



Report back on the Americas Breakout Session

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- Regulatory Situation of Animal Biotechnology in:
 - Argentina, Brazil, Colombia, United States.
- South-South Cooperation in Biotechnology.
- Discussion Panel to analyze hypothetical scenarios.



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Regulatory Situation of Animal Biotechnology in:

Country	Current Regulation	National Authority	Criteria	Approved animals
Argentina	GM: 1991 NBT: Res. No, 21/2021	Secretary of Agriculture CONABIA (1991)	* Case by case/ Science-based/ Data quality/ Comparative analyses. Risk assessment (technical, robust & transparent evaluation).	GM: Bovine/Spodoptera 180 working days.
				NBT: 4 bovines/ 7 pigs/ 2 equines 80 working days.
Brazil	LMO: Law 11105, 2005 GnEd: RN16, 2018	MAPA CTNBio (2005)	Case by case/ Science-based/ Data quality/ Comparative analyses. Risk assessment (technical, robust & transparent evaluation). Regulation of processes and products. Applied to plants, microorganisms, vaccines, animals, insects, gene therapies.	GM: Mice/Mosquitoes/Spodoptera/Aquadvantage salmon
				GnEd/No-GM: Acquabounty tilapia/Nelore cattle sperm - muscle gain (Acceligen)/ SLICK Holstein bovine/ Hornless bull sperm
Colombia	LMO: Decree No.4525, 2005 GnEd: Res. No. 22991, 2022	ICA Biosafety Commission (2005)	Case by case/ Science-based/ Data quality/ Comparative analyses. Risk assessment (technical, robust & transparent evaluation).	GM: None GnEd: PRRS-pig
USA		FDA/EPA/USDA	Intentional Genomic Alterations (IGA). * Safety to the animal/to consumers & effectiveness Risk based review (Guidance for Industry #187A) - Category 1: No review of data prior to marketing. - Category 2: Prior risk review/ potential ED. - Category 3: Approval application.	FDA-CVM approvals GM: Aquadvantage salmon (food)/SBC LAL-C Chicken (Biopharm)/LFB R69 Rabbit (f)/GalSafe Pig (f&bp)

South-South Cooperation

- Regional regulation meetings.
 - GT8 Agriculture GMC-Mercosur: “biotechnology commission”.
 - GT5 CAS “Public policies in biotechnology”.
- Biosafety agreement between Argentina and Brazil.
- Biosafety agreement between ARG-BRA-PAR-URU
- South-South cooperation.

Discussion Panel

Scenario 1: Genome Edited Swine

- **The trait:** A simple knockout that prevents infection with FMD. Not known to occur naturally in the population. Heterogenous expression.
- **Deployment:** Rapid integration into commercial sow herd in country of origin. No regulatory requirements for traceability or labeling.
- **Trade Concern:** Maintenance of trade in pork products with trading partner countries.



- **Application:** Can the applicant seek approval only for food use?
- **Market Conditions:** Will the product require any traceability or labeling specific to the genetic status of the animal?
- **FAD Status:** Does this product pose any concerns with Foreign Animal Disease considerations?

Scenario 2: Genome Edited Cattle

- **The trait:** Template driven edit incorporating Angus polled allele into Jersey dairy cattle.
- **Deployment:** Trait has been introduced into several lines of elite Jersey cattle.
- **Trade Concern:** Consortium of Jersey breeders would like to export semen.



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Conclusions

- There is no “Best” Approach: Different Countries – Different Effective/Functional Regulatory Approaches for both GM and GnEd animals.
- Regulations in animal biotech seek: to protect public health & safety, allow production and marketing of safe products, and instill trust in the food supply.
- **General criteria: Case by case/ Science-based/ Data quality/ Comparative analyses.**
- **Risk assessment** (technical, robust & transparent).
- There are different regulatory triggers.
 - For LMOs: **product vs. process.**
 - For GnEd: Focus on product.

Conclusions

- Most jurisdictions with GnEd regulation, the result is a differentiated picture:
 - all/most SDN1 and SDN2 not covered by the regulatory definitions.
 - all/most SDN3 covered by the regulatory definitions.
- These conclusions have been reflected in various ways:
 - **clarification plus an additional rule** to submit organisms developed with NBTs to verify whether those organisms fall under the definitions (e.g. Brazil, Argentina).
 - **a change of the rules**, e.g.:
 - exempting certain categories of genome edited organisms (e.g. USA).
 - adjusting the definitions, (e.g. aligning with Cartagena Biosafety Protocol). Introducing the **Novel Genetic Combination** definition (e.g. Colombia).
- There is no need for creating a new category. LMO and non-LMO (conventional) are enough.

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