



Canadian Food  
Inspection Agency

Agence canadienne  
d'inspection des aliments

# Canadian and International Regulatory Aspects of Gene Editing Technology in Plant Products

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Canada

# *How is Biotechnology Defined in Canada?*

*“...the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.”*

Genome editing is a general term for technologies used to create specific and targeted genetic changes in plants, animals or micro-organisms.

Examples of genome editing techniques include:

- Zinc finger nucleases
- TALENs (Transcriptional activator-like effector nucleases)
- CRISPR/Cas9 (clustered regularly interspaced short palindromic repeats / CRISPR associated protein 9)
- ODM (Oligonucleotide Directed Mutagenesis)

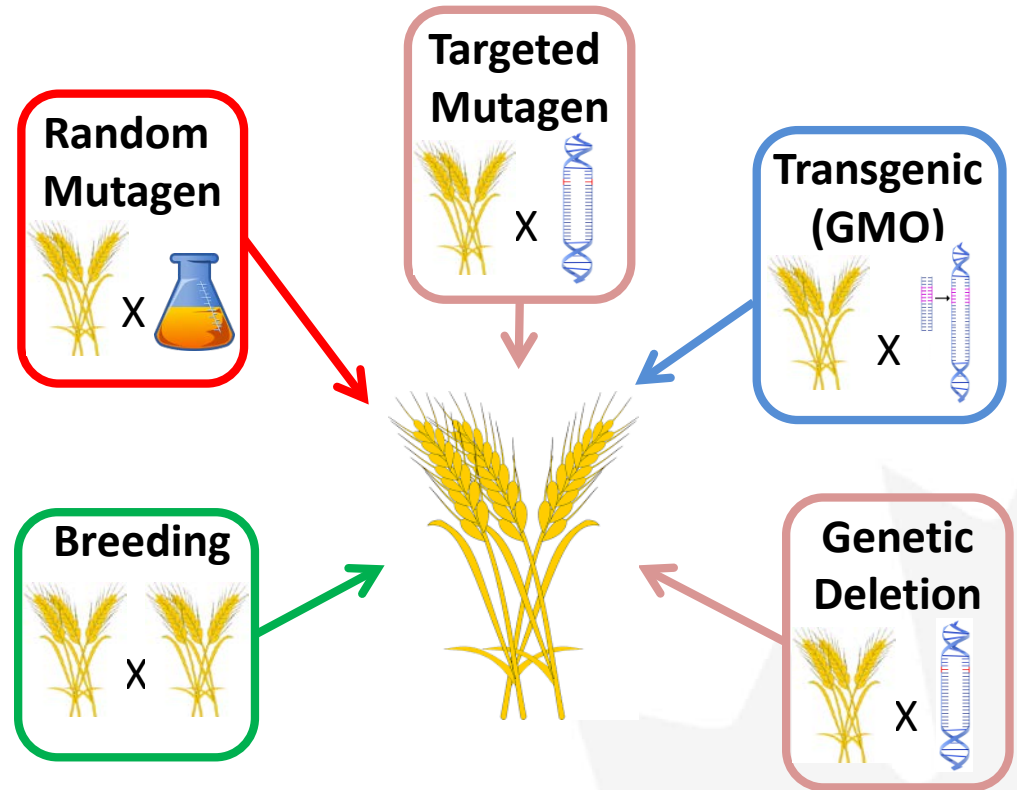
# Oversight of Biotechnology in Canada

Lead	Product	Regulation
CFIA	Livestock feed	<i>Feeds Act</i>
	Seeds	<i>Seeds Act</i>
	Fertilizer	<i>Fertilizers Act</i>
	Veterinary biologics	<i>Health of Animal Act</i>
HC	Pesticides	<i>Pest Control Products Act</i>
	Novel foods, drugs, and biologics, medical devices	<i>Food and Drugs Act</i>
ECCC, HC, DFO	All other substances	<i>Canadian Env. Protection Act</i>
AAFC, GAC, ISED	Non-regulatory considerations	<i>Market access, industrial policy, socio-economic impacts, trade</i>

# Canadian Regulatory Approach

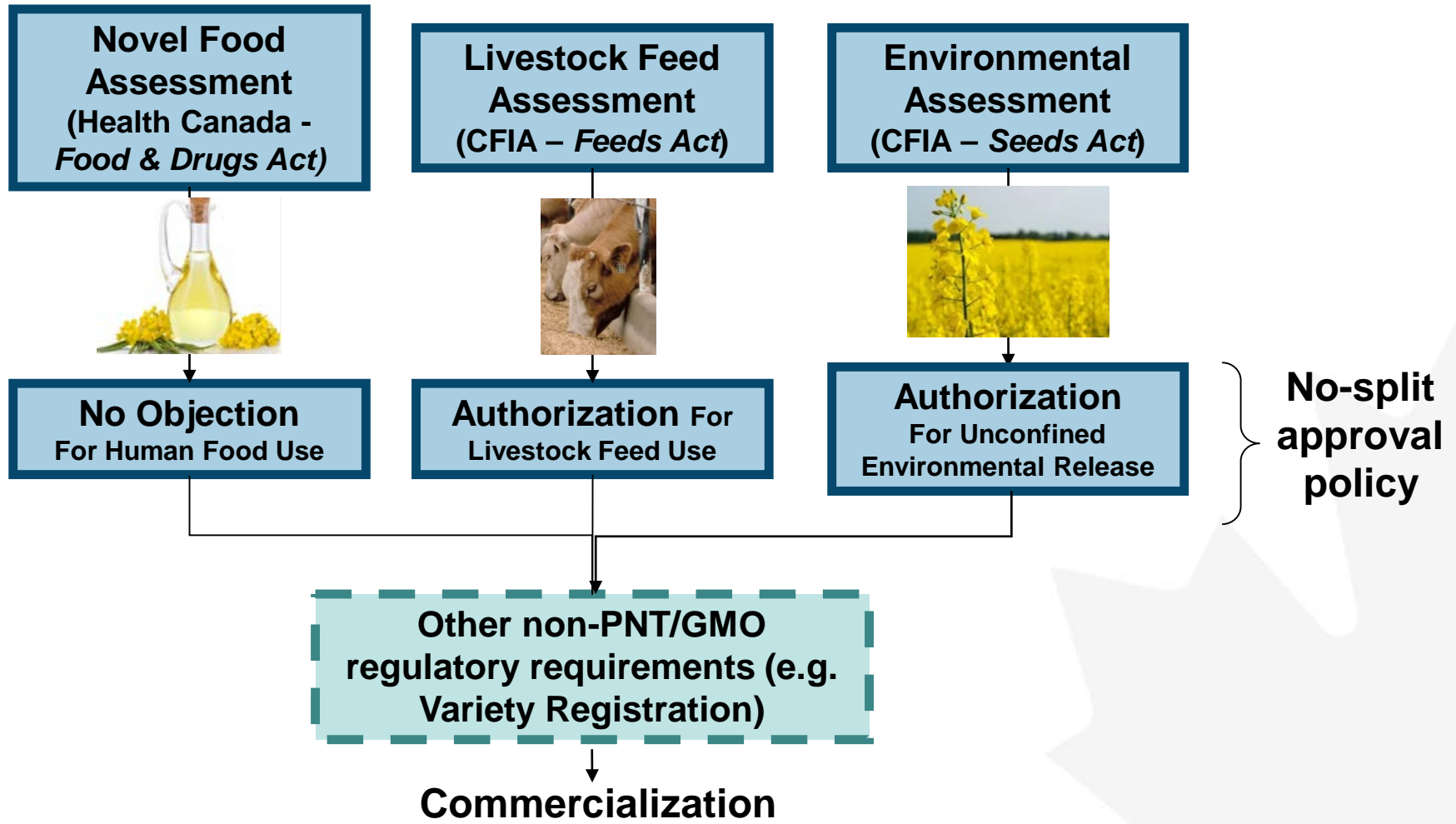
Same trait, regardless of technology

Canada regulates  
**PRODUCTS**



*With many paths to the same result, the consistent, risk-based regulatory approach is to regulate products, not processes,*

# Authorization Pathway



# *Risk-Based Approach*

## **Three Regulatory Areas: Food, Feed, Environment**

- Not every novel product triggers all three (e.g., tropical plants)

## **Risk-Appropriate Regulation**

- Pre-market assessment required for “novel” products
- Not every product of biotechnology would be considered ‘novel’ (e.g., [Orange petunia](#))

## **Flexibility of Information Requirements**

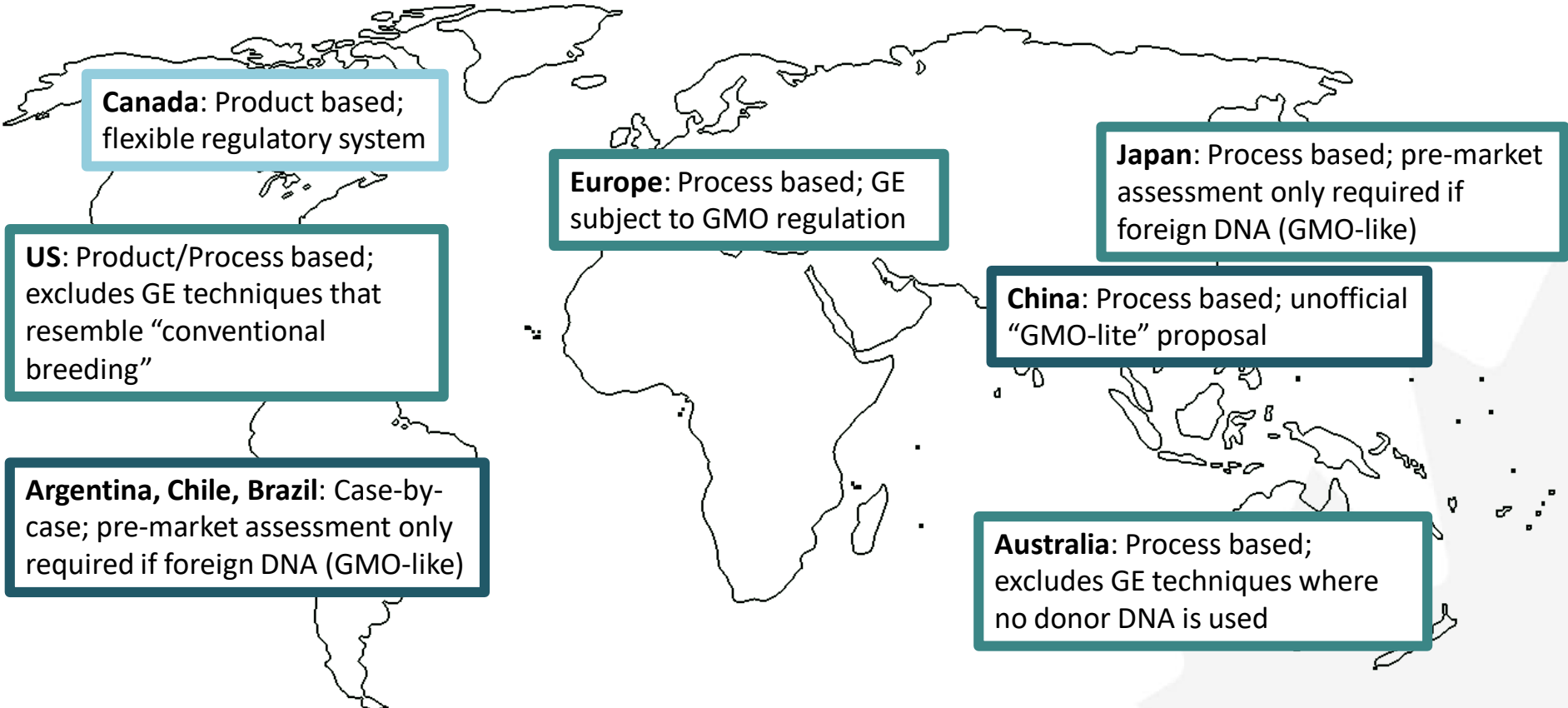
- Not prescriptive, can use own data, or bridge to other sources
- Policy options exempt certain classes of products from being assessed (e.g., re-transformation, stacked products, familiar products)

# *Take Home Messages/ Next Steps*

- Canada regulates PRODUCTS, which may include some but not all products of genome editing.
- Canada's regulations have the flexibility to include evolving technologies, and, if a product is novel, to be flexible in how safety is demonstrated.
- Improved guidance will aim to increase predictability and transparency in determinations of regulatory status
- Your active participation in providing input into this evolution is both necessary and appreciated



# International Context



**Canada:** Product based; flexible regulatory system

**US:** Product/Process based; excludes GE techniques that resemble “conventional breeding”

**Argentina, Chile, Brazil:** Case-by-case; pre-market assessment only required if foreign DNA (GMO-like)

**Europe:** Process based; GE subject to GMO regulation

**China:** Process based; unofficial “GMO-lite” proposal

**Japan:** Process based; pre-market assessment only required if foreign DNA (GMO-like)

**Australia:** Process based; excludes GE techniques where no donor DNA is used



# *For more information about novel products in Canada*

**Health Canada Web address:**

<https://www.canada.ca/en/health-canada.html>

**Feed Web address:**

<http://www.inspection.gc.ca/animals/feeds/eng/1299157225486/1320536661238>

**Environmental Release (PNT) Web address:**

<http://www.inspection.gc.ca/plants/plants-with-novel-traits/eng/1300137887237/1300137939635>