

OVERVIEW OF BRAZILIAN LEGISLATION ON ACCESS BENEFIT SHARING

MANUELA DA SILVA - FIOCRUZ – OSWALDO CRUZ FOUNDATION – BRAZIL



THE NEW BRAZILIAN ABS LEGISLATION

5/21/2015

L13123



Presidência da República
Casa Civil
Subchefia para Assuntos Jurídicos

LAW Nº 13.123, FROM 20 OF MAI 2015

Regulates the section II of § 1 and § 4 of article 225 of the Federal Constitution, Article 1, point *j* of Article 8, point *c* of Article 10, Article 15 and §§ 3 and 4 of Article 16 of the Convention on Biological Diversity, promulgated by Decree No. 2519 of 16 March 1998, provides for access to genetic heritage, on the protection and access to associated traditional knowledge and the benefit sharing for conservation and sustainable use of biodiversity; revokes the Provisional Act 2.186/2001, 23 August 2001, and takes other measures.

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

13/05/2016

Decreto nº 8772



Presidência da República
Casa Civil
Subchefia para Assuntos Jurídicos

DECREE Nº 8.772, FROM 11 OF MAY 2016

Regulates Law No. 13,123, of May 20, 2015, which provides for access to genetic resources, the protection and access to associated traditional knowledge and the sharing of benefits for conservation and sustainable use of biodiversity.

After almost 6 months since the law came into force, the Decree regulating it was published



ABS NATIONAL COMPETENT AUTHORITY

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

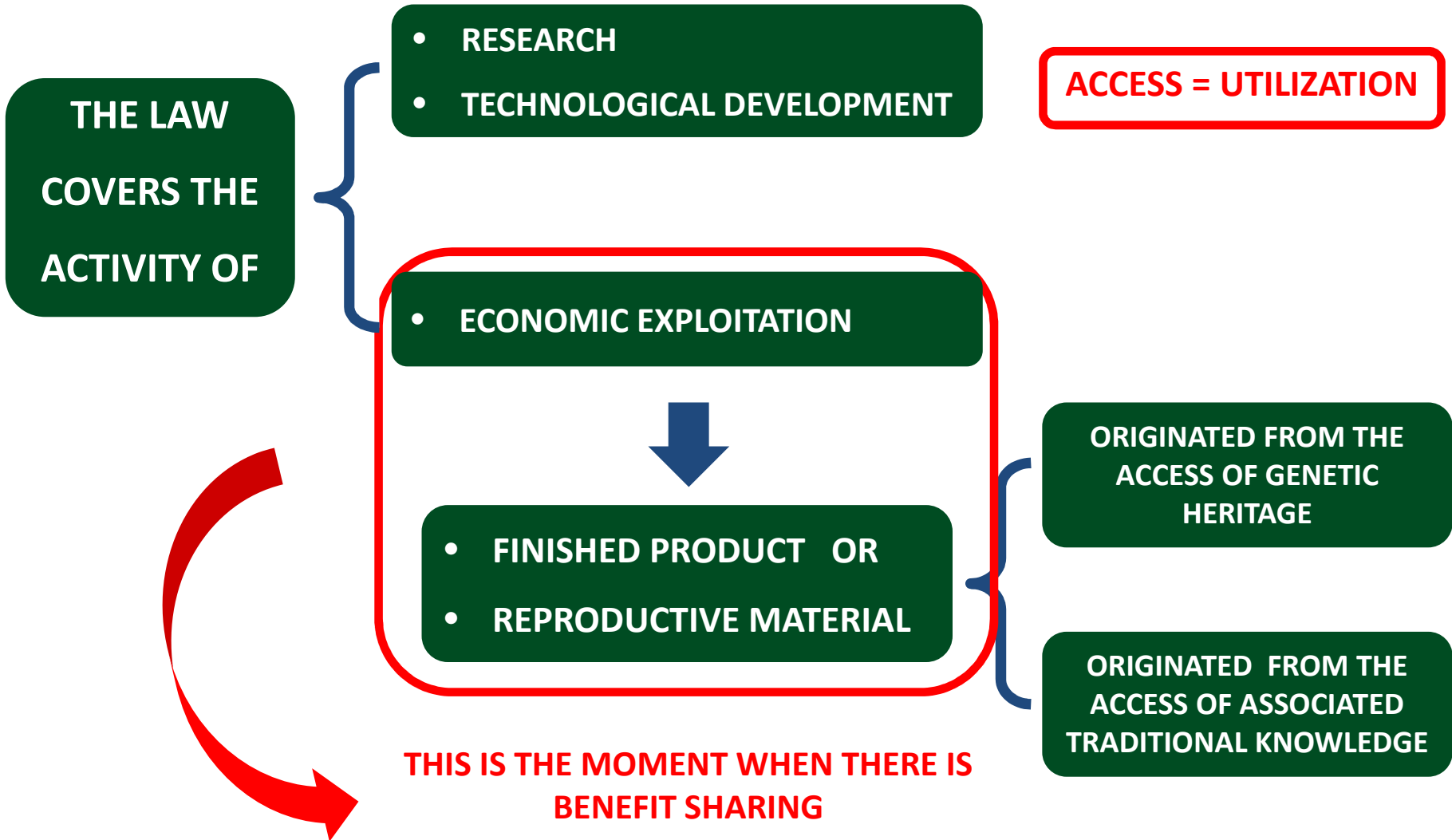
CGen consists of representatives from bodies and entities of the federal public administration that are competent on the various actions of this law and the representation of civil society.

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



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



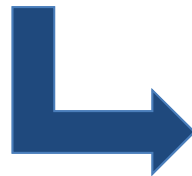
SCOPE OF THE LAW 13.123/15

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**



SCOPE OF THE LAW 13.123/15

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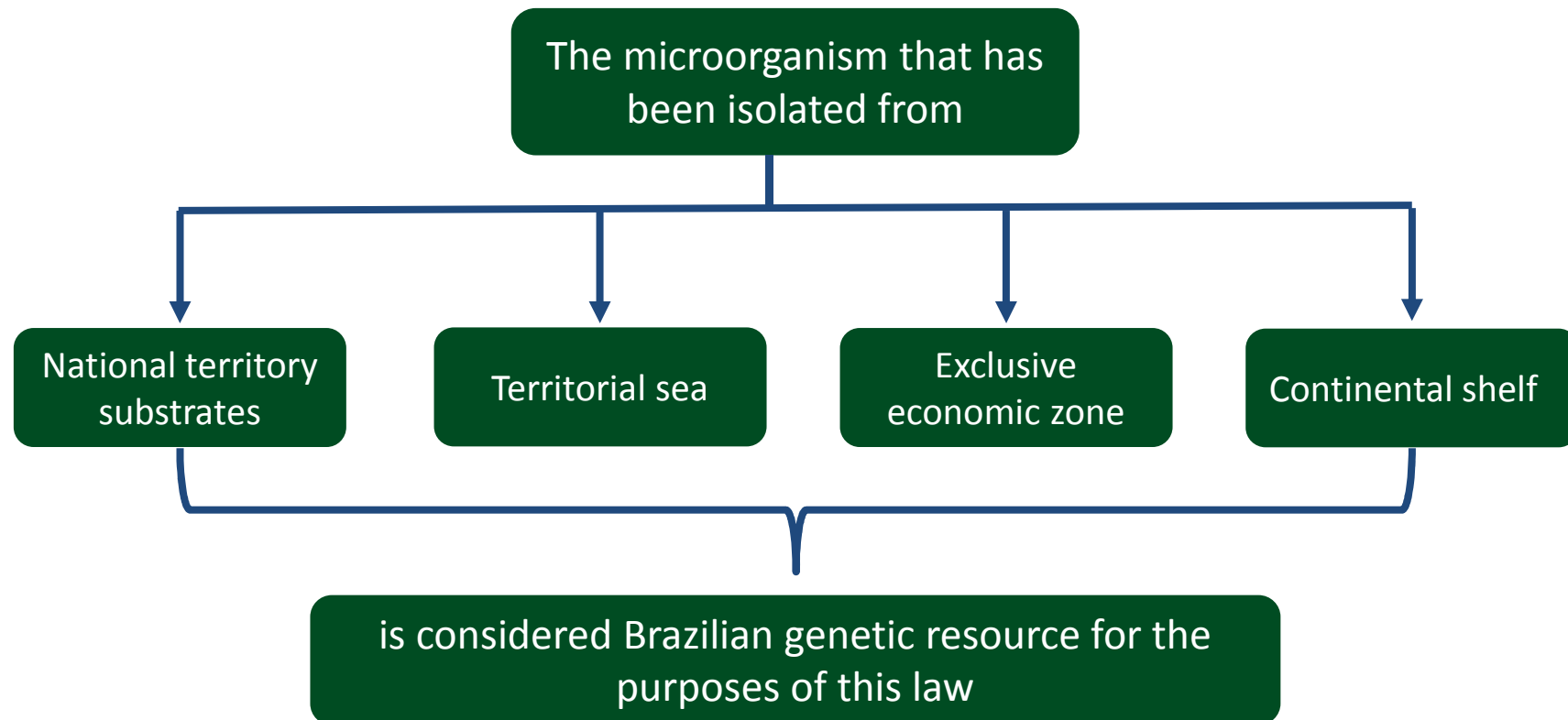
information of genetic origin from plants, animals, microorganisms or species of other nature, including substances derived from the metabolism of these living beings

**USE OF INFORMATION FROM
GENETIC SEQUENCES PUBLISHED IN
PUBLIC DATA BASES (Ex: 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

NOTIFICATION BEFORE



ECONOMIC EXPLOITATION



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



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

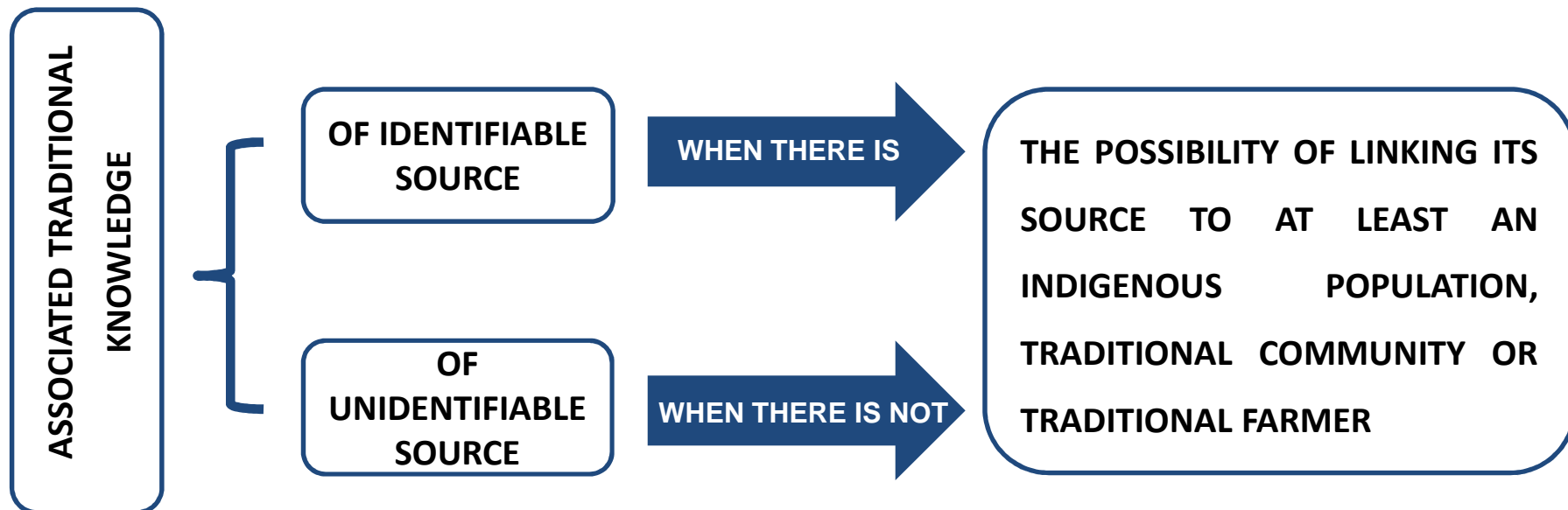
II - national institution of scientific research and technology, public or private, when access is made in association with legal entity based abroad

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

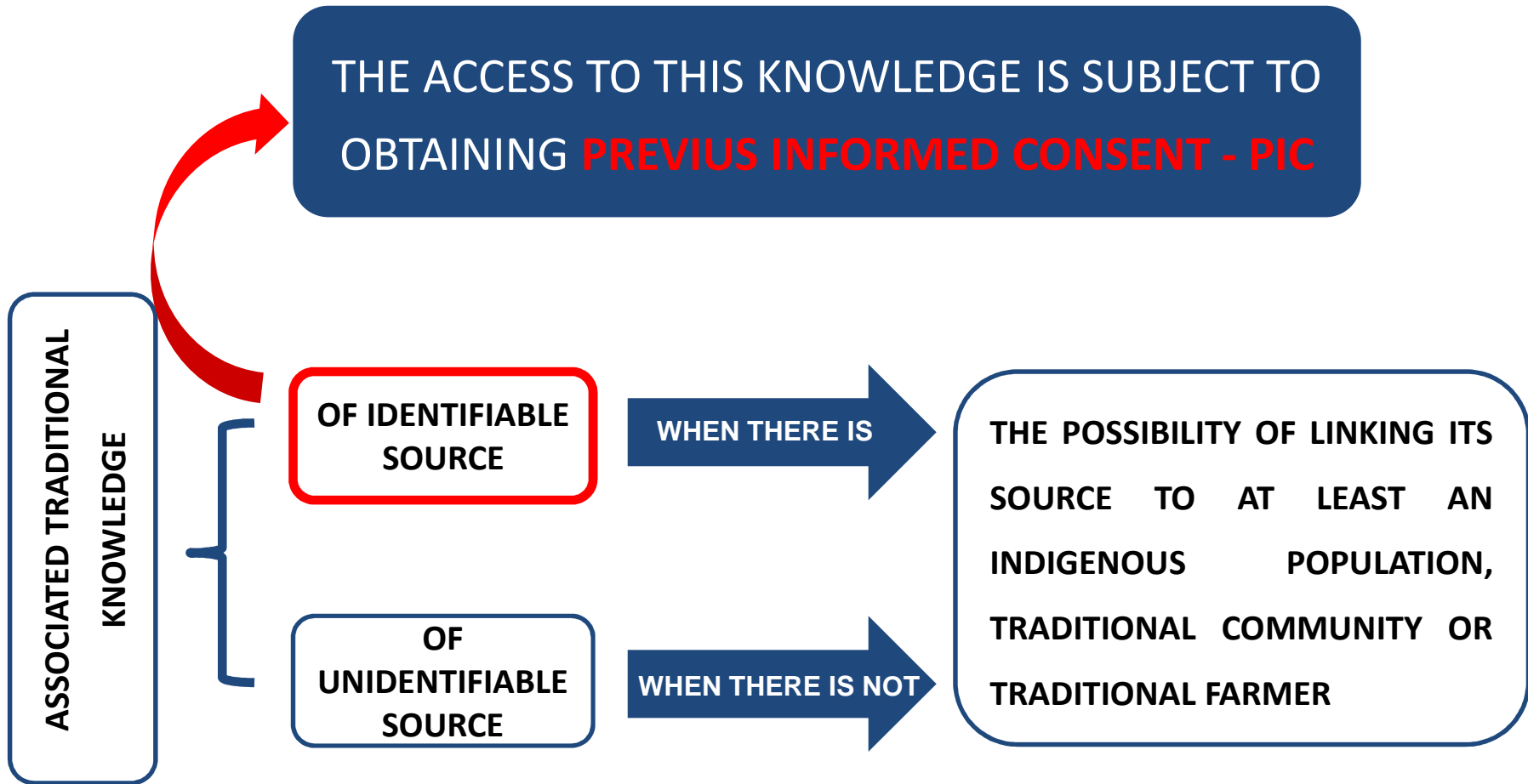
WHEN THERE IS

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



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

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

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



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**



LEGAL OPINION: DIFFERENCES BETWEEN SHIPMENT 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 Nº 13.123/15. PONDERAÇÃO DE INTERESSES CONSTITUCIONAIS. INCENTIVO AO DESENVOLVIMENTO CIENTÍFICO. OMISSÃO JURÍDICO-NORMATIVA DE DECRETO REGULAMENTADOR (JÁ SUPRIDA PELO DECRETO Nº 8772/2016) NORMA DE APLICABILIDADE PLENA. HIPÓTESES. VIABILIDADE DE PESQUISA. DIFERENCIAÇÃO 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 SHIPMENT AND SENDING IN CASES OF SCIENTIFIC PARTNERSHIPS

Sending:

- There is no need of a previous registration;
- There is no transfer of responsibility on the sample;
- The sample is accompanied by a legal instrument;
- Access is initially made in Brazil and then abroad for further studies;
- The sample is destroyed or returned.

Shipment:

Needs to be registered in advance;

There is transfer of responsibility on the sample;

The sample is accompanied by a Material Transfer Term;

Access is only made abroad, under the responsibility of the recipient.



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 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

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 heritage
- Recovery, creation and maintenance of *ex situ* collections
- Training of human heritage associated with the use and conservation of genetic heritage and associated traditional knowledge
- Support for the efforts of indigenous peoples, traditional communities and traditional farmers in the sustainable management and conservation of genetic heritage



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



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

ATIVIDADE DE ACESSO

Novo Cadastro

Atualizar Cadastro

REMESSA

Novo Cadastro

Atualizar Remessa

NOTIFICAÇÃO DE PRODUTO

Novo Cadastro

Atualizar Notificação

CRENCIAMENTO DE COLEÇÃO EX SITU

Tipo de Usuário:

Independente

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?

Não

Este cadastro está vinculado a cadastro anterior de remessa?

Não

Equipe

Adicionar +

Nome Completo	Documento	Instituição	Nacionalidade
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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

ATIVIDADE DE ACESSO

Novo Cadastro

Atualizar Cadastro

REMESSA

Novo Cadastro

Atualizar Remessa

NOTIFICAÇÃO DE PRODUTO

Novo Cadastro

Atualizar Notificação

CRENCIAMENTO DE COLEÇÃO 'EX SITU'

Novo Cadastro

Atualizar Credenciamento

Tipo de Usuário

Responsável

Adicionar +

CPF

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

Estas atividades são baseadas em acesso realizado anteriormente?

Este cadastro está vinculado a cadastro anterior de remessa?

Equipe

Adicionar +

Nome Completo

Objeto do Acesso:

Patrimônio Genético

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

Sim

Tem autorização de acesso?

Não - Sem solicitação em tra

Termo de Compromisso:

Anexar Documento:

Escolher arquivos

Nenhum arquivo selecionado

Finalidade do Acesso:

- Pesquisa Científica
- Bioprospecção
- Desenvolvimento Tecnológico

Estas atividades são baseadas em acesso realizado anteriormente?

Não

Este cadastro está vinculado a cadastro anterior de remessa?

Não

Documento

Instituição

Nacionalidade



SisGen

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

Tempo Restante: 59:55

PAGINA INICIAL > ENVIO > CADASTRO DE REMESSA

Cadastro de Remessa de Amostra de Patrimônio Genético

ATIVIDADE DE ACESSO

Novo Cadastro

Atualizar
Cadastro

REMESSA

Novo Cadastro

Atualizar
Remessa

NOTIFICAÇÃO DE PRODUTO

Novo Cadastro

Atualizar
Notificação

CREDENCIAMENTO DE COLEÇÃO 'EX SITU'

Tipo de Usuário:

Independente

Responsável pelo cadastro

Adicionar +

CPF	Habilitado	
_____	Sim	 

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

Selecione

Este cadastro está vinculado a cadastro anterior de acesso?:

Selecione

Termo de Transferência de Material:

Anexar Documento

Nenhum arquivo selecionado

Atividades de acesso no exterior

Especificação das atividades a serem realizadas no exterior



SisGen

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

Tempo Restante: 59:55

PÁGINA INICIAL > ENVIO > CADASTRO DE REMESSA

Cadastro de Remessa

ATIVIDADE DE ACESSO

Novo Cadastro

Atualizar Cadastro

REMESSA

Novo Cadastro

Atualizar Remessa

NOTIFICAÇÃO DE PRODUTO

Novo Cadastro

Atualizar Notificação

CREDENCIAMENTO DE COLEÇÃO 'EX SITU'

Tipo de Usuário:

Responsável pelo cadastro

Adicionar +

CPF

Esta remessa foi realizada em 17/11/2015?:

Este cadastro está vinculado a qual atividade de acesso anterior de acesso?:

Termo de Transferência de Propriedade: _____

Anexar Documento

Nenhum

Atividades de acesso no exterior

Especificação das atividades a serem realizadas no exterior

Objetivos e uso pretendido

Sector de aplicação:

Seção:

Divisão:

Grupo:

Classe:

Subclasse:

Sobre o componente do Patrimônio Genético a ser remetido

Adicionar +

DADOS CADASTRAIS

Alterar Meu Cadastro

Cadastrar Instituição

Alterar Cadastro de Instituição

Alterar Senha



SisGen

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

Tempo Restante: 59:55

PAGINA INICIAL > ENVIO > CADASTRO DE REMESSA

Cadastro de Remessa de Amostra

ATIVIDADE DE ACESSO

Novo Cadastro
Atualizar Cadastro

REMESSA

Novo Cadastro
Atualizar Remessa

NOTIFICAÇÃO DE PRODUTO

Novo Cadastro
Atualizar Notificação

CREDENCIAMENTO DE COLEÇÃO 'EX SITU'

Tipo de Usuário:

Responsável pelo cadastro

Adicionar +

CPF	Habilitado
_____	Sim

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

Este cadastro está vinculado a cadastro anterior de acesso?:

Termo de Transferência de Material:

Anexar Documento

Escolher arquivos Nenhum arquivo selecionado *

Atividades de acesso no exterior

Especificação das atividades a serem realizadas no exterior

Instituição Destinatária no Exterior

Nome Institucional

País:

Região:

Município:

Código Postal:

Endereço:

Telefone:

Email:

Representante Legal da Instituição Destinatária

Adicionar +

Fundamento Legal do Sigilo

- Sigilo Comercial e Empresarial - Lei nº 6.404/1976, Lei nº 10.406/2002, Lei nº 11.101/2005 e outras
- Sigilo Industrial - Lei nº 9.279/1996
- Imprescindíveis à segurança da sociedade ou do Estado - Art. 23 da Lei nº 12.527/2011

* Campos Obrigatórios.



SisGen

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

Tempo Restante: 59:50

PÁGINA INICIAL > CREDENCIAMENTO DE COLEÇÃO 'EX SITU' > NOVO CREDENCIAMENTO

Novo Credenciamento

ATIVIDADE DE ACESSO

Novo Cadastro

Atualizar Cadastro

REMESSA

Novo Cadastro

Atualizar Remessa

NOTIFICAÇÃO DE PRODUTO

Novo Cadastro

Atualizar Notificação

CREDENCIAMENTO DE COLEÇÃO 'EX SITU'

Novo Credenciamento

Tipo de Usuário:

Coleção Ex Situ:

Grupos Taxonômicos Colecionados:

Adicionar Tipo de Amostra Conservada:

Adicionar Curador:



SisGen

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

Tempo Restante: 59:18

PÁGINA INICIAL > NOTIFICAÇÃO DE PRODUTO > CADASTRO DE NOTIFICAÇÃO DE PRODUTO

ATIVIDADE DE ACESSO

Novo Cadastro

Atualizar Cadastro

REMESSA

Novo Cadastro

Atualizar Remessa

NOTIFICAÇÃO DE PRODUTO

Novo Cadastro

Atualizar Notificação

CREDENCIAMENTO DE COLEÇÃO 'EX SITU'

Novo Credenciamento

Cadastro de Notificação de Produto

Tipo de Usuário:

Responsável pelo cadastro

Adicionar +

CPF	Habilitado	
1234567890	Sim	✎ ✖

Número de Cadastro de Acesso/Remessa

Adicionar +

Tipo de Produto para Notificação:

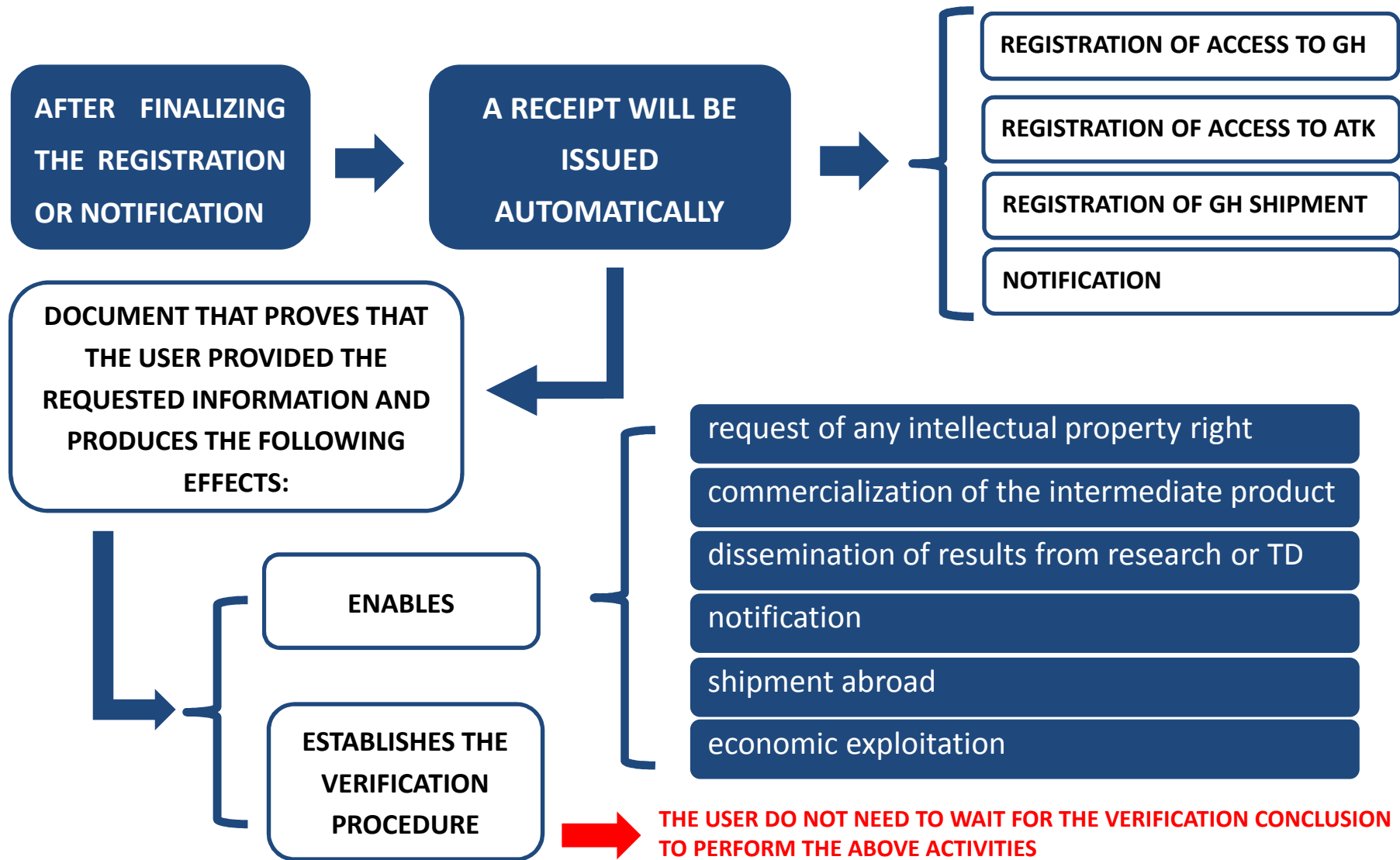
Identificação Comercial do Produto:

Classificação NCM do Produto:

Sector de Aplicação:



NATIONAL SYSTEM FOR GENETIC HERITAGE AND ASSOCIATED TRADITIONAL KNOWLEDGE MANAGEMENT



CERTIFICATE OF ACCESS REGULARITY

UPON REQUEST OF THE USER AND
AFTER DETERMINATION OF CGEN WILL
BE ISSUED



CERTIFICATE OF ACCESS
REGULARITY



ADMINISTRATIVE ACT BY
WHICH THE COMPETENT
AUTHORITY DECLARES THAT



ACCESS TO GENETIC HERITAGE

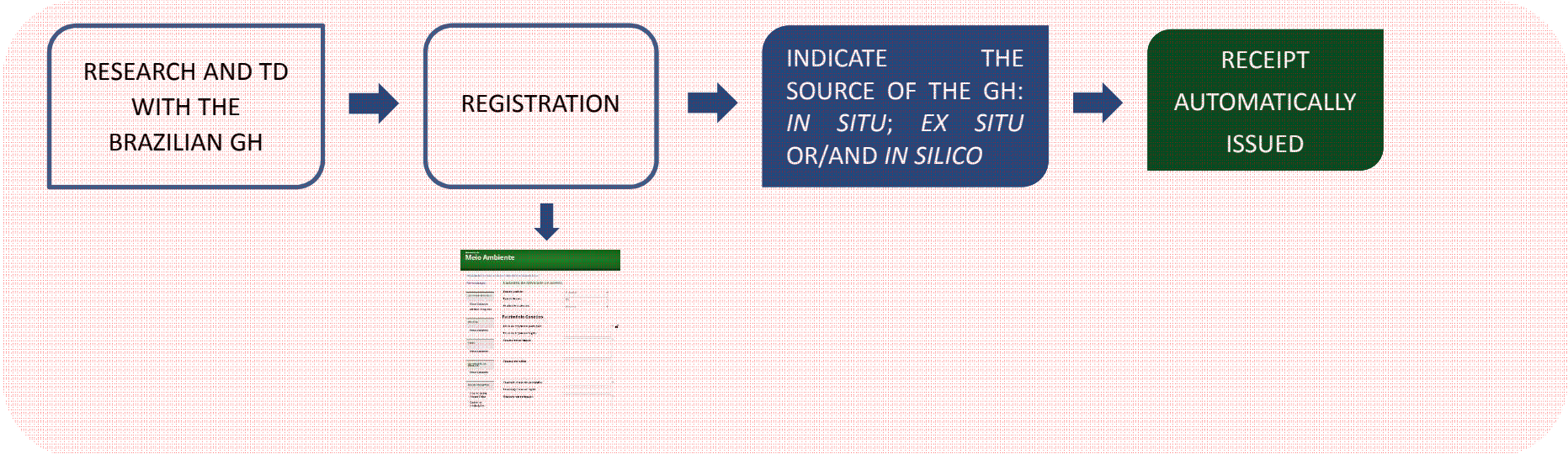
ACCESS TO ASSOCIATED
TRADITIONAL KNOWLEDGE

COMPLY WITH THE
REQUIREMENTS OF THE
LAW

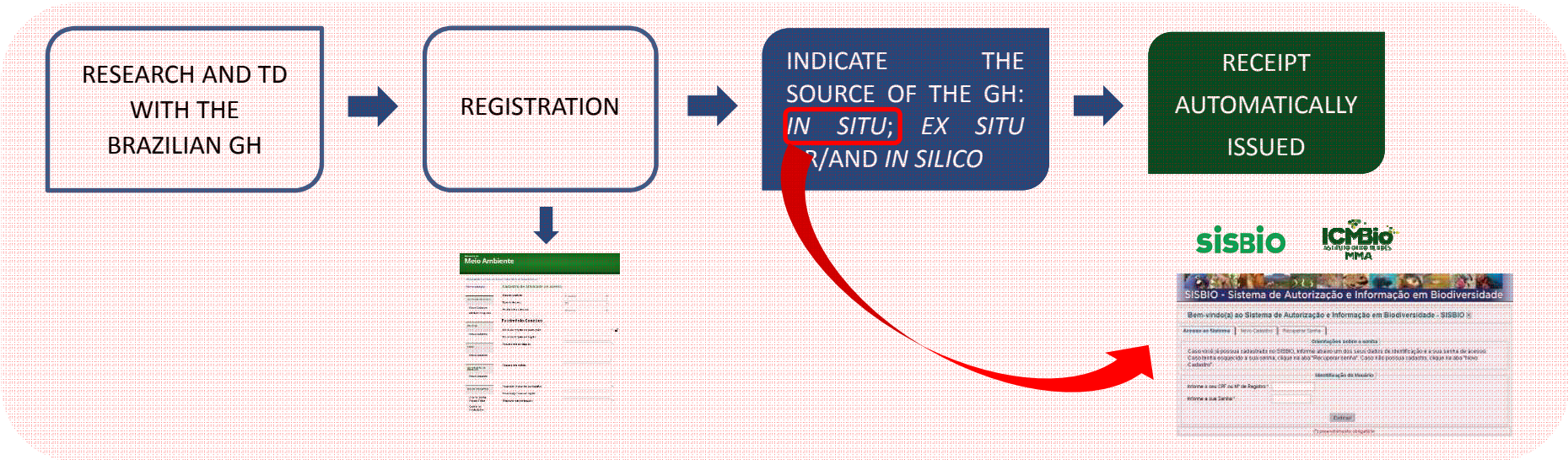
PREVENTS APPLICATION OF ADMINISTRATIVE PENALTIES SPECIFICALLY
REGARDING ACCESS ACTIVITIES UNDERTAKEN UNTIL ISSUING THE CERTIFICATE



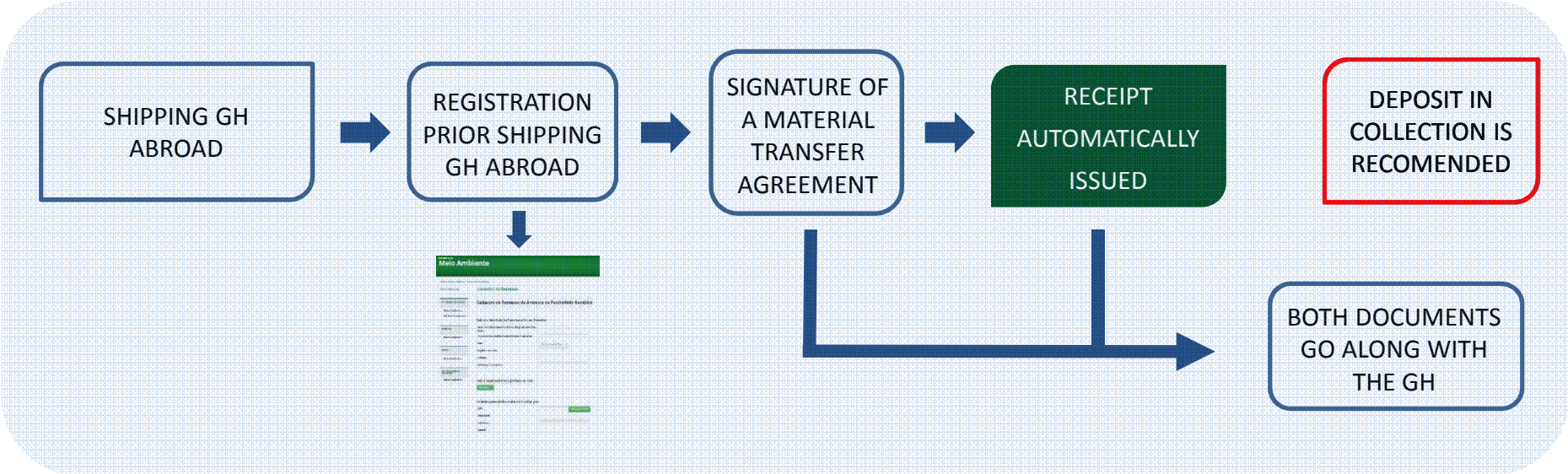
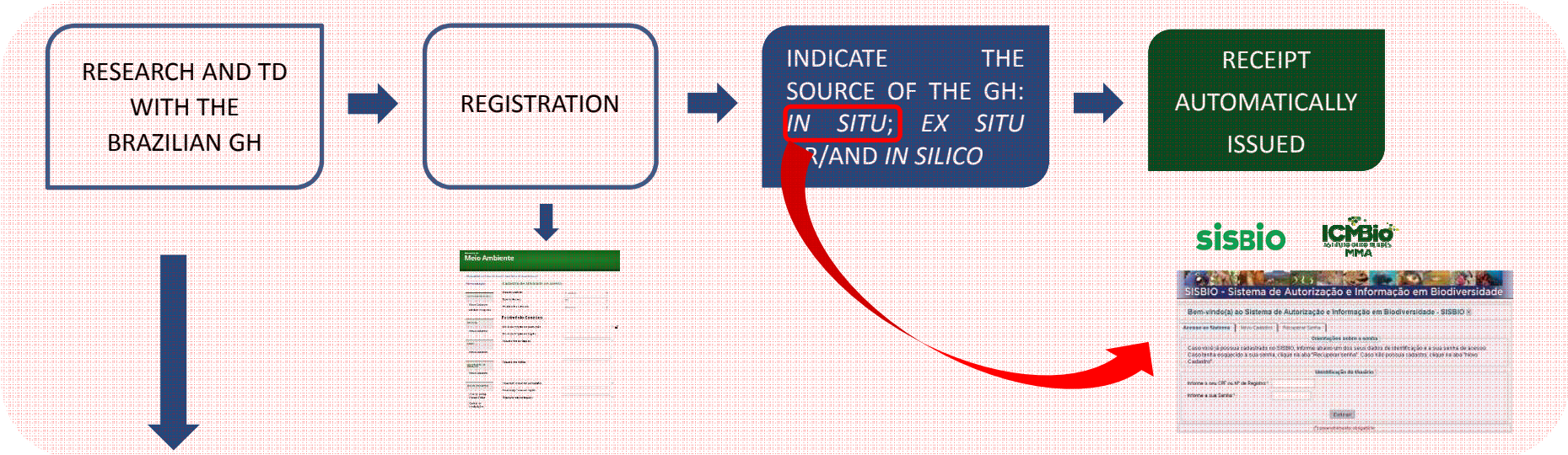
FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT



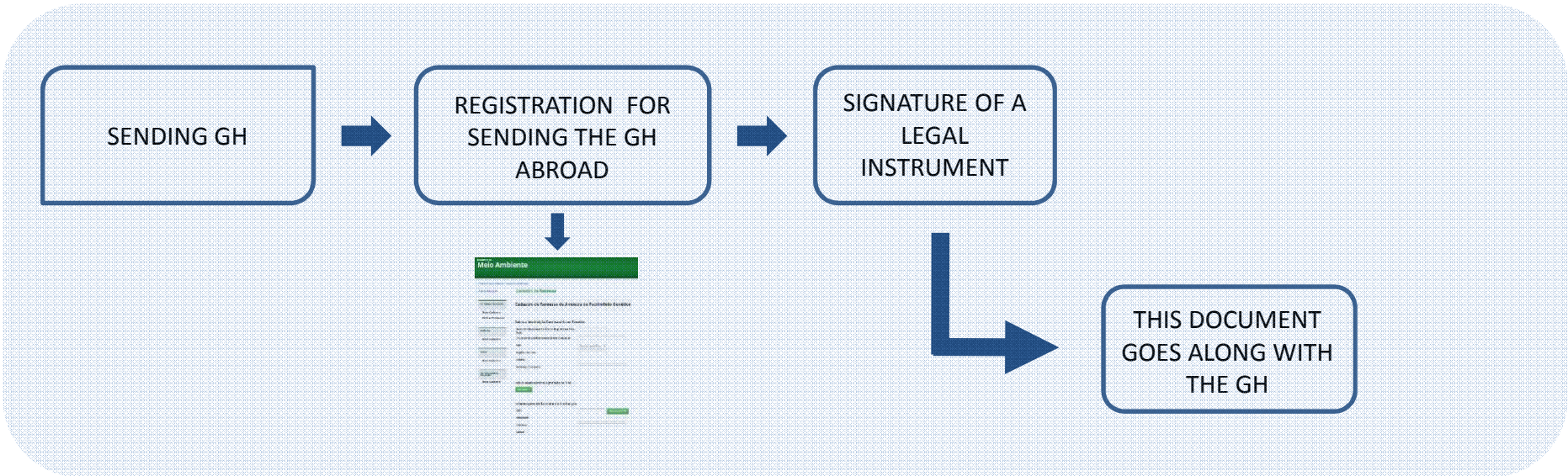
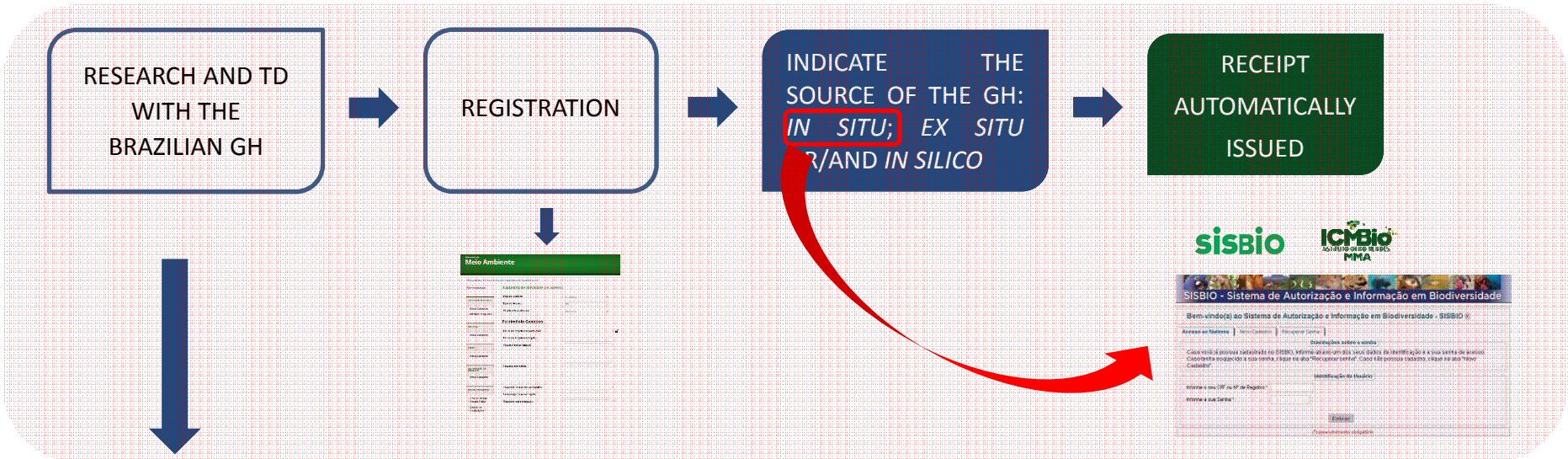
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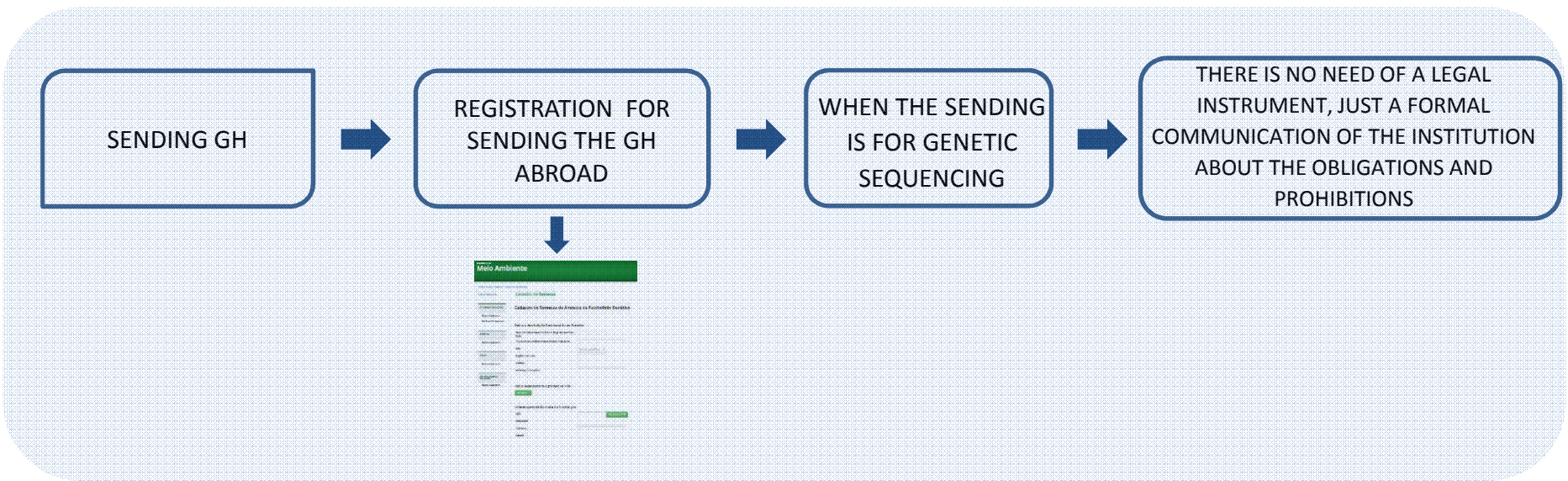
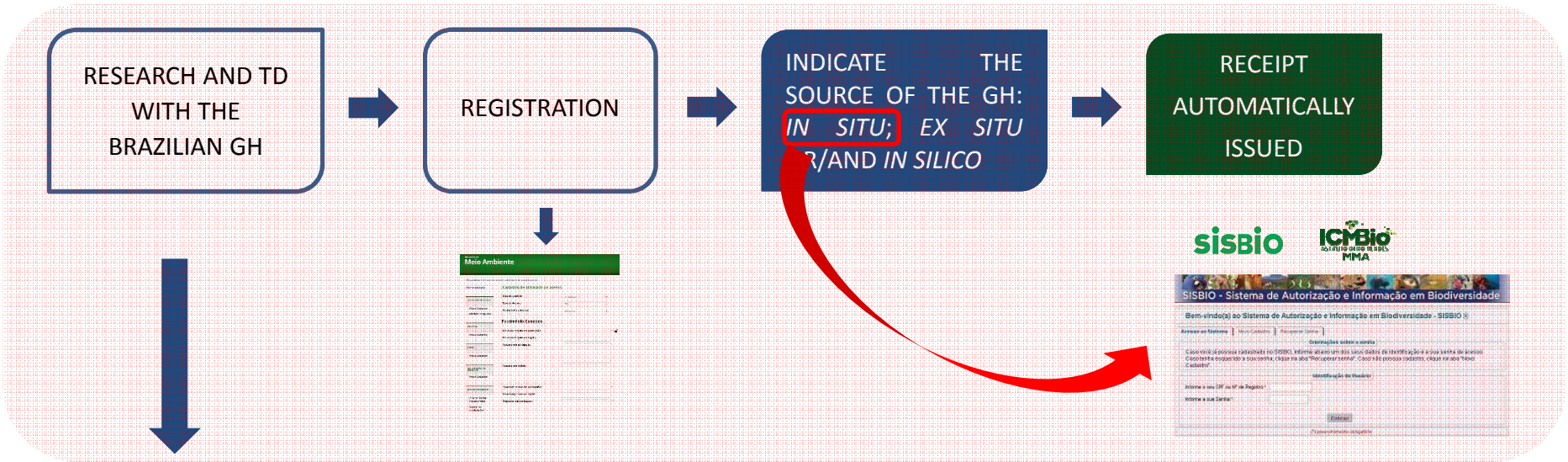
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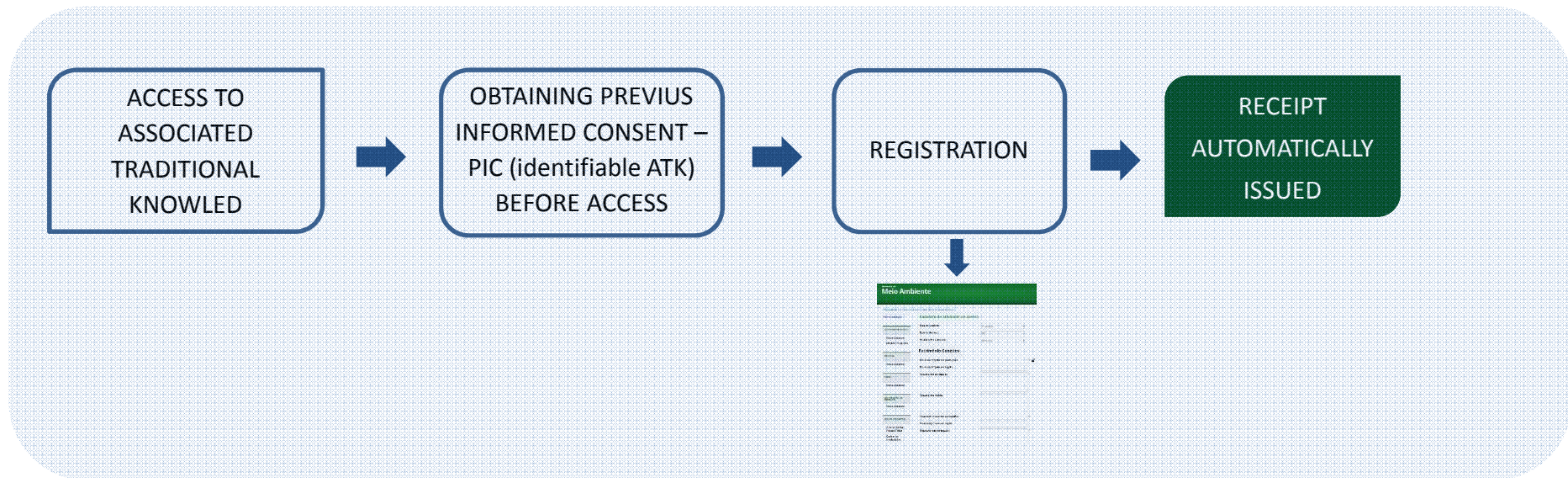
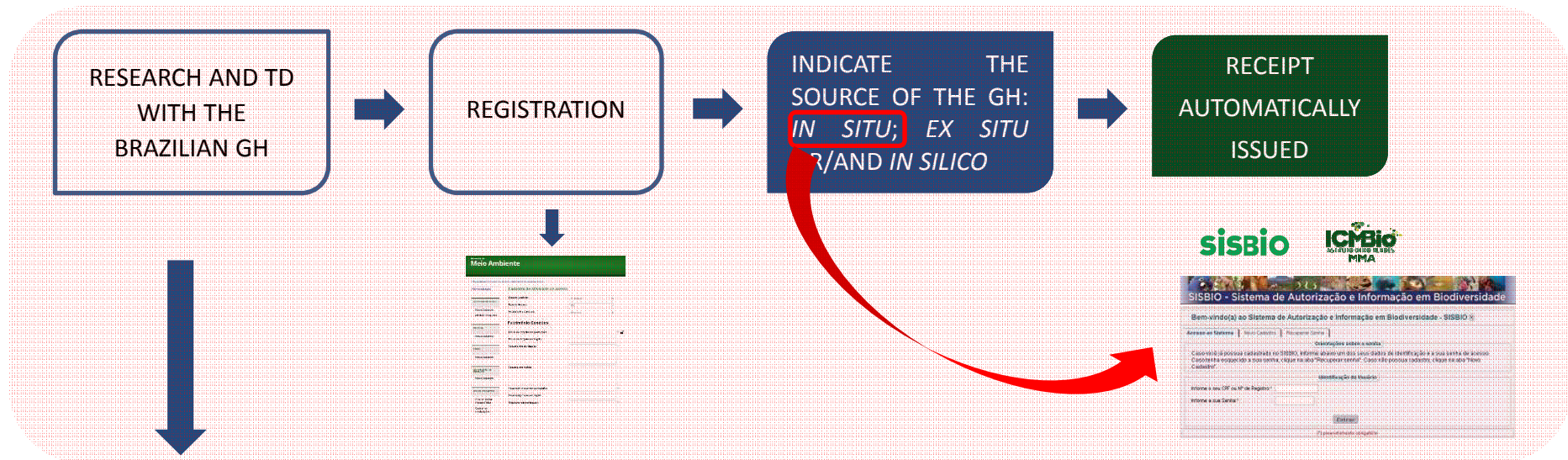
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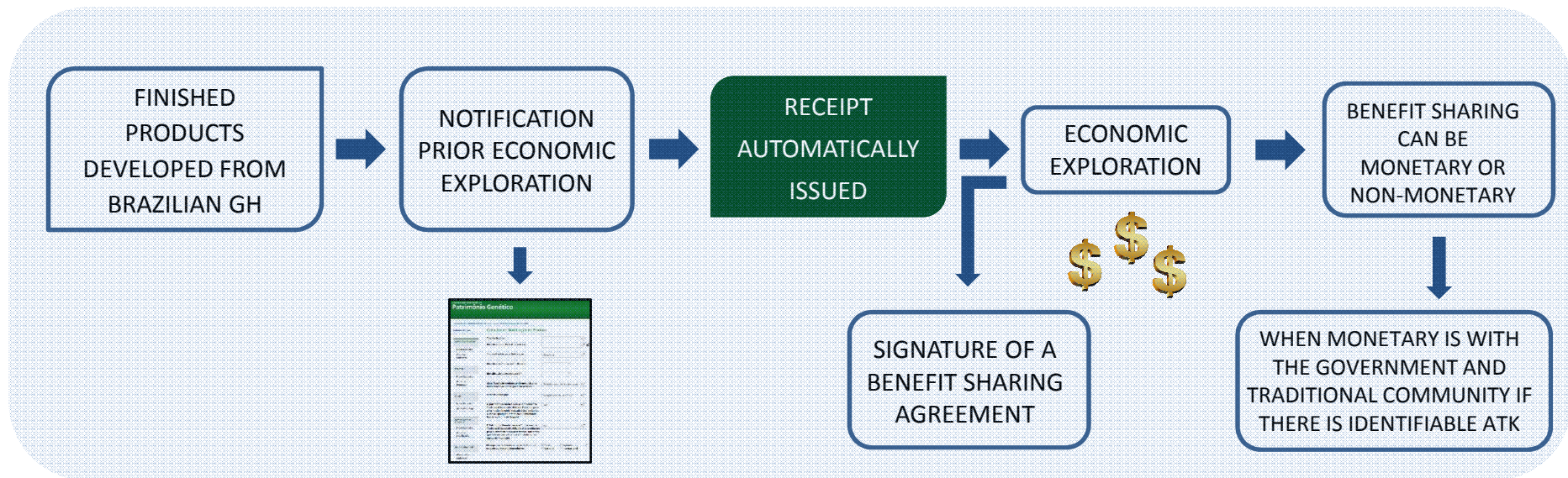
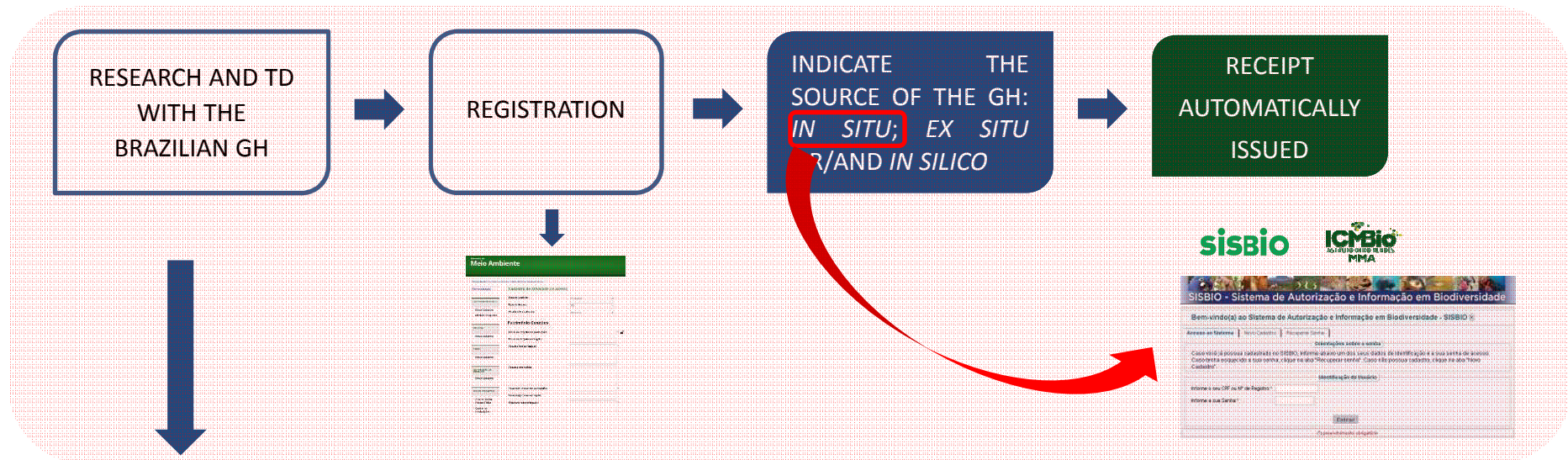
FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT



FOR COMPLYING WITH THE LAW: ACCESS TO GR AND ATK



FOR COMPLYING WITH THE LAW: ECONOMICAL EXPLORATION



REGULARIZATION

Flexible rules were established for the regularization of the liability resulting from the failure to comply with the Provisional Act 2.186/2001. All the penalties were extinguished, with the exception of fines

RESEARCH

TECHNOLOGICAL DEVELOPMENT

100% fine exemption

with the remaining balance with the possibility to be reversed, for instance, conservation projects, in the distribution of products in programs of social interest



REGULARIZATION

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**The regularization is conditioned to the signature of a
Commitment Agreement**



REGULARIZATION

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In the case of access to genetic heritage or associated TK for research purposes, the user will be exempted from signing the Commitment Agreement, regularizing through the registration



REGULARIZATION

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REMEMBERING THAT THIS REGULARIZATION IS IN RELATION TO THE ACTIVITIES THAT WERE IN THE SCOPE OF THE LAST LEGISLATION (MP 2.186/2001), OR WHATSOEVER, RESEARCH INVOLVING TAXONOMY, EPIDEMIOLOGY, PHILOGENY, ETC ... ARE OUT OF THIS REGULARIZATION!



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



You are here » Home » Research and teaching » Access to genetic resources

Access to genetic resources

- * Biodiversity Law
- * FioCruz and Law 13.123
- * Nagoya Protocol

And associated traditional knowledge



Since 2015, Brazil has a new legislation which provides for the use of Brazilian biodiversity by science and production chain. It is the Law 13.123, known as the Biodiversity Law. Its rules define, in the jargon of the area, "access to genetic resources, protection, access to associated traditional knowledge 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.

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32

The Law and FioCruz

- * New ABS Brazilian legislation Law: presentation (Portuguese)
- * The new institutional procedures (Portuguese)
- * Material Transfer Agreement (Portuguese)
- * Material Transfer Agreement (English)
- * Biodiversity FioCruz's electronic system (Portuguese)

Biological Collections



Audio-visual (Portuguese)

Video of lecture on Brazilian ABS legislation in Ensp/FioCruz

VPPLR



Know the Vice-Presidency of Research and Reference Laboratory of FioCruz

News



FioCruz took part of the thirteen meeting of the Conference of the Parties to the Convention on Biological Diversity (Portuguese)

Legislation

- * Read, in the whole, the new Brazilian ABS legislation (Portuguese)
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Document

- * Implementation of the Nagoya Protocol on access and benefit-sharing

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- * Presentation on the Brazilian ABS legislation
- * Report of the workshop on international exchange of genetic resources between Brazil and the EU
- * Subsidies for the workshop on Monitoring and sectoral workflows on ABS legislation

Read More

- * Brazilian mission discusses flow of genetic resources in Europe
- * Featured in the Journal of Science - New Biodiversity Law: Challenges and prospects for R&D
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THANK YOU!

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

