Food Safety aspects of regulations for genetically engineered/modified (GM) animals in Argentina

Fourth International Workshop on Regulatory Approaches for Animal Biotechnology

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Regulatory Framework

Ministerio de Agricultura, Ganadería y Pesca
Presidencia de la Nación

- Since 1991, Argentina has a Regulatory Framework, stipulating as a methodology the Risk Analysis associated with field trials and for the authorization of the extensive cultivation of GMOs.

- Guarantee the safe use of GMOs, both for the agroecosystem and for their consumption as human and animal food.

- The authorization for the commercialization of transgenic events depends on the Secretariat of Agriculture, previous approval of the three levels of technical assessments.

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SENASA – Food/Feed

Ministry of Agriculture, Livestock and Fisheries - Environment

Ministry of Agriculture, Livestock and Fisheries - Markets

Argentine Legislation on Food/Feed Safety Assessment

Ministerio de Agricultura, Ganadería y Pesca
Presidencia de la Nación

- Performed by the National Service for Agrifood Health and Quality (SENASA)
- Resolution SENASA 412/02 “Fundaments and Criteria for the Assessment of Food/Feed derived from Genetically Modified Organisms”.
- Resolution SENASA 1265/99 “Advisory Technical Committee on the use of Genetically Modified Organisms”.

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GM Animals – Food safety assessment backgound in Argentina

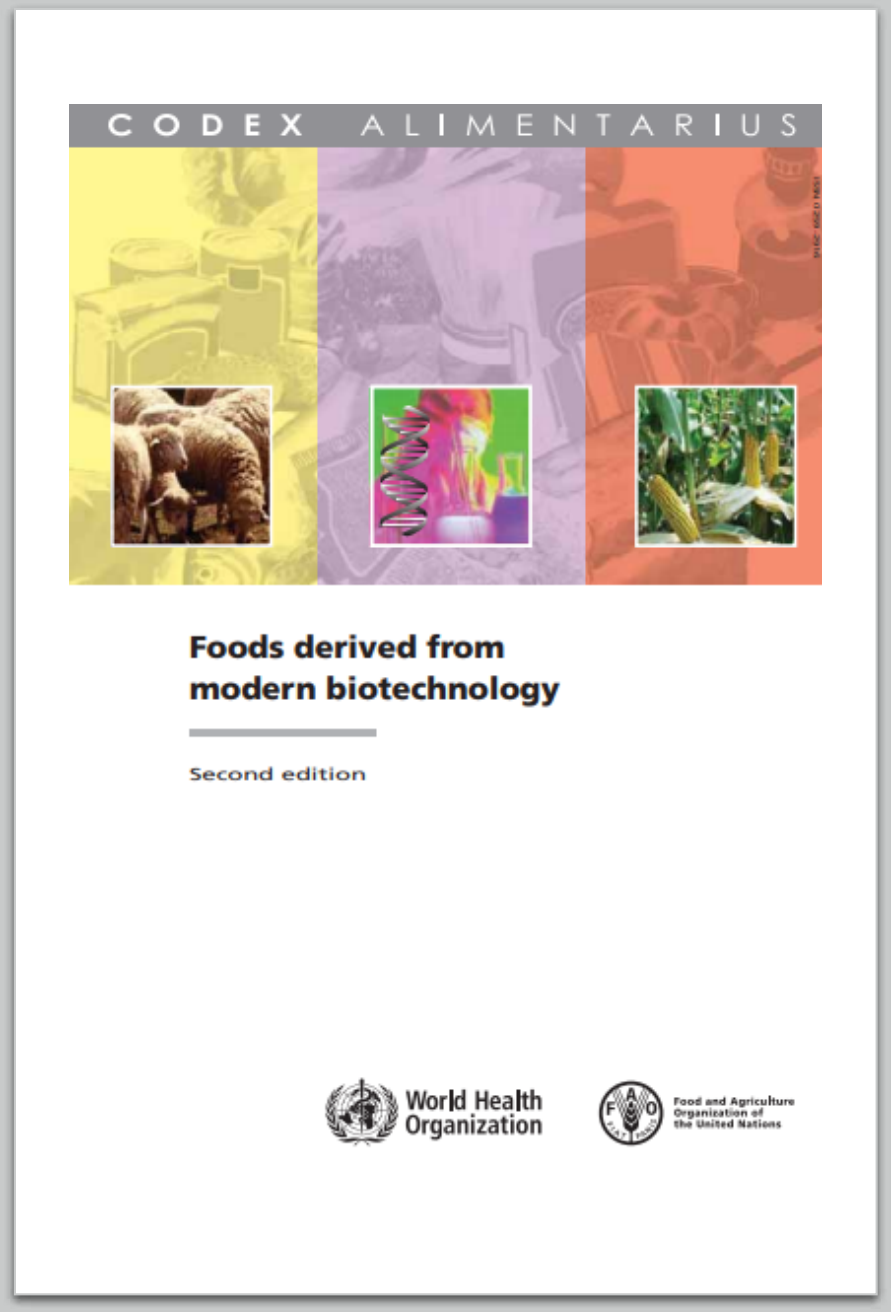
- Argentina have more than 2 decades of experience in the safety assessment of GM plants, but no requests for evaluation of GM animals for food/feed have been received so far.
- There is legislation for GM plants, but there is no specific standard for evaluating GM food / feed animals.
- However, basic approaches for GM plant also apply to GM food animals, so they can be rapidly adapted to assess them.
- Currently, specific regulations under development based in Codex Guidelines.
- No mandatory segregation or special handle are required differentially to the regulation applied to conventional animals once the event is approved.

NORMATIVE BACKGROUND CONSIDERED

- **Codex Alimentarius - FAO- WHO**

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. **CAC/GA 44-2003**

- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals. **CAC/GL 68/2008**



CRITERIA APPLIED FOR THE RISK ASSESSMENT IN FOODS DERIVED FROM GM ANIMALS

- Comparative approach: use of a suitable conventional comparator.
- Case by case: Random insertion. Each request is a new evaluation.
- Scientific base: data and information based on sound scientific principles.
- Data quality: data and information must be of sufficient quality and quantity.
- Familiarity: in relation to the species and the novel traits that may have been already evaluated.
- History of safe consumption: reflects a degree of safety accepted by consumers.

The criteria and methodologies for the food safety assessment are intended to:

- Identify and characterize unintended effects, and evaluate their biological significance.
- Safety of the novel traits.
- Determine potential hazards (safety impacts) or nutritional concerns and gather information on their character and severity.


The objective of the Risk Assessment is to conclude that the GMA and the new foods derived from it, are as safe as and not less nutritious than the conventional counterpart.

Evaluation Process - Key Evidence

- Event Description and Molecular Characterization
- Animal Health
- Composition
- Allergenicity potencial
- Toxicological potential
- Nutritional Value

Event description and Molecular characterization

- History of food use, pathogenic characteristics of the donor and recipient organism;
- Characterization of the genetic modification(s) in the recombinant-DNA animal ultimately used as food or for food production
- Genes, vector map, No. of inserts, insertion methods;
- Use of antibiotic resistance marker genes
- Genetic stability;
- Expression products, biological function.
- Genetic construction; No. of insertion sites; No. of copies and sequences;
- Potential ORFs.

Animal Health

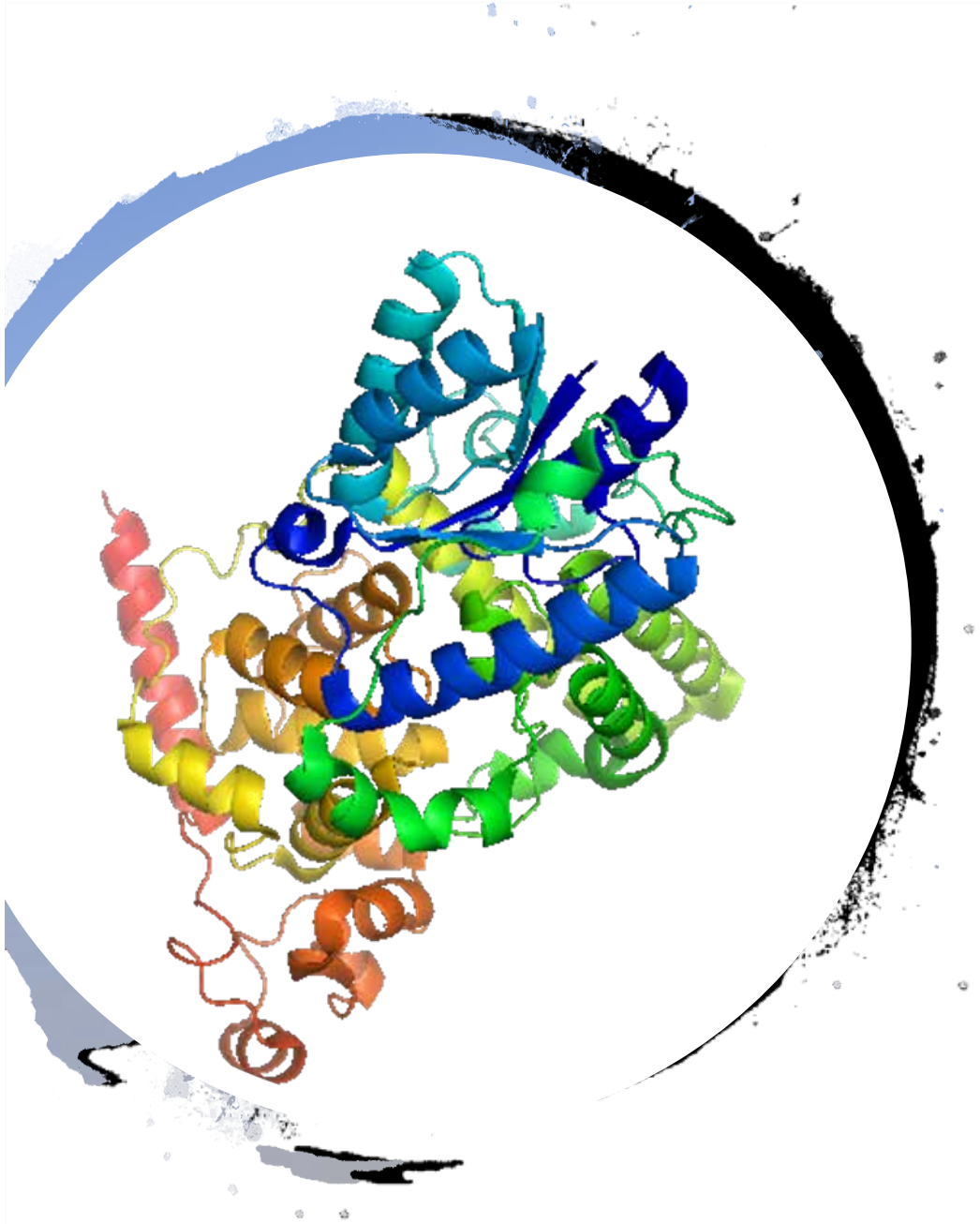
- Animals that have a history of safe consuption generally do not contain genes encoding for toxic substances.
- Therefore, animal health status is an excellent indicator of a potencial safe consumption.
- Compare the health status of the GM animal and the conventional counterpart, taking into account the development phase.

Compositional and Nutritional Assessment

- GM animal composition and conventional counterpart.
- Nutrients and antinutrients are compared.
- Other components may be required according to the type of GMO.
- Food safety and nutritional aspects of the GMO (animal feeding test).

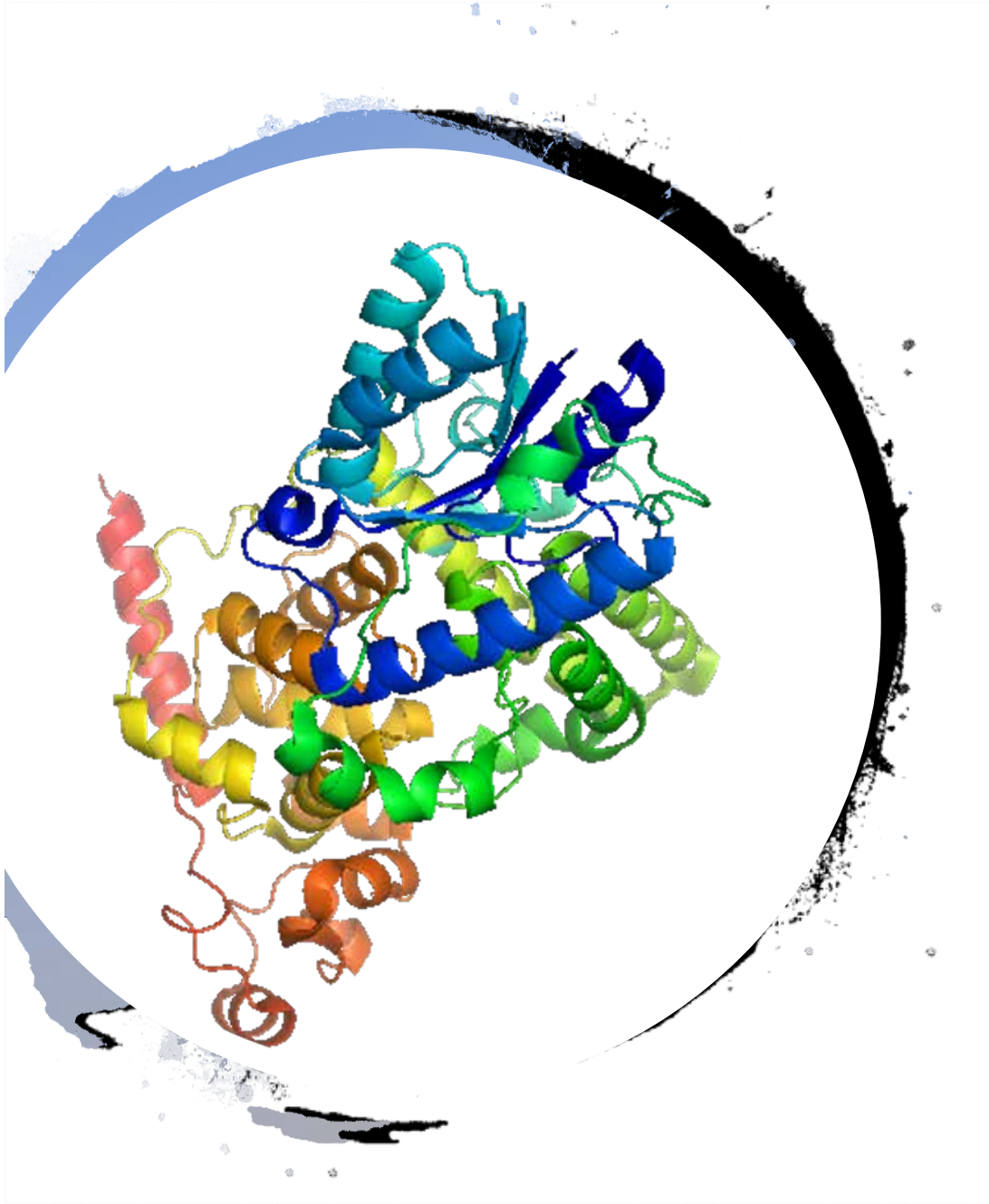
Compositional and Nutritional Assessment

- When there are statistically significant differences, patterns of changes are analyzed.
- Evaluate that difference in the context of the natural variability of the species.
- When the mean values are not included in the ranges of the comparisons made and the bibliography, it has to be verified that the statistical differences are not biologically significant.



Toxicity Assessment

- Novel substances expressed.
- Determination of toxicological potential based on the "weight of evidence".
- If there is a history of safe consumption, it is NOT necessary to conduct toxicological studies in animals.

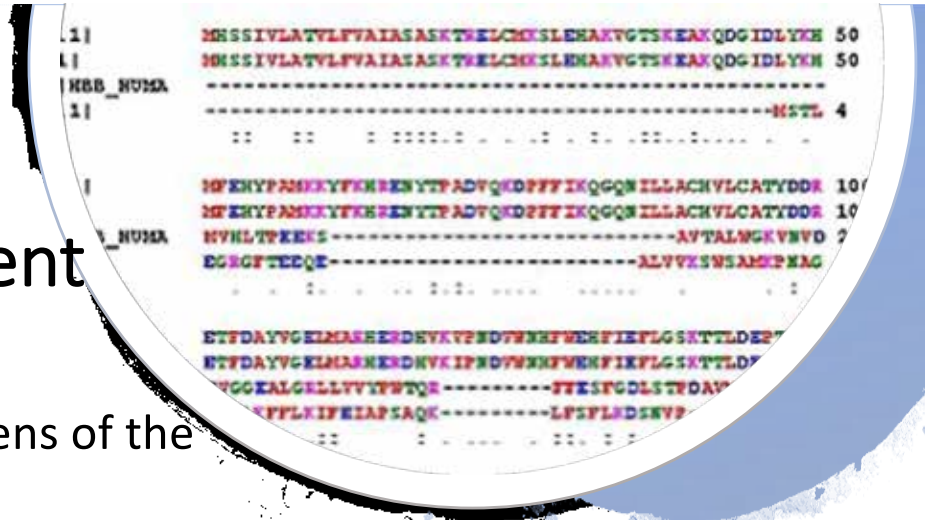


Toxicity Assessment

- Identification of known toxins in donor and recipient species.
- Identification of new toxins encoded by the transgenes.
- Similarity of expression products with known toxins (Bioinformatics).
- Thermal stability and resistance to gastric and intestinal model systems.
- Acute toxicology tests in animals, of the novel proteins with no history of consumption.

Allergenicity Assessment

- Identification of known allergens of the donor and recipient species.
- Identification of potential new allergens encoded by the transgenes.
- Similarity of expression products with known allergens (Bioinformatics: a window of 80 amino acids is compared).
- Other evidence: molecular weight (10 kDa), expression levels in food, resistance to processing (heat or other in vitro digestibility, glycosylation, IgE assays with serum from sensitive patients (if applicable).



Nutritional Assessment

- When the nutritional profile is intentionally modified or changes in the bioavailability of nutrients are expected, feeding trials with the whole food may be requested.
- Nutritional value, nutrient bioavailability, and safety are compared.
- Use conventional foods whose nutritional composition is closer, as appropriate comparator.
- For specific population subgroups, additional nutritional assessments may be necessary.

Decision Documents - SENASA

www.argentina.gob.ar/senasa

- Explain the risk assessment that is carried out.
- Reports on the evaluated event.
- Details the food safety assessment and conclusions.
- Published on the SENASA website (spanish and english)
- https://www.argentina.gob.ar/senasa/programas-sanitarios/biotecnologia

Thank you very much!

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