

Animal Biotechnology Regulation & Opportunities for Harmonization

Regulatory Approaches in Different Countries

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Foreign Agricultural Service

United States Department of Agriculture

Multiple Roles of REGULATIONS:

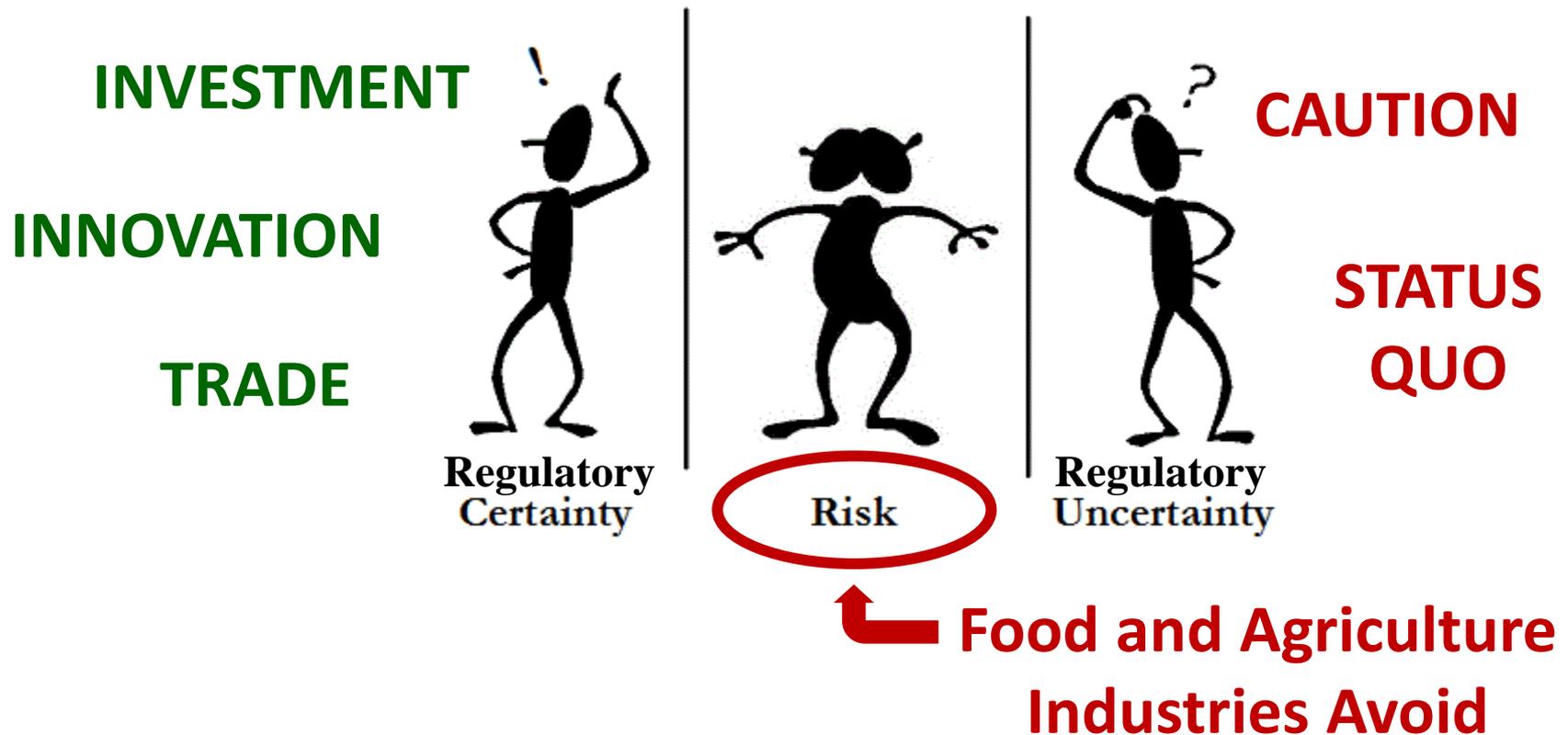
- Protect public health & safety
- Instill trust in the food supply
- Encourage development of new ideas and innovations



Global Regulatory Goals

- Science-based, risk-based and defensible
- Timely and predictable (important for innovation)
- Transparent to all
- Credible to the public – whose concerns may reflect non-scientific, values-based issues
- **Effective regulations**
 - Protect public safety
 - Allow production and trade of safe products

Regulatory Approaches Impact Innovation and Trade



No “Best” Approach: Different Countries – Different Effective Regulatory Approaches

- *New* biotechnology laws vs. utilized *Existing* laws
- Differences in existing regulatory structures and legal enabling authorities, as well as different philosophies
- Oversight by different authorities (ministries):
 - Agriculture (or Fisheries), Environment, or Food
 - Shared oversight by multiple ministries
- Different regulatory triggers: product vs. process

Using Existing Laws – United States

- In 1986, the U.S. government established the ***Coordinated Framework for the Regulation of Biotechnology***. (updated in 1992, 2017)
- Individual U.S. Agencies issue regulations to implement their individual pre-existing laws and create guidances to help sponsors prepare their regulatory submissions.



Genetically Engineered Animals under the Coordinated Framework

- Lead regulatory agency varies with intended use of the animal and/or traits and characteristics



Food/Biopharma



Insecticides



Crop Pests

- Since 2009, the Food and Drug Administration (FDA) regulates under their authority for “*new animal drugs*,” with drug being “*an article intended to alter the structure or function*” of the animal (**trigger**)
- New animal drug approval is based on a showing that the product is “safe” (for animals, humans, and the environment) and “effective” for the **intended use**



Creating New Laws – Brazil



- New Law (2005) governing “GMOs”
- **Trigger:** identification as “GMO”
- Created a National Biosafety Council, and established the National Biosafety Policy
- Restructured National Biosafety Technical Commission (CTNBio) responsible for regulation of biotechnology



Other countries have also created GMO laws (e.g., Australia, New Zealand, EU, Argentina)

BRAZIL: CTNBio

“GMO” laws covering Animals:

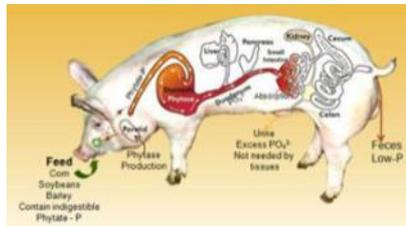
- **April 27, 2009, CTNBio issued Normative Resolution (Nº 7) regulating the development, commercial use, and import of GM animals and their release into the environment**
 - Provides on rules for planned release into the environment of Risk Class I Genetically Modified Microorganisms (GMM) and Genetically Modified Animals (GMA) and their derivatives.
- **January 15, 2018, CTNBio issued Normative Resolution (Nº 16) for regulatory approach to Precision Breeding Innovation Techniques, including gene edited products.**



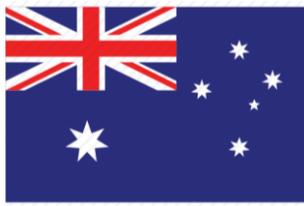
Existing and New Laws – Canada



- **Canadian Regulatory Framework for Biotechnology (1993)** → Use of existing legislation; animals and related food and feed products in Canada were already subject to rigorous health and safety regulations
- GE animal products regulated under Environmental Protection Act (1999; written with GE animals in mind)
- **Regulatory guidance for animate biotechnologies**, including livestock, fish, insects (Environment Canada)



- **Safety of foods** from GE animals assessed by Health Canada and Canadian Food Inspection Agency under **Novel Foods Regulations** (**trigger** – product identified as novel)
- Canada is unique: **“novel” covers conventional breeding**



Shared Responsibility – Australia and New Zealand



Shared Food Safety Authority:

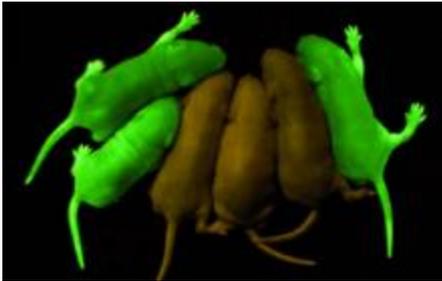
- **Food Standards Australia New Zealand (FSANZ) develops food standards for Australia and New Zealand.**
- The Code is enforced by state and territory departments, agencies and local councils in Australia; the Ministry for Primary Industries in New Zealand and the Australian Department of Agriculture and Water Resources for food imported into Australia.

Environmental assessments separate: different laws/regulations

- Australia: Office of the Gene Technology Regulator (OGTR)
- New Zealand: Environmental Protection Authority (EPA)

Commercialization of Animal Biotechnology

Research



Transgenic models
(rodents, fish, pigs, etc.)

Pets



GloFish (2003 USA)
~15% of U.S. market

Medicine



from: Goat milk (*EU2006/US2009*)
Rabbit milk (*EU2010/US2014*)
Eggs (*EU/US 2015*) . . .

Vector Control



Oxitec mosquito
(2014 Brazil)

Food



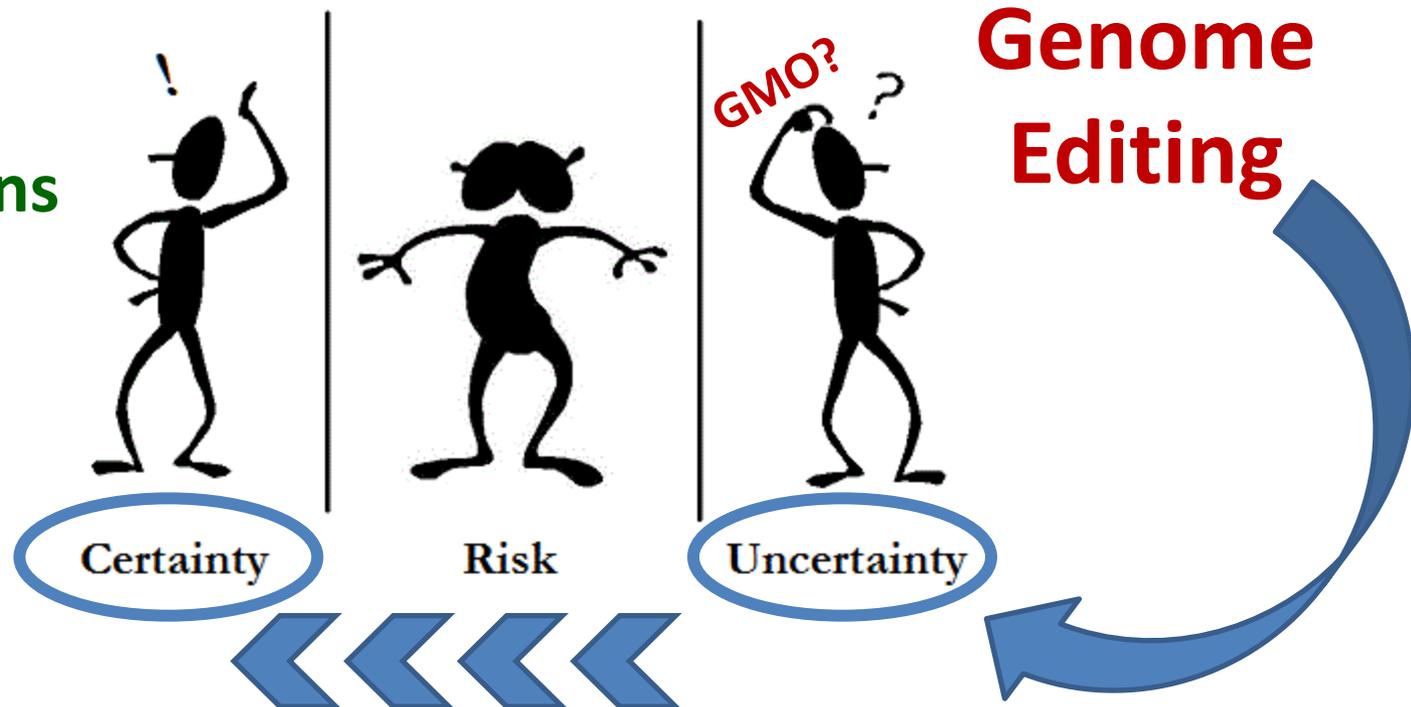
AquAdvantage Salmon
(2015 USA, 2016 Canada)

Now on
market in
Canada

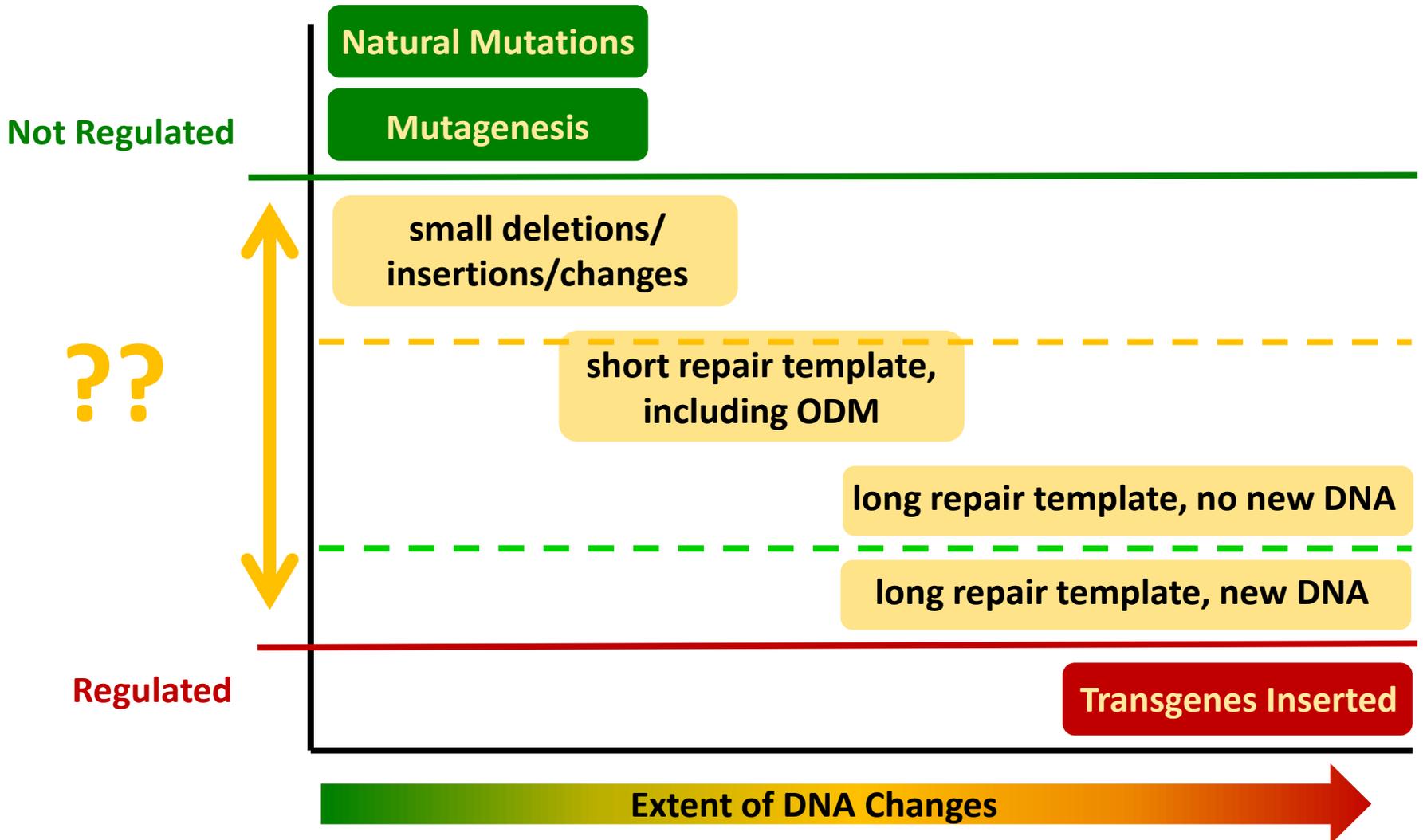
Regulatory Approaches for Genome Editing?

- In some cases, traits could be introduced via natural breeding, but more quickly (decreased generation time) and precisely
- Some may not require additional regulations

Local Solutions
for Regional
Problems



“When to Regulate?” Debate



Global Regulatory Status

Canada: Not regulated unless product identified as novel

United States: For plants – USDA ‘Am I Regulated?’ letters, FDA & EPA not determined; **uncertainty for animals**

Argentina, Brazil, Colombia, Chile: Case by case approaches; foreign DNA insertions generally regulated as GMO

Norway: Proposed; foreign DNA insertion regulated; case-by-case tiered approach – notification, expedited, standard review

Europe: Awaiting summer 2018 European Court of Justice ruling

China, Japan, Korea: Issue still being debated; no formal guidance

Israel: Foreign DNA insertions regulated

Philippines: Under consideration; Foreign DNA insertions generally regulated as GMO

Australia: Under review; possibly regulated whenever when templates involved; case-by-case review

New Zealand: Initial “non-GMO” ruling for gene editing struck down by courts

 Countries with regulatory policy

 Countries with **pending** policies, regulations, or legal rulings

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2018: First determination that genome edited animal is not a GMO, but a conventional animal

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HOW TO ADDRESS GE ANIMALS •

GE animal: Applicant's previous consultation

CONABIA

Is there a new combination of genetic material?

NO

Non
GMO

GE animal does not fall under GMA Regulations

YES

GMO

GE animal falls under GMA Regulations

» CONABIA will determine if the final product has a new combination of genetic material.

X If it does not, the Applicant will be informed that the GE animal does not fall under GM-Animal Regulations.

✓ Otherwise, the GE Animal product will have to go through the regulatory process.



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» CONABIA may recommend the authorities the adoption of **follow-up or monitoring measures** for an individual genome-edited animal not regarded as GMO based on its features and/or novelty.



Global Regulatory Goals and Challenges for Genome Edited Animals

Goals:

- Regulatory approaches that reflect **characteristics** and **potential risk** of **products** of new technologies
- Allow safe products to be used by farmers and go to market (using country's **existing** animal production systems)

Challenges and Trade Concerns:

- Regulatory approaches for biotechnology for many countries **developed for crops** (even if intended to cover animals as well).
- Provisions required for conventional genetic engineering may not apply to products of genome editing (*e.g., testing*).
- Potential **misalignment** of countries' regulatory approaches.

Targets of Opportunity for Regulatory Compatibility and Cooperation

What is required?

- Agreement on what comprises relevant information
- Sharing of technically reliable scientific information

What makes it easier?

- Require only for information necessary for risk assessment or risk management
- Exchange of best practices and experience with other regulators
- Regional approaches or bilateral agreements, when possible

Think Globally

Think International Trade

- Regulations and technologies should develop together
- New technologies can't solve problems . . .
if they can't get to the farmers
- Involve farmers, producers, breeders
- Crucial to work across countries – not in isolation
 - The Market is Global (**Regional Approaches**)



Ideally, regulations should enable safe new products to reach the market.

Encourage development of new ideas and innovations . . .

Provide opportunity to utilize and combine the most appropriate and targeted tools to meet the challenges of the future.

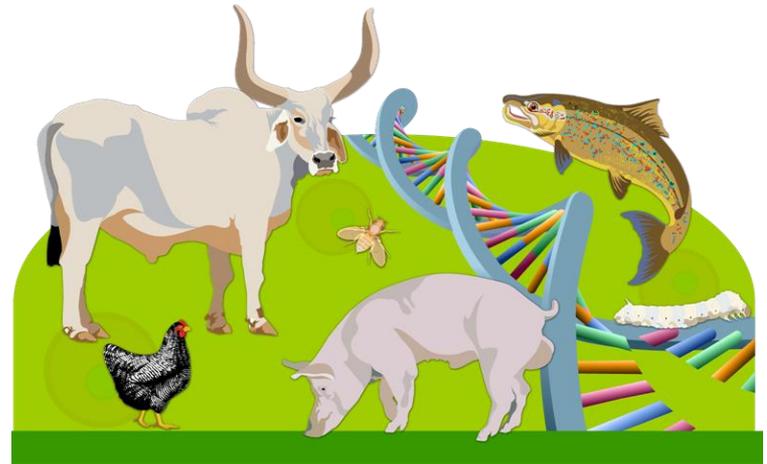


**« Nous avons considéré tous les risques potentiels
sauf le risque d'éviter tous les risques »**



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USDA FAS Staff
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USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

Merci!



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