

THE BRAZILIAN LEGISLATION ON ACCESS AND BENEFIT SHARING

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of the Genetic Heritage Management Council (Brazilian ABS Competent Authority)

General Manager of Fiocruz Covid-19 Biobank



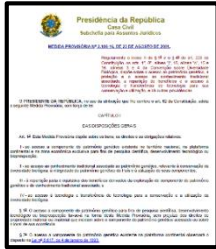
THE NEW BRAZILIAN ABS LEGISLATION AND ITS ORIGIN

May 2000
case of
biopiracy in
Brazil

The Swiss company Novartis negotiated a contract with the institution Bioamazonia in which it would finance equipment and the collection / isolation / characterization of microorganisms from the Amazon on a large scale. In return, Bioamazônia would pass on access rights and exclusivity on these MOs for the company to develop pharmaceutical products



THE NEW BRAZILIAN ABS LEGISLATION AND ITS ORIGIN



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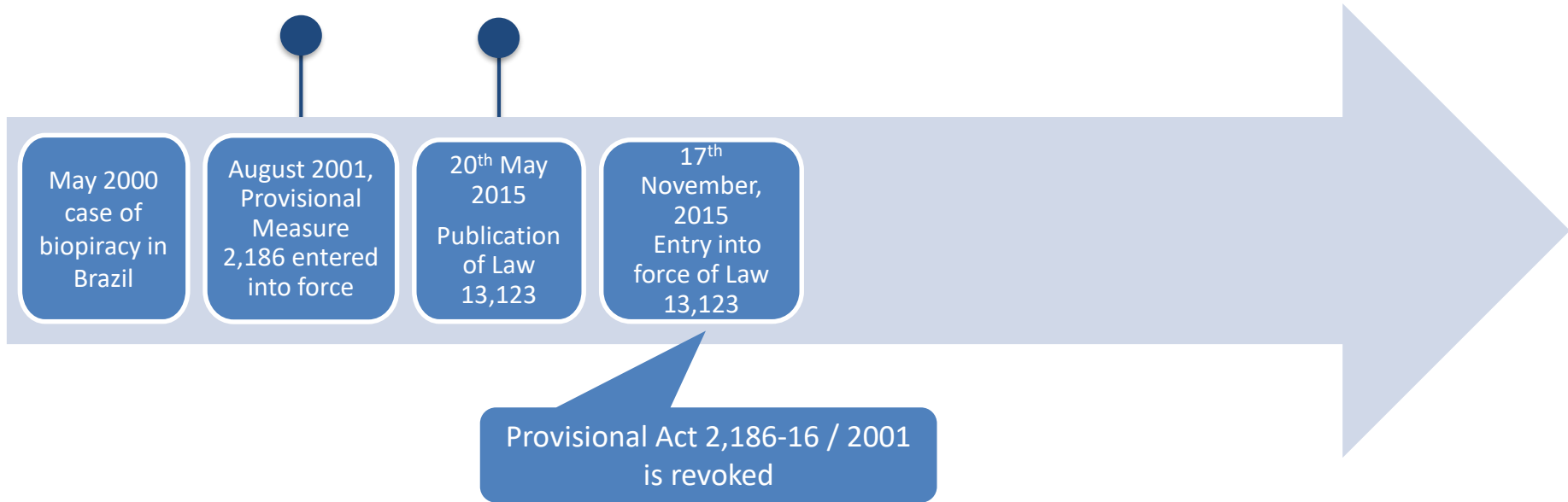
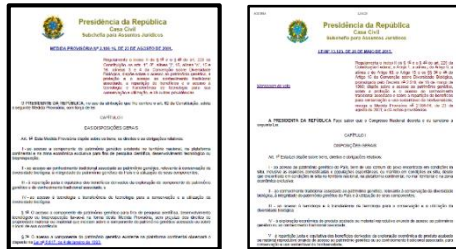
August 2001,
Provisional
Measure
2,186 entered
into force

20th May
2015
Publication
of Law
13,123

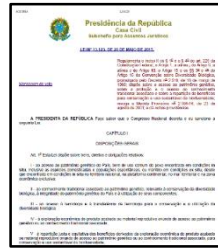
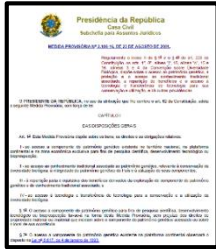
The Law on access and benefit sharing is based on the Federal Constitution and on the Convention on Biological Diversity



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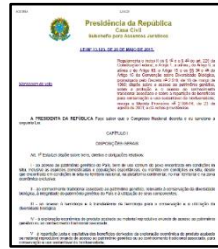
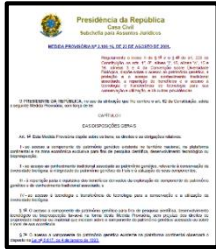
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17th
November,
2015
Entry into
force of Law
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11th May 2016
Publication of
Decree 8.772
that regulates
the Law



THE NEW BRAZILIAN ABS LEGISLATION AND ITS ORIGIN



Genetic Heritage Management Council, the ABS Competent National Authority, consists of representatives of **9 Ministries** and **9 representatives of civil society**, **3 of each of the following sectors: Business; Indigenous peoples, traditional communities and traditional farmers; Academia**

May 2000
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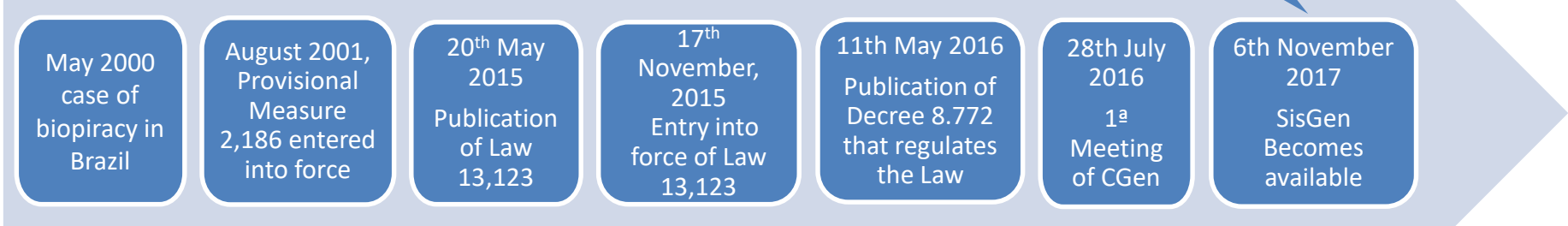
28th July
2016
1^a
Meeting
of CGen



THE NEW BRAZILIAN ABS LEGISLATION AND ITS ORIGIN



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



ABS NATIONAL COMPETENT AUTHORITY

The National Competent Authority, the Genetic Heritage Management Council (CGen), is constituted of representatives from 9 ministries and 9 representatives of civil society:

- Business sector
- Sector of entities or organizations representing indigenous populations, traditional communities and traditional farmers
- Academic sector

CGEN WORKS THROUGH:

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

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

Composição da Câmara Setorial da Academia:

Coordenadora: Manuela da Silva

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Ministério da Ciência, Tecnologia, Inovações e Comunicações

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Ministério da Saúde

Níve Aguiar Colonello
ninive.colonello@saude.gov.br



Câmara Setorial da Academia

PRÓXIMA REUNIÃO

21ª Reunião Ordinária da Câmara Setorial da Academia

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

Link da reunião: [Clique aqui](#)

Data: 23/08/2022

Horário: 09h às 13h

Local: Internet (Microsoft Teams).

Orientações para ingresso e utilização da ferramenta TEAMS: [Clique aqui](#)

Pauta:

1. Propostas referentes à exigência de associação de instituição estrangeira com instituição brasileira
2. GT SisGen Academia
3. Módulo Pesquisa sem fins comerciais SisGen/CNPq
4. GT Capacitação (PROJETO GEF/ABS DO MMA/PNUD/BID - BRA/18/003 - PROTOCOLO DE NAGOIA ABS)
5. Representatividade das Câmara setoriais e Regimento Interno
6. Fundo Nacional de Repartição de Benefícios

Documentos:

N/A

Reuniões Anteriores

Publicado em 22/01/2021 10h40 | Atualizado em 15/09/2022 15h49

Compartilhe: [f](#) [t](#) [l](#)




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

Reunião	Documentos	Pauta	Memória	Lista de Presença
1ª Reunião - 14/08/17	Clique aqui	Clique aqui	Clique aqui	-
2ª Reunião - 25/09/17	Clique aqui	Clique aqui	Clique aqui	Clique aqui
19ª Reunião - 15/02/22		Clique aqui	Clique aqui	Clique aqui
20ª Reunião - 07/06/22		Clique aqui	Clique aqui	Clique aqui
21ª Reunião - 23/08/2022		Clique aqui		



Links/Documentos

Publicado em 16/05/2022 11h21 | Atualizado em 20/10/2022 12h21

Compartilhe:   

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 - 2021*
11. Termo de Transferência de Material - TTM (Português) - Resolução nº 27
12. Material Transfer Agreement – MTA (English) - Resolution 27
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 involving genetic heritage; 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



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

Cachoeira do Veado

- > Saiba Mais
- > Dúvidas Frequentes
- > Estatísticas
- > Destaques
- > Manual
- > Legislação Específica
- > Verificar Autenticidade
- > Relatório de Atividades
- > Dados de Licenciamento



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**
- **ECOLOGY**
- **TAXONOMY**
- **PHYLOGENY**



SCOPE OF THE LAW 13.123/15

**REACHES ALL RESEARCH
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DEFINITION

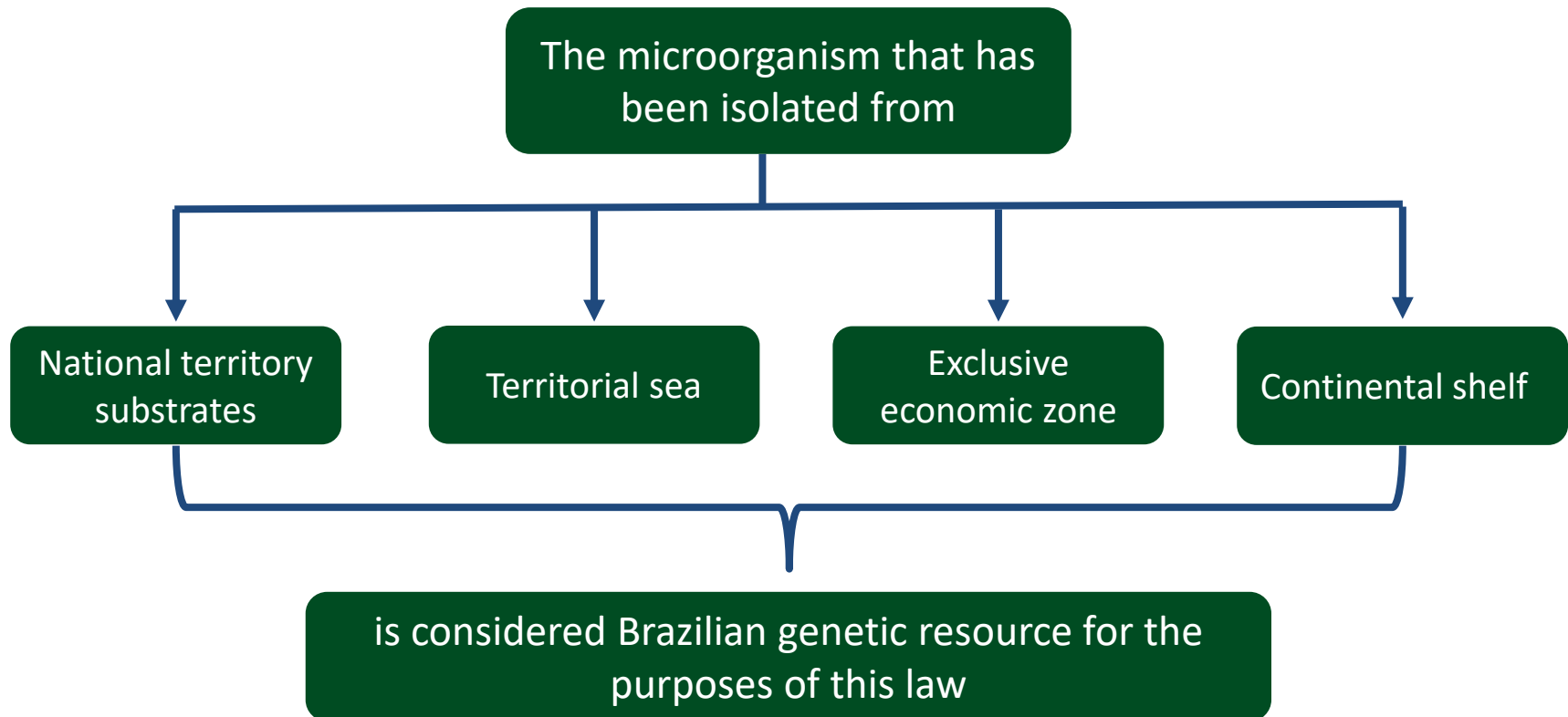
information of genetic origin from plants, animals, microorganisms or species of other nature, including substances derived from the metabolism of these living beings

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



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



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

NOTIFICATION

FINISHED PRODUCT

REPRODUCTIVE MATERIAL

REGISTRATION

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



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

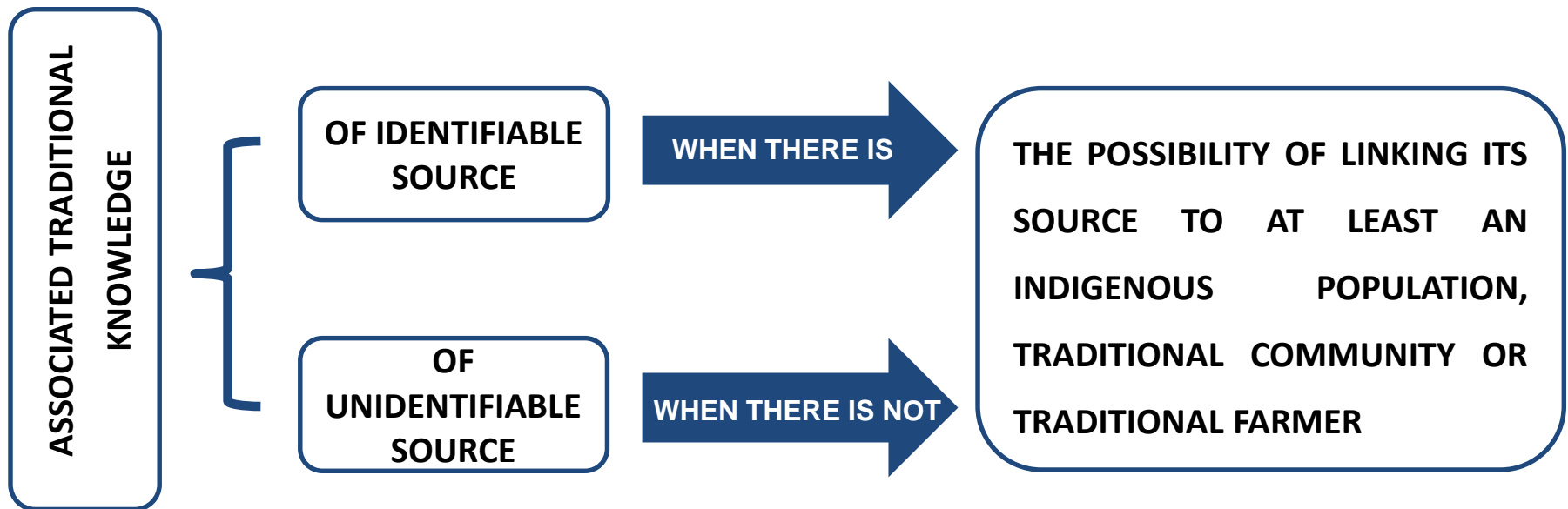
II - national institution of scientific research and technology, public or private, when access is made in association with legal entity based abroad

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 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



MATERIAL TRANSFER AGREEMENT - MTA

Resolution CGen N° 27 ratifies and updates the MTA:

- It allows the inclusion of clauses of interest to the sender or recipient in the MTA and in the Shipment Invoice models, as well as the exclusion of clauses, provisions and information in the MTA model that are not applicable to a specific shipment, provided that these modifications do not conflict with the provisions of this Resolution or the relevant legislation.
- It allows 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 Brazilian researcher will register in SisGen, attach a copy of the signed MTA (that can be a “umbrella” MTA) and a sequentially numbered Shipment invoice, with a description of the samples to be sent.
- When the shipment of different genetic heritage occurs on the same date and for the same recipient, a single shipment record in SisGen can be performed.

THE MTA, SHIPMENT INVOICE AND THE RECEIPT OF THE REGISTRATION MUST ACCOMPANY THE GENETIC HERITAGE



MATERIAL TRANSFER AGREEMENT - MTA

Some new information and clauses

- In the case of the association of the foreign institution with a Brazilian institution so that the foreigner can conduct the research or development activities, this MTA can be recognized as the legal instrument that formalizes the association between the signatory parties, provided that it contains a specific clause for this purpose
- The registration of research or development activities by the Brazilian institution associated with the foreign RECIPIENT may be previously:
 - the application of any intellectual property right; or
 - the commercialization of the intermediate product; or
 - the dissemination of results, final or partial, in scientific or communication media, or
 - notification of finished product or reproductive material developed as a result of access

Therefore, the activity can start any time without any obligation, provided that the registration is done before the activities listed above.



MATERIAL TRANSFER AGREEMENT - MTA

Some new information and clauses

- The responsibility for the genetic heritage samples is definitively transferred to the RECIPIENT, including in cases of deposit in an *ex situ* collection.
- The validity refers exclusively to this MTA and does not apply to the genetic heritage samples identified in the Shipment Invoice(s) attached thereto or to the possibility of transferring these genetic heritage samples to third parties
- If the Shipment Invoice(s) authorize the transfer of genetic heritage samples to third parties, they may be transferred even after the expiration of the MTA. The RECIPIENT must send to CGen (cgen@mma.gov.br) annually, at the end of the fiscal year, all the MTAs signed with subsequent recipients, accompanied by the respective Shipment Invoice(s) corresponding to each transfer



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) would be made available for the foreigner to provide the necessary information about the research project to be developed. The pre-registration would be accessed by the pre-defined research institution, acting as a Brazilian partner, who would evaluate the pre-registration. If the institution agrees, it would validate the pre-registration that becomes the registration with a number and then would 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

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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**

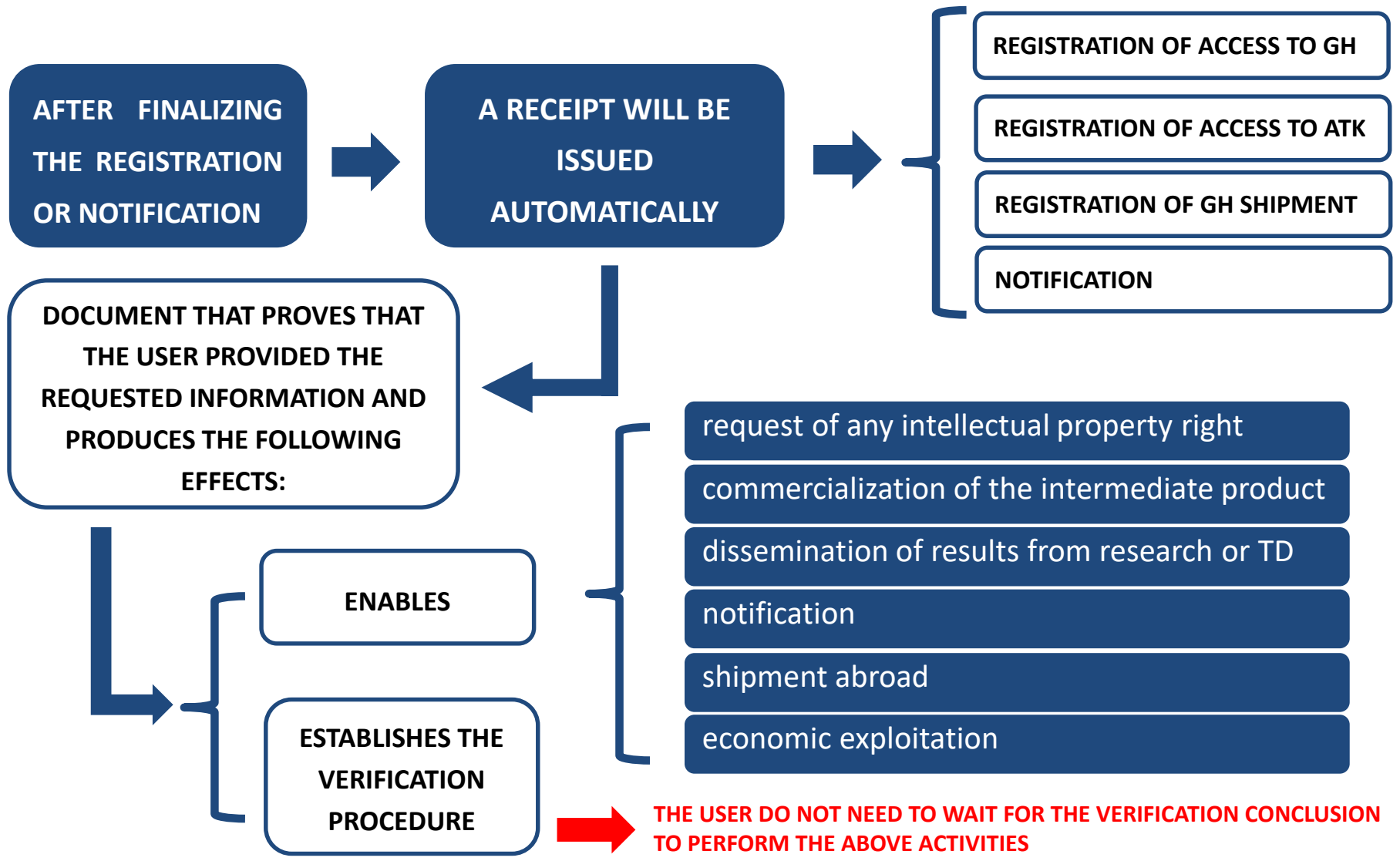


BENEFIT SHARING

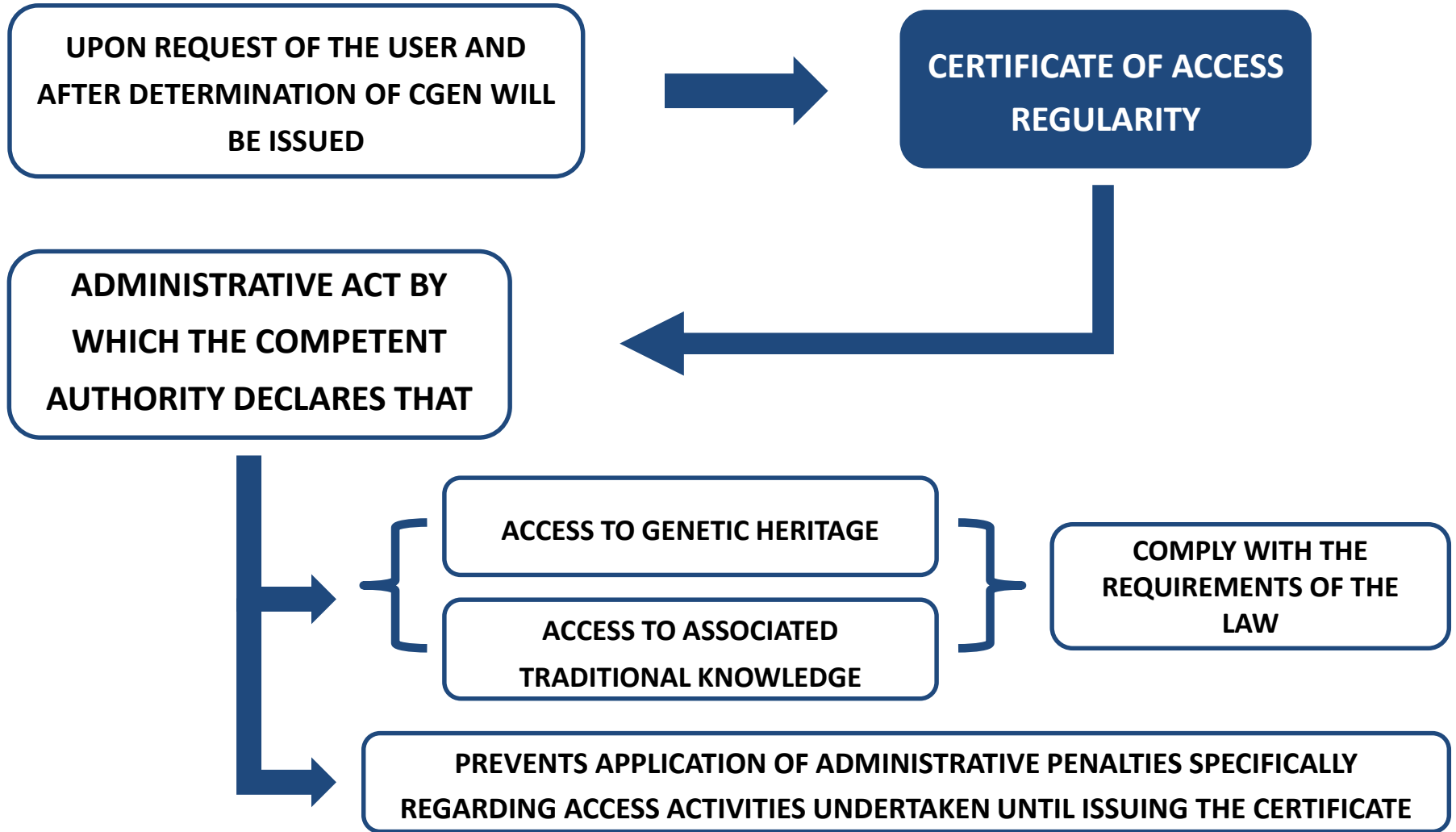
Through the National Fund of Benefit Sharing the National Program of Benefit Sharing – PNRB will be established in order to promote, among others:

- 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





CERTIFICATE OF ACCESS REGULARITY



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



Thank you!

Manuela da Silva

Coordinator of the Sectoral Chamber of Academia
of CGen (Brazilian ABS Competent Authority)

General Manager of the Fiocruz Covid-19 Biobank

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