for ABS. Therefore, despite the fact that Brazil has not yet ratified the Nagoya Protocol (NP) on Access to Genetic Resources and the Fair and Equitable Distribution of Access and

Benefit Sharing (ABS), the Law 13,123 is aligned with this international agreement.

The construction process of this new legislation was complex, considering the different interests and points of view of the various sectors of civil society, represented by academia, business sector, and holders of associated traditional knowledge, as well as those of the different ministries. The Law is regulated through Decree No. 8,772 of 11 May 2016 and to enable compliance with the legislation, the National System of Genetic Resource Management and Associated Traditional Knowledge (SisGen) was developed by the Ministry of Environment.

The Law 13,123 has a broader scope than the previous legislation and involves research, technological development, and economic exploitation of products arising from access to genetic resources (GR) and associated traditional knowledge (ATK). Due to the new definitions of GR [genetic information from plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms], access to GR [research or technological development carried out on genetic heritage samples] and research [experimental or theoretical activity carried out on genetic heritage or associated traditional knowledge with the objective of building new knowledge by means of a systematic process that creates and tests hypothesis, describes and interprets fundamentals of observed phenomena and facts], the Law includes activities such as basic research related to taxonomy, phylogeny, epidemiology, and ecology, among others, as well as the obtention of genetic sequence from GR and their use.

Brazil set a precedent when it included genetic information in the scope of its ABS legislation, taking into account that in the last two meetings of the Conference of the Parties to the CBD (COP 13 and COP 14) and of the Parties to the NP (COP-MOP 2 and COP-MOP 3) the issue of Digital Sequence Information (DSI) was discussed



**THANK YOU!**

**Manuela da Silva**

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**FIOCRUZ**

**FUNDAÇÃO OSWALDO CRUZ**

**HEALTH MINISTRY**

