Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Canadian Food Inspection Agency



Our vision:
To excel as a science-based regulator, trusted and respected by Canadians and the international community.

Our mission:
Dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy.

Environmental release of plants with novel traits in Canada: A product-based approach to regulatory oversight

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Canada

OUTLINE

- Canadian regulatory framework for biotechnology
- Plants with novel traits (PNTs)
- How new plant breeding techniques relate to PNTs
- Canadian regulatory programs and policies for PNTs

How is Biotechnology Defined in Canada?

"**biotechnology** *means 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."*

– Canadian Environmental Protection Act (CEPA)

- This definition of biotechnology applies both to conventionally produced products and to those produced using techniques such as gene editing
- Products of biotechnology fall under the jurisdiction of CEPA or CEPA-equivalent acts (eg., *Seeds Act*, *Feeds Act*, *Food and Drugs Act*)

Regulatory Principles: Canadian Regulatory Framework for Biotechnology (1993)

- Intended to ensure that the benefits of biotechnology products and processes are realized in a way that protects health, safety, and the environment
- Use of existing legislation - products of biotechnology are not treated differently than other products with similar characteristics
- Regulation triggered primarily by ‘product’ and its novel trait - not ‘process’
- Novel traits can be introduced by such methods as traditional breeding, mutagenesis, cell fusion, recombinant DNA techniques, and other techniques
- Science-based, case-by-case assessment

Novelty Approach - Plants with Novel Traits

Defined as:

- plants into which one or more traits have been intentionally introduced, **and**
- where the introduced trait is both new to cultivated populations of the species in Canada **and** has a potential to affect the specific use and safety of the plant with respect to the environment and human health

Traits that were present in stable cultivated populations prior to 1996 are not considered new

The PNT definition is aligned with regulatory approaches for novel feeds and novel foods, including those derived from PNTs, although there are separate triggers for regulation for requiring pre-market assessment process

Regulation of a Novel Plant Product – Multiple Departments and Groups

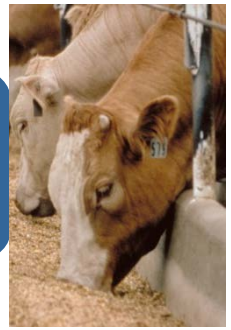
Canadian Food Inspection Agency (CFIA)
Health Canada (HC)

Product

Ie. Canola with Herbicide

CFIA – Plants with Novel Traits

CFIA – Novel Feed



HC – Novel Food

Plants with Novel Traits: Novelty Determination

- It is proponent's responsibility to characterize their plants and to self-identify to the CFIA when they have produced a regulated product
- The CFIA welcomes proponents to consult with us if they are unsure of whether their product may be regulated
- The CFIA has the ultimate decision-making authority in regulatory status determination
  - CFIA reserves the right to require proponent to provide scientific justification for determination that the plant is not a PNT
- Determination of whether a plant is a PNT is "product-based" not "process-based"

New Plant Breeding Techniques and Environmental Release of PNTs

The technique used to introduce a trait into a plant does not play a role in determination of whether the plant is a PNT

Example: Herbicide tolerant (HT) canola derived through:

- **Mutagenesis** (tolerance to imidazolinone and other AHAS inhibitors)
- **rDNA technology** (tolerance to glyphosate or glufosinate ammonium)
- **Gene editing** (herbicide tolerance)

Plants with any of the traits above raise the same concerns with respect to environmental safety: e.g. management of volunteers, development of HT weeds – consequently are treated alike.

New Plant Breeding Techniques and Environmental Release of PNTs *(cont'd)*

Product-based approach to regulating novel plant products allows the Canadian regulatory system to adjust to any new developments in the science of plant breeding.

This flexibility means that the Canadian system does not specifically define product types that either are, or are not, regulated.

Proponents are therefore encouraged to contact regulatory authorities early in the product development process to discuss potential regulatory requirements

Canadian Regulatory Programs and Policies for PNTs:

- Field trials (confined release)
- Unconfined release
- Stacks
- Retransformation and remutation

Summary

Considerations for all products, including those developed using NPBTs:

- Determination of novelty is based on newness + potential environmental impact.
- If the trait is not new, or does not have the potential to impact the environment, then it is not a PNT.
- If new, and if potential environmental impact is identified, then assessment of appropriate, risk-based application package.
- Contact with regulators to discuss novelty, data requirements, regulatory process, *etc*., is always welcomed

For more information…

Please visit our website for more information:

http://www.inspection.gc.ca

It contains all of our directives, fact sheets, PNTs under review and authorized, and links to other government departments regarding novel products

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Questions?


Canada

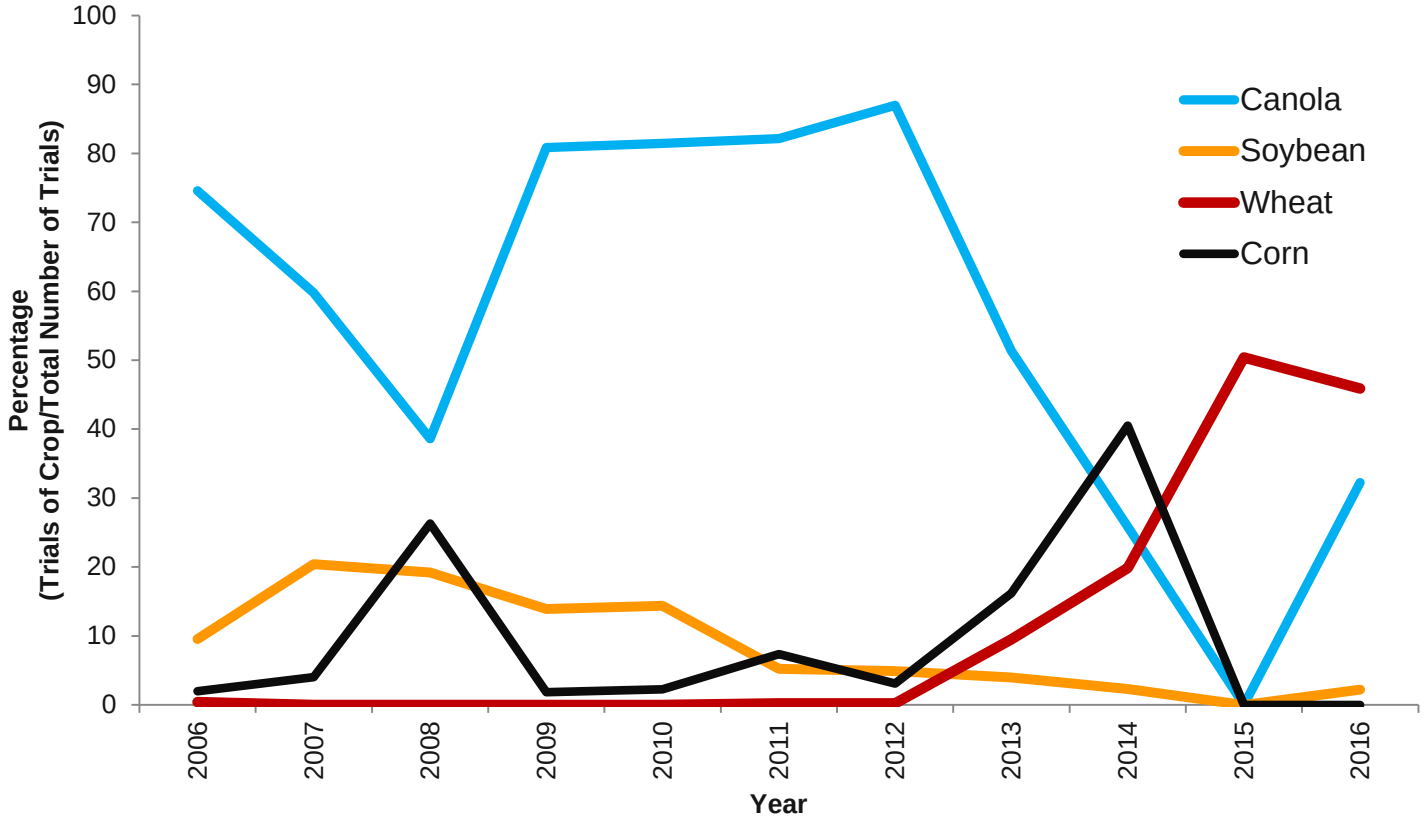
Additional information regarding Environmental Release programs

CRFT Program: Objectives

- To provide an opportunity for plant developers to study their plant in an agronomic setting, while minimizing environmental exposure
- To allow developers to generate data required to be submitted as part of a regulatory process, such as:
  - unconfined environmental release
  - variety registration
  - pesticide registration, etc.
- All trials are subject to conditions designed to:
  - prevent persistence and spread of the plant in the environment
  - prevent contamination of feed and food chain with unapproved plant material

CRFT Program: Trends

- More wheat coming into the CRFT program
- Relatively less canola, soybean, and corn
- Anticipate seeing more diversity of crop kinds in the future as technological advances make this more feasible



Unconfined Environmental Release Program

- Purpose: To allow the release of a PNT into the environment with limited or no restrictions
  - May require stewardship plans (eg: herbicide tolerance, insect resistance management)
- Authorized products have been assessed to be **as safe as comparable products** with a history of safe use
  - Does the addition of one or more traits change the plant's impact on the environment in comparison to the same crop being grown in an agricultural setting?

Unconfined Environmental Release Program

- Before granting unconfined release, plant must first be assessed for environmental risk, including risk to human health
  - Plant assessed for:
    - weediness,
    - potential for and consequences of gene flow,
    - plant pest potential,
    - impact on non-target organisms
    - impact on biodiversity

Stacked events

- The PBO must be notified prior to intentional release into the environment of stacks.
- To determine if the conditions of authorization of the individual plant lines are compatible, or if further information is required
  - potential incompatible management requirements,
  - possible extension of cultivation to a new area of the country,
  - other considerations
- Response within 60 days of notification - informing the proponent of any concerns the PBO may have regarding the unconfined environmental release of the stack.

Plants with Same Novel Trait as a Previously Authorized PNT: Retransformation/Remutation

When:

- A new line is developed with the same novel trait as in a previously authorized PNT,
- And following characterization by the developer it fits criteria specified in the policy including:
  - Intended use is similar;
  - plant does not display any additional novel traits;
  - the novel genes are expressed at similar levels as that of the authorized line;

Then:

- No data review by the regulators may be required before unconfined release of such a “follow-up” line.

For example, hundreds of lines of Imidazolinone tolerant crops followed this approach