Regulatory Cooperation in Latin America

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Inter-American Institute for Cooperation on Agriculture

¿What is IICA?

- Specialized agency of the **Inter-American System** for the promotion of agriculture and rural welfare.
  - Established in **October 1942** by USDA Secretary **Henry Wallace**.
  - 33 Member States - Inter-American Board of Agriculture (**IABA**)

What does IICA do in biotechnology?

- Hemispheric program in B&B created in **2006.**
- Independent and timely channel for **exchange of information** on B&B.
- **Joint work** with public agencies, research institutes, universities and private sector in the countries.
- Relevant actions:
  - **Institutional support and strengthening.**
  - **Biosafety training.**
  - **Efficient communication of biotechnology.**

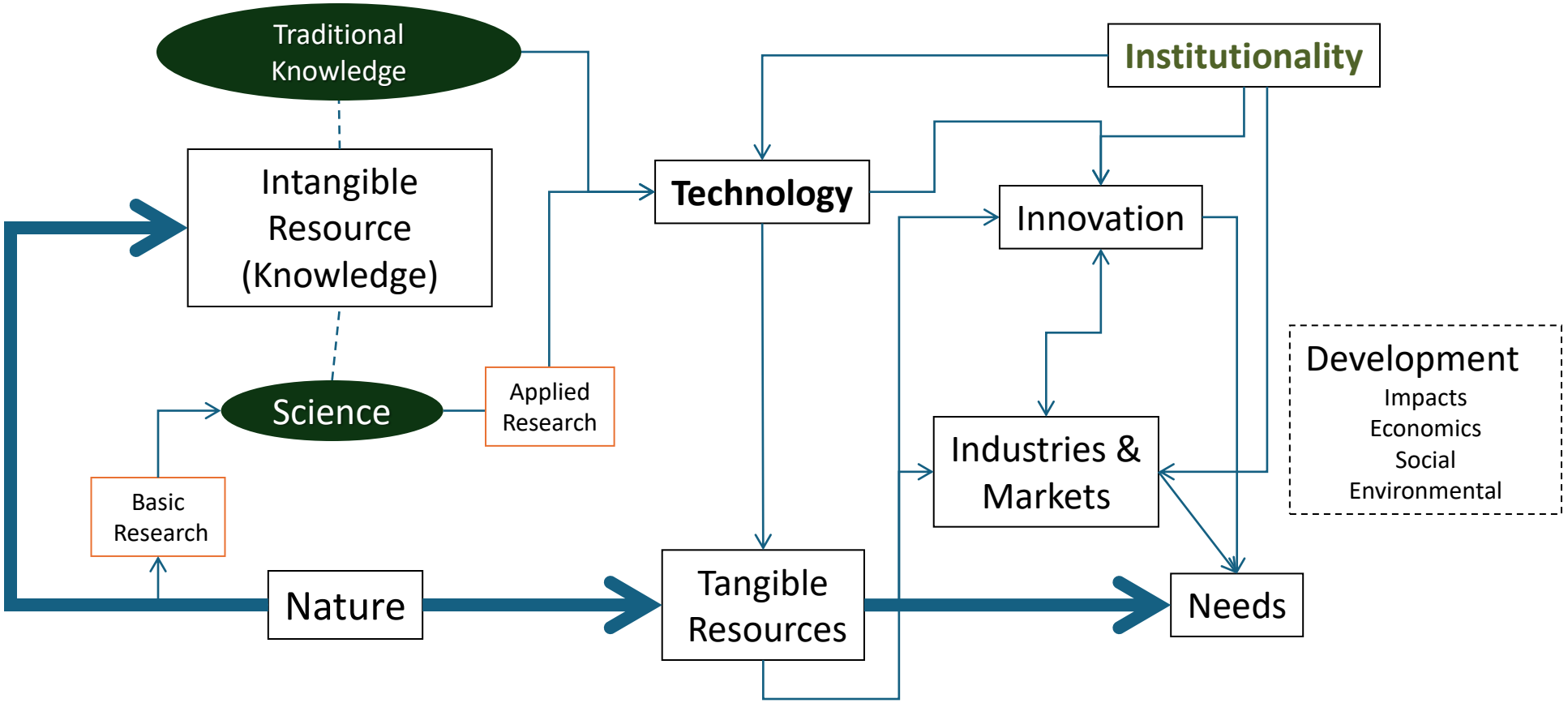
Cooperation

- Cooperation is **fundamental** to life in society and to building the future.

- In biotechnology, IICA cooperates with **different sectors** and establishes **public and private partnerships**.

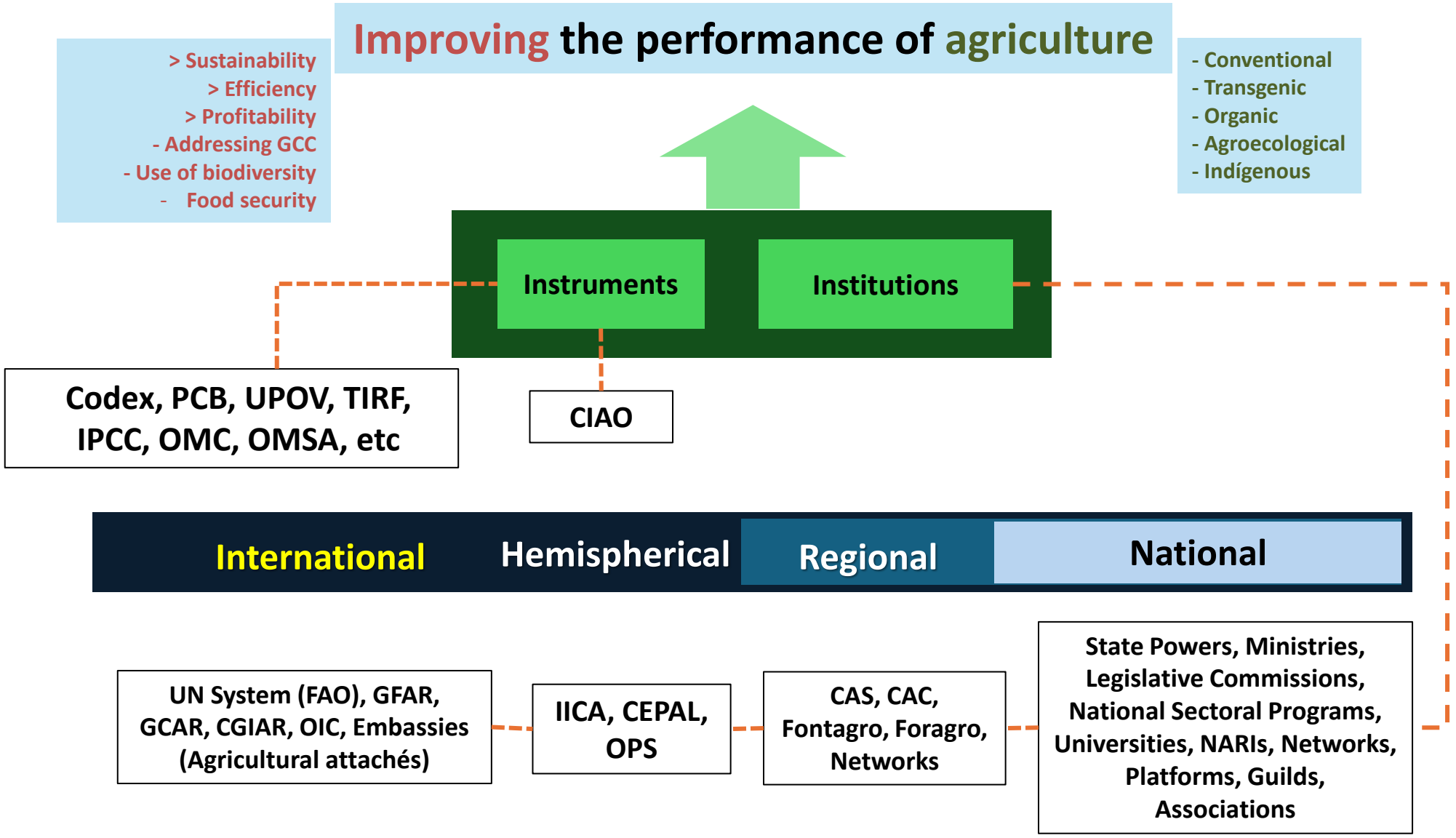
- **Co-operation**
  - Recognizing strengths.
  - Sharing responsibilities.
  - Coordinating work teams.

Science, Technology, Innovation & Institutional Framework



Rocha, 2009

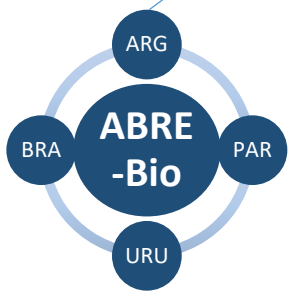
Institutional Framework of the Agricultural Sector in Latin America



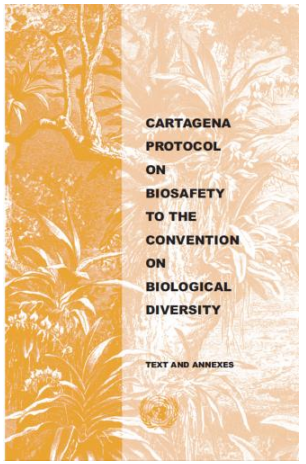
Rules for environmental release of plants and animals generated by different bio-techniques in LATAM

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

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 or policies.

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 promotes the safe use of the technology.

- **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, and same analysis, although under different national regulatory systems, must arrive to the same conclusions)

- **General criteria**:
  - Assessment is in a case by case basis
  - Information, assesment and technical decisions are science-based
  - For the assessment, data quality is essential
  - Risk assessment and comparative analysis are useful tools
  - Use of Cartagena Protocol of Biosafety definitions and Annex III

Definitions

Cartagena Protocol LMO definition

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

Clarifying definition

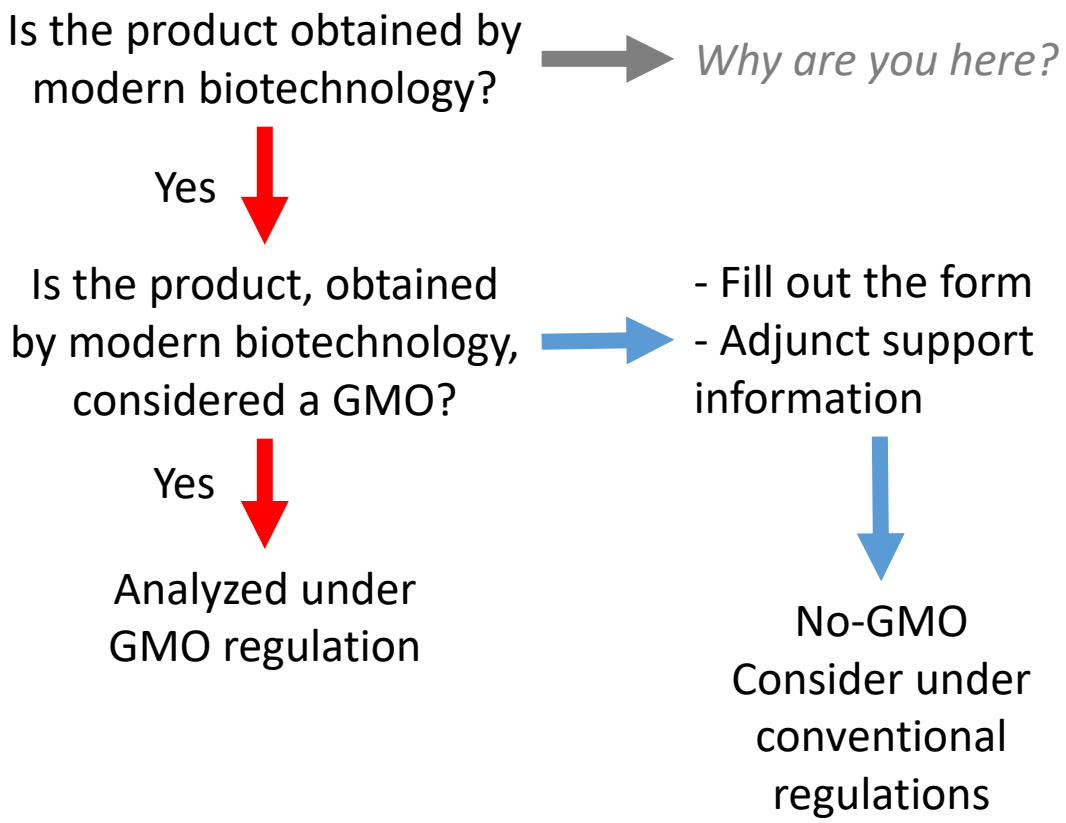
"NEW COMBINATION OF GENETIC MATERIAL. For the purposes of these regulations, **a new combination of genetic material** is understood as **a stable insertion in the genome** of one or more genes or DNA sequences encoding double-stranded DNA, RNA, proteins, or regulatory sequences **that could not be obtained by conventional breeding or are not found in nature**".

Biotech Regulation in LATAM

For GnEd products:

- Assessment inquires about transgenic nature of the product.
- **No need for a new category** (LMO or conventional).
- Introduced a consultation process.

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	**2** **- Porcine Reproductive and Respiratory Syndrome (PRRS) Resistant Pig** **- SLICK cow**
Dominican Republic	0	**1 PRRS Resistant Pig**

Additional information in ISBR-2025

ARG: Andrés Maggi, Facundo Simeone, Mariana Murrone, Perla Godoy

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

COL: Yenny Pinilla

Guatemala-Honduras-El Salvador

Customs Union Agreement between HON-GUA-ESV

Objective

- To allow the free transit of goods and people.

History

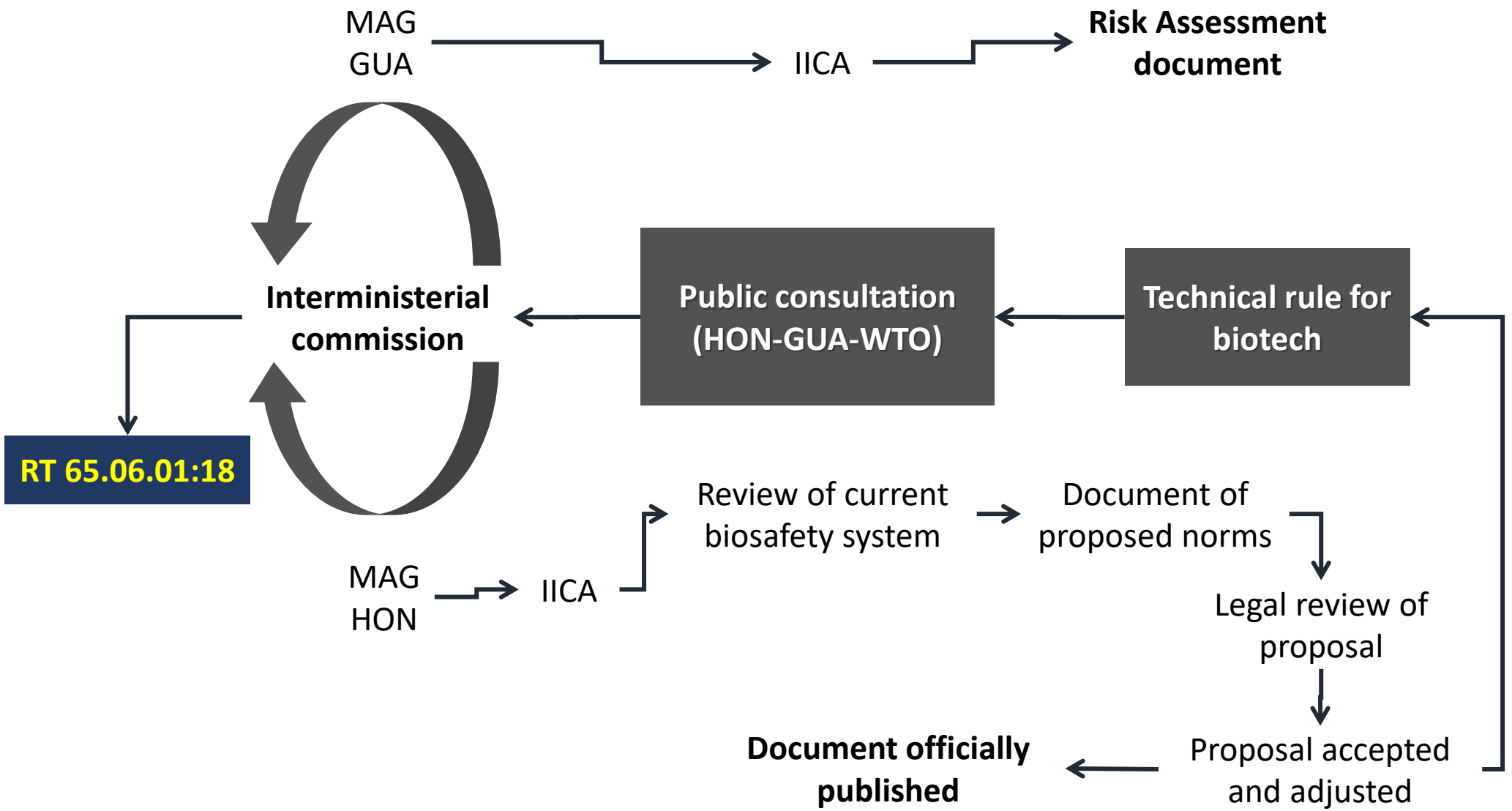
- Process began on 12-Dec.-2007.
- Approved on 26-Feb.-2015.
- ESV adheres to the agreement on 20-Aug.-2018

Situation in 2015

- Honduras grows **GM corn**, Guatemala and El Salvador do not.
- Guatemala is part of the **Mesoamerican center of origin of corn**.
- All three countries are **Parties** of the Cartagena Protocol on Biosafety (CPB).
- Public perception of LMOs is **very sensitive** ranging from very negative to very positive.
- **Technical cooperation** was established on several routes:
  - Guatemala (2015-2019)
  - Honduras (2016-2019)
  - Customs Union (GUA-HON-ESV, 2018-2019)
  - El Salvador (2021-present)

Regulatory cooperation

Bilateral Commission Work



GUA: 2015-07-17
GUA: 2015-09-01
ICABB: 2015-09-18
GUA: 2015-11-18
GUA-HON: 2016-01-21
HON: 2016-06-01
HON: 2017-09-11
HON: 2018-01-10
HON: 2018-02-03
GUA-HON: 2018-03-12/16
GUA-HON: 2018-05-17
GUA-HON: 2018-07/11
GUA-HON: 2018-08-04
HON: 2019-01-16
GUA: 2019-02-11/15
GUA-HON: 2019-03-10/14
GUA-HON: 2019-03-14
GUA-HON: 2019-03-21
GUA: 2019-03-26
HON: 2019-04-15
GUA: 2019-06-01
GUA: 2019-09-20
GUA: 2019-10-02
GUA: 2019-10-08
GUA: 2020-02-19
GUA: 2020-02-24/28
HON: 2021
GUA: 2021-01
GUA: 2021
ESV: 2021-03
ESV: 2021-09
ESV: 2021-12
ESV: 2023-07

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

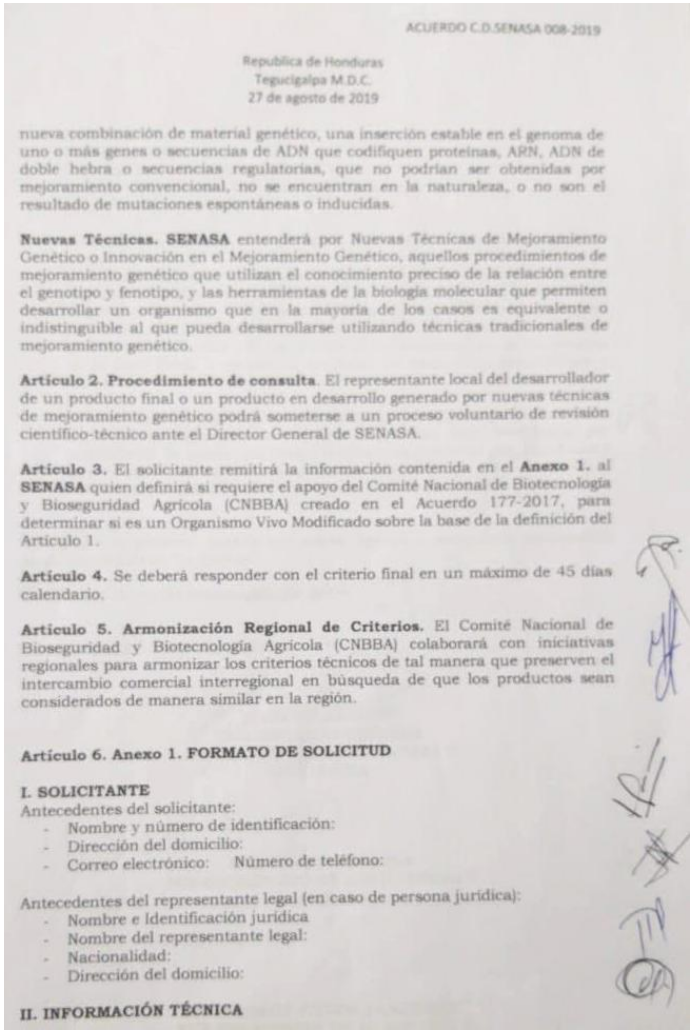
3. **DOCUMENTOS A CONSULTAR**

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.

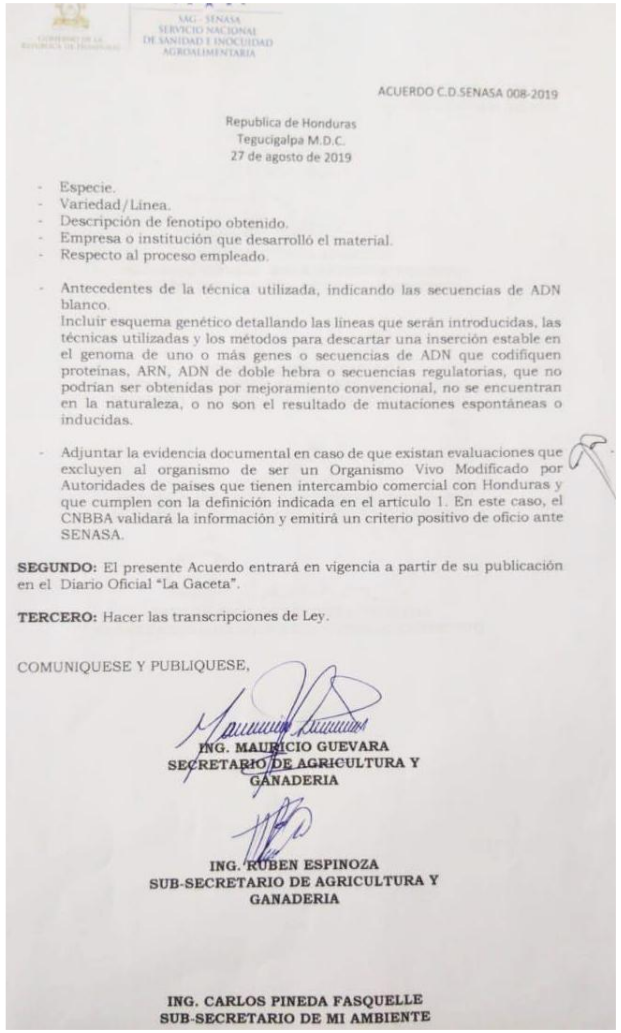
Artículo 5. Armonización Regional de Criterios. El Comité Nacional de Bioseguridad y Biotecnología Agrícola (CNBBA) colaborará con iniciativas regionales para armonizar los criterios técnicos de tal manera que preserven el intercambio comercial interregional en búsqueda de que los productos sean considerados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

Regulatory cooperation between Argentina-Brasil-Paraguay and Uruguay: Long cooperation history with a novel mechanism

Sub-regional Initiatives

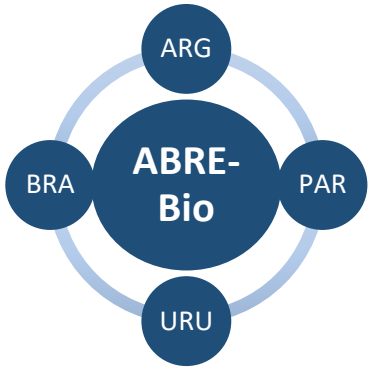
- **ABRE-Bio (URU-PAR-BRA-ARG):**
  - International Network of Biosafety Agencies for Biotechnology (12 June, 2023).

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**.

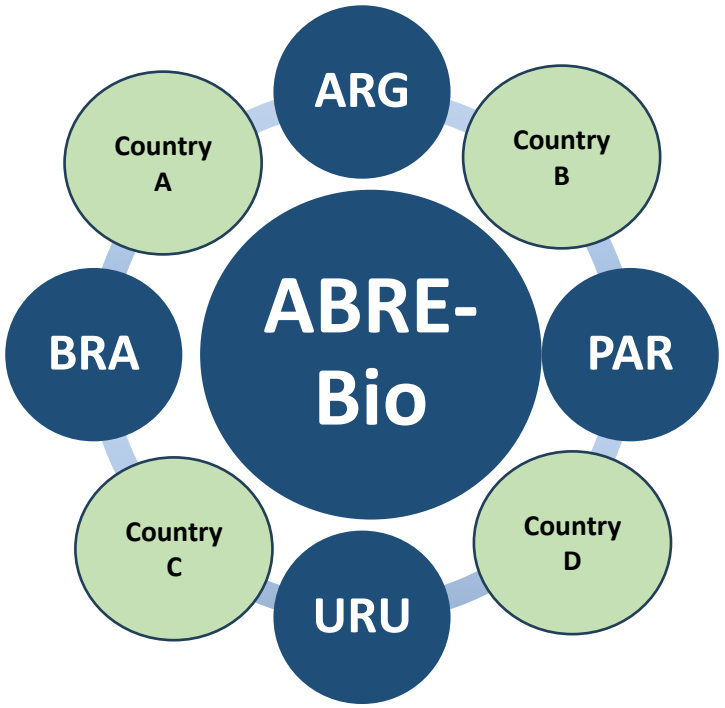


Sub-regional Initiatives

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)

Suggestions / Lessons Learned

- It is urgent to involve the animal regulators in biotech discussions.
  - Who is the national competent authority for animal biosafety assessment?
  - How GM animals fit in the current national legislation?
  - What are the main concerns of animal biotech regulators?
- 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 countries generates trust, security, and certainty.
  - Same for interaction developers-regulators.

https://repositorio.iica.int/items/b285f223-c6cb-4e7b-b73e-efb07cf040b8

Suggestions / Lessons Learned

- **Recognize the political environments is essential and strategic**
  - Currently, **political instability is the rule** for the majority of LATAM countries.
    - Biotech actions must be low-profile in such polarized environments (*e.g*. **BOL, CHL, COL, MEX, NIC, PER, VEN**).
  - It is important to **recognize** the margin- and time-action (COL, GUA, HON, ECU, PER).
    - Politically, biotech is used as a" joker".
  - In some countries, **"wait"** is the best option (BOL, COL, MEX, PER, VEN).
    - The waiting time could be active in terms of offering training outside the country (BOL, ECU, PER).
  - **Biotech leader-countries** must be shown as examples: **ARG, BRA, COL, CRC, HON, PAR, URU.**
  - Political discussion could be more effective if **regional initiatives** (**CAS & CAC**) are involved.

Final Remarks

- In LATAM, there is no “Best” regulatory approach: Different Countries – Different Effective/Functional Regulatory Approaches for both GM and GnEd products.
- Biotech regulations seek: to protect public health & safety, allow production and marketing of safe products, and instill trust in the food supply.
- **General common criteria**: **Case by case/ Science-based/ Data quality/ Comparative analyses / Risk assessment** (technical, robust & transparent).
- There is **no need for creating a new category.** LMO and non-LMO (conventional) are enough.
- Subregional initiatives are useful spaces for technical discussion in polarized political environments.

Contact

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