



Latin American Experience of Regulatory Cooperation

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

International Specialist in Biotechnology and Biosafety

Session 10: How countries make agency decisions and is it possible to harmonize?

4th International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnology

Sao Paulo, 15 September, 2022

Inter-American Institute for Cooperation on Agriculture

¿What is IICA?

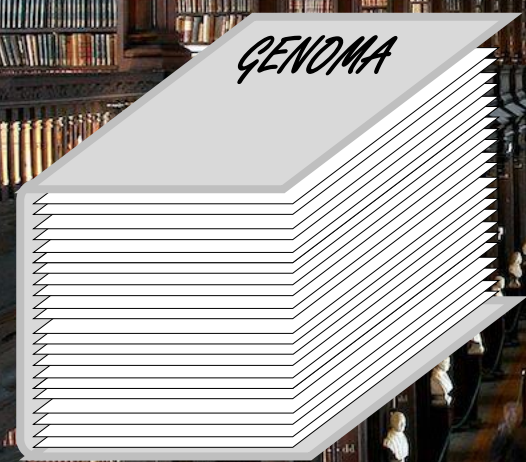
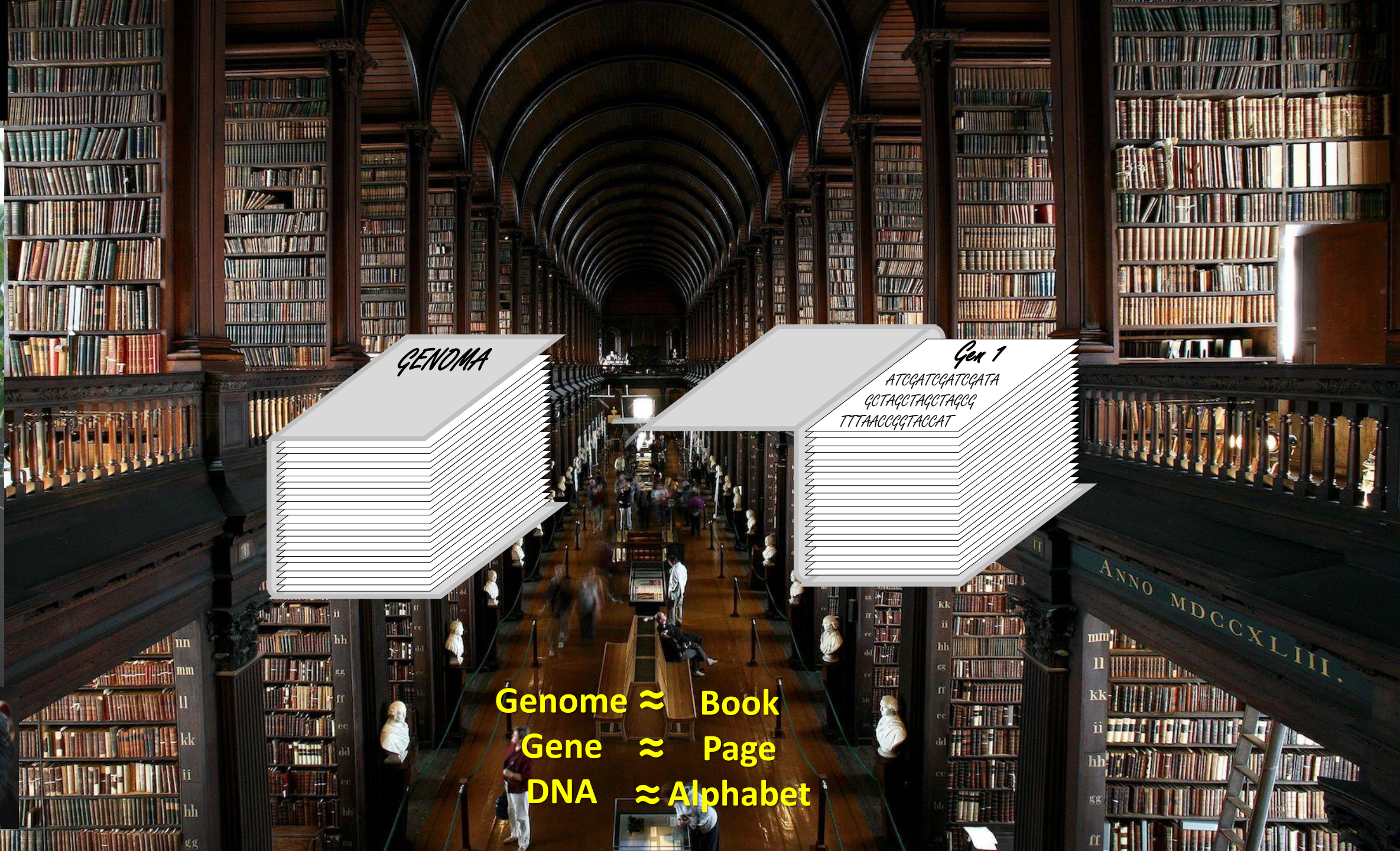
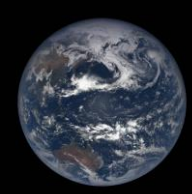
- Specialized agency of the **Inter-American System** for the promotion of agriculture and rural welfare.
 - Established in **October 1942** by USDA Secretary Henry Wallace.
 - 34 Member States - Inter-American Board of Agriculture (**IABA**)

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



1942 - 2022



Genome \approx Book
Gene \approx Page
DNA \approx Alphabet

ANNO MDCCXLIII.

mm
ll
kk
ii
hh
gg

ii
hh
gg
ff
ee
dd
cc
bb
aa

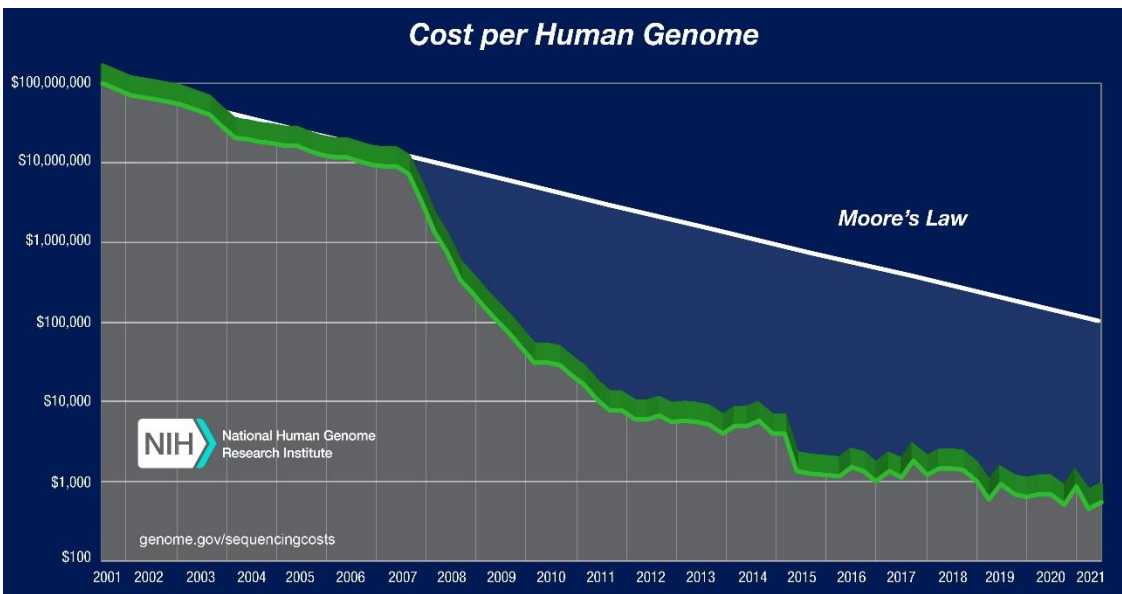
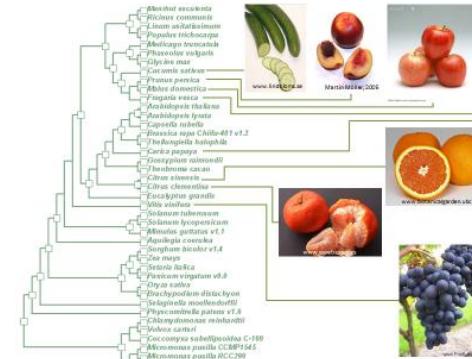
kk
ii
hh
gg
ff
ee
dd
cc
bb

mm
ll
kk
ii
hh
gg
ff

DNA Sequencing reads the books called genomes



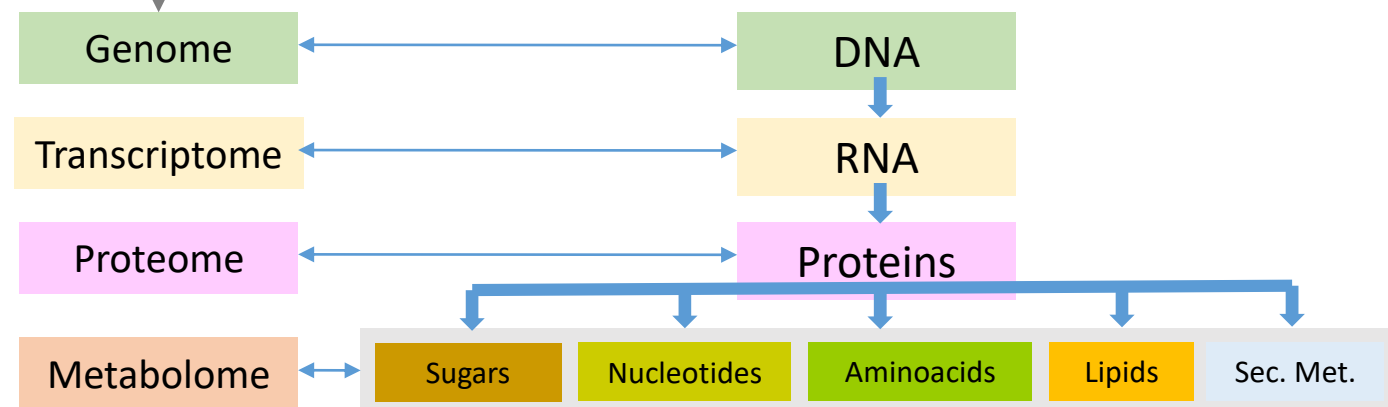
- Highly specialized laboratory technique
- Generates fundamental information for various purposes



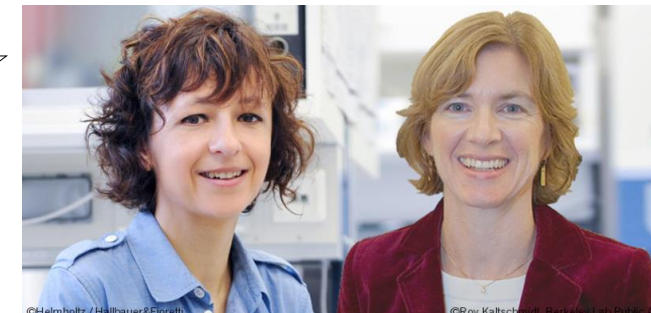
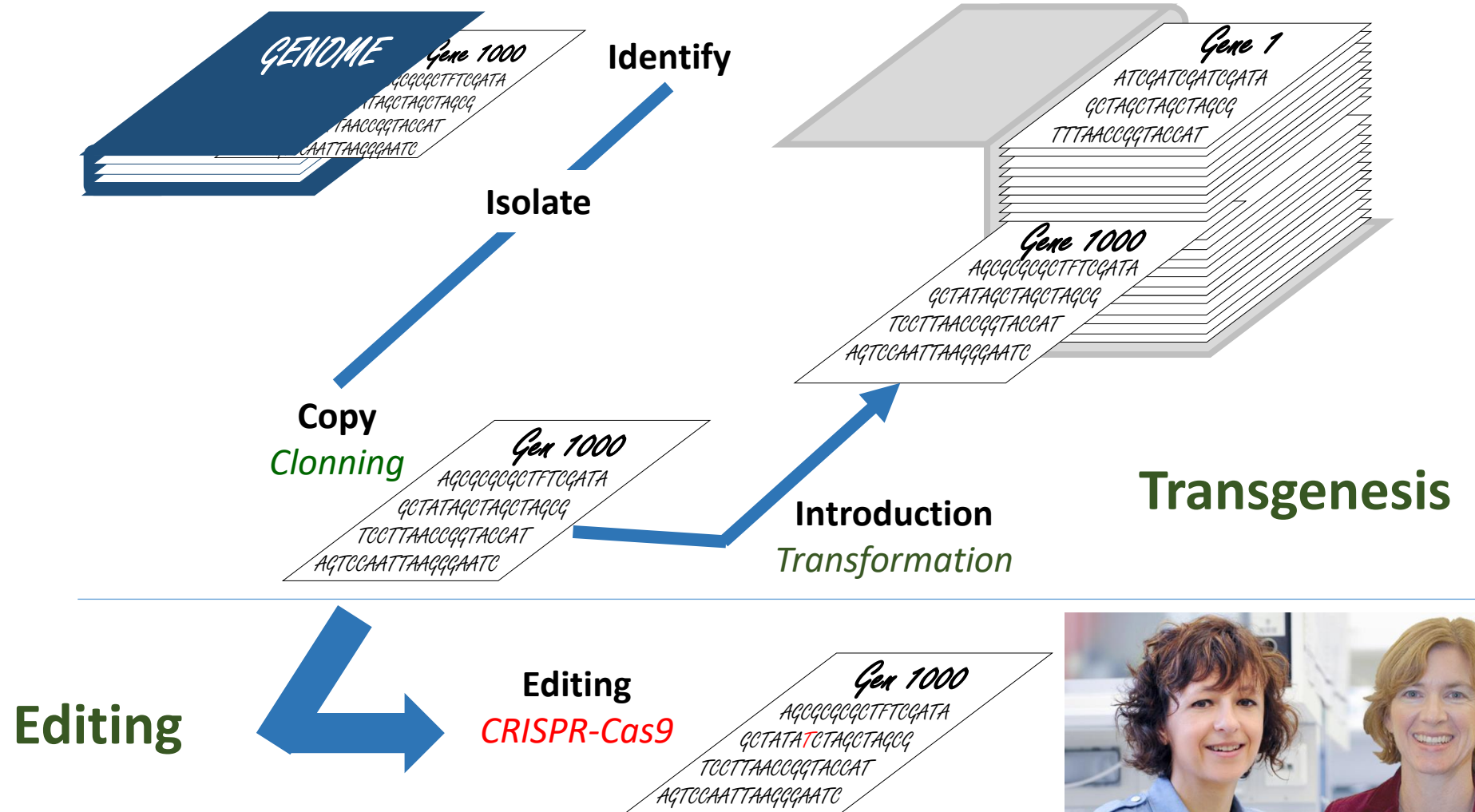
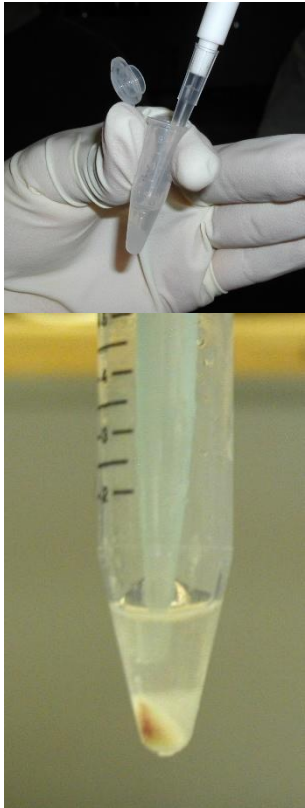
Wetterstrand KA. DNA Sequencing Costs: Data from the NHGRI Genome Sequencing Program www.genome.gov/sequencingcostsdata. Accessed 11/02/2022

Source: <http://www.genomesonline.org>

To 6/09/2022	Number
Organisms	468 058
Projects	485 208



Isolation and manipulation of genes and genomes



Premio Nobel de Química 2020

Genome Editing

- Several techniques have been generated and have given shape to what is known by different names:
 - "genome editing", "gene editing", "genome engineering", "New Breeding Techniques (NBTs)", "Precision Breeding Techniques (PBTs)", or "Precision Breeding Innovations (PBIs), Plant Breeding Innovation (PBI), **Precision Biotechnology (PB)**" **-If there is no consensus on the name, how do you expect to harmonize policies?-**
- **Very precise** techniques, but more **complex to explain** in detail.
- All of these are examples of **genome manipulation** but are **different** from genetic modification based on **transgenesis**. GnEd Products are NON-GMO.

3 yo



10 yo

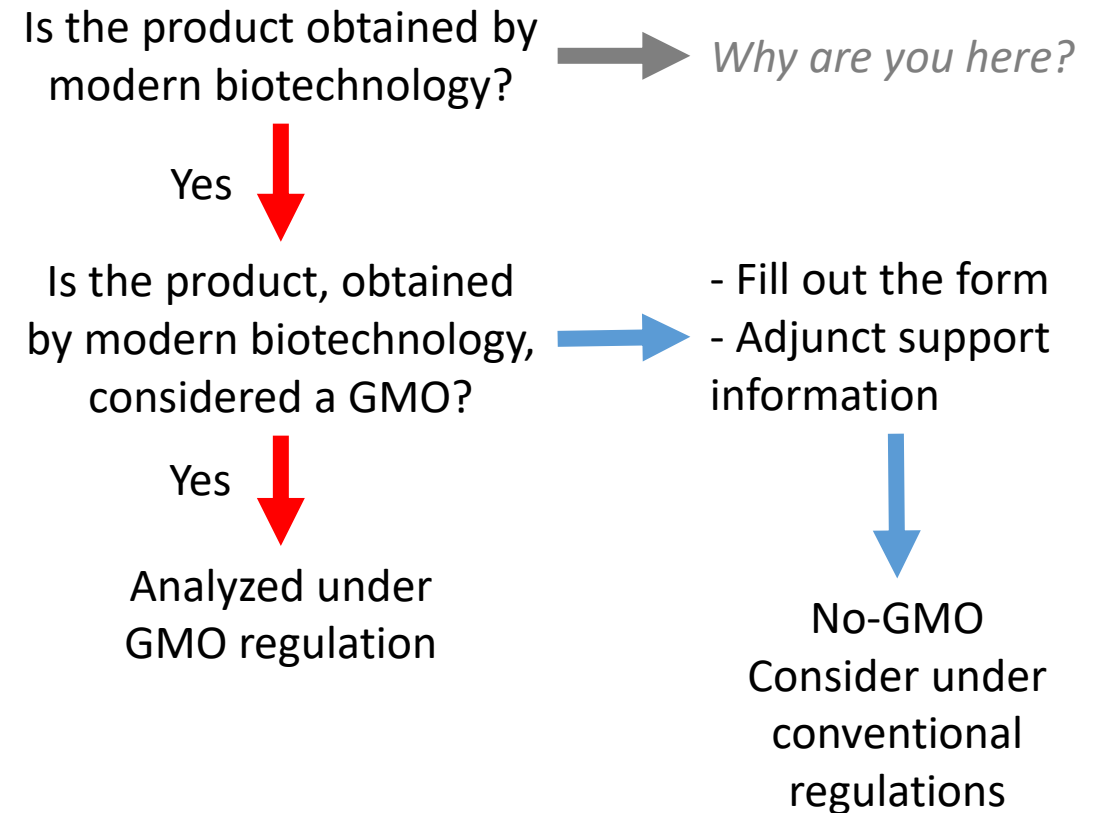


Genome Editing

- Regulation:

- Promote the safe use of the technology
- Case-by-case evaluation (**it is not the risk assessment of CPB**)
- Inquire about their transgenic nature
- **No need for a new category**
- Consultation process

Consultation process



GnEd products are not LMOs

(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;

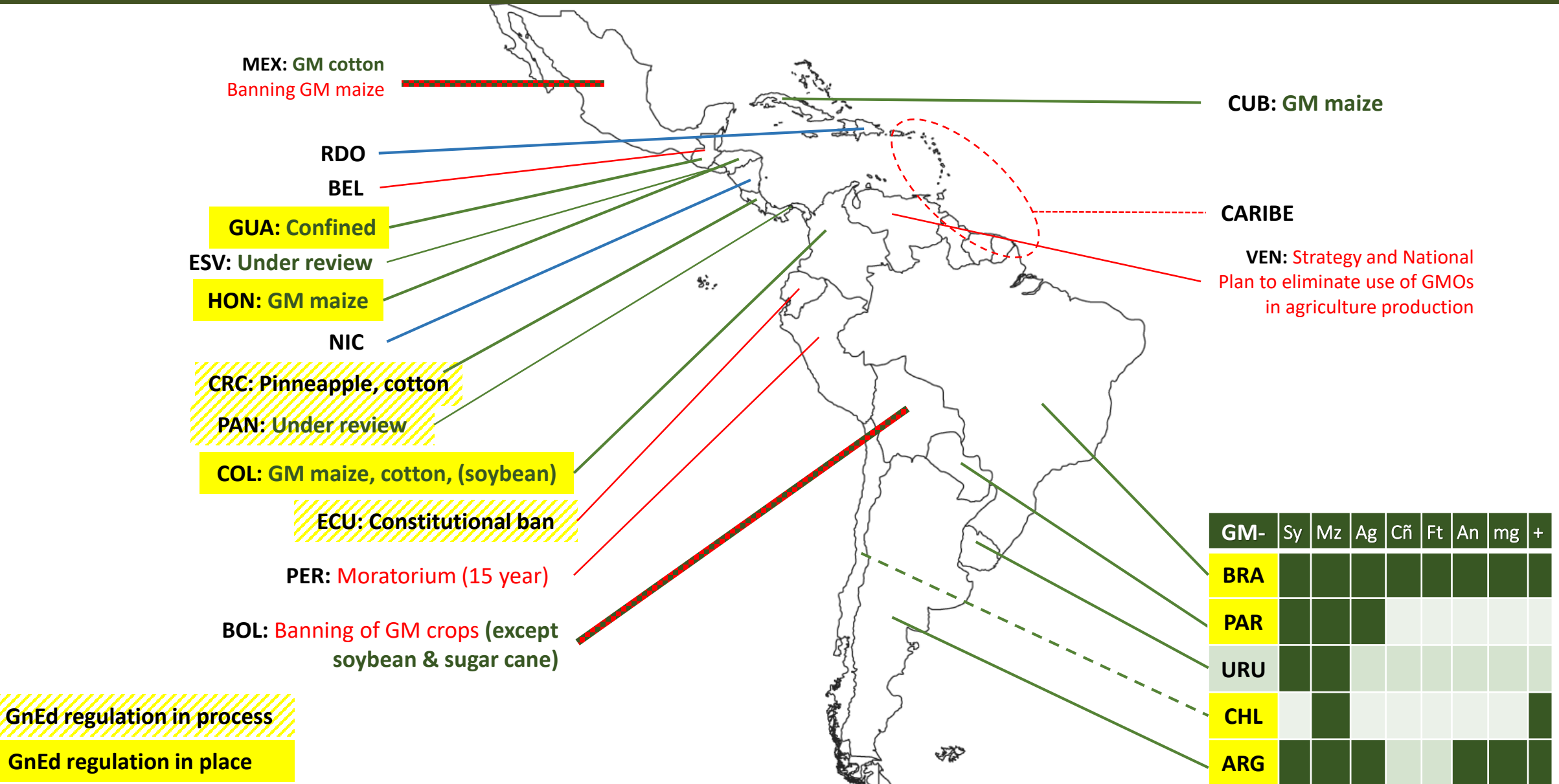
(i) "Modern biotechnology" means the application of:

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



"4.6. 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**".

Regulation for GMO's and GnEd products in LAC (2022)



Guatemala – Honduras (2019)

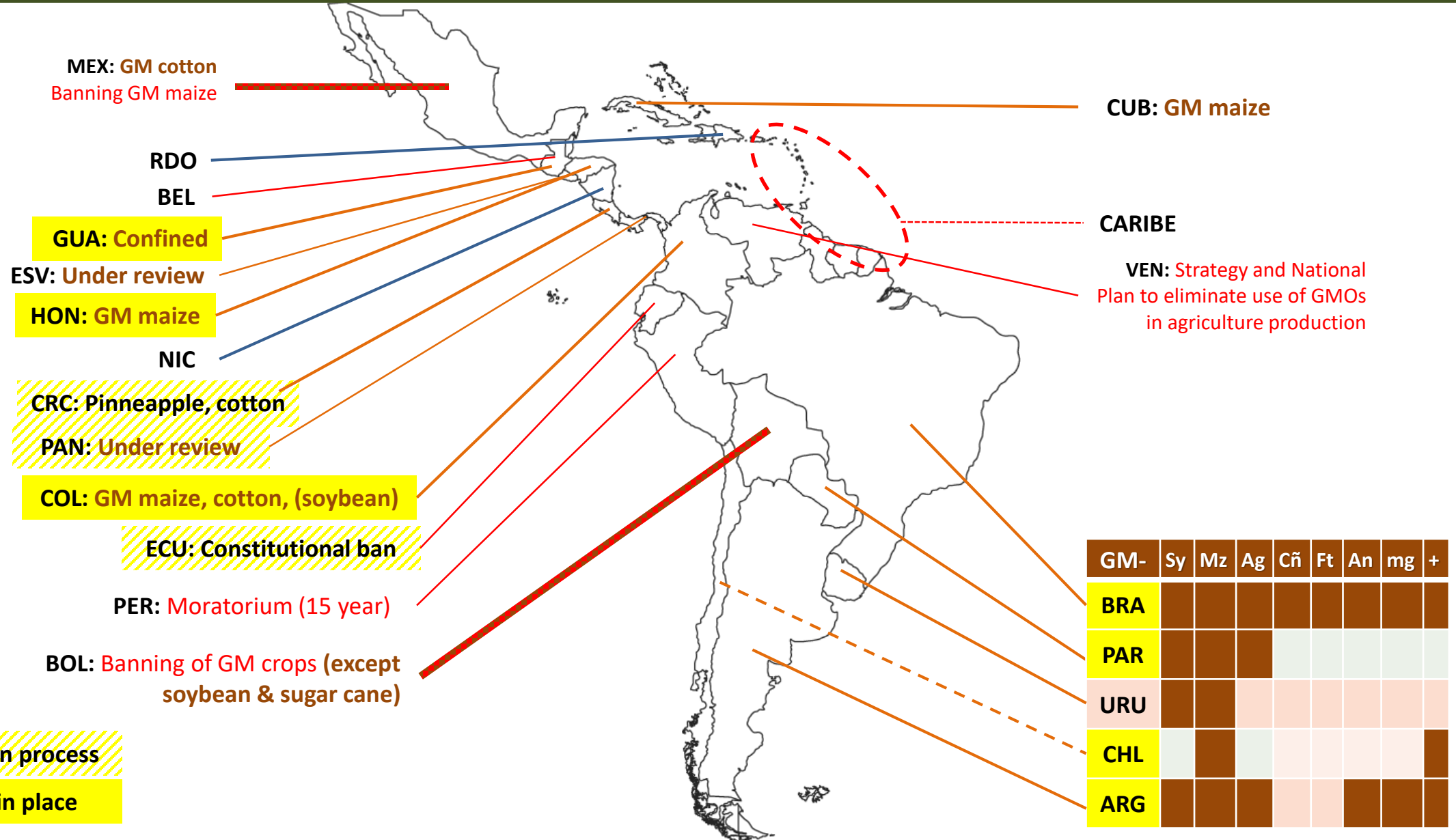
Technical Rule RT 65.06.01:18

- Customs Union Agreement GUA-HON-(ESV)
- Biosafety Technical Rule for LMOs of agricultural use (plants y animals).
- “4.6. 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”.

Reglamento Técnico RT 65.06.01:18

- *Acuerdo de Unión Aduanera GUA-HON-(ESV)*
- *Reglamento Técnico de Bioseguridad para OGM de uso agrícola RT (plantas y animales).*
- “4.6. *NUEVA COMBINACIÓN DE MATERIAL GENÉTICO. Para el presente reglamento se entiende como **combinación nueva de material genético** una **inserción estable en el genoma**, de uno o más genes o secuencias de ADN que codifique ADN de doble hebra, ARN, proteínas, o secuencias regulatorias que **no podrían ser obtenidas por mejoramiento convencional o no se encuentran en la naturaleza.**”*

Regulation for GMO's and GnEd products in LAC (2022)



Panama (in process)



Propuesta Técnica para el Fortalecimiento del Sistema Regulatorio de Biotecnología y Bioseguridad para el Sector Agrícola de Panamá

Documento generado en respuesta a la solicitud del Ministro de Desarrollo Agropecuario de Panamá (oficio DM-1771-2021)

Junio de 2022

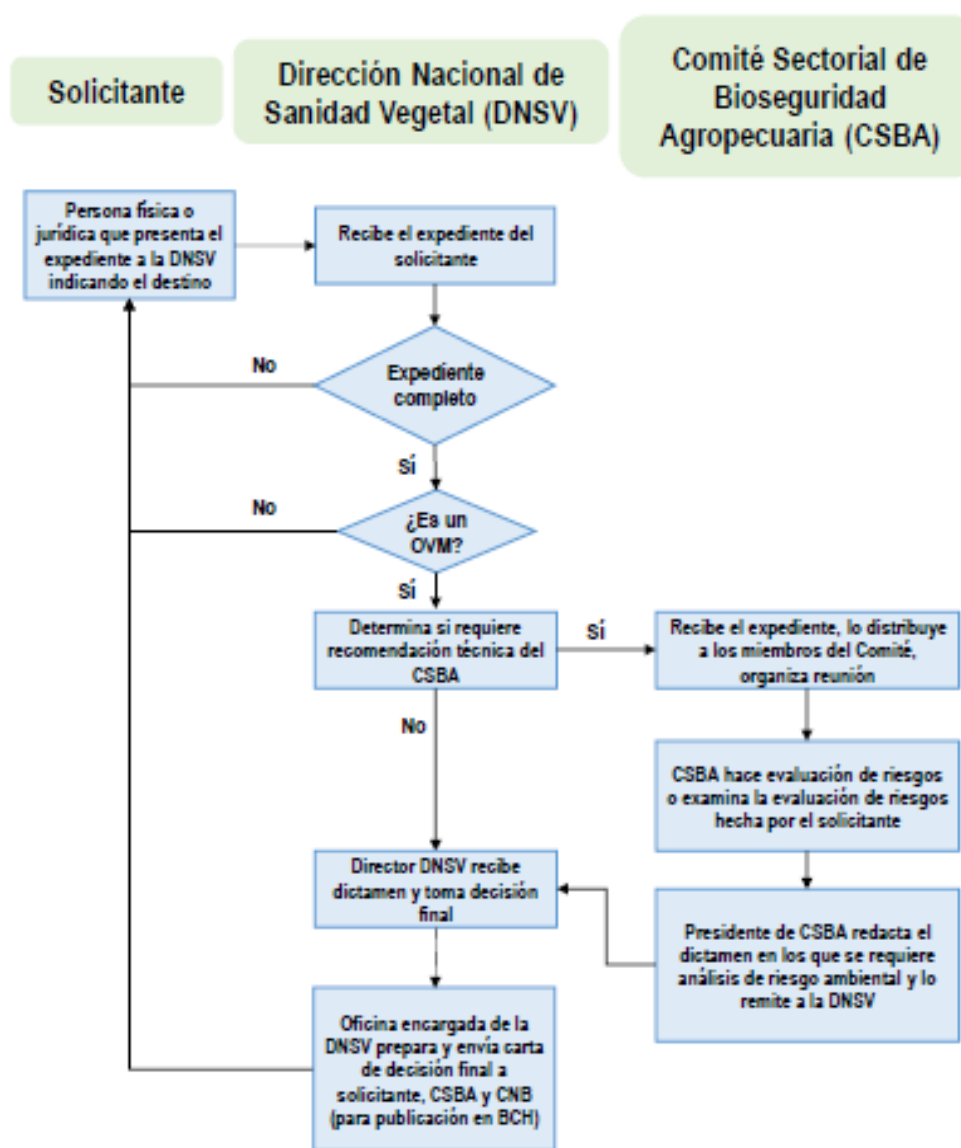
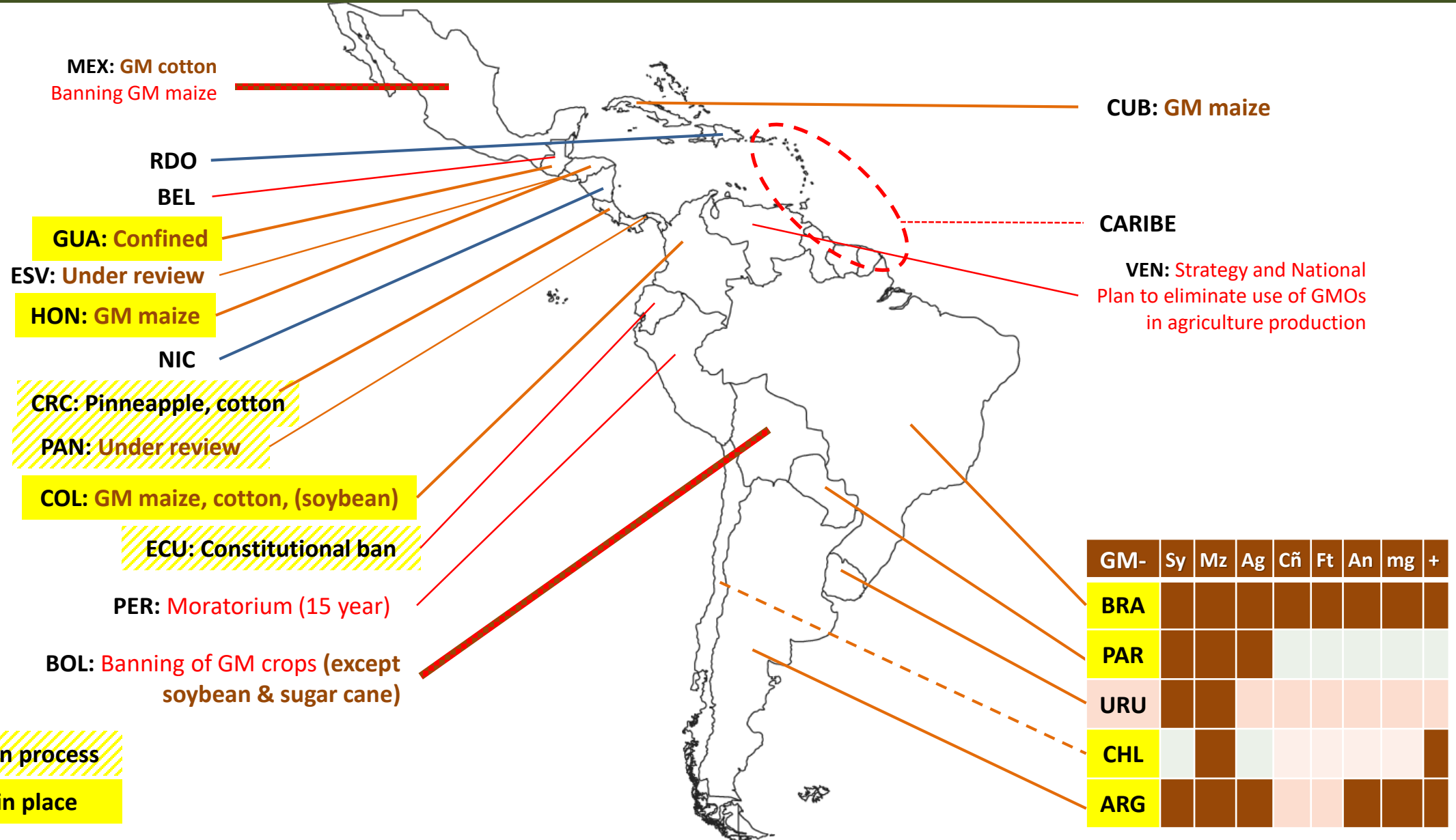


Figura 6. Propuesta de flujograma para toma de decisiones sobre productos de la biotecnología de uso agrícola.

Regulation for GMO's and GnEd products in LAC (2022)



Ecuador

REGLAMENTO AL CODIGO ORGANICO DEL AMBIENTE

Decreto Ejecutivo 752


Registro Oficial Suplemento 507 de 12-jun.-2019

Estado: Vigente

CAPITULO II BIOSEGURIDAD

Art. 229.- Normas de bioseguridad para organismos genéticamente modificados resultantes de la biotecnología moderna.- Se entenderá por productos de la biotecnología moderna a los organismos vivos genéticamente modificados resultantes de la biotecnología moderna.

Las instituciones competentes en materia de bioseguridad emitirán las normativas sectoriales pertinentes para prevenir o evitar los posibles riesgos que pudieran ocasionar los organismos vivos genéticamente modificados resultantes de la biotecnología moderna al ambiente, a la diversidad biológica o a la sanidad animal o vegetal; teniendo también en cuenta los riesgos para la salud humana, a través del establecimiento de parámetros técnicos, administrativos y demás consideraciones para una gestión integral de los posibles riesgos.

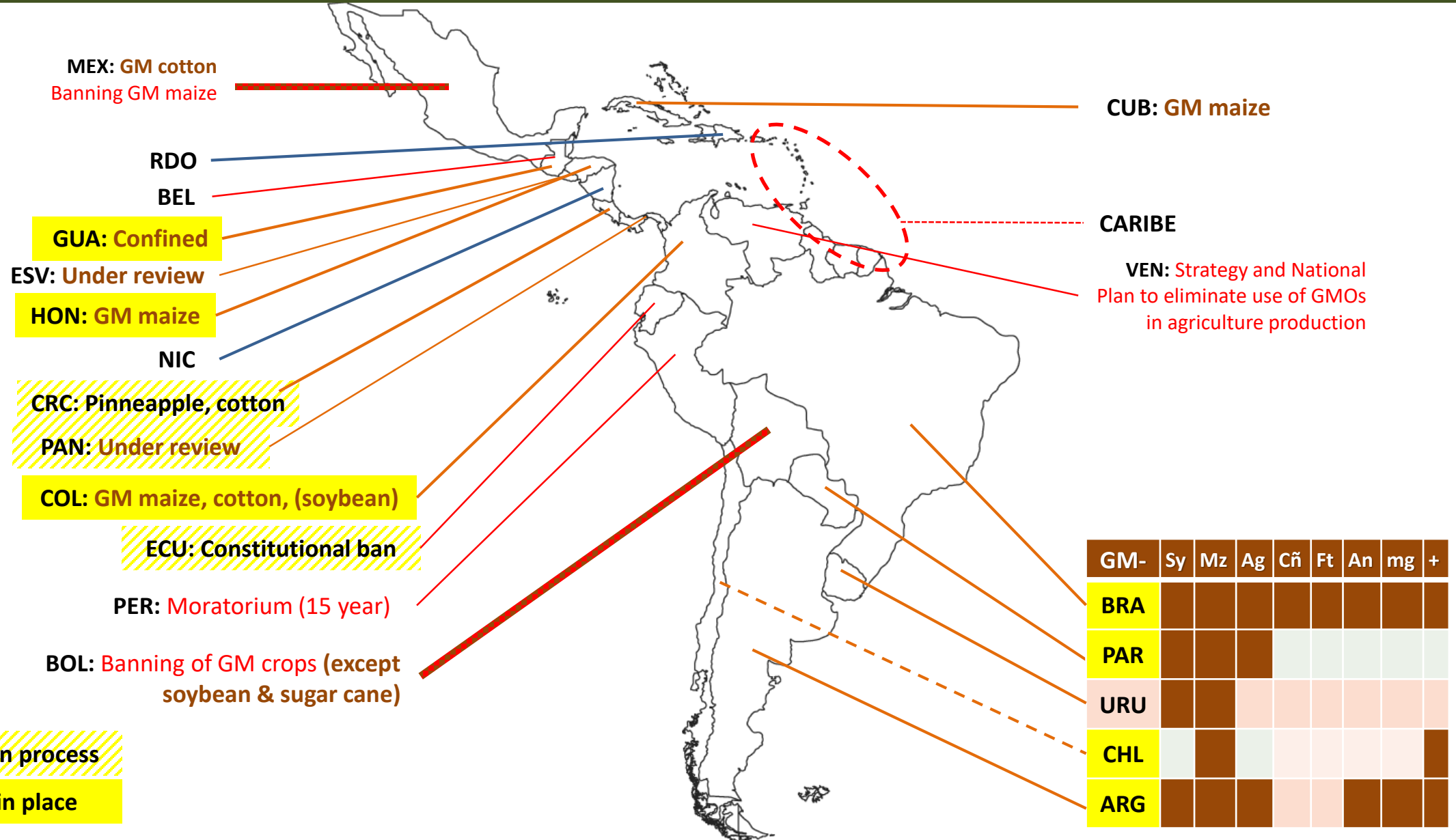
 **Art. 230.-** Excepciones.- Quedan excluidos del ámbito de aplicación de este capítulo:

a) Organismos provenientes del mejoramiento genético de especies que no posean ADN recombinante o foráneo en el genoma resultante;

b) Análisis de genoma humano, cultivo de células troncales de seres humanos, la modificación de células germinales humanas; pruebas de diagnóstico de enfermedades humanas, animales y vegetales, la manipulación genética de células germinales humanas y la terapia genética; así como la bioseguridad de hospitales; y,

c) Otros que la Autoridad Ambiental Nacional determine.

Regulation for GMO's and GnEd products in LAC (2022)



Regulation for GMO's and GnEd products in LAC (2022)

CAC



MEX: GM cotton
Banning GM maize

CUB: GM maize

RDO

BEL

CARIBE

GUA: Confined

ESV: Under review

HON: GM maize

NIC

VEN: Strategy and National Plan to eliminate use of GMOs in agriculture production

CRC: Pineapple, cotton

PAN: Under review

COL: GM maize, cotton, (soybean)

ECU: Constitutional ban

PER: Moratorium (15 year)

BOL: Banning of GM crops (except soybean & sugar cane)

G5-



	GM-	Sy	Mz	Ag	Cñ	Ft	An	mg	+
BRA									
PAR									
URU									
CHL									
ARG									

GnEd regulation in process

GnEd regulation in place

CAS Statement on GmEd



NUEVAS TECNOLOGÍAS DE MEJORAMIENTO Y ACCESO DE PRODUCTOS GMs A TERCEROS MERCADOS

CONSEJO AGROPECUARIO DEL SUR (CAS)
XXXIV REUNION ORDINARIA

Safe use

Asynchrony

Regulatory
cooperation

Consideran que:

1. El uso de las nuevas tecnologías de producción agropecuaria debe ser realizado de forma segura para garantizar el futuro de la producción de alimentos y el abastecimiento mundial de manera sostenible.
2. La asincronía en el proceso de aprobación de productos GMs, observada entre países exportadores y países importadores está causando un gran impacto negativo en el sistema de producción de alimentos.
3. La asincronía en el proceso de aprobación de productos GMs, constituye una barrera en el comercio internacional que debe ser minimizada.

Declaran que:

1. Resulta necesario promover actividades de cooperación en la construcción de capacidades conjuntas mediante la formación de expertos en nuevas tecnologías, así como también en el fortalecimiento de sus marcos regulatorios.
2. Los países de la región deben trabajar conjuntamente para intensificar el intercambio de informaciones en la aprobación de productos GMs, buscando reducir la asincronía en la aprobación de estos organismos en la región.
3. Los países del CAS procurarán conjuntamente promover la aprobación en terceros mercados de eventos de interés regional.

Regulation for GMO's and GnEd products in LAC (2022)



MEX: GM cotton
Banning GM maize

CUB: GM maize

RDO
BEL

CARIBE



GUA: Confined
ESV: Under review

HON: GM maize

NIC

VEN: Strategy and National Plan to eliminate use of GMOs in agriculture production



CRC: Pinneapple, cotton

PAN: Under review

COL: GM maize, cotton, (soybean)

ECU: Constitutional ban



PER: Moratorium (15 year)

BOL: Banning of GM crops (except soybean & sugar cane)

	GM-	Sy	Mz	Ag	Cñ	Ft	An	mg	+
BRA									
PAR									
URU									
CHL									
ARG									

GnEd regulation in process

GnEd regulation in place

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 (or Fisheries), Environment, or Food.
 - Shared oversight by multiple ministries or even multiple countries.
- General agreement on what needed to be regulated (i.e., similar requirements for rDNA/GMO products).

Multiple Roles of Regulations

- Protect public health & safety
- Instill trust in the food supply
- Encourage development of new ideas and innovations



Global Regulatory Goals

- **Science-based, risk-proportionate, and defensible**
- **Credible** to the public – whose concerns may reflect non-scientific, values-based issues
- **Timely** and **predictable** (important for innovation)
- **Transparent** to all
- **Effective regulations**
 - **Protect public safety**
 - **Allow production and marketing of safe products**

Modernizing Regulatory Approaches – Same Regulatory Goals

- **Protection goals remain the same**
 - all products (biotech or conventional) safe for humans, animals, and the environment.
- Regulatory approaches that reflect **characteristics** and **potential risk** of **products** of new technologies.
- Allow **safe** products to be used by farmers and be sold and traded in the global market.

Final Remarks

- **Recognize the political environments is essential and strategic**

- Currently, **political instability is the rule** for the majority of LAC countries
 - Biotech actions must be low-profile in such polarized environments (e.g. **BOL, CHL, ECU, MEX, NIC, PAN, PER, VEN, COL?**)
- It is important to **recognize** the margin- and time-action (GUA, HON, ECU)
 - Politically, biotech is used as a "joker"
- In some countries, **"wait"** is the best option (BOL, MEX, NIC, 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, GUA, HON, PAR, URU**
- Political discussion could be more effective if **regional initiatives (CAS & CAC)** are involved. (NABI?)



How countries make agency decisions and is it possible to harmonize?

Harmonize policies is almost impossible.

Regulatory cooperation is a feasible and viable,

but for that, recognize and accept the heterogeneity and harmonize criteria are essential elements

Contact



IICA Sede Central

<http://www.iica.int>

Pedro Rocha, *Ph.D.*

E-mail: Pedro.Rocha@iica.int