

Workshop Biodiversity and Biobank



BIOLOGICAL COLLECTIONS AND THE BRAZILIAN LEGISLATION ON ACCESS BENEFIT SHARING (LAW OF BIODIVERSITY)

MANUELA DA SILVA - FIOCRUZ – FUNDAÇÃO OSWALDO CRUZ
COORDINATOR OF FIOCRUZ BIOLOGICAL COLLECTIONS



THE NEW BRAZILIAN ABS LEGISLATION



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

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



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13/05/2016

Decreto nº 8772



Presidência da República
Casa Civil
Subchefia para Assuntos Jurídicos

DECREE Nº 8.772, FROM 11 OF MAY 2016

After almost 6 months since the law came into force, the Decree regulating it was published. Thus, we had a scenario in which there was a law in force without regulation, which prevented its implementation.

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 NEW BRAZILIAN ABS LEGISLATION

5/21/2015

L13123



Presidência

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

Now we have law and regulation, but after 2 years of the publication of the new law, we are still waiting for SisGen

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

After almost 6 months the law came into force, the regulation was published. We had a scenario in which there was a law in force without regulation, which prevented implementation.

use of biodiversity.

General Convention on Biological Diversity, 1992, Article 15, paragraph 4, and the Convention on Biological Diversity, 1992, Article 15, paragraph 4, provides for access to associated traditional conservation and sustainable use of genetic resources. Decree nº 8772, 23 August 2001, and

Decreto nº 8772

Presidência da República
Casa Civil
Departamento de Assuntos Jurídicos

11 OF MAY 2016

15, which provides for access to associated traditional conservation or conservation and sustainable



THE NEW BRAZILIAN ABS LEGISLATION

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§ 1º Para a aplicação do disposto no inciso VII do caput do art. 14, e para o extinção de alterações previstas nos arts. 14 e art. 15 da Lei nº 13.439 de 2017, os participantes do Programa Cereja Reformam fornecerão informações, pareceres e outros documentos necessários à instrução dos procedimentos de fiscalização, acompanhamento, esclarecimento de denúncias e reclamações.

§ 2º O ato de extinção das alterações previstas no § 1º, nos prazos definidos pelo Ministério das Cidades, assegura a adoção de medidas para o bloqueio de recursos e a suspensão da participação no Programa Cereja Reformam.

Art. 20. Este Decreto entra em vigor na data de sua publicação.

Brasília, 29 de junho de 2017; 196ª da Independência e 129ª da República.

MICHEL TEMER
Henrique Meireles
Dyego Henrique de Oliveira
Mário Aurélio de Queiroz Campos

DECRETO Nº 9.885, DE 29 DE JUNHO DE 2017

Altera o Decreto nº 8.971, de 24 de janeiro de 2017, que aprova a Estrutura Regimental e o Quadro Demonstrativo dos Cargos em Comissão e das Funções de Confiança do Ministério do Meio Ambiente, reorganiza cargos em comissão e subordina cargos em comissão do Grupo-Direção e Assessoramento Superiores - DAS por Funções Comissionadas do Poder Executivo - FCPe.

O PRESIDENTE DA REPÚBLICA, no uso da atribuição que lhe confere o art. 84, caput, inciso VI, alínea "a", da Constituição,

D E C R E T A :

Art. 1º Ficam reanexados, na forma do Anexo II, os seguintes cargos em comissão do Grupo-Direção e Assessoramento Superiores - DAS e Funções Comissionadas do Poder Executivo - FCPe:

I - do Ministério do Meio Ambiente para a Secretaria de Gestão do Ministério do Planejamento, Desenvolvimento e Gestão:

- a) um DAS 102.2;
- b) uma FCPe 102.3;
- c) uma FCPe 102.2; e
- d) uma FCPe 102.1; e

II - da Secretaria de Gestão do Ministério do Planejamento, Desenvolvimento e Gestão para o Ministério do Meio Ambiente:

- a) um DAS 101.5;
- b) três DAS 101.4;
- c) seis DAS 101.3;
- d) duas DAS 101.2;
- e) uma FCPe 101.3;
- f) uma FCPe 101.2; e
- g) uma FCPe 101.1.

Art. 2º O Anexo I ao Decreto nº 8.971, de 24 de janeiro de 2017, passa a vigorar com as seguintes alterações:

"Art. 2º -

II -

- b) -
- 3. Departamento de Áreas Protegidas;
- 4. Departamento de Patrimônio Genético; e
- 5. Departamento de Apoio ao Conselho de Gestão do Patrimônio Genético.

....." (NR)

"Art. 21-A. O Departamento de Apoio ao Conselho de Gestão do Patrimônio Genético exercerá as funções de Secretaria-Executiva e Coordenação, conforme o art. 11 do Decreto nº 8.971, de 24 de janeiro de 2017. (NR)

Art. 2º O Anexo II ao Decreto nº 8.971, de 24 de janeiro de 2017, passa a vigorar na forma do Anexo I a este Decreto.

Art. 4º Os ocupantes dos cargos em comissão que deixarem de existir na Estrutura Regimental do Ministério do Meio Ambiente por força deste Decreto ficam automaticamente encerrados.

Art. 5º Os apontamentos decorrentes das alterações promovidas na Estrutura Regimental do Ministério do Meio Ambiente deverão ocorrer na data de entrada em vigor deste Decreto.

Parágrafo único. O Ministro de Estado do Meio Ambiente publicará, no Diário Oficial da União, no prazo de vinte dias, contado da data de entrada em vigor deste Decreto, relação nominal dos ocupantes dos cargos em comissão e das Funções de Confiança a que se refere o Anexo I, que indicará, inclusive, o número de cargos e funções vagas, suas denominações e seus níveis.

Art. 6º Este Decreto entra em vigor em 27 de julho de 2017.

Brasília, 29 de junho de 2017; 196ª da Independência e 129ª da República.

MICHEL TEMER
Dyego Henrique de Oliveira
José Sarney Filho

ANEXO I
(Anexo II ao Decreto nº 8.971, de 24 de janeiro de 2017)

a) QUADRO DEMONSTRATIVO DOS CARGOS EM COMISSÃO E DAS FUNÇÕES DE CONFIANÇA DO MINISTÉRIO DO MEIO AMBIENTE.

UNIDADE	CARGO/FUNÇÃO	DENOMINAÇÃO/CARGO/FUNÇÃO	VEDADAS/FCPE
	2	Assessor Especial	DAS 102.3
	1	Assessor	DAS 102.4
	2	Assistent	DAS 102.2
	1	Assistente Técnico	DAS 102.1
GABINETE	1	Chefe de Gabinete	DAS 101.5
	1	Assessor Técnico	DAS 102.3
Coordenação-Geral de Apoio Administrativo	1	Coordenador-Geral	DAS 101.4
	2	Assistente	DAS 102.2
	2	Assistente Técnico	DAS 102.1
Divisão	1	Chefe	DAS 101.2
Ondena	1	Ondena	DAS 101.4
Assessoria Parlamentar	1	Chefe de Assessoria	DAS 101.4
Assessoria de Comunicação Social	1	Chefe de Assessoria	DAS 101.4
SECRETARIA-EXECUTIVA	1	Secretário-Executivo	NE
	1	Diretor de Programa	DAS 101.4
	2	Assessor	DAS 102.4
Gabinete	1	Chefe	DAS 101.4
	2	Assessor Técnico	DAS 102.3
Coordenação	1	Coordenador	DAS 101.3
SUBSECRETARIA DE PLANEJAMENTO, ORGANIZACAO E ADMINISTRACAO	1	Subsecretário	DAS 101.5
Coordenação	1	Coordenador	DAS 101.3
Coordenação-Geral de Gestão Administrativa	1	Coordenador-Geral	DAS 101.4
Coordenação	2	Coordenador	DAS 101.3
Sede	1	Chefe	DAS 101.1
Divisão	1	Chefe	DAS 101.2
Divisão	2	Chefe	FCPE 101.2
Coordenação-Geral de Gestão de Pessoas	1	Coordenador-Geral	FCPE 101.4
Coordenação	2	Coordenador	DAS 101.3
Divisão	3	Chefe	FCPE 101.2
Divisão	1	Chefe	DAS 101.2
Coordenação-Geral de Tecnologia da Informação	1	Coordenador-Geral	DAS 101.4

Este documento pode ser verificado no endereço eletrônico <http://www.in.gov.br/imprensa/detalhes.html>, pelo código 00012017063000003

Coordenação	2	Coordenador	DAS 101.3
Divisão	2	Chefe	FCPE 101.2
Coordenação-Geral de Compras e Contratos	1	Coordenador-Geral	DAS 101.4
Coordenação	1	Coordenador	FCPE 101.3
Coordenação	1	Coordenador	DAS 101.3
	2	Assistente	DAS 102.2
Coordenação-Geral de Orçamento e Finanças	1	Coordenador-Geral	FCPE 101.4
Coordenação	1	Coordenador	DAS 101.3
Coordenação	1	Coordenador	FCPE 101.2
Divisão	2	Chefe	FCPE 101.2
	4	FC-1	
	4	FC-2	
DEPARTAMENTO DE GESTÃO ESTRATÉGICA	1	Diretor	DAS 101.5
Coordenação	1	Coordenador	DAS 101.3
Coordenação-Geral de Planejamento Institucional	1	Coordenador-Geral	FCPE 101.4
	1	Assessor Técnico	FCPE 102.3
	1	Assistente Técnico	FCPE 102.1
Coordenação-Geral de Gestão de Informações sobre Meio Ambiente	1	Coordenador-Geral	FCPE 101.4
	1	Assistente	FCPE 102.2
DEPARTAMENTO DE RECURSOS HUMANOS	1	Diretor	DAS 101.5
Coordenação-Geral de Acompanhamento de Projetos de Cooperação Multilateral	1	Coordenador-Geral	FCPE 101.4
Coordenação-Geral de Acompanhamento de Projetos de Cooperação Bilateral	1	Coordenador-Geral	DAS 101.4
DEPARTAMENTO DO FUNDO NACIONAL DO MEIO AMBIENTE	1	Diretor	DAS 101.5
Coordenação-Geral de Fomento	1	Coordenador-Geral	FCPE 101.4
DEPARTAMENTO DE APOIO AO CONSELHO NACIONAL DO MEIO AMBIENTE	1	Diretor	DAS 101.5
	1	Assessor Técnico	FCPE 102.3
	1	Assistente Técnico	FCPE 102.1
ASSESSORIA DE ASSUNTOS INTERNACIONAIS	1	Chefe de Assessoria	DAS 101.5
	1	Assessor	DAS 102.4
CONSULTORIA JURÍDICA	1	Consultor Jurídico	DAS 101.5
	1	Assistente	DAS 102.2
Serviço	1	Assistente Técnico	FCPE 102.1
	1	Chefe	FCPE 101.1
Coordenação-Geral de Monitoria Finalística	1	Coordenador-Geral	FCPE 101.4

Documento assinado digitalmente conforme MP nº 2.200-2 de 24/08/2001, que institui a Infraestrutura de Chaves Públicas Brasileira - ICP-Brasil.

da República Civil Assuntos Jurídicos

1º DE MAI 2015

of article 225 of the Federal point c of Article 10, Article 15 attention on Biological Diversity, in 1998, provides for access to associated traditional conservation and sustainable use of 186/2001, 23 August 2001, and

creto nº 8772

da República Civil Assuntos Jurídicos

1 OF MAY 2016

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

After almost 6 months since the law came into force, the regulation that was published was a law in force with regulation, which prevented implementation.



ABS NATIONAL COMPETENT AUTHORITY



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



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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



ABS NATIONAL COMPETENT AUTHORITY

CGEN WORKS BY MEANS OF:

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



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- IV. Executive Secretary

[Deliberação nº 5](#)

Data: 21/03/2017

Assunto: Cria a Câmara Setorial da Academia, em caráter permanente, para conduzir discussões técnicas e apresentar propostas de interesse do setor acadêmico relacionadas à legislação de acesso e repartição de benefícios nos termos da Lei nº 13.123, de 20 de maio de 2015 e do Decreto nº 8.772, de 11 de maio de 2016.

Publicação no D.O.U.: 20/04/2017 - Seção 1 - Pág. 110



SECTORIAL CHAMBER PARTICIPANTS

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



SCOPE OF THE LAW 13.123/15



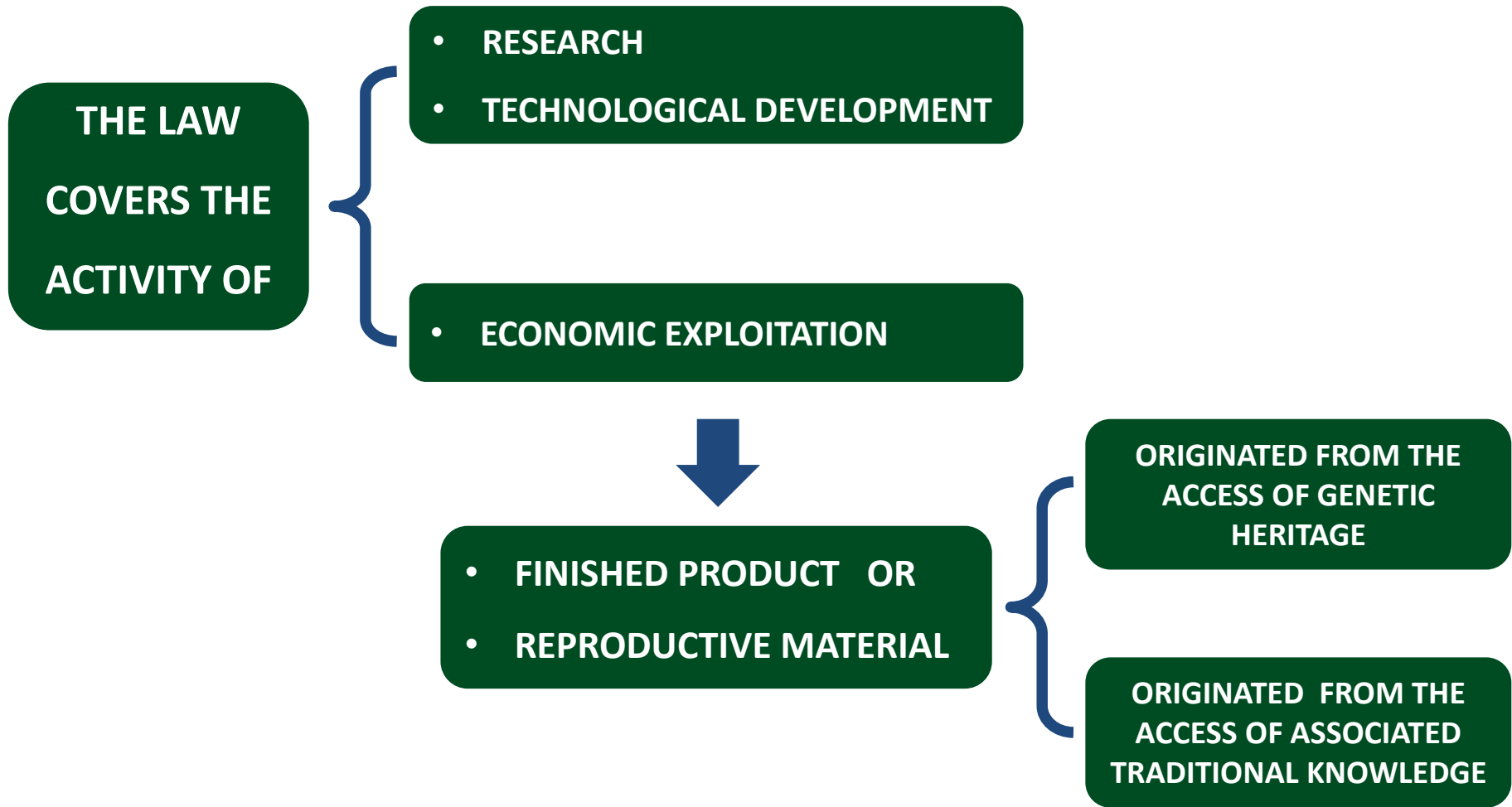
SCOPE OF THE LAW 13.123/15

**THE LAW
COVERS THE
ACTIVITY OF**

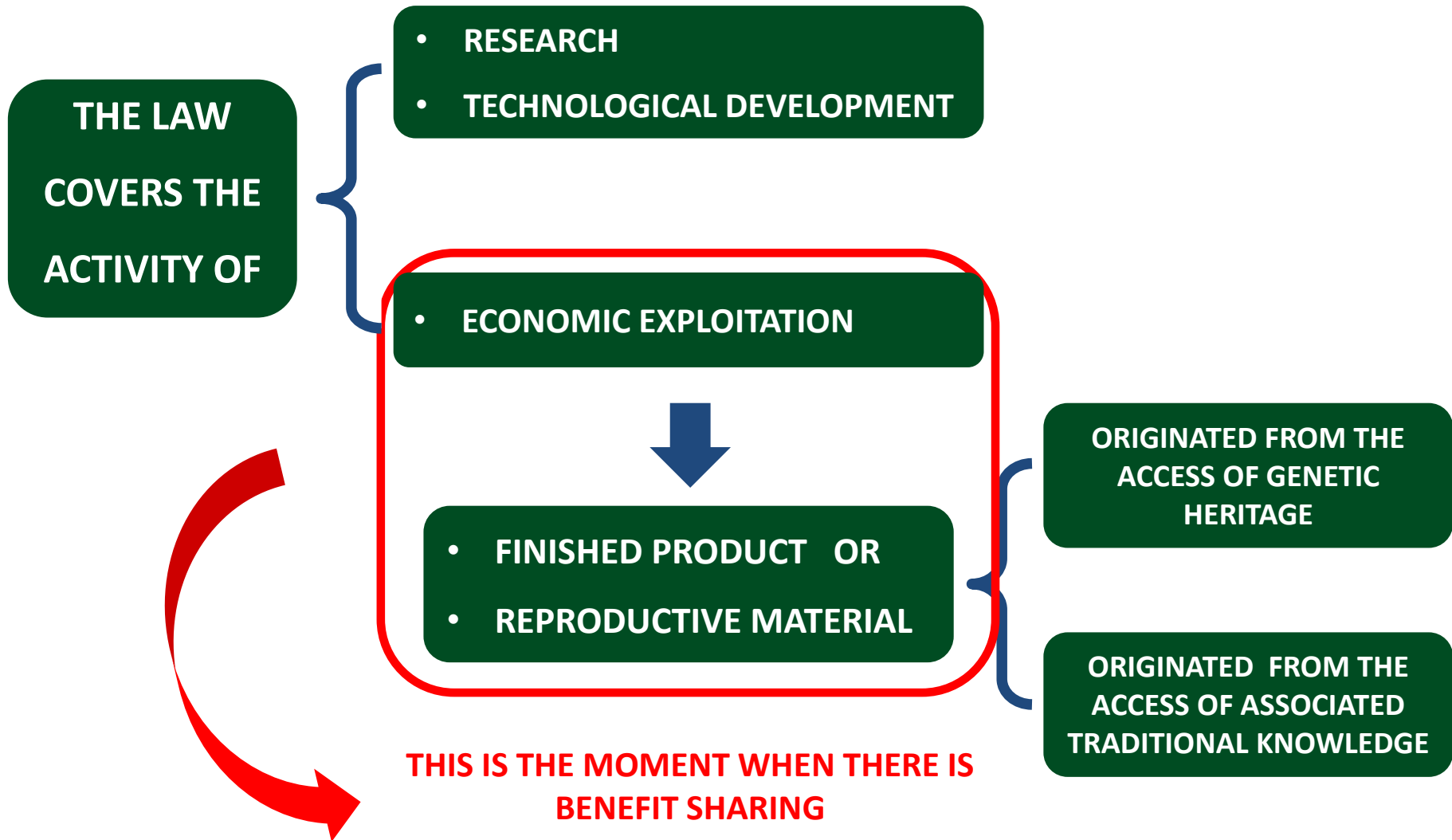
- RESEARCH
- TECHNOLOGICAL DEVELOPMENT
- ECONOMIC EXPLOITATION



SCOPE OF THE LAW 13.123/15



SCOPE OF THE LAW 13.123/15



SCOPE OF THE LAW 13.123/15

THE LAW
COVERS THE
ACTIVITY OF

- RESEARCH
- TECHNOLOGICAL DEVELOPMENT

ACCESS = UTILIZATION

- ECONOMIC EXPLOITATION



- FINISHED PRODUCT OR
- REPRODUCTIVE MATERIAL

ORIGINATED FROM THE
ACCESS OF GENETIC
HERITAGE

ORIGINATED FROM THE
ACCESS OF ASSOCIATED
TRADITIONAL KNOWLEDGE

THIS IS THE MOMENT WHEN THERE IS
BENEFIT SHARING



SCOPE OF THE LAW 13.123/15

DIFERENTLY FROM THE PREVIOUS LEGISLATION, THE NEW LAW:



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**



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



SCOPE OF THE LAW 13.123/15

DIFERENTLY FROM THE PREVIOUS LEGISLATION, THE NEW LAW:

**REACHES ALL RESEARCH
(EXPERIMENTAL OR
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BASIC RESEARCH SUCH AS:

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



SCOPE OF THE LAW 13.123/15

DIFERENTLY FROM THE PREVIOUS LEGISLATION, THE NEW LAW:

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(EXPERIMENTAL OR
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GENETIC HERITAGE**

DEFINITION

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



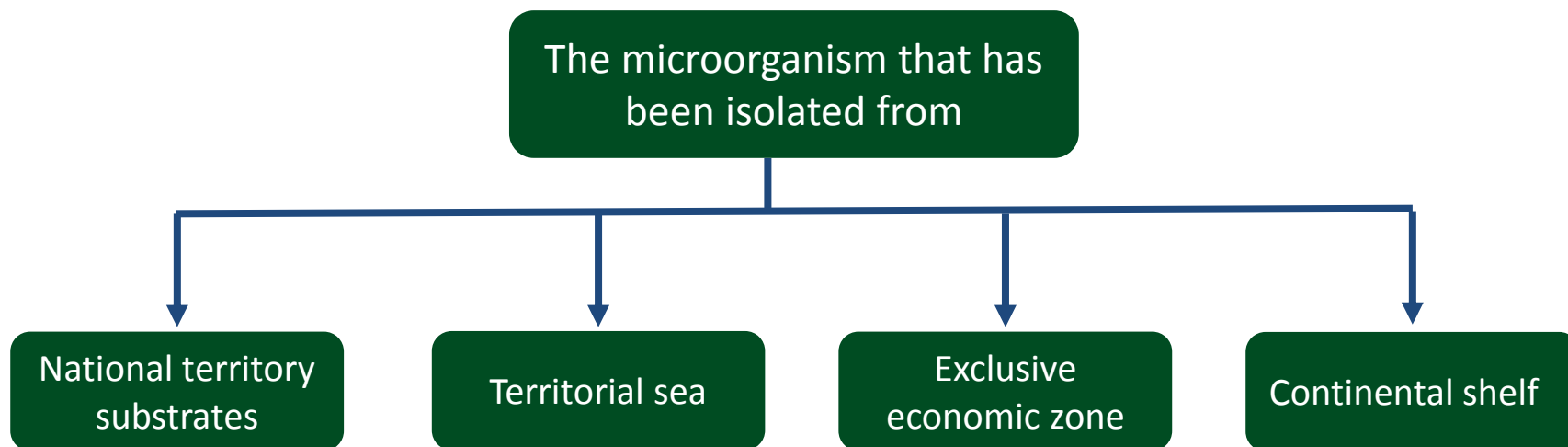
SCOPE OF THE LAW 13.123/15

OTHER NOVELTY IN THE LAW IS THE PARAGRAPH ON MICROORGANISMS



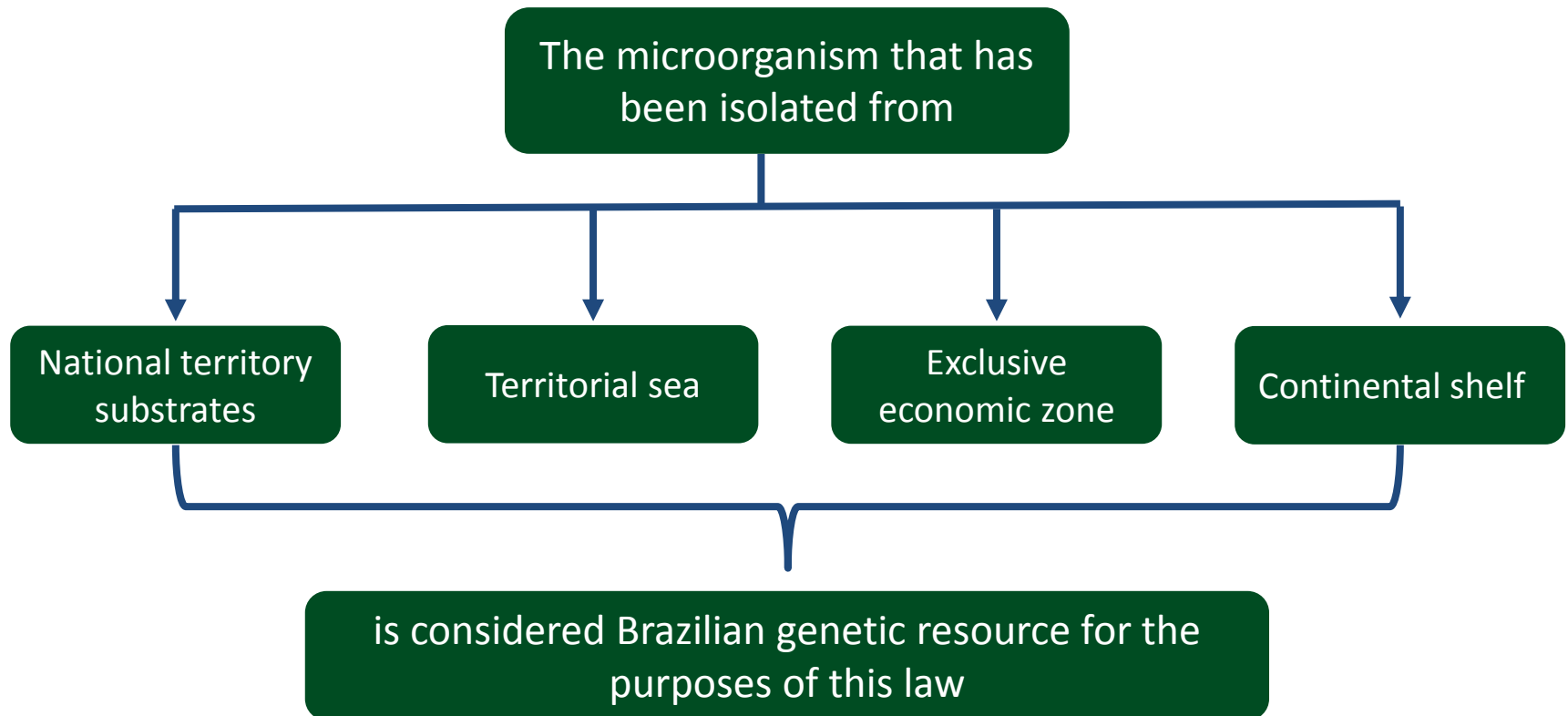
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SCOPE OF THE LAW 13.123/15

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FOR COMPLYING WITH THE LAW



FOR COMPLYING WITH THE LAW

REGISTRATION



RESEARCH

TECHNOLOGICAL DEVELOPMENT



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



SHIPMENT ABROAD OF GENETIC HERITAGE



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 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



MATERIAL TRANSFER AGREEMENT

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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 MODEL APPROVED BY CGEN

Ministério do Meio Ambiente

CONSELHO DE GESTÃO DO PATRIMÔNIO GENÉTICO

RESOLUÇÃO Nº 1, DE 5 DE OUTUBRO DE 2016

Aprova 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 a esta 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 Esta Resolução entra em vigor na data de sua publicação.

3. O DESTINATÁRIO declara que utilizará as amostras de patrimônio genético recebidas para:

OBJETIVO	USO PRETENDIDO E SETOR DE APLICAÇÃO
<input type="checkbox"/> Pesquisa	Usos pretendidos: Setor de aplicação do projeto / atividade de pesquisa:
<input type="checkbox"/> Desenvolvimento tecnológico	Usos pretendidos: Setor de aplicação do projeto / atividade de desenvolvimento tecnológico:
<input type="checkbox"/> Depósito em coleção ex situ	

3.1. a) O DESTINATÁRIO deverá informar ao CGen (cgen@mma.gov.br) qualquer alteração nas informações indicadas no item 3.

[OU]

3.1. b) As amostras objeto do presente TTM deverão ser utilizadas exclusivamente para os objetivos, uso pretendido e setor de aplicação indicados no item 3.

[OU]

3.1. c) O DESTINATÁRIO depende de autorização do(a) REMETENTE para qualquer alteração nos objetivos, uso pretendido e setor de aplicação indicados no item 3.

4. Trata-se de variedade tradicional local ou crioula ou de raça localmente adaptada ou crioula?

Sim.

Não.

5. O DESTINATÁRIO reconhece que não é provedor das amostras de patrimônio genético objeto deste TTM.

6. Fica vedado o repasse a terceiros de amostras de patrimônio genético objeto dessa remessa.

[OU]

6. As amostras do patrimônio genético poderão ser repassadas a terceiros.

6.1. Para o repasse, o DESTINATÁRIO exigirá do destinatário subsequente a assinatura de novo TTM contendo todas as cláusulas deste TTM, podendo alterar os objetivos, uso pretendido e setor de aplicação previstos no item 3. deste documento.

6.2. O DESTINATÁRIO é responsável por informar qualquer repasse subsequente do material objeto deste TTM ao CGen (cgen@mma.gov.br).

6.3. O disposto nos itens 6.1 e 6.2 aplica-se a todos os repasses subsequentes.



SENDING OF GENETIC HERITAGE



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



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



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



RESEARCH BY FOREIGNERS



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BRAZILIAN BIODIVERSITY CAN ONLY BE ACCESSED BY



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BRAZILIAN BIODIVERSITY CAN ONLY BE ACCESSED BY

FOREIGN INSTITUTION
(LEGAL ENTITY LOCATED
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in partnership with

BRAZILIAN INSTITUTION
(PUBLIC OR PRIVATE)



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

The image shows a screenshot of the SisGen (Sistema de Registro de Acesso a Recursos Genéticos) registration form. The form is titled 'Meio Ambiente' and is divided into several sections for data entry:

- Administrado:** Includes fields for 'Cadastro de atividade de acesso', 'Tipo de usuário', 'Tipo de Acesso', 'Procedência do Acesso', and 'Processo'.
- Patrimônio Genético:** Includes fields for 'Espécie', 'Estrutura de registro em português', 'Espécie de espécies em inglês', and 'Recurso em português'.
- Recursos em Inglês:** Includes a field for 'Recurso em Inglês'.
- Informações de Acesso:** Includes fields for 'Número de Acesso em português', 'Número de Acesso em Inglês', 'Número de Acesso em Inglês', and 'Número de Acesso em Inglês'.



BENEFIT SHARING



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CLEAR AND FIXED RULES FOR BENEFIT SHARING WERE ESTABLISHED



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THAT CAN BE:

- **MONETARY, WITH THE PERCENTAGE OF 1% OF ANNUAL NET REVENUE OR UP TO 0.1% BY SECTORIAL AGREEMENT, OR**
- **NON MONETARY**



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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



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- **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**



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benefit sharing:**

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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



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



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

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



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Genetic Heritage from *ex situ* Collections



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

Associated Knowledge **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:



BENEFIT SHARING

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

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



CGEN CREATED ELECTRONIC SYSTEM



CGEN CREATED ELECTRONIC SYSTEM

The National System for Genetic Heritage and Associated Traditional Knowledge Management (SisGen) was created to manage:



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



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ACCESS TO ASSOCIATED TRADITIONAL KNOWLEDGE

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NOTIFICATION

FINISHED PRODUCT

REPRODUCTIVE MATERIAL



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NOTIFICATION

FINISHED PRODUCT

REPRODUCTIVE MATERIAL

ACCREDITATION

NATIONAL INSTITUTIONS MAINTAINING *ex situ*
COLLECTIONS THAT HOLD GENETIC HERITAGE



ELECTRONIC SYSTEM FOR REGISTRATION AND NOTIFICATION



ELECTRONIC SYSTEM FOR REGISTRATION AND NOTIFICATION

AFTER FINALIZING
THE REGISTRATION
OR NOTIFICATION



ELECTRONIC SYSTEM FOR REGISTRATION AND NOTIFICATION

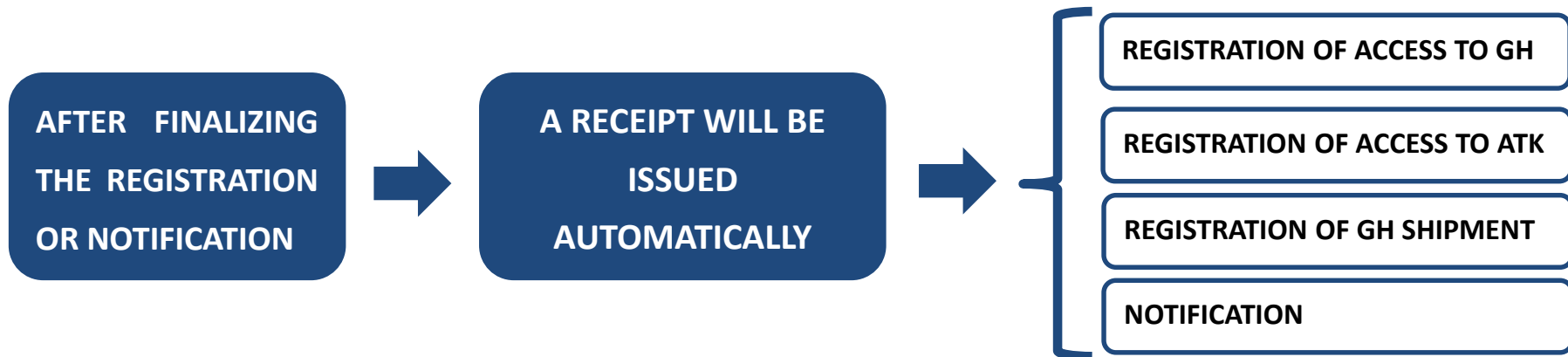
AFTER FINALIZING
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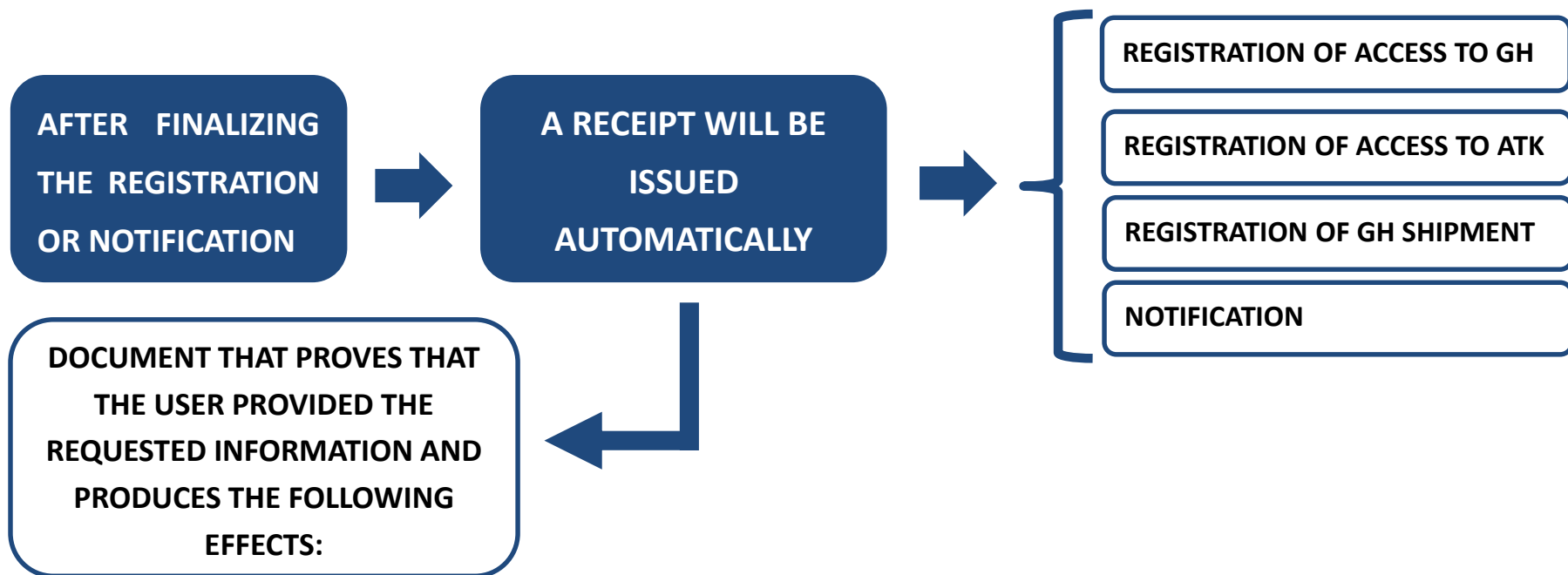
A RECEIPT WILL BE
ISSUED
AUTOMATICALLY



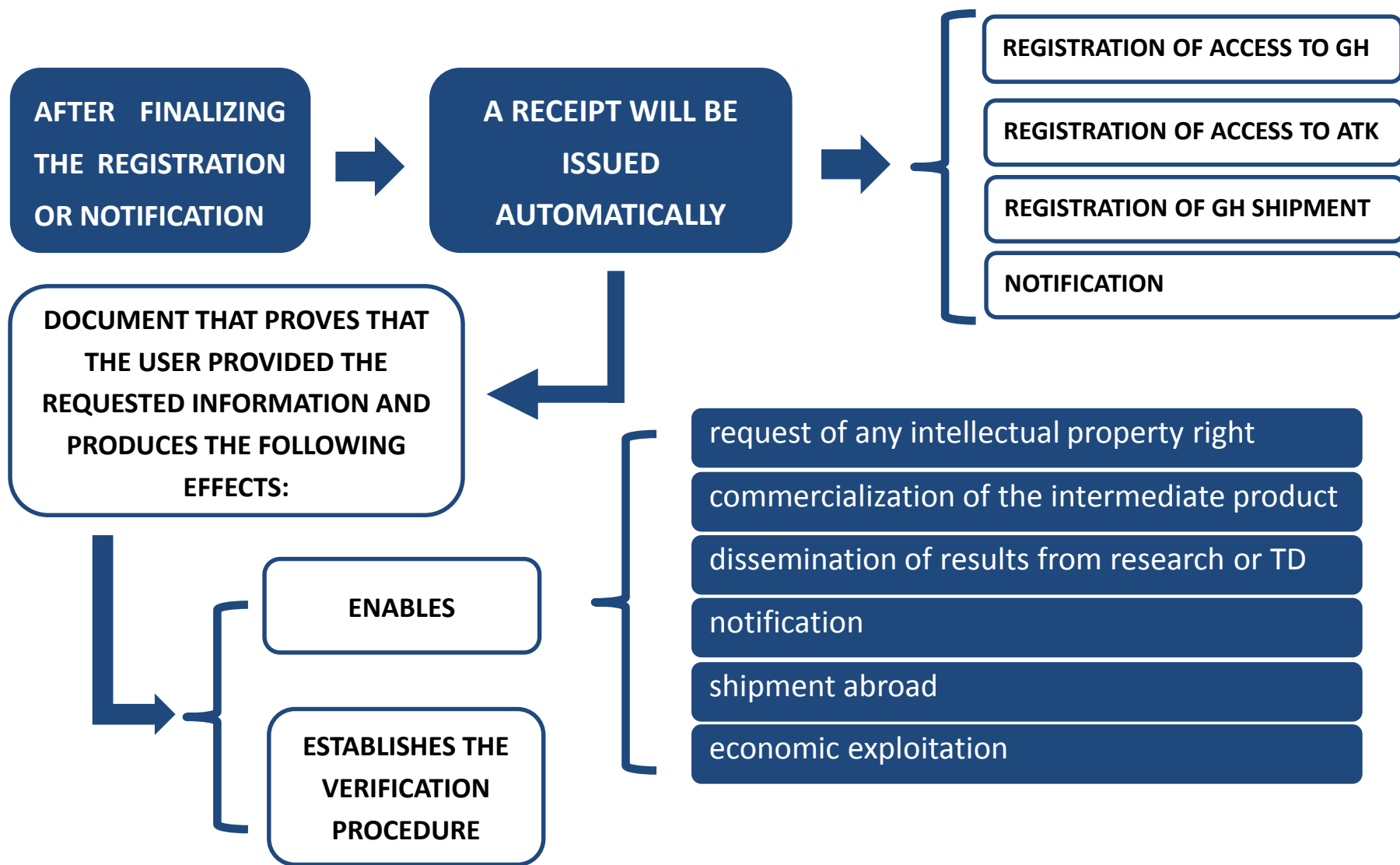
ELECTRONIC SYSTEM FOR REGISTRATION AND NOTIFICATION



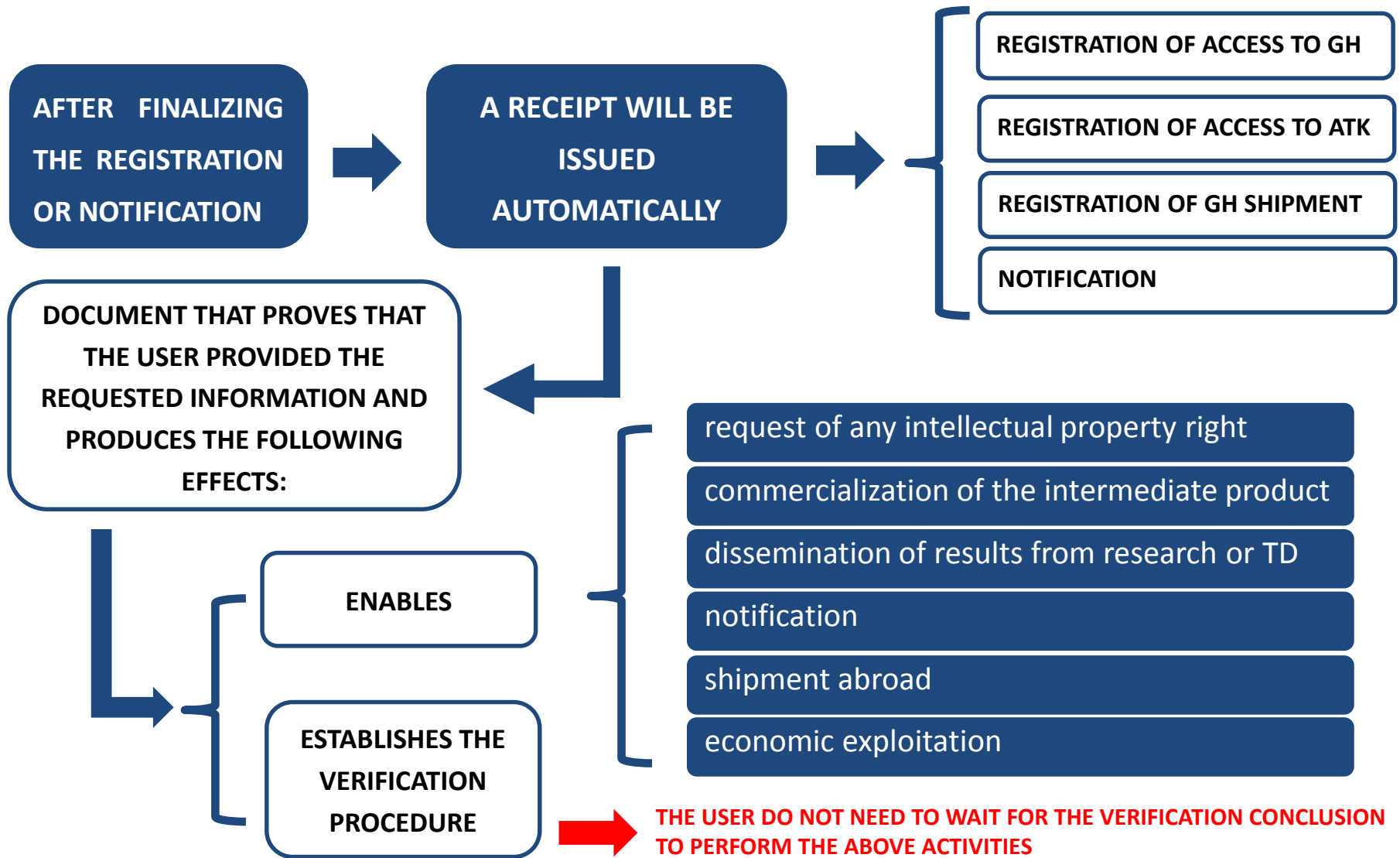
ELECTRONIC SYSTEM FOR REGISTRATION AND NOTIFICATION



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REGULARIZATION REGARDING THE PROVISIONAL MEASURE 2.186/2001



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

TECHNOLOGICAL DEVELOPMENT

100% exemption from fine payment

The regularization is conditional upon signature of a commitment term, but only for development. In the case of research, the user will be regularized by means of registration



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RESEARCH

TECHNOLOGICAL DEVELOPMENT

100% exemption from fine payment

**THE PERIOD FOR REGULARIZATION IS ONE YEAR AFTER THE ELECTRONIC SYSTEM IS
MADE AVAILABLE**



ADMINISTRATIVE INFRINGEMENTS AND THEIR PENALTIES

Administrative infractions against the genetic heritage or associated traditional knowledge are **any action or omission that violates the norms of the Law**

Administrative offenses shall be punishable by the following penalties:

- Warning
- 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
- Apprehension
- Temporary suspension of the manufacture and sale of the product





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- ACCESS TO INFORMATION

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

Access to genetic resources and associated traditional knowledge

- Biodiversity Law
- Fiocruz and Law 13.123
- Nagoya Protocol



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

The Law and Fiocruz

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

Biological Collections



Audio-visual (Portuguese)

Video of lecture on Brazilian ABS legislation in Ensp/Fiocruz

VPPCB



Know the Vice-Presidency of Research and Biological Collections

News



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

Legislation

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Read More

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- Workshop makes recommendations for exchange of components of Brazilian biodiversity
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THANK YOU!

Manuela da Silva

manuela.dasilva@fiocruz.br

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HEALTH MINISTRY

