



Agriculture and  
Agri-Food Canada

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Agroalimentaire Canada

Canada



# Canada's Regulatory Approach to Products of Plant Breeding

# Outline

- Policy Considerations
- Canada's Regulatory Framework
- Guidance for new plant breeding innovations
  - Health Canada: Novel food
  - Canadian Food Inspection Agency (CFIA): Novel Seed
- Transparency

# Policy Considerations

- Innovation necessary to help address global challenges, such as enhancing food security, improving agriculture sustainability and climate resilience
- Science- and risk-based regulatory frameworks are necessary to encourage investment and innovation, while facilitating trade and protecting health and safety
- The oversight of gene-edited products should be clear and proportionate to their risk
- International cooperation, policy alignment and trade predictability

In this context, Seed developers asked Canada to clarify how its “novelty” approach applies - based on a product’s characteristics, not the technology used

# Updating Canada's Regulatory Guidance: Science-based

- Health Canada published a scientific opinion on the regulation of gene-edited plant products in the context of the *Novel Food Regulations*
- The CFIA published a rationale for updated guidelines on which plants are regulated under the *Seeds Regulations*
- **Key Conclusions:**
  - Gene editing technologies do not pose any unique risks to food or environmental safety compared with other plant breeding practices.
  - Gene-edited plant products should be regulated like all other plant products
  - Maintain product based approach to regulating “novel” foods and seeds → regulation remains based on the characteristics and not the specific process used to introduce those characteristics

# Health Canada's Updated Guidance

What foods derived from NGTs will **NOT** require pre-market notification and assessment as novel foods under the new guidance?

1. Foods derived from plants with genetic modifications that do not alter an endogenous protein in a way that introduces or increases similarity with a known **allergen or toxin** relevant to human health;
  2. Foods derived from plants with genetic modifications that do not increase levels of a known **endogenous allergen**, a known **endogenous toxin**, or a known **endogenous anti-nutrient** beyond the documented ranges observed for these analytes in the plant species;
  3. Foods derived from plants with genetic modifications that do not have an impact on **key nutritional composition and/or metabolism**;
  4. Foods derived from plants with genetic modifications that do not intentionally change the **food use** of the plant; and
  5. Foods derived from plants with genetic modifications that do not result in the presence of **foreign DNA** in the final plant product.
- **If a plant does not meet all 5 criteria, foods derived from that plant are considered novel foods and require pre-market assessment.**

# Canadian Food Inspection Agency (CFIA) Guidance Updates: Seed

Regulatory principles have not changed: Plant breeders remain responsible for notifying the CFIA of plants that have the potential to impact that environment.

Updated guidance published on May 3<sup>rd</sup> clarifies that:

- Almost all conventionally-bred plants are substantially equivalent to other plants of that species in Canada, except herbicide tolerant (HT) plants)
- Gene-edited plants are regulated using a product-based approach, like any other product of plant breeding
- Plants developed by inserting foreign DNA and all HT plants and require CFIA assessment and authorization

# Transparency for NGTs

- To address public interest in greater transparency regarding gene-edited plant products, Health Canada developed the [Transparency Initiative](#).
  - Provide information on the types of gene-edited plant products that may be used as food in the Canadian market
  - [List of non-novel products of plant breeding for food use](#)
    - Products notified through the Transparency Initiative
    - Products reviewed through [Novelty Determination Process](#)
- Seed sector has committed to fully participate in mechanisms that support transparency, including
  - best-practices for introducing new plant lines to the marketplace, as established by industry and commodity associations
  - Industry led [Canadian Variety Transparency Database](#) to indicate varieties developed with gene editing. There will be government oversight to monitor the database for completeness and accuracy.

QUESTIONS?





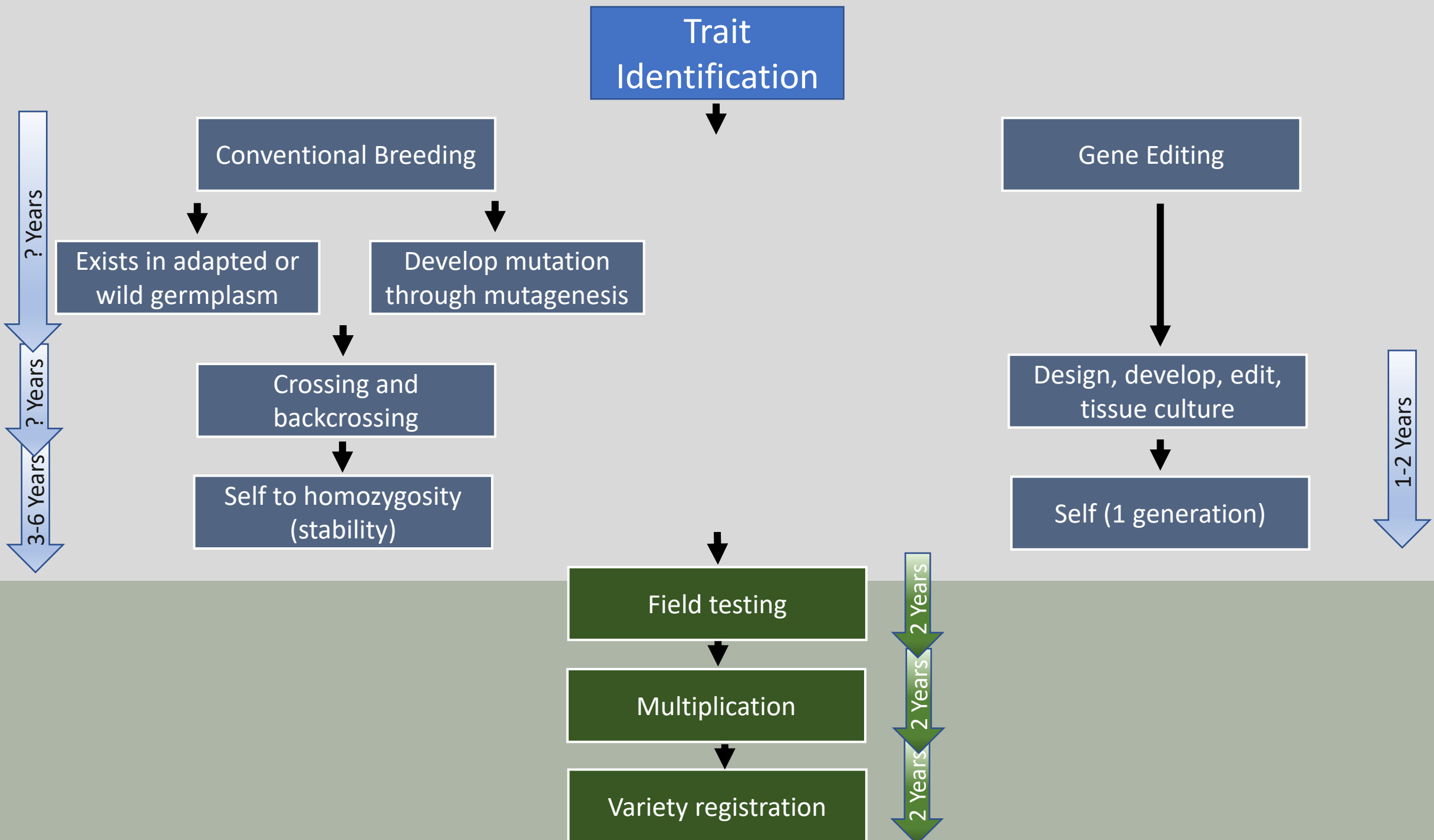
Canadian Plant Breeder  
Perspective:  
Innovation and New  
Genomic Techniques

Dr Jodi Souter  
Co-Owner of J4 Agri-Science  
Adjunct Professor UBC  
Plant Breeder  
Farmer  
2020 Nuffield Scholar

What is Gene Editing?

A Tool





# Opportunities





Thank You!



**CANADA  
GRAINS COUNCIL**

**Value Chain Perspectives on Transparency,  
Traceability, and Market Choice**

**Krista Thomas, VP Seed Innovation & Trade Policy**



The global grain handling system delivers **affordable nutrition** to the world.

A typical Panamax vessel carrying wheat holds enough calories to sustain 91 million people for one day, or 250,000 people for one year.

**I have been living through a seven-year drought. The moisture levels in the soil have been depleted at the deepest layer. We urgently need drought resistant varieties.**

***Cherilyn Jolie-Nagel,  
Saskatchewan, Canada***





# Canadian Variety Transparency Database

This database is part of a broader, seed industry-led effort to provide varietal level transparency.

Database – PBR

Database – Corn Hybrid

**Plant Breeders' Rights**

Variety Use Agreement

**Canadian Variety Transparency Database**

Accredited Labs

Registered Seed Establishments

Document Libraries

Seed Testing Resources

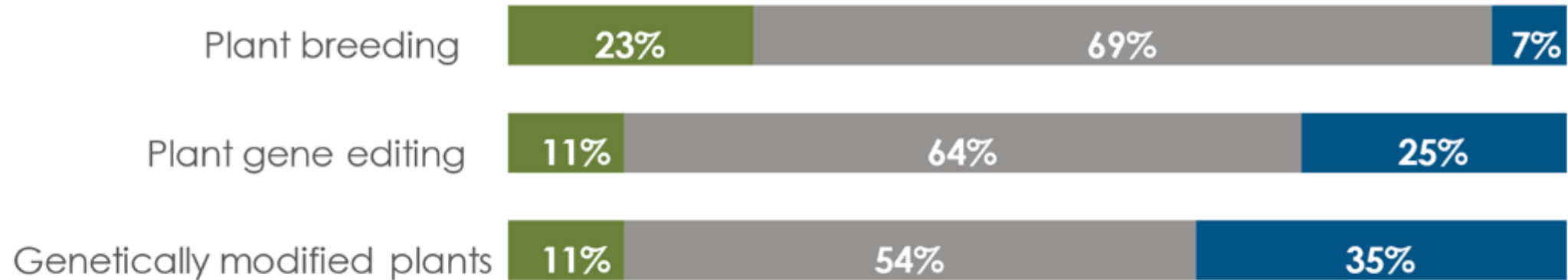
Contact Us

Variety Reg. #	Variety	Crop	Canadian Representative	Status	Health Canada Notification
6121	<b>BINSCARTH</b>	Barley, (Forage Type), six-row, spring	WAGON WHEEL SEED CORP. (ROGER & WARREN KAEDING)	National Registration	Not required
6301	<b>CORCY</b>	Barley, (Forage Type), six-row, spring	LA COOP FÉDÉRÉE	National Registration	Not required
4805	<b>SOMMERVILLE</b>	Barley, (Forage Type), six-row, spring	THOMPSONS LIMITED	National Registration	Not required

<https://seeds-canada.ca/en/seed-resources/transparency-database>

# Impressions of Breeding & Gene Editing

■ Positive    ■ Neutral    ■ Negative



# Closing Thoughts

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Regulations or policies, once in place, are hard to change.

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Aligning with trading partners early-on, helps to set the stage for future regulatory cooperation opportunities.

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Regulatory requirements should be sufficient to protect the public. Adding additional requirements beyond what is necessary does not make the public feel safer and comes with a global cost.