

Session V - Nov 4, 5;
International Virtual Workshop
Series on Regulatory
Approaches for Animal
Biotechnology

***Paraguay's path to enable
the development of
biotechnology through
policy***

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MINISTERIO DE
**AGRICULTURA
Y GANADERÍA**



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PARAGUAY

- Landlocked country.
- Exporter of agricultural products.
- Fourth biggest exporter and sixth biggest producer of soybean.
- Maize-beef-sugar-rice






Destinations - Access to new markets

- 55 new markets open for soybean grain
- 41 markets for soybean oil
- 51 markets for soybean flour
- 63 markets for corn
- 34 for wheat
- 60 markets for rice

Soybean destinations



Policy development and implementation

- 18481/97: By which a Commission of Biosafety is created.  2004. First Commercial Approval (RR Soybean)
- 12706/08: Whereby Decree No. 18481 Creating the Biosafety Commission (COMBIO) is modified and expanded.  2011. Second Commercial Approval (Cotton)
- 9699/12: By which the National Commission of Agricultural and Forest Biosafety (CONBIO) is created.  2012. Commercial Approvals of Corn and Soybean. All Intermediate Combinations

What have we learned?

- Effective public acceptance could not follow a 'one size fits all' approach.
- Regulatory oversight should be **science based**.
 - Implementing it may not be as simple as it sounds, but it **should be**.
 - **Sound** risk assessment principles developed by the combined set of OECD, WHO, and FAO *Codex Alimentarius* documents over the past 32 yrs.
- Regulatory requirements did not appear to occur as a result of scientific rigour
 - Social, legal, and political constraints.
- Need to revise the escalating information requirements
 - Rationale for a more pragmatic approach

Regulation updates

- Ministerial Decision 988/13: which regulates articles 33 and 34 of Resolution 1348/12.



Approvals of intermediate combinations are regulated. (fast track)

- Ministerial Decision 27/15: "By which the documents Form 1, Regulated Assays Form 2: Commercial Release, and the Guide to Form 2: Commercial Release are approved".



Forms for Regulated Assays and Commercial Release (Problem Formulation)



Capacities for the Risk Assessment of GMOs: Challenges to Build Sustainable Systems

Danilo Fernández Ríos¹, Clara Rubinstein² and Carmen Vicién^{3}*

Strategies

Members have implemented periodic follow-up meetings, special sessions to discuss particular issues or update risk assessors on new information and developments, share publications, etc.

Open discussions are encouraged among participants and with other interested parties, contributing to improve the level of participation of Paraguayan representatives in regional and international meetings such as OECD working groups and other fora.



Current situation

- Over 20 years of safe use of Biotechnology.
- Familiarity with Events.
- Scientific publications on the Safety of Biotechnology.
- Repetitions of evaluations already conducted by other agencies.
- Communication between Agencies and participation in international fora.
- Support from Specialized Scientific Organizations.

Latest updates

- Ministerial Decision 840/19: Approves Form 3 for New Breeding Techniques.
Defines Criteria for decision-making
- Ministerial Decision 1030/19: Regulation of Ministerial Decision 1348 and the Mechanism for the Commercial Release of GMOs that have been commercially released in other countries.
Novel Events
Approved Events in other countries

New regulatory mechanisms

- MERCOSUR/GMC/RES. No. 23/19
 - Mechanism to Decrease Low Level Presence of Genetically Modified Organisms among Member States.
 - Consider Risk Assessments Conducted According to the CODEX.

Latest updates

- Ministerial Decision No. 840/19: Approves Form 3 for New Breeding Techniques.



Define Criteria for Decision Making and Approves Form 3

- Compared with bulk conventional breeding techniques and traditional USDA approaches, genome editing has been shown to offer significant advantages and added value across all sectors of agriculture.
- Genome editing was regarded by most agricultural scientists as a game-changing player in food production and food security.
- Would not replace conventional breeding or modern GM crops, but expands the scope of modern tools.

- Ministerial Decision No. 1030/19: Approves the Commercial Release Mechanism for GMOs that have been granted commercial release in other countries.



- Novel Events
 - Conventional R. A.
- Approved Events in other countries.
 - Simplified approval procedure

- Compared with both conventional breeding techniques and traditional GE/GM approaches, genome editing has been shown to offer significant advantages and added value across **all sectors of agriculture**.

- Genome editing was regarded by most agricultural scientists as a **complementary** utensil in their innovation tool box.

- Would not replace conventional breeding or traditional GE/GM techniques in the short or medium terms

MECHANISM FOR THE ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS (GMOS) COMMERCIALY APPROVED IN OTHER COUNTRIES (MAG Ministerial Decision 1071/2019)

- **Assessments within the framework of authorizations carried out in other countries for food and feed safety in cases where they have been based on CODEX Guidelines.**

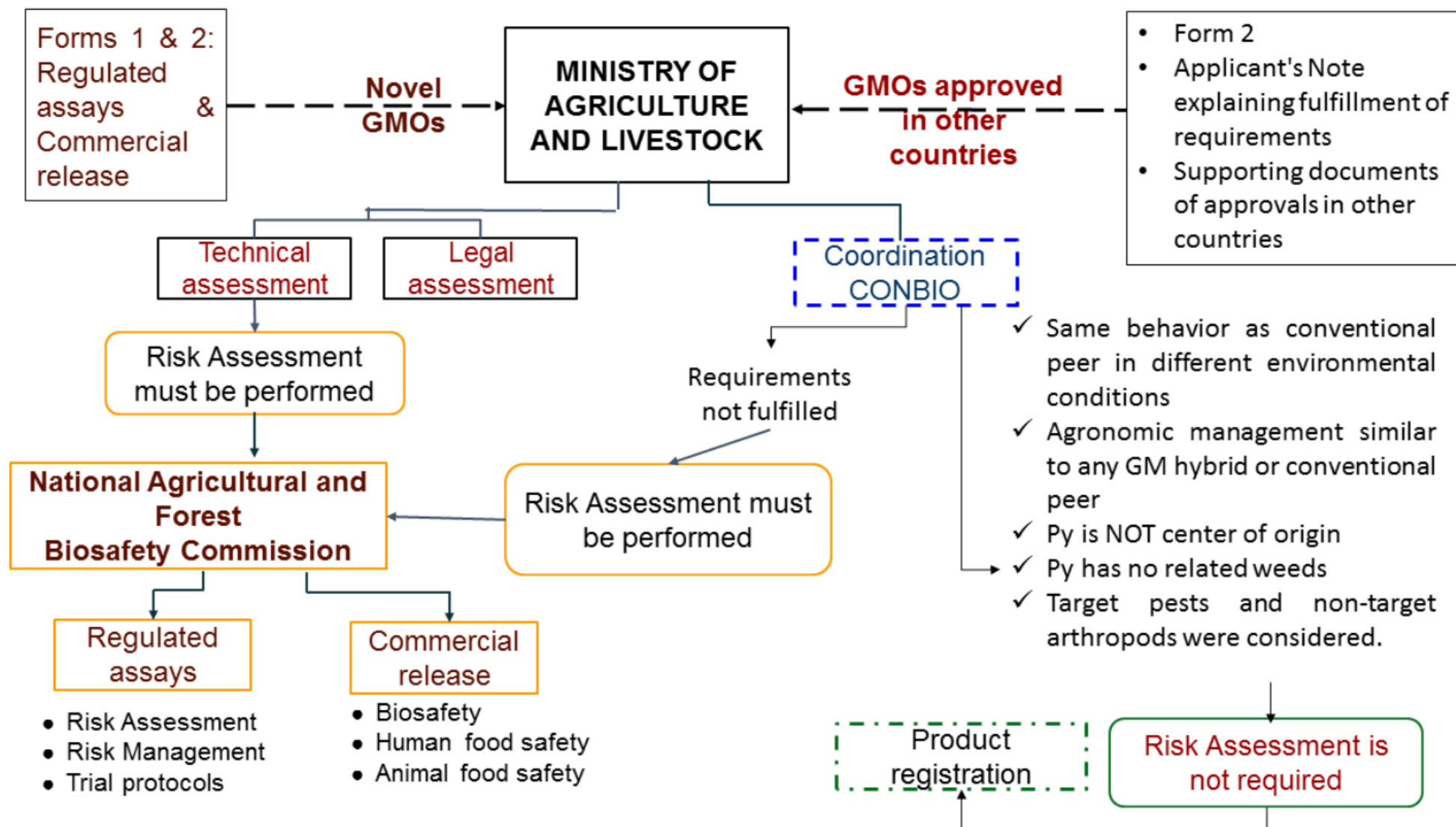
Conditions:

- **Approved in countries that have experienced regulatory systems and have authorized GMOs for commercial planting.**
- **Familiarity in Scientific and Technical Aspects.**

MECHANISM FOR THE ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS (GMOS) COMMERCIALY APPROVED IN OTHER COUNTRIES (MAG Ministerial Decision 1071/2019)

Conditions:

- **The GMO under evaluation has been studied in different environmental conditions, behaving in the same way as its conventional counterpart.**
- **The GMO will be agronomically managed in a manner similar to any GM or conventional variety/hybrid of the species.**
- **Paraguay is not a center of origin for the crop.**
- **In Paraguay there are no related weeds with which GMOs could cross.**

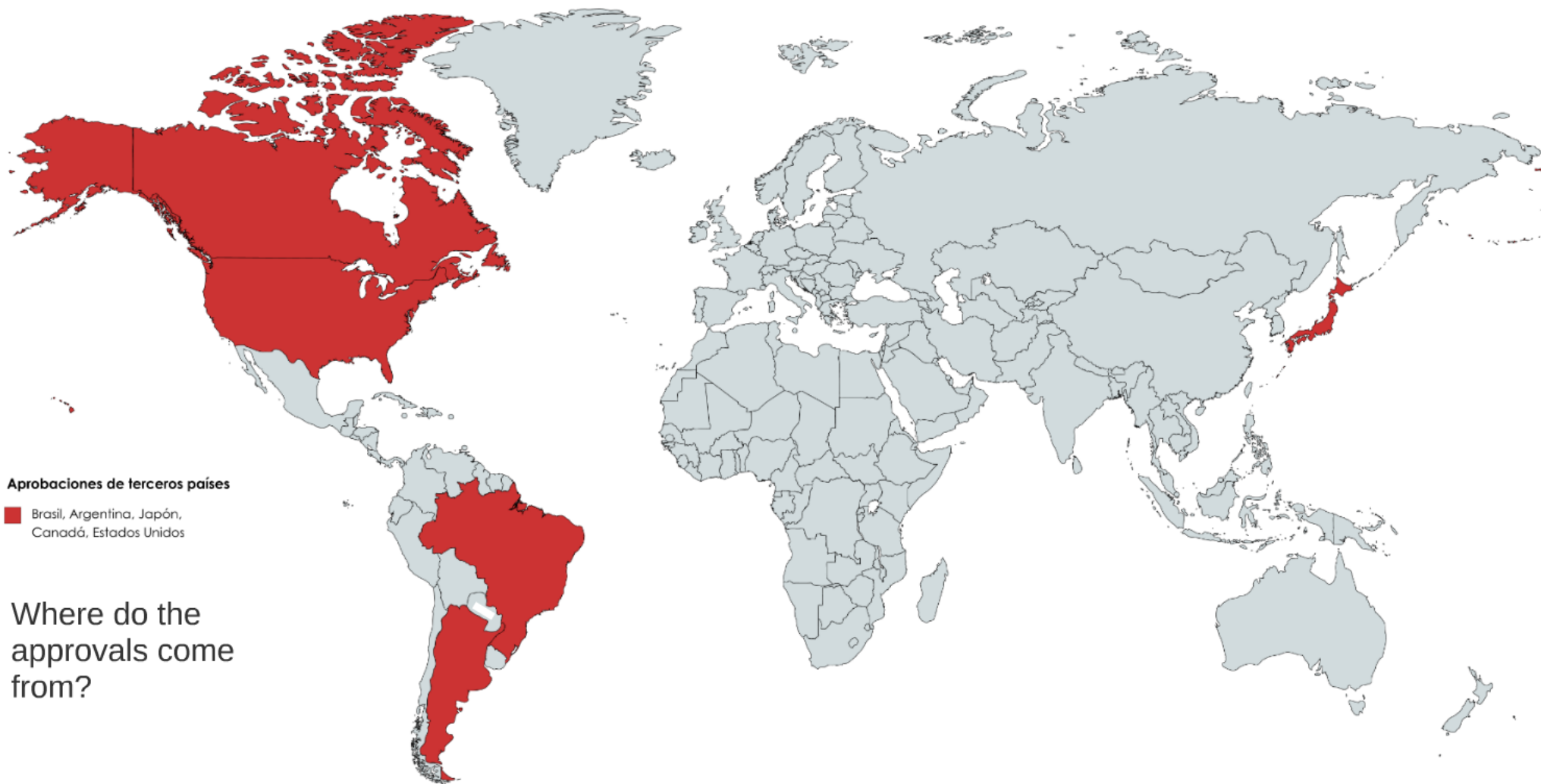




Paraguay's Path Toward the Simplification of Procedures in the Approval of GE Crops

Nidia Benítez Candia¹, Danilo Fernández Ríos^{1} and Carmen Vicién²*

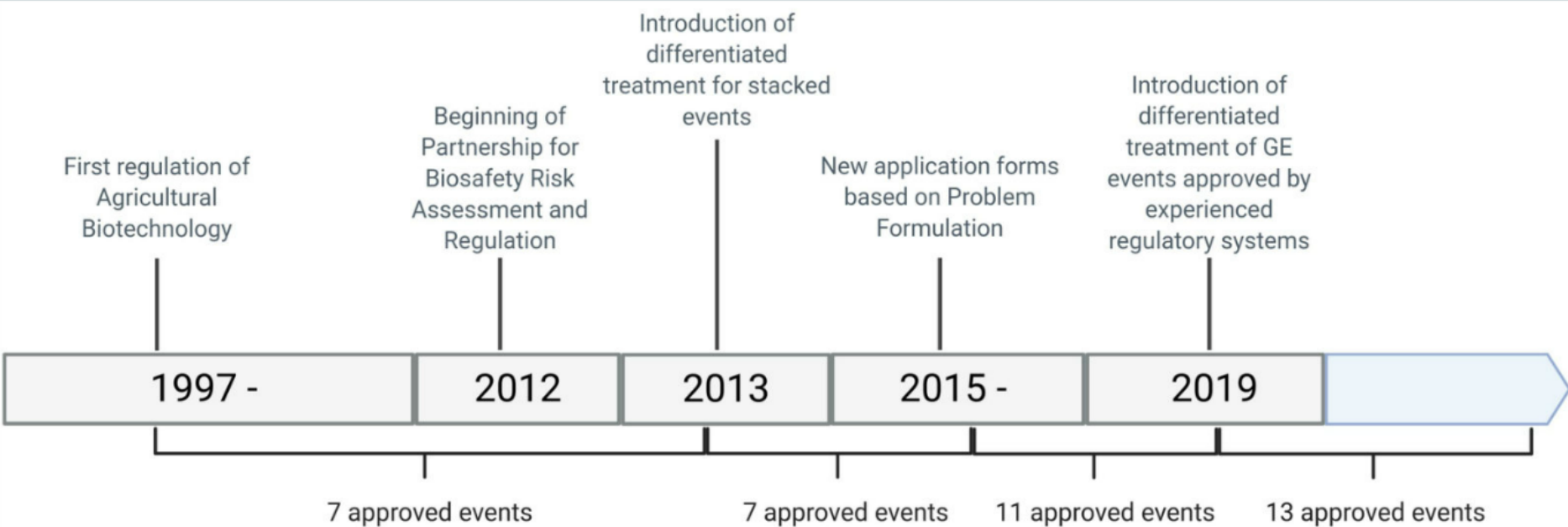
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Aprobaciones de terceros países

■ Brasil, Argentina, Japón,
Canadá, Estados Unidos

Where do the
approvals come
from?



19



12



7

Results

- Decreasing the time of an approval from 3 years to 3 months or less.
- Decreasing asynchronies in approvals.
- Reducing the costs of approvals.
- Approving species of lesser commercial interest.
- Allowing the participation of smaller companies.
- Facilitating Farmers' Access to New Technologies.

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