

Regulatory challenges and global trade implications of genome editing in agriculture

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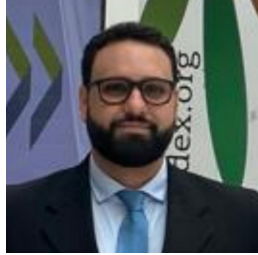
GE Regulatory Landscape

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Who am I?



- Bachelor of Science (Biology).
- Postgraduate degree in Plant Molecular Genetics.
- PhD in Agricultural Sciences.
- Graduate on risk analysis for the agri-food sector at the Graduate School “Agronomist Alberto Soriano” (FAUBA).
- Adjunct Professor (Biology and Biotechnology) (FACEN-UNA).
- Research Professor (FACEN-UNA).
- Member of the Mycology Investigation and Safety Team (MISTpy).
- PRONII Level 2 Researcher (CONACYT).
- Member of the National Commission of Agricultural and Forestry Biosafety (CONBIO) of the Ministry of Agriculture and Livestock (MAG).





Regulatory challenges and global trade implications of genome editing in agriculture



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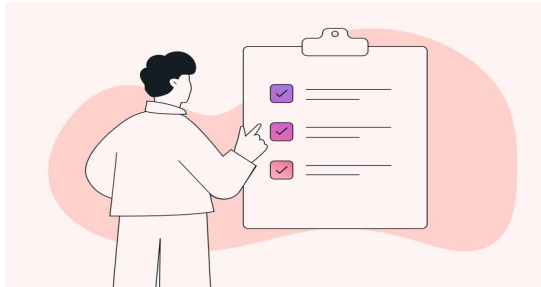
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Introduction

- Innovation in plant breeding plays a critical role in advancing the SDGs, particularly in areas like zero hunger, good health and well-being, and climate action.
- Gene editing has become a key tool for improving crop productivity, disease resistance, and adaptation to adverse climatic conditions.
- Its adoption faces regulatory challenges owing to divergent policies between regions.



high costs, delays in commercialization



Analyze the main regulatory challenges and their impact on global trade and propose strategies for harmonization

Triggers

Characteristic	Process-Based	Product-Based
Basis for Regulation	rDNA, "modern biotechnology"	Final product's traits and whether they are novel or unfamiliar
Scientific Foundation	Risk is not necessarily inherent to the process	Aligned with international scientific consensus
Primary Question	New combination?	New traits or characteristics that could pose a risk?
Efficiency	Can regulate low-risk products and under-regulate high-risk products?	Risk proportionate
Adaptability to Technology	Definitions can be challenging	More adaptable?

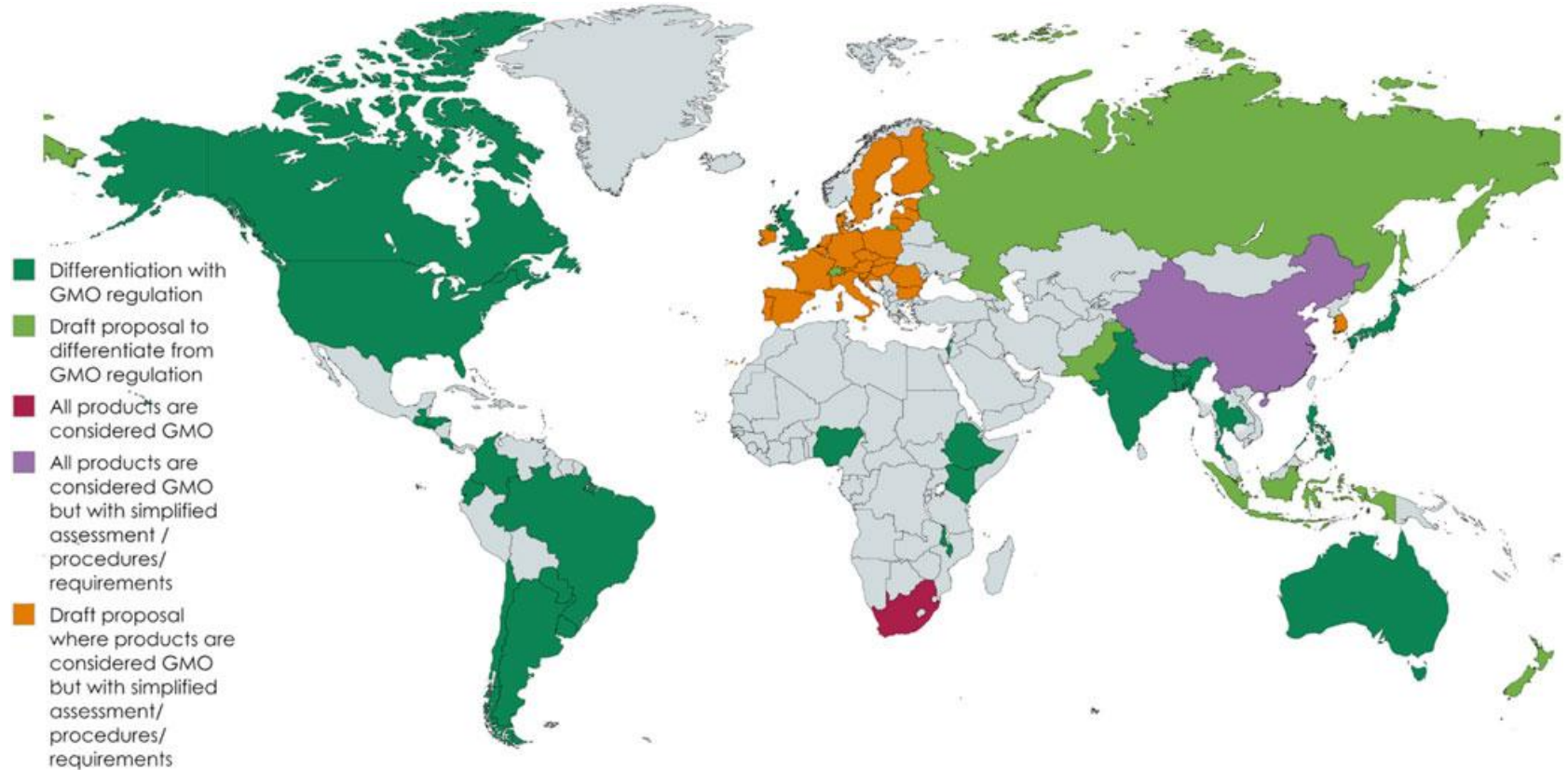


Challenges

- **Lack of Early Clarity (Pre-market)**
 - Uncertainty about the regulatory path during early R&D
- **Disproportionate Data Requirements (Pre-market)**
 - Requiring GM-like data for products indistinguishable from conventionally bred plants
- **Redundancy for Similar Products (Pre-market)**
 - Requiring individual regulatory evaluations for every new variety with the same functional change
- **Post-market requirements**
 - Labeling, traceability, segregation, etc.
- **“Patchwork” of Global Policies (Trade)**
 - The same product may be considered conventional in one country but GM in another



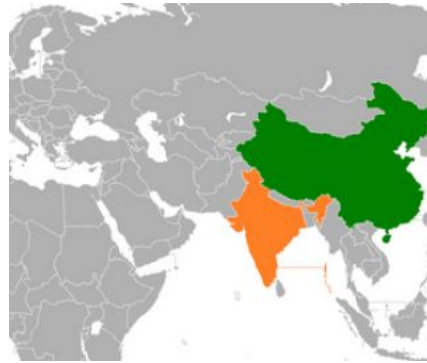
Global overview



Current trends



- Adaptive frameworks
- Case-by-Case
- Risk proportionality



- More flexible frameworks
- China reduced approval times
- India exempted SDN1 and SDN2 products without foreign DNA



- Prior Consultation
- Conventional Classification
- Regional Cooperation



- Classification as GM
- Undefined Pre- and Post-Market requirements
- Potential for future changes

Opportunities and examples of cooperation

ABRE-BIO

*Agências de Biossegurança
em Rede para Biotecnologia*

FSANZ

*Food Standards Australia
New Zealand*

NEPAD

*New Partnership for Africa's
Development*

**These models demonstrate that regional cooperation improves
efficiency, security, and competitiveness**

- Promote regulatory synchronization
- Reduce regulatory costs and times
- Foster regional development through innovation and technological cooperation
- Strengthen inter-agency collaboration

- Joint food system with unified safety criteria

- Strengthening regulatory capacities and harmonizing biosafety policies

ABRE-BIO

MEMORANDO DE ENTENDIMIENTO MULTILATERAL ENTRE EL MINISTERIO DE ECONOMÍA DE LA REPÚBLICA ARGENTINA,

EL MINISTERIO DE CIENCIA, TECNOLOGÍA E INNOVACIÓN DE LA REPÚBLICA FEDERATIVA DE BRASIL,

EL MINISTERIO DE AGRICULTURA Y GANADERÍA DE LA REPÚBLICA DE PARAGUAY

Y

EL MINISTERIO DE GANADERÍA, AGRICULTURA Y PESCA DE LA REPÚBLICA ORIENTAL DEL URUGUAY

PARA LA CREACIÓN DE LA RED INTERNACIONAL DE BIOSEGURIDAD DE PRODUCTOS DERIVADOS DE LA BIOTECNOLOGÍA MODERNA

El Ministerio de Economía de la República Argentina, el Ministerio de Ciencia, Tecnología e Innovación de la República Federativa de Brasil, el Ministerio de Agricultura y Ganadería de la República de Paraguay y el Ministerio de Ganadería, Agricultura y Pesca de la República Oriental del Uruguay (en lo sucesivo, las "Partes")

Deseando continuar con el desarrollo y fortaleciendo el intercambio de profesionales y la cooperación entre las Partes en el campo de la ciencia y la tecnología;

Reconociendo que una cooperación más estrecha contribuye a fortalecer las relaciones entre las Partes, de conformidad con sus capacidades e intereses comunes, sus respectivas leyes y reglamentos, y cooperando en igualdad de condiciones;

Anhelando fortalecer la innovación producida por las instituciones públicas y privadas en los países donde se encuentran las Partes, en particular en el campo de la agricultura, la ganadería, la pesca y la agroindustria;

Considerando que:

1) Por el lado argentino, la Dirección Nacional de Bioeconomía, a través de la Coordinación de Innovación y Biotecnología, es la encargada de realizar el seguimiento y evaluación de las solicitudes presentadas para desarrollar actividades con Organismos Genéticamente Modificados (OGM), en conjunto con la Comisión Nacional Asesora de Biotecnología Agropecuaria (CONABIA), y que esta Comisión, en conjunto con la Coordinación de Innovación y Biotecnología, tiene como objetivo garantizar la bioseguridad en el agroecosistema, y el Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA), es el organismo encargado de realizar la

 b.

Firmado en 8 (ocho) originales, 4 (cuatro) en portugués y 4 (cuatro) en español, siendo todos los textos igualmente auténticos.

En _____, el día 12 del mes de Junio de 2023.

POR EL MINISTERIO DE ECONOMÍA DE LA REPÚBLICA ARGENTINA


SERGIO TOMÁS MASSA

POR EL MINISTERIO DE CIENCIA, TECNOLOGÍA E INNOVACIÓN DE LA REPÚBLICA FEDERATIVA DE BRASIL


LUCIANA SANTOS

POR EL MINISTERIO DE AGRICULTURA Y GANADERÍA DE LA REPÚBLICA DE PARAGUAY


CARLOS ALCIBIADES GIMÉNEZ DÍAZ

POR EL MINISTERIO DE GANADERÍA, AGRICULTURA Y PESCA DE LA REPÚBLICA ORIENTAL DEL URUGUAY

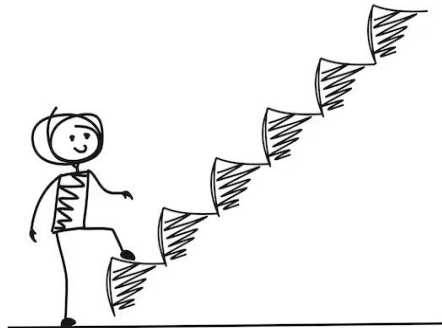

FERNANDO MATTOS COSTA

12 de junio de 2024. Siendo el último signatario de este acuerdo, declaro que, a partir de este momento, el acuerdo entra en plena vigencia.



Thanks to: Alejandra Ferenczi and Facundo Simeone

ABRE-BIO



Regulatory Alignment

- Prevent or reduce regulatory asynchronies between countries.
- Harmonize approval pathways for biotech products.
- Promote mutual recognition of data and testing (data transportability, local trial requirements).

Market Access & Regional Products

- Promote the production, use and consumption of biotech products.
- Enable national and regional products to reach the market.

Institutional & Strategic Cooperation

- Strengthen public-private partnerships and involve research institutions in testing and validating new mechanisms.
- Foster inter-agency collaboration and promote good regulatory practices (GMs and NBTs).
- Advance broader agreements between exporter–importer countries to harmonize approaches and facilitate trade.

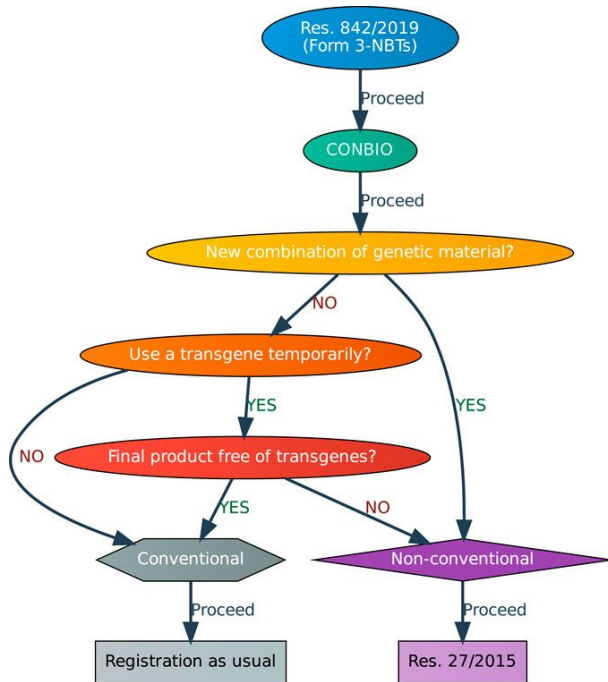
Argentina-Brazil Agreement

Main benefits of the system

- Feasibility pre-assessment for small and medium developers without legal representation in the destination country.
- Joint determination of the regulatory status of products derived from NBTs.
- In the process of expanding it to Paraguay and Uruguay.



Some recommendations



01. Regulatory evaluations should use conventionally bred products as the primary **comparators**
02. Resolutions should formally and explicitly classify GE organisms as "**conventional**" when they do not contain foreign DNA or novel genetic combinations
03. Requirement for molecular characterization should be limited to the **species** level if the edited trait is within the range of natural or induced variation
04. Regulatory frameworks should formally **recognize** prior determinations made by competent authorities in other countries that have compatible biosafety systems
05. GE oversight should be based on a precise legal definition that references **conventional breeding**



Thank You!
For Your Time and Attention

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