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

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

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.

Regulates Law No. 13,123, of May 20, 2015, which provides for access to genetic resources, the protection and access to associated traditional knowledge and the sharing of benefits for conservation and sustainable use of biodiversity.
The Brazilian ABS National Competent Authority is the Genetic Heritage Management Council - CGen

CGen will consist of representatives from bodies and entities of the federal public administration that are competent on the various actions of this law with maximum participation of 60% and the representation of civil society in at least 40% of the members.

Based on the Decree, there will be 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
THE LAW COVERS THE ACTIVITY OF

- RESEARCH
- TECHNOLOGICAL DEVELOPMENT

ECONOMIC EXPLOITATION

- FINISHED PRODUCT OR
- REPRODUCTIVE MATERIAL

ACCESS = UTILIZATION

ORIGINATED FROM THE ACCESS OF GENETIC HERITAGE

ORIGINATED FROM THE ACCESS OF ASSOCIATED TRADITIONAL KNOWLEDGE

THIS IS THE MOMENT WHEN THERE IS BENEFIT SHARING
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

DIFFERENTLY FROM THE PREVIOUS LEGISLATION, THE NEW LAW:

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

DEFINITION

information of genetic origin from plants, animals, microorganisms or species of other nature, including substances derived from the metabolism of these living beings
DIFERENTLY FROM THE PREVIOUS LEGISLATION, THE NEW LAW:

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

- 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
DIFERENTLY FROM THE PREVIOUS LEGISLATION, THE NEW LAW:

**Scope of the Law 13.123/15**

**Reach**

- All research (experimental or theoretical) conducted with the Brazilian genetic heritage

**Definition**

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

**Use**

- Use of information from genetic sequences published in public data bases (GenBank)
The microorganism that has been isolated from

- National territory substrates
- Territorial sea
- Exclusive economic zone
- Continental shelf

is considered Brazilian genetic resource for the purposes of this law.
ACTIVITIES THAT ARE SUBJECT TO THE LAW

I. Access to genetic heritage and associated traditional knowledge;

II. Shipment abroad of genetic heritage

III. Economic exploitation of finished product or reproductive material from access to genetic heritage and associated traditional knowledge
FOR COMPLYING WITH THE LAW

REGISTRATION

RESEARCH

TECHNOLOGICAL DEVELOPMENT

NOTIFICATION BEFORE

ECONOMIC EXPLOITATION
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 economic exploitation will be required:

I. prior notification of the finished product or the reproductive material to CGen

II. presentation of the benefit-sharing agreement (BSA) within 1 year from the time of notification, except in the case of finished product or reproductive material from access to ATK of identifiable origin. In this case, the agreement must be presented at the time of notification.
THE AUTHORIZATION 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
THE TRADITIONAL KNOWLEDGE ASSOCIATED TO GENETIC HERITAGE CAN BE RECOGNIZED IN SCIENTIFIC PUBLICATIONS, RECORDS IN REGISTERS OR DATABASES AND CULTURAL INVENTORIES.

- WHEN THERE IS OF IDENTIFIABLE SOURCE
- WHEN THERE IS NOT OF UNIDENTIFIABLE SOURCE

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

- **When there is an identifiable source:**
  - Associated traditional knowledge
  - The possibility of linking its source to at least an indigenous population, traditional community or traditional farmer.

- **When there is not an identifiable source:**
  - Of unidentifiable source
  - Associated traditional knowledge

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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 PREVIOUS INFORMED CONSENT - PIC

OF IDENTIFIABLE SOURCE

OF UNIDENTIFIABLE SOURCE

WHEN THERE IS

WHEN THERE IS NOT
SHIPMENT ABROAD OF GENETIC HERITAGE

DEFINITION: TRANSFERRENCE 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 RECEPIENT INSTITUTION

REGISTRATION FOR SHIPMENT ABROAD MUST BE PERFORMED PRIOR SHIPMENT AND DEPENDS ON:

• THE SIGNATURE OF MATERIAL TRANSFER AGREEMENT – MTA

• THE SUPPLY OF INFORMATION ABOUT THE PROVIDER AND RECEPIENT INSTITUTIONS, GENETIC HERITAGE AND INTENDED USE
The MTA formalizes the shipment abroad of samples of genetic heritage accessed or available for access

It will predict that:

• It shall be interpreted in accordance with Brazilian law
• The recipient institution will not be considered provider of the GH

It will contain clauses that:

• Inform on access to ATK when applicable
• Authorizes or prohibits the transfer of the GH to third parties
The MTA formalizes the shipment abroad of samples of genetic heritage accessed or available for access.

It will predict that:
- It shall be interpreted in accordance with Brazilian law.
- The recipient institution will not be considered provider of the GH.

It will contain clauses that:
- Inform on access to ATK when applicable.
- Authorizes or prohibits the transfer of the GH to third parties.

In the case of authorization, the transfer of genetic heritage to third parties will also depend on a MTA containing the above requirements. This obligation will be applied to all subsequent transfers.
SENDING OF GENETIC HERITAGE

DEFINITION: SENDING OF GH FOR SERVICES PROVIDED ABROAD, AS PART OF A RESEARCH OR TECHNOCLOGICAL DEVELOPMENT, IN WHICH THE RESPONSIBILITY FOR THE GH IS NOT TRASFERED
DEFINITION: SENDING OF GH FOR SERVICES PROVIDED ABROAD, AS PART OF A RESEARCH OR TECHNOLOGICAL DEVELOPMENT, IN WHICH THE RESPONSIBILITY FOR THE GH IS NOT TRANSFERRED

SERVICES PROVIDED ABROAD ARE CONSIDERED

TESTS

SPECILIZED TECHNIQUES

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

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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

Is the Government, represented by the Ministry of the Environment

Associated TK of identifiable source

Are the indigenous people, traditional communities and traditional farmers

The beneficiary of 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.
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
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
ELECTRONIC SYSTEM FOR REGISTRATION
ELECTRONIC SYSTEM FOR REGISTRATION

REGISTRATION OF THE INSTITUTION

Cadastrar Instituições

Pessoa: Jurídica

Pessoa Jurídica

CNPJ:

Porte Empresa:

Nome Institucional (Conforme CNPJ):

Título do Estabelecimento (Nome Fantasia):

CEP:

Logradouro:

Númere:

Complemento:

Bairro:

Cidade:

UF:

Pais:

Representante legal:

Adicionar um novo Representante
ELECTRONIC SYSTEM FOR REGISTRATION

REGISTRATION OF THE ACCESS ACTIVITY

Cadastro de atividade de acesso

Tipo do Usuário:

Objeto do Acesso:

O acesso foi realizado antes de 17/11/2015?

Finalidade do Acesso:

Estas atividades são baseadas em acesso realizado anteriormente?

Equipe:

Selecione

Patrimônio Genético

Conhecimento Tradicional Associado

Patrimônio Genético e Conhecimento Tradicional Associado

Parceria com instituição sediada no exterior

Resultado Obtidos

Tipo do Resultado:

* Campos Obrigatórios.

Termos de uso do SISGen:

Ao se cadastrar no SISGen, o usuário reconhece e declara:
REGISTRATION OF THE ACCESS ACTIVITY

ELECTRONIC SYSTEM FOR REGISTRATION

Cadastro de atividade de acesso
Tipo de Usuário: Independente
Objeto do Acesso:
O acesso foi realizado antes de 17/11/2015?
Finalidade do Acesso: 
Estas atividades são baseadas em acesso realizado anteriormente?
Equipe:
Parceria com instituição sediada no exterior
Resultados Obtidos
Tipo de Resultado:

Selecione
Pesquisa
Desenvolvimento Tecnológico
Pesquisa e Desenvolvimento Tecnológico
ELECTRONIC SYSTEM FOR REGISTRATION

REGISTRATION OF THE ACCESS ACTIVITY

ABOUT THE GENETIC HERITAGE SOURCE
ELECTRONIC SYSTEM FOR REGISTRATION

REGISTRATION OF THE ACCESS ACTIVITY

ABOUT THE GENETIC HERITAGE SOURCE
ELECTRONIC SYSTEM FOR REGISTRATION

REGISTRATION OF THE ACCESS ACTIVITY

ABOUT THE GENETIC HERITAGE SOURCE
ELECTRONIC SYSTEM FOR REGISTRATION

REGISTRATION OF THE SHIPMENT ABROAD

Cadastro de Remessa de Amostra de Patrimônio Genético

Tipo de Usuário:

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

Identificador do Cadastro de Acesso:

Informações do Projeto

Especificação das atividades a serem realizadas no exterior

Sobre PG

Dados não encontrados

Instituição Destinatária no Exterior

Nome Institucional

País:

Região:

Município:

Código Postal:

Endereço:

Telefone:

Email:

Signatário do TTM pela Instituição Remetente
ELECTRONIC SYSTEM FOR REGISTRATION

REGISTRATION OF THE SHIPMENT ABROAD

PROVIDER INSTITUTION

RECIPIENT INSTITUTION

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ELECTRONIC SYSTEM FOR REGISTRATION

REGISTRATION OF THE SHIPMENT ABROAD

DEPOSIT IN EX SITU COLLECTION

Cadastro de Remessa de Amostra de Patrimônio Genético

- Tipo de Usuário:
- Esta remessa foi realizada em data anterior a 17/11/2015:
- Identificador do Cadastro de Acesso:

Informações do Projeto
- Especificação das atividades a serem realizadas no exterior:

Sobre PG
- Dados não encontrados

Instituição Destinatória no Exterior
- Nome Institucional:
- País:
- Região:

Depósito de Sub-Amostra
- Identificação da Coleção de Depósito:
- Nº do Voucher de depósito concedido pela Coleção:
- Data do Depósito da Coleção:
ELECTRONIC SYSTEM FOR REGISTRATION AND NOTIFICATION

After finalizing the registration or notification, a receipt will be issued automatically. This document that proves that the user provided the requested information and produces the following effects:

- Enables
- Establishes the verification procedure

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

- Request of any intellectual property right
- Commercialization of the intermediate product
- Dissemination of results from research or TD
- Notification
- Shipment abroad
- Economic exploitation

Examples of registration:
- Registration of access to GH
- Registration of access to ATK
- Registration of GH shipment notification
CERTIFICATE OF ACCESS REGULARITY

Upon request of the user and after determination of CGEN will be issued.

Administrative act by which the competent authority declares that

Certificate of Access Regularity

Access to Genetic Heritage

Access to Associated Traditional Knowledge

Prevents application of administrative penalties specifically regarding access activities undertaken until issuing the certificate.

Comply with the requirements of the law.
FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT

- Research and TD with the Brazilian GH
- Registration
- Indicate the source of the GH: In situ; Ex situ or/and In silico
- Receipt automatically issued
FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT

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

Web Interface:

[Image of a web interface for registration]

Source: The Brazilian GH:
- IN SITU;
- EX SITU
- OR/AND IN SILICO

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FOR COMPLYING WITH THE LAW: RESEARCH AND TECHNOLOGICAL DEVELOPMENT

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

SHIPPING GH ABROAD

1. SHIPMENT PRIOR SHIPPING GH ABROAD
2. SIGNATURE OF A MATERIAL TRANSFER AGREEMENT
3. RECEIPT AUTOMATICALLY ISSUED
4. DEPOSIT IN COLLECTION IS RECOMMENDED

BOTH DOCUMENTS GO 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

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 AND IN SILICO

RECEIPT AUTOMATICALLY ISSUED

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 GH AND ATK

RESEARCH AND TD WITH THE BRAZILIAN GH ➔ REGISTRATION ➔ INDICATE THE SOURCE OF THE GH: IN SITU; EX SITU/AND IN SILICO ➔ RECEIPT AUTOMATICALLY ISSUED

ACCESS TO ASSOCIATED TRADITIONAL KNOWLED ➔ 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 AND IN SILICO

RECEIPT AUTOMATICALLY ISSUED

FINISHED PRODUCTS DEVELOPED FROM BRAZILIAN GH

NOTIFICATION PRIOR ECONOMIC EXPLORATION

RECEIPT AUTOMATICALLY ISSUED

ECONOMIC EXPLORATION

SIGNATURE OF A BENEFIT SHARING AGREEMENT

BENEFIT SHARING CAN BE MONETARY OR NON-MONETARY

WHEN MONETARY IS WITH THE GOVERNMENT AND TRADITIONAL COMMUNITY IF THERE IS IDENTIFIABLE ATK

FINISHED PRODUCTS DEVELOPED FROM BRAZILIAN GH

NOTIFICATION PRIOR ECONOMIC EXPLORATION

RECEIPT AUTOMATICALLY ISSUED

ECONOMIC EXPLORATION

SIGNATURE OF A BENEFIT SHARING AGREEMENT

BENEFIT SHARING CAN BE MONETARY OR NON-MONETARY

WHEN MONETARY IS WITH THE GOVERNMENT AND TRADITIONAL COMMUNITY IF THERE IS IDENTIFIABLE ATK
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.

90% 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.
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.

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

- RESEARCH
- TECHNOLOGICAL DEVELOPMENT

90% fine exemption
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.

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.
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
THANK YOU!

Manuela da Silva
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FIOCRUZ
FUNDAÇÃO OSWALDO CRUZ
HEALTH MINISTRY