Animal Biotech Regulation in Latin America

Pedro J. Rocha S., *Ph.D.*

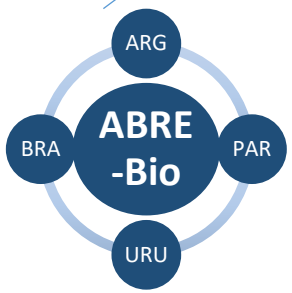
International Specialist in Biotechnology and Biosafety

ISBR-2025; Mon 4: Global Status of Animal Biotech Regulation
Gent, Belgium, 3 November, 2025

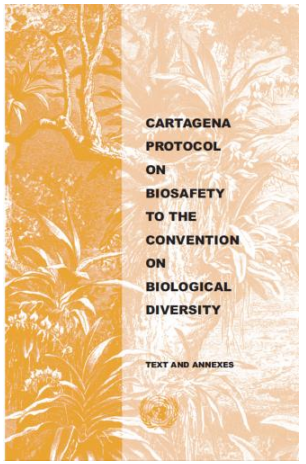
Rules for environmental release of plants and animals generated by different bio-techniques in LATAM

Customs Union Agreement GUA-HON-ESV

Southern Agricultural Council (G5-CAS)



Country	LMOs Rules		GnEd Rules	
	Plants	Animals	Plants	Animals
Mexico	Constitutional			
Belize				
Guatemala				
Honduras				
El Salvador				
Costa Rica				
Panama				
Dominican Republic				
Argentina				
Brasil				
Chile				
Paraguay				
Uruguay				
Bolivia				
Colombia				
Ecuador	Constitutional			
Peru				
Venezuela				



LMOs

"NOVEL COMBINATION OF GENETIC MATERIAL. A stable insertion into the genome of one or more genes or DNA sequences encoding double-stranded DNA, RNA, proteins, or regulatory sequences that could not be obtained by conventional breeding or are not found in nature."

GnEd

- Yes
- No
- Yes– restrictive
- In process
- No rule but decision taken

No “Best” Approach: Different Countries – Different Effective Regulatory Approaches

Heterogeneity recognition

- Differences in existing regulatory structures and legal enabling authorities, as well as different philosophies.
- Different regulatory triggers: **product vs. process** (GMO).
- Oversight by different authorities (ministries):
  - Agriculture, Environment, or Health.

For the development of biotechnology in LATAM, regulatory co-operation seeks harmonize criteria not regulations.

American hemisphere and international commitments

Mega-Biodiverse countries

Economy	Codex[1] (member since)	UPOV[2] (Act – Year of suscription)	CDB (Year of ratification)[3]	PCB (Year of ratification)[3]	PNAPBS (Year of ratification)[3]	PSNKL (Year of ratification)[3]
Argentina	1963	78-1994	1994		2016	
Belize	1992		1993	2004		
Bolivia	1971	78-1999	1994	2002	2016	
Brazil	1968	78-1999	1994	2003	2021	
Canada	1963	91-2015	1993			
Chile	1969	78-1996	1994			
Colombia	1969	78-1996	1994	2003		2020
Costa Rica	1970	91-2009	1994	2007	2024	
Ecuador	1970	78-1997	1993	2003	2017	
El Salvador	1975		1994	2003		
Dominican Republic	1971	91-2007	1996	2006	2014	
Guatemala	1968		1995	2004	2014	
Honduras	1988		1995	2008	2013	
Mexico	1969	78-1997	1993	2002	2012	2012
Nicaragua	1971	78-2001	1995	2002	2020	
Panama	1972	91-2012	1995	2002	2012	
Paraguay	1969	78-1997	1994	2004		
Peru	1963	91-2011	1993	2004	2014	2022
United States	1963	91-1999				
Uruguay	1970	78-1994	1993	2011	2014	
Venezuela	1969		1994	2002	2018	2018

[1] According to *List of Codex members* . 189 members (http://www.fao.org/fao-who-codexalimentarius/about-codex/members/en/)

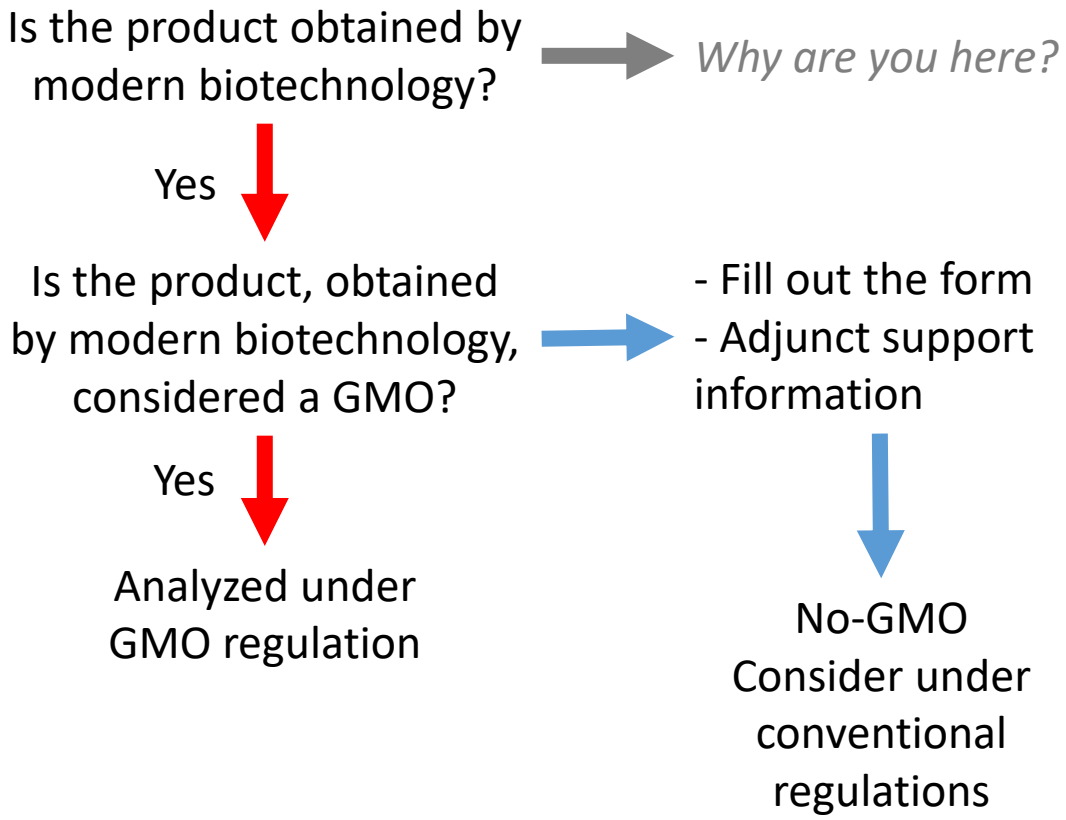
[2] According to the International Union for the Protection of New Varieties of Plants, as of November 01, 2021, there were 77 members, which subscribe to some of the acts of 1961, 1972, 1978 or 1991. (https://www.upov.int/edocs/pubdocs/es/upov_pub_423.pdf)

[3] According to the Secretariat of the Convention on Biological Diversity (CBD), as of Feb 10, 2022, there were 196 parties to the CBD; 173 parties to the CPB, 142 parties to the PNAPBS and 54 parties to the PSNKL. (https://www.cbd.int/information/parties.shtml)

Biotech Regulation in LATAM

- Regulation:
  - Promote the safe use of the technology.
  - Case-by-case evaluation.
  - **Similar concerns**:
    - How to ensure the veracity of the information presented?
    - How to be transparent with the public but maintaining confidentiality?
    - How to avoid duplicative efforts (same information, same applicant, same criteria, same analysis in different systems)
  - Inquire about transgenic nature of the product.
  - **No need for a new category** (LMO or conventional).
  - Consultation process for GnEd products.

Consultation process for GnEd



Approved biotech animals in selected countries of LATAM

(In process)

Country	GM animal currently produced	GnEd animal currently produced
Argentina	**0 animals** / 112 plants / 22 microrganisms	**20 animals** / 57 plants / 4 microorganisms
Brazil	**Aquabounty GM salmon; Oxytec GM mosquito**	Higher yield tilapia Nelore bull myostatin, Holstein SLICK PRRS Pig, Mosquitoes, etc (vicit CTNBio page)
Colombia	0	**1 Porcine Reproductive and Respiratory Syndrome (PRRS) Resistant Pig**
Dominican Republic	0	**1 PRRS Resistant Pig**

Additional information in ISBR-2025

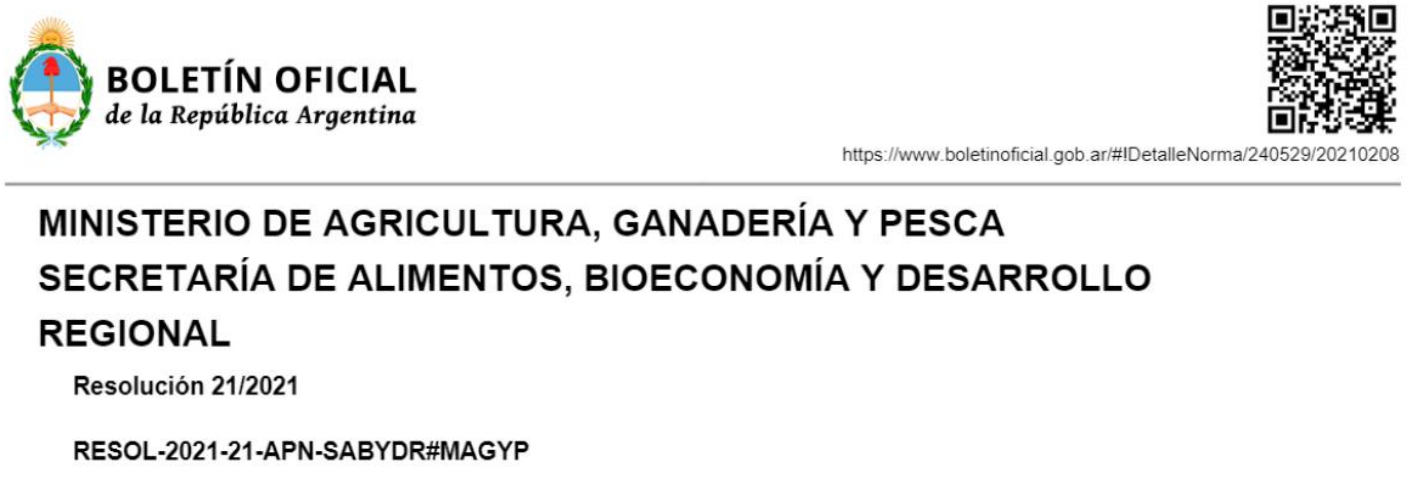
ARG: Andrés Maggi, Facundo Simeone, Mariana Murrone

BRA: Luiz Sergio De Almeida Camargo, CTNBio: http://ctnbio.mctic.gov.br/

COL: Yenny Pinilla

Argentina

- Resolution 36-2019 / Res. 173, 2015 / **Res. 21-2021**
- Establishes the procedures for determining when a product obtained by NBT is (or not) covered by Resolution 763/2011.
- For a genetic change to be considered a new combination of genetic material, it will be analyzed whether there has been a stable insertion into the genome of one (1) or more genes or DNA sequences that are part of a defined genetic construct.



BOLETÍN OFICIAL
de la República Argentina

https://www.boletinoficial.gob.ar/#IDetalleNorma/240529/20210208

MINISTERIO DE AGRICULTURA, GANADERÍA Y PESCA
SECRETARÍA DE ALIMENTOS, BIOECONOMÍA Y DESARROLLO REGIONAL

Resolución 21/2021

RESOL-2021-21-APN-SABYDR#MAGYP

Ciudad de Buenos Aires, 04/02/2021

VISTO el Expediente N° EX-2020-72811589- -APN-DGD#MAGYP del Registro del MINISTERIO DE AGRICULTURA, GANADERÍA Y PESCA, y

CONSIDERANDO:

Brazil

DIÁRIO OFICIAL DA UNIÃO

Publicado em: 22/01/2018 | Edição: 15 | Seção: 1 | Página: 2-8
Órgão: Ministério da Ciência, Tecnologia, Inovações e Comunicações / Comissão Técnica Nacional de Biossegurança

RESOLUÇÃO NORMATIVA Nº 16,.DE 15 DE JANEIRO DE 2018

ANEXO I

Estabelece os requisitos técnicos para apresentação de consulta à CTNBio sobre as Técnicas Inovadoras de Melhoramento de Precisão

I. In relation to original organism (Parentals), indicate:

1. identification of the genetic technology, purpose and intended use of the resultant organism and its derivatives;
2. taxonomic classification, from family to the most detailed level of the organism to be released, including when appropriate, subspecies, cultivar, pathovar, strain and serotype;
3. the classification of risk of genetically modified organism, according to the Normative Resolution No. 2, of November 27, 2006;
4. the gene(s) and/or manipulated genetic element(s), organism(s) of origin and their specific functions, where applicable;
5. the genetic strategy(ies) used to produce the modification(ions) desired; the genetic map(s) of the constructs used in the process, indicating all the genetic elements present;
6. molecular characterization of the result of the manipulation in the recipient organism (parental and final product), where applicable, providing information related to:
(a) number of copies manipulated (e.g. number of genomic sequences, number of alleles, etc.);
(b) location of the manipulated region in the genome, when possible; and
(c) identification of the presence of off-target genetic modifications, if any;
7. the product of expression of the genomic region(s) manipulated, described in detail, when applicable.

II. In relation to the product (descent, line or final product), state:

1. evidence of the absence of recombinant DNA/RNA molecules through the use of molecular methods;
2. if the product containing DNA/RNA molecules for topical/systemic use has recombinant ability to insert into the target species and/or into non-target species;
4. whether the product referred to in the submission has been commercially approved in other countries;
5. if the product uses the principle of gene drive that may enable the phenotypic change conferred to be potentially disseminated throughout the recipient organism's population. In this case, explain the care to monitor the organism, using at least two different strategies; e
6. how the possibility of any off-target effects of the technology that may be present in the product was evaluated.

NATIONAL BIOSAFETY TECHNICAL COMMISSION

NORMATIVE RESOLUTION No. 16, OF JANUARY 15, 2018

Sets forth the technical requirements for submitting an inquiry to the CTNBio concerning Precision Breeding Innovation Techniques (PBI).

THE NATIONAL BIOSAFETY TECHNICAL COMMISSION (CTNBio), using its legal and regulatory powers and in observance of sections XV and XVI of article 14 of Law No. 11.105 of March 24, 2005;

Whereas there is a need to assess Precision Breeding Innovation (PBI) techniques, which also comprise the so-called New Breeding Technologies (NBTs) in the light of Law No. 11.105 of March 24, 2005;

Whereas Law No. 11.105, of 2005 defines recombinant DNA/RNA molecules, genetic engineering, and genetically modified organism (GMO) in Article 3, sections III, IV and V, respectively;

Whereas these PBI techniques are based on a set of new methodologies and approaches-that differ from the transgenic genetic engineering strategy that results in the absence of recombinant DNA/RNA in the final product;

Whereas the PBI techniques can introduce innovative uses of molecular biology tools, which can result in:

1. Precise edition of genomes, by the induction of specific mutations, generating or modifying wild and/or mutated alleles without insertion of transgene(s);

2. Genetic transformation and/or control of gene expression (activation/inactivation);

3. Epigenetic regulation of gene expression by natural mechanisms with no genetic modification in the individual;

4. Genetic transformation and/or control of gene expression with genes of sexually compatible species;

5. Temporary and non-inheritable genetic transformation of cells and tissues;

6. Permanent or non-host infection of genetically modified viral elements;

7. The creation of alleles with autonomous inheritance, and recombination potential with the possibility of altering a whole population (gene drive);

8. The construction of heterologous genes or new copies of homologous genes.

Resolves:

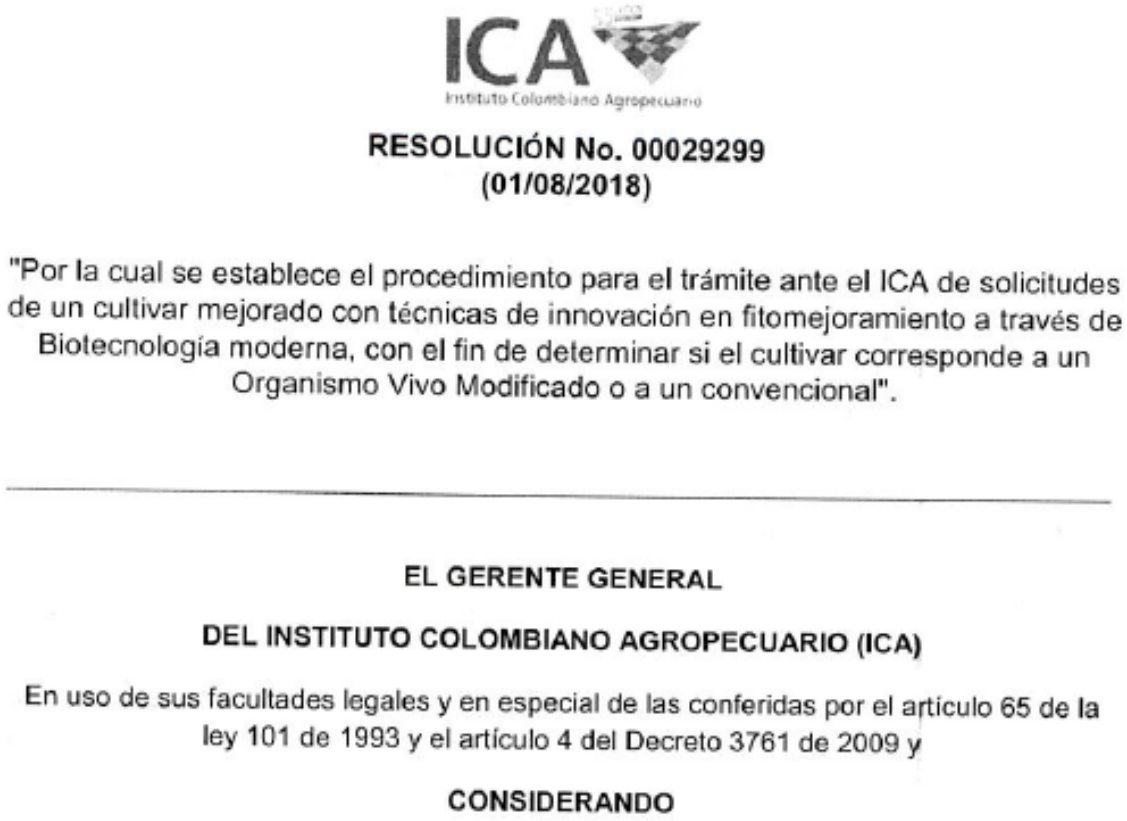
Article 1. The techniques described in Annex I hereto are examples, though not limited, of Precision Breeding Innovation (PBI) techniques that could originate a product that is not considered as a Genetically Modified Organism (GMO) and its derivatives, as per definitions of Law 11.105, of March 24, 2005.

Paragraph 1. The product referred to in the main section of this article is defined as the descent, lineage or final product of a process that uses Precision Breeding Innovation Techniques in one of its phases of development.

Paragraph 2. The cases to be classified are not restricted to the technologies described in Annex I, since the ongoing and fast progress of different technologies will lead to new products, to which the provisions of this Normative Resolution shall also apply.

Colombia

- Resolution 22299
  - It seeks: “To establish the procedure applicable to a cultivar when, in its plant breeding process, in any of its stages, it has used innovative breeding techniques through modern biotechnology and the **final product does not contain foreign genetic material, therefore it will not be considered a GMO**.”
- Summary
  - “NBT-derived crops whose final product does not contain foreign genetic material must comply with the provisions of ICA Resolution 3168 of 2015… when it is a GMO, it must comply with the provisions of Decree 4525 of 2005.”
- **Resolution 22991- 2022**
  - Which **establishes the procedure** for processing applications before the ICA for new products obtained through Innovation in Genetic Breeding in order to **determine** whether they correspond to **GMOs or conventional organisms.**



ICA
Instituto Colombiano Agropecuario

RESOLUCIÓN No. 00029299
(01/08/2018)

"Por la cual se establece el procedimiento para el trámite ante el ICA de solicitudes de un cultivar mejorado con técnicas de innovación en fitomejoramiento a través de Biotecnología moderna, con el fin de determinar si el cultivar corresponde a un Organismo Vivo Modificado o a un convencional".

EL GERENTE GENERAL

DEL INSTITUTO COLOMBIANO AGROPECUARIO (ICA)

En uso de sus facultades legales y en especial de las conferidas por el artículo 65 de la ley 101 de 1993 y el artículo 4 del Decreto 3761 de 2009 y

CONSIDERANDO

2022R00022991

Resolución 22991 de 2022
“Por la cual se establece el procedimiento para el trámite ante el ICA de las solicitudes de nuevos productos obtenidos por Innovación en Mejoramiento Genético, con el fin de determinar si corresponden a Organismos Vivos Modificados (OVM) o a Organismos Convencionales”.

Sub-regional Initiatives

- **Enabling Protocol for the Process of Deep Integration towards the Free Transit of Goods and Natural Persons between Guatemala-Honduras-El Salvador**


REPUBLICA DE EL SALVADOR EN LA AMERICA CENTRAL 1

EL SALVADOR UNÁMONOS PARA CRECER

DIARIO OFICIAL

DIRECTOR: Tito Antonio Bazán Velásquez

TOMO N° 420 | SAN SALVADOR, MARTES 7 DE AGOSTO DE 2018 | NUMERO 143

Decree 58-2018, published in Vol 420, 7 August 2018

RT 65.06.01:18 Technical Regulations for the Biosafety of Living Modified Organisms for Agricultural and Livestock Use

Resolution Ministerial Instance AU No 60-2019

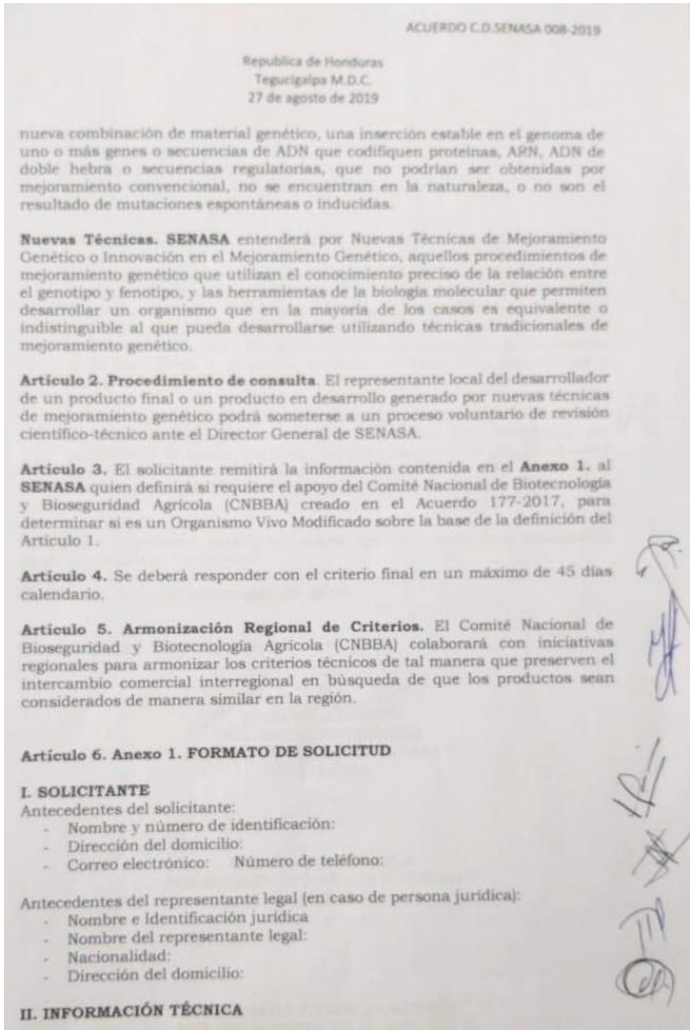
3. DOCUMENTOS A CONSULTAR

Para la correcta interpretación y aplicación del presente Reglamento Técnico se deben consultar los siguientes documentos:

3.1. Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convenio sobre la Diversidad Biológica.

3.2. *Codex Alimentarius.*

Honduras



ACUERDO C.D.SENASA 008-2019

Republica de Honduras
Tegucigalpa M.D.C.
27 de agosto de 2019

nueva combinación de material genético, una inserción estable en el genoma de uno o más genes o secuencias de ADN que codifiquen proteínas, ARN, ADN de doble hebra o secuencias regulatorias, que no podrían ser obtenidas por mejoramiento convencional, no se encuentran en la naturaleza, o no son el resultado de mutaciones espontáneas o inducidas.

Nuevas Técnicas. SENASA entenderá por Nuevas Técnicas de Mejoramiento Genético o Innovación en el Mejoramiento Genético, aquellos procedimientos de mejoramiento genético que utilizan el conocimiento preciso de la relación entre el genotipo y fenotipo, y las herramientas de la biología molecular que permiten desarrollar un organismo que en la mayoría de los casos es equivalente o indistinguible al que pueda desarrollarse utilizando técnicas tradicionales de mejoramiento genético.

Artículo 2. Procedimiento de consulta. El representante local del desarrollador de un producto final o un producto en desarrollo generado por nuevas técnicas de mejoramiento genético podrá someterse a un proceso voluntario de revisión científico-técnico ante el Director General de SENASA.

Artículo 3. El solicitante remitirá la información contenida en el **Anexo 1.** al **SENASA** quien definirá si requiere el apoyo del Comité Nacional de Biotecnología y Bioseguridad Agrícola (CNBBA) creado en el Acuerdo 177-2017, para determinar si es un Organismo Vivo Modificado sobre la base de la definición del Artículo 1.

Artículo 4. Se deberá responder con el criterio final en un máximo de 45 días calendario.

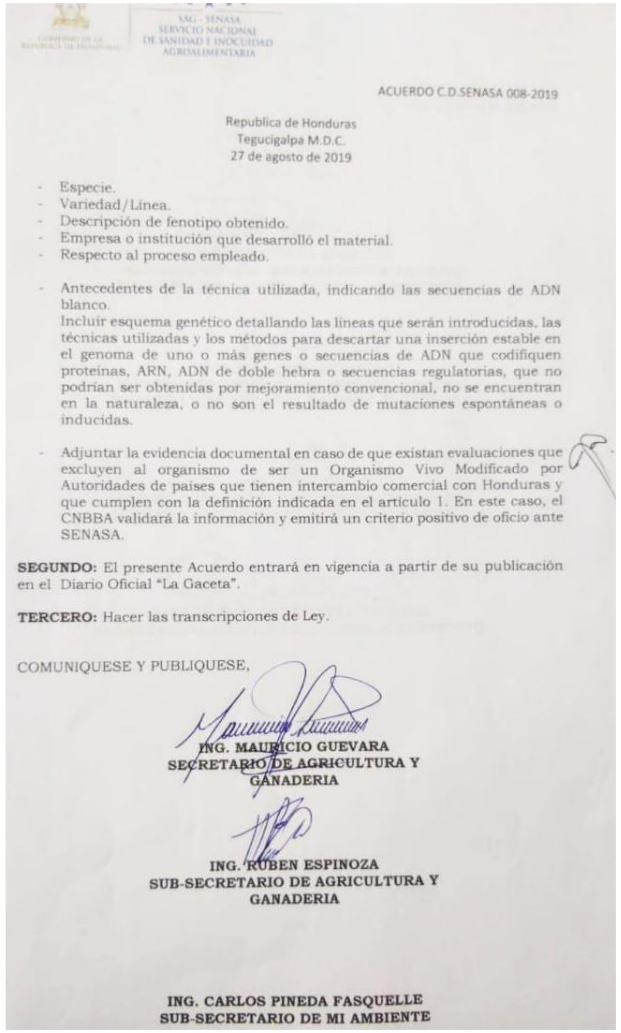
Artículo 5. Armonización Regional de Criterios. El Comité Nacional de Bioseguridad y Biotecnología Agrícola (CNBBA) colaborará con iniciativas regionales para armonizar los criterios técnicos de tal manera que preserven el intercambio comercial interregional en búsqueda de que los productos sean considerados de manera similar en la región.

Artículo 6. Anexo 1. FORMATO DE SOLICITUD

I. SOLICITANTE
Antecedentes del solicitante:
- Nombre y número de identificación:
- Dirección del domicilio:
- Correo electrónico: Número de teléfono:

Antecedentes del representante legal (en caso de persona jurídica):
- Nombre e Identificación jurídica
- Nombre del representante legal:
- Nacionalidad:
- Dirección del domicilio:

II. INFORMACIÓN TÉCNICA



SAG - SENASA
SERVICIO NACIONAL DE SANIDAD E INOCUIDAD AGROALIMENTARIA

ACUERDO C.D.SENASA 008-2019

Republica de Honduras
Tegucigalpa M.D.C.
27 de agosto de 2019

- Especie.
- Variedad/Línea.
- Descripción de fenotipo obtenido.
- Empresa o institución que desarrolló el material.
- Respecto al proceso empleado.

- Antecedentes de la técnica utilizada, indicando las secuencias de ADN blanco.
  Incluir esquema genético detallando las líneas que serán introducidas, las técnicas utilizadas y los métodos para descartar una inserción estable en el genoma de uno o más genes o secuencias de ADN que codifiquen proteínas, ARN, ADN de doble hebra o secuencias regulatorias, que no podrían ser obtenidas por mejoramiento convencional, no se encuentran en la naturaleza, o no son el resultado de mutaciones espontáneas o inducidas.

- Adjuntar la evidencia documental en caso de que existan evaluaciones que excluyen al organismo de ser un Organismo Vivo Modificado por Autoridades de países que tienen intercambio comercial con Honduras y que cumplen con la definición indicada en el artículo 1. En este caso, el CNBBA validará la información y emitirá un criterio positivo de oficio ante SENASA.

SEGUNDO: El presente Acuerdo entrará en vigencia a partir de su publicación en el Diario Oficial "La Gaceta".

TERCERO: Hacer las transcripciones de Ley.

COMUNIQUESE Y PUBLIQUESE,

ING. MAURICIO GUEVARA
SECRETARIO DE AGRICULTURA Y GANADERIA

ING. RUBEN ESPINOZA
SUB-SECRETARIO DE AGRICULTURA Y GANADERIA

ING. CARLOS PINEDA FASQUELLE
SUB-SECRETARIO DE MI AMBIENTE

Year of approval	Company	Crop	Event	Approval	Use
2002	Monsanto	Corn	MON 810 + NK 603	C	
2010	Pioneer	Corn	TC 1507	C	
2011	Bayer	Rice	LLRice 62	C	
2012	Monsanto	Corn	MON 89034	C	
2013	Monsanto	Corn	MON 88017	C	
2013	Monsanto	Corn	MON 89034 + MON 88017	C	
2015	Dow	Corn	MON 89034 + NK 603 + TC 1507	C	
2020	Syngenta	Corn	SYN BT11 x MIR 162 x GA21, Agrisure ® VIP3	C	
2022	Tropic Biosciences	**Banana**	GnEd: Non Browning Cavendish Banana	E	
2022	Tropic Biosciences	**Banana**	GnEd: Non Browning Cavendish Banana	C	
2022	Tropic Biosciences	**Banana**	GnEd: Extended Shelf Life	E	
2022	Standard Fruit Company	**Banana**	GnEd: Resistant to fusarium race 4	E	
2022	Pairwise	**Mustard Green**	GnEd: Improved flavor profile	C	
2024	Dole/Elo Life Systems	**Banana**	GnEd: Banana with reduce oxidation	C	
2024	Dole/Elo Lyfe Systems	**Banana**	Banana resistant to fusarium race 4	C	
2024	Bayer	Corn	Transgenic Corn	E	
2024	Dole/Elo Lyfe Systems	Banana	GM: resistant to Fusarium Race 4	E	
2024	Dole/Elo Lyfe Systems	**Banana**	GnEd: Bananas (GMO/Conventional)	E	

Additional information in ISBR-2025: Roger Orellana

Adapted from: GAIN-USDA, 2024. *Agricultural Biotechnology Annual Report*. Honduras. Rep. No. HO2024-0008, 16pp.
https://www.fas.usda.gov/data/honduras-agricultural-biotechnology-annual-10

Sub-regional Initiatives

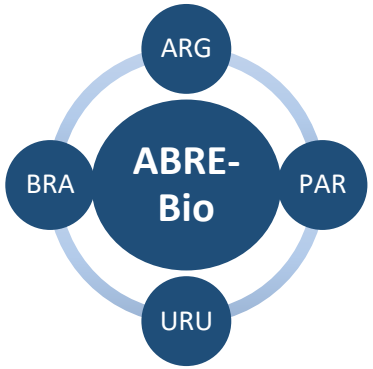
- **ABRE-Bio (URU-PAR-BRA-ARG):**
  - International Network of Biosafety Agencies for Biotechnology (12 June, 2023).

Objectives

- Promote the **exchange** of scientific information and **cooperation** in:
  - Risk assessment of LMOs and determination of the regulatory status of GnEd products.
- Develop **common criteria** for biosafety assessment while **preserving their sovereign regulatory frameworks** and **respecting specific legislations**.
  - **Reduce time, costs and eventual asynchrony of approved events**.
  - Share/disseminate best regulatory practices and experiences.
- **Foster innovation** in agriculture, livestock, and fisheries to address local challenges.

Governance

- Rotating secretariat/coordination (URU-2025).
- National focal points, every two months meetings.
- **Reciprocity analysis**.

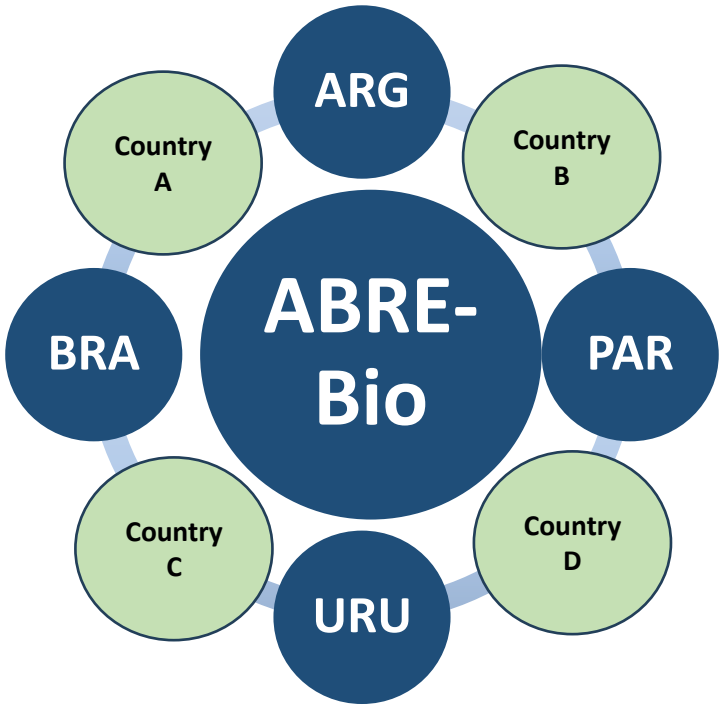


Sub-regional Initiatives

LMO final decision	Authority	Government Ministry	Final decision making authority
Argentina	SAGYP	Ministerio de Economía	SAGYP
Brasil	CTNBio	MCTI	CTNBio CNBS (when requested)
Paraguay	MAG	MAG	MAG
Uruguay	GNBio	SNB (MGAP, MIEM, MA, MEF, MRREE)	GNBio

GnEd analysis	Authority	Government Ministry	Final decision making authority
Argentina	CONABIA-CIyB (SAGYP)	Ministerio de Economía	CONABIA
Brasil	CTNBio	MCTI	CTNBio CNBS (when requested)
Paraguay	CONBIO	MAG	MAG
Uruguay	GTT	MGAP y MA	DIGEBIA - MGAP

LMO analysis	ERA	Food safety	Socioeconomic
Argentina	CONABIA-CIyB SAGYP Min. de Economía	SENASA SAGYP Min. de Economía	MERCADOS SAGYP Min. de Economía
Brasil	CTNBio - MCTI	CTNBio - MCTI	CNBS
Paraguay	MADES - miembros CONBIO	INAN / FACEN - miembros CONBIO	MIC - miembros CONBIO
Uruguay	ERB - SNB	ERB - SNB	OPYPA - MGAP



Additional information in ISBR-2025

ARG: Perla Godoy, Andrés Frankow, Facundo Simeone.

PAR: Danilo Fernández.

URU: Alejandra Ferenczi, Ma Lucía Zeballos.

Information kindly shared by Alejandra Ferenczi (URU, 2025)

Final Remarks

Key actions:

- Carry out regular **in-person training** for biosafety regulators.
- **Focus on case studies** rather than generating new guidance materials.
- **Interaction between regulators** from different agencies and economies generates trust, security, and certainty.

Contact

IICA Headquarters

http://www.iica.int

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E-mail: Pedro.Rocha@iica.int