Food Safety assessment of food derived from GM animals and Nutrition Considerations

Fourth International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies

September 12-16, 2022
São Roque, Brasil

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Principles for Risk Analysis of Foods Derived from Modern Biotechnology

Risk assessment
Risk management
Risk communication
Consistency
Capacity building and information exchange
Review processes

Sources: Foods derived from modern biotechnology

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS-C**AC/GL 68-2008**

GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS **CAC/GL 9-1987**

Recombinant-DNA animal means an animal in which the genetic material has been changed through *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.

Conventional counterpart means an animal breed with a known history of safe use as food from which the recombinant-DNA animal line was derived, as well as the breeding partners used in generating the animals ultimately used as food, and/or food deriived from such animals.

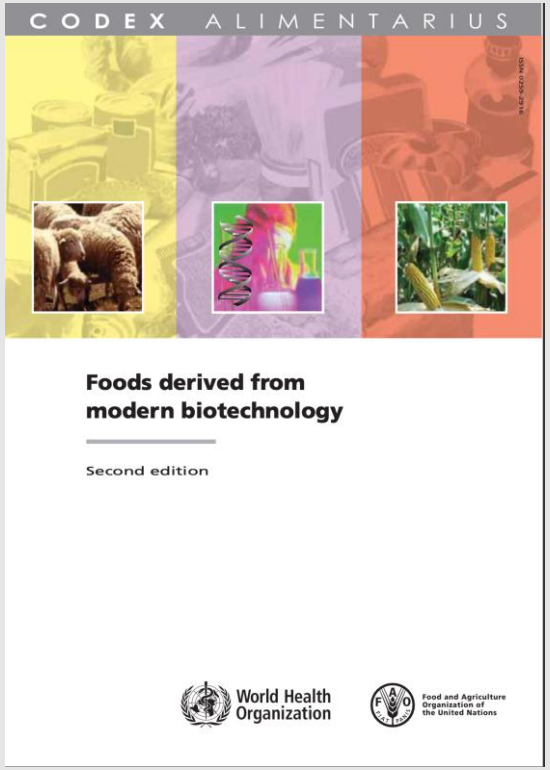
Nutrient means any substance normally consumed as a constituent of food:
a) that provides energy; or
b) that is needed for growth and development and maintenance of healthy life; or c) a deficit of which will cause characteristic biochemical or physiological changes to occur.

Framework of food safety assessment

Source:
GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS-C**AC/GL 68-2008**

pg 57 – 76

https://www.fao.org/sustainable-food-value-chains/library/details/en/c/265868/



A. general description of the recombinant-DNA animal;

B. description of the recipient animal prior to the modificationa nd its use as food or for food production;

C. description of the donor organism or other source(s) of the introduced recombinant- DNA ;

D. description of the genetic modification(s) including the construct(s) used to introduce the recombinant-DNA;

E. description of the methods used to produce the initial recombinant-DNA animal and the processes to produce the recombinant-DNA animal ultimately used as food or for food production;

F. characterization of the genetic modification(s) in the recombinant-DNA animal ultimately used as food or for food production;

G. Safety assessment:
   a) health status of the recombinant-DNA animal,
   b) expressed substances (non-nucleic acid substances),
   c) compositional analyses of key components,
   d) food storage and processing, and
   e) intended nutritional modification;

H. Other considerations.

Aditional considerations for the Safety Assessment of Foods Derived from r-DNA animals Modified for Nutritional or Health Benefits

a) the recombinant-DNA animal exhibits a particular trait in portion(s) of the animal intended for food use; and

b) the trait is a result of:
(i) introduction of a new nutrient(s) or related substance(s),

(ii) alteration of either the quantity or bioavailability of a nutrient(s) or related substance(s),

(iii) removal or reduction of undesirable substance(s) (e.g. allergens or toxicants), or

(iv) alteration of the interaction(s) of nutritional or health relevance of these substances.

a) Identification of new or altered hazards relative to the conventional counterpart ;
b) r--DNA animals modified for nutritional or health benefits result in food products with a composition that may be significantly different from their conventional counterparts, so choice of an appropriate comparator is of a great importance for the safety assessemnt;
c) Upper levels of intake and public health implications of exceeding this levels and ADI (acceptable daily intake);
d) Bioavailability of the nutrient(s), related substance(s) or undesirable substance(s) in the food that were the subject of the modification in the r-DNA animal might be established, where appropriate.
e) Dietary exposure assessment is the estimation of the concentration of the nutrient(s) or related substance(s) in a food, the expected or foreseeable consumption of that food, and any known factors that influence bioavailability . Exposure should be evaluated in a contexto of the total diet and the assessment based on the custumary dietary composition .
f) Consumption patterns will vary from country to country depending on the importance of the food in the diet(s) of a given population(s).
g) Assessments of different consumption scenarios , considering changes in biovailability and distribution of exposures within the relevant population.

- Gene-edited pigs, above, have been made resistant to the PRRS virus - a deadly pig disease. Photograph: Murdo Macleod/The Guardian

Rosita Isa, a cow genetically modified to produce human-like milk. Photograph: INTA (National Agricultural Technology Institute Argentina)

A genetically modified mosquito emerges from its pupa. Photograph: Oxitec

Gene-edited chicks at the Roslin Institute. Photograph: Courtesy of Valerie White/Norrie Russell/Roslin Institute

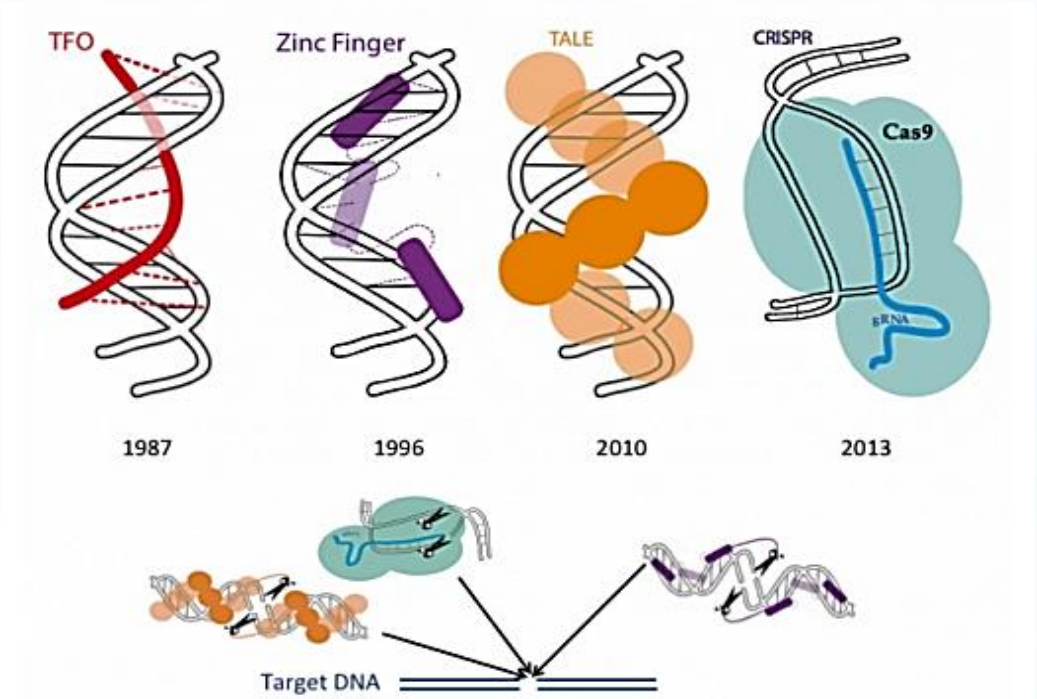
GalSafe pig for human food consumption and potential therapeut uses.

FDA has determined that food from the AquAdvantage Salmon and the GalSafe pig are as safe and nutritious to eat as food from non-GMO salmon and pigs

one of AquaBounty's genetically engineered salmon behind a regular salmon of the same age. Photograph: AquaBounty Technologies

https://www.theguardian.com/environment/2018/jun/24/genetically-engineered-animals-the-five-controversial-science

... CRISPRs Technology brought a revolution in Genome Editing and is democratizing the use of biotechnology in agriculture

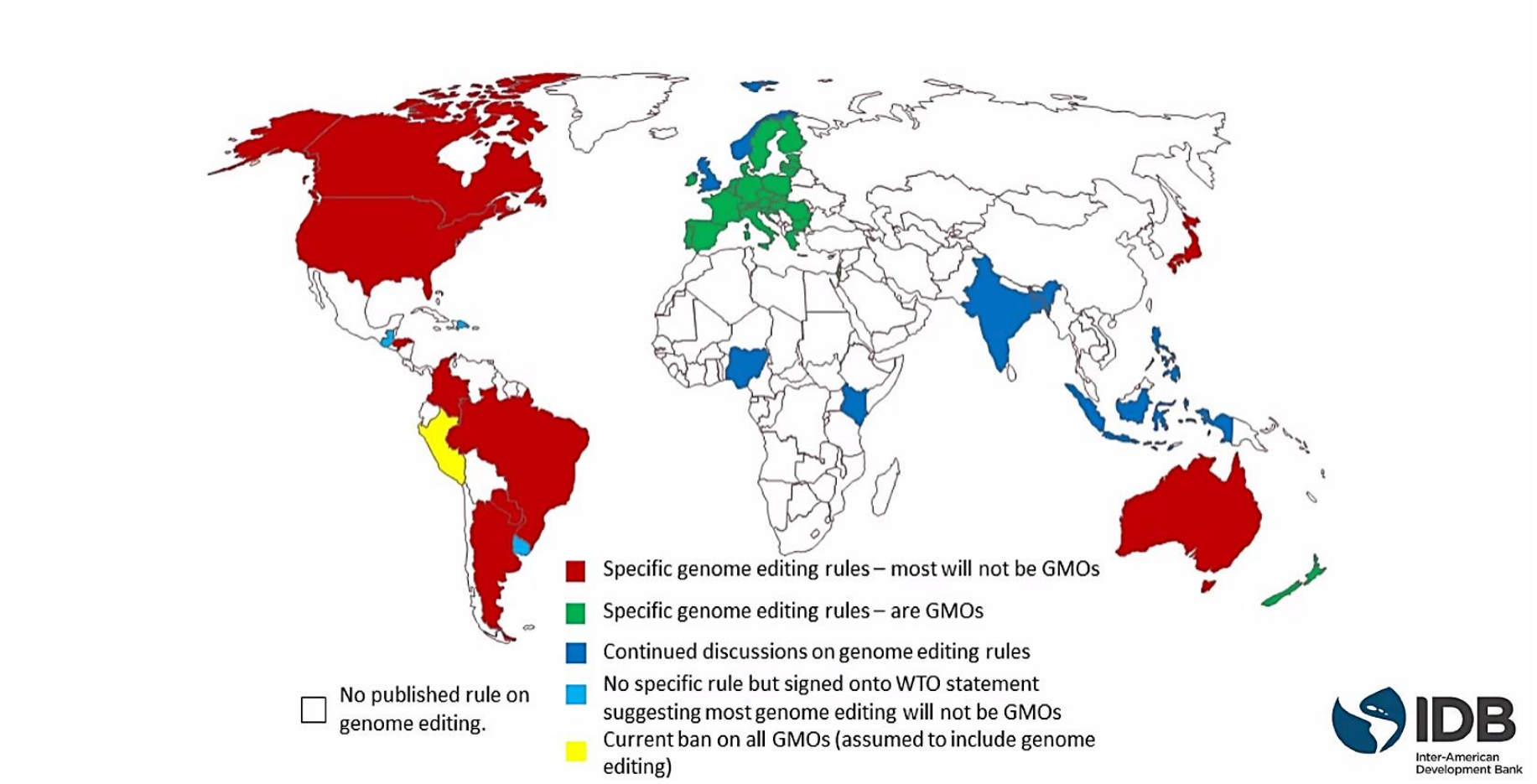


The guidelines for the assessment of r-DNA animals might not apply to New Breeding Techniques including CRISPR, so national and regional legislation should be considered.

Jennifer Doudna Emmanuelle Charpentier Feng Zhang

Global Regulatory Status

New Breeding Techniques



Agronomic Biofortification

Enrichment of food of animal origin with biologically active compounds, for the production of eggs, milk, or meat enriched with ingredients such as polyunsaturated fatty acids, vitamins, and /or
macro- and micronutrients.

Biofortification of **milk and cheese** with micro elements (**Cu, Mn Zn**) to prevent from micronutrient deficiencies.

Dairy cattle fed with supplemented with **omega-3** generate milk with higher omega-3 content.

Biofortification of **eggs** with **Vitamin K ;**

Eggs with higher Omega 3 and 6 Omega-3 - by hens fed a diet with flaxseed

Consumption of provitamin A carotenoid biofortified crops, such as maize, supports vitamin A (VA) status in animals and humans. Laying hens that consume β-cryptoxanthin–biofortified maize deposit β-cryptoxanthin into egg yolk

Biofortification of meat with vitamin D

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4573109/
https://www.mdpi.com/2304-8158/9/11/1619
https://www.researchgate.net/publication/330729531_Biofortification_of_meat_with_vitamin_D
https://www.hindawi.com/journals/jchem/2018/8084127/

GM Salmon

nature International weekly journal of science

NATURE | NEWS

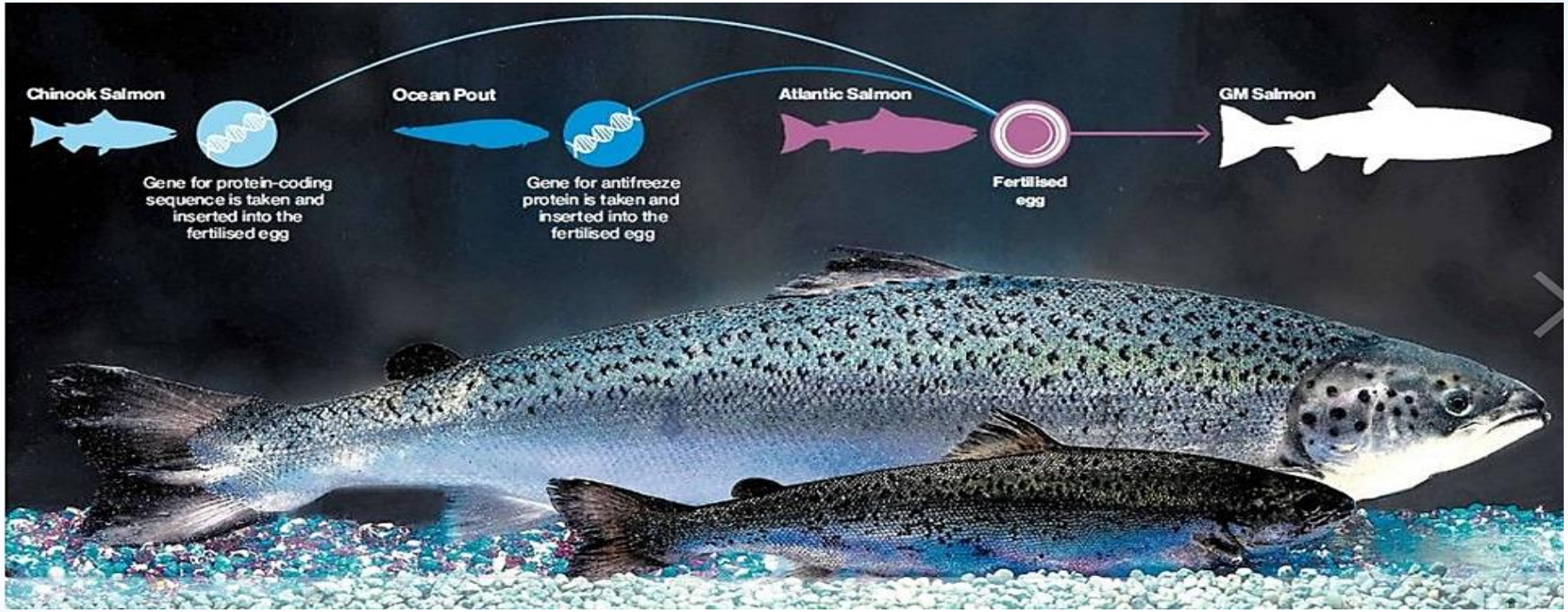
First genetically engineered salmon sold in Canada

US firm AquaBounty Technologies says that its transgenic fish has hit the market after a 25-year wait.

Emily Waltz

04 August 2017

Approved for consumption in Brazil on May 2021



Aedes sp. First GM insect GM (sterile male) released in Brasil

Authorized for commercial use in Brazil (March 2021)

GM Male Sterile Carterpillar (Lagarta do cartucho)
Spodoptera frugiperda

First LPMA for authorized research in May 2019 by CTNBio

intrexon

Embrapa

Considered Non GM by CTNBio (2019)

Genome Edited Tilapia

While AquaBounty's GMO salmon remains blocked in US, Argentina exempts the company's sustainable gene-edited tilapia from regulation

Fish Farming Expert | December 19, 2018

Image Credit: Medium

The Fish Site

Find species, diseases, articles... Breeding & genetics Farm management Health & welfare

Gene edited tilapia secure GMO exemption

REGULATIONS · POLITICS · GENETICS & BREEDING · BIOTECHNOLOGY

by The Fish Site
18 December 2018, at 2:06p.m.

A line of tilapia that has been gene edited will not be classified as a genetically modified organisms (GMOs) in Argentina, according to a government advisory commission.

The line, known as FLT 01, has been developed by Intrexon and its subsidiary AquaBounty Technologies., the biotechnology company best known for its AquaAdvantage salmon strain. The tilapia were developed using gene editing

Myostatin gene
Natural Mutation

Bovine breed
Belgian blue bull

Take Home Messages

- **Risk Analysis Principles –** should always be considered;
- **Guideline for the conduct of Food Safety Assessment of Foods Derived from recombinant-DNA Animals-CAC/GL 68-2008 ;**
- **Framework of food safety assessment –** should always be considered;
- **General Principles for the Addition of Essential Nutrients to Foods CAC/GL 9-1987;**
- **r-DNA animals Modified for Nutritional or Health Benefits -** Bioavailability of the nutrient(s), appropriate comparator, dietary exposure assessment, Upper levels and ADI, consumption patterns and different consumption scenarios;
- **r-DNA animals Modified for Nutritional for Health Benefits** are **not** substantial equivalent to the comparator;
- **New breeding Techniques may not** require Food Safety Assessment of Foods Derived from recombinant-DNA Animals and should be evaluated in a **case by case basis**.
- **Agronomic Biofortification** - alternative for nutrition enhancement.

Thank you, gracias, obrigada ... marilia.nutti@embrapa.br