
An Overview of Canada's Regulatory Frameworks for Genetically Engineered and Gene- Edited Crops

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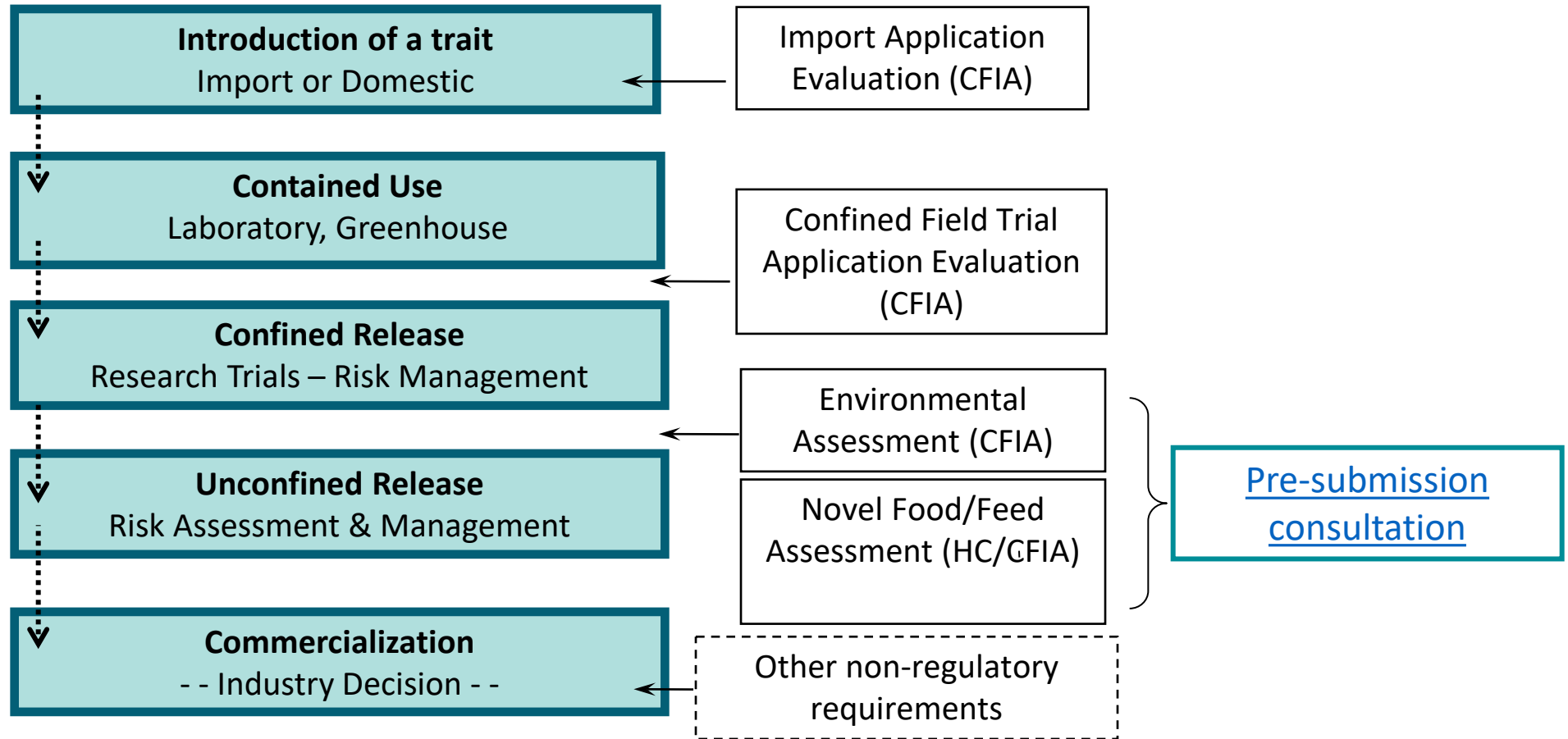
In this presentation...

- Canada's regulatory framework (overview)
- Environmental program for plants with novel traits (PNTs)
- Feed program for feeds derived from PNTs
- Food program for foods derived from PNTs

Overview of Canada's Regulatory Approach

- Product-based regulation
 - Traits/characteristics determine regulatory status, not the technology used to develop the plant
- Authority within regulations for department/agency to approve novel foods, novel feeds, and plants with novel traits after completion of pre-market assessment
 - *Food and Drug Regulations*
 - *Feeds Regulations*
 - *Seeds Regulations*
- Regulation based on intended use
 - Food – Health Canada – Food and Nutrition Directorate
 - Livestock feed – Canadian Food Inspection Agency – Animal Feed and Veterinary Biologics Division
 - Release into Canadian environment – CFIA – Plant Biosafety Office (BPO) and Plant and Biotechnology Risk Assessment (PBRA) Unit

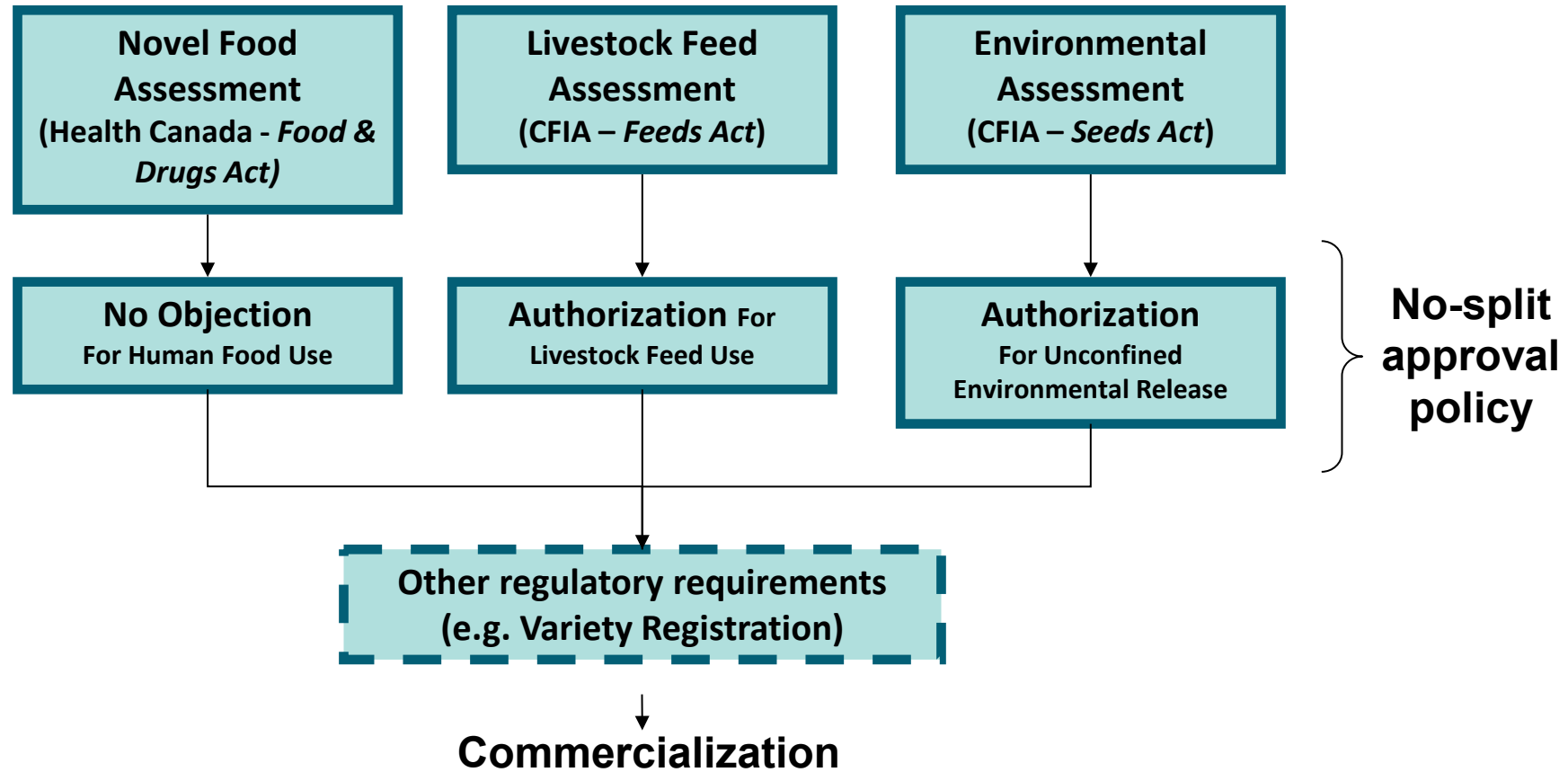
Regulatory Pathway for Products of Plant Breeding



Co-ordinated Authorizations

- Authorizations are co-ordinated under HC and CFIA's 'no split' approval policy (2000)
 - Products determined to be novel by the respective groups (and the product is submitted for food, feed, and/or unconfined environmental release)
 - If multiple groups determine a product to be novel, then:
 - Assessors work together to evaluate the product
 - Authorization of the product is co-ordinated
- Used to minimize the potential for unapproved products entering the Canadian environment, food or feed supplies

Authorization Process



***Regulatory overview of environmental
release (for cultivation)***

Regulatory Responsibility

- Regulatory oversight of environmental release (cultivation) of new plants under Part V of the *Seeds Regulations* (under the *Seeds Act*)
- Administered by the Canadian Food Inspection Agency (CFIA)
 - Plant Biosafety Office
 - Co-ordinates environmental assessments, policy development for PNTs, authorizations, etc.
 - Plant Biotechnology Risk Assessment Unit
 - Conducts environmental assessments for unconfined release of PNTs, guidance development

What is subject to Part V?

Plants into which 1 or more traits have been intentionally introduced, where (1) the trait is new to cultivated populations of the species in Canada, and (2) the plant has a potential to have a significant negative environmental effect, including impacts to human health.

The 5 environmental safety criteria considered are:

- weediness potential
- impacts of gene flow to related plants
- plant pest potential
- impacts on non-target organisms
- impacts on biodiversity

[Guidelines for determining when to notify the Canadian Food Inspection Agency \(directive 2009-09\)](#)

- [Rationale for updated guidance determining whether a plant is subject to Part V of the *Seeds Regulations*](#)

Plants with novel traits (PNT) Guidance for Products of Plant Breeding

- Updated in May 2023
- Regulatory principles have not changed: Plant breeders remain responsible for notifying the CFIA of plants that have the potential to impact the environment.
- Updated guidance 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 **containing foreign DNA** require CFIA pre-market assessment and authorization
 - CFIA administers a **streamlined process for novel HT plants that do not contain foreign DNA**

Novelty status determination for PNTs

- If requested, the Canadian Food Inspection Agency (CFIA) can:
 - review information about new plant lines, and
 - provide advice on whether the line is considered novel for the purposes of environmental release in Canada
- [How to request a novelty determination](#)
- [List of non-novel products of plant breeding for environmental release](#)

Importing PNTs into Canada

- PNTs (and/or products derived from them) imported into Canada are subject to CFIA review under the *Plant Protection Act and Regulations*.
 - Those authorized for unconfined release may not require an Import Permit
 - Those not authorized for unconfined release require an Import Permit
- PNTs (and/or products derived from them) are subject to the same phytosanitary import requirements as unmodified counterparts.

Guidelines

- [D-96-13: Import Requirements for Plants with Novel Traits, including Transgenic Plants and their Viable Plant Parts](#)
 - [Permit Application Process](#)

Contained use of PNTs in Canada

- For PNTs grown in containment (e.g., laboratory or greenhouse), developers are recommended to follow [Canada's Laboratory Biosafety Guidelines](#).
- If the PNT is to be taken outside of containment, the developer/proponent must apply for either confined or unconfined environmental release.

Confined research field trial program

- Provides developers with pathway to grow PNTs for research purposes under terms and conditions of confinement designed to minimize any impact the PNT may have on the environment.
- Allows developers to:
 - Evaluate field performance of their PNT
 - Collect information to address environmental safety criteria required for applications for unconfined release
 - Undertake academic research

Guidelines

- [Directive 2000-07: Conducting Confined Research Field Trials of Plants with Novel Traits in Canada](#)
 - [Crop-specific terms and conditions](#)

Unconfined environmental release program

Guidelines

- [Directive 94-08 \(Dir 94-08\) Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits](#)

Pre-market Environmental Safety Assessment Process

- Submission via MyCFIA, currently \$2,463.62 fee/application. Fees increase each year on March 31 with Consumer Price Index.
- Molecular biology, agronomy and non-target organism safety assessments conducted by Plant Biotechnology Risk Assessment Unit (PBRA)
- First-come, first-served review queue
- Outcome: **Authorization Letter**

List of Completed Safety Assessments

- [Decision Documents - Determination of Environmental and Livestock Feed Safety](#)
- [Database of authorized products - Plants with novel traits \(PNT\) and novel feeds from plant sources approved in Canada](#)

Environmental release of stacked plant products in Canada

- Authorization of PNT for unconfined release includes permission to cross PNT with other plants to develop new varieties
- Authorized PNTs can also be combined through breeding (i.e., a stack)
- Plant Biosafety Office (PBO) requires notification of all stacked products before introduction into the Canadian marketplace
 - Required **at least 60 days prior** to anticipated environmental release of stacked plant
 - Ensures any conditions of authorization on parental PNTs are compatible and appropriate for the stacked plant
 - Confirms if any additional information is required to assess the safety of the stacked plant
 - PBO may issue a letter informing proponent of any concerns and request/review additional data to support environmental safety of the stacked plant
- Additional information and assessment required if:
 - Conditions of authorization on parental PNTs not applicable to the stacked plant or conditions in stewardship plans of parental PNTs no longer effective for the stacked plant
 - Novel traits of parental PNTs are expressed differently in the stacked plant
 - Stacked plant produces an additional novel trait

Retransformation/Remutation policy

- Retransformation (identical construct), remutation (identical mutation) as previously authorized plant of same species
- RTs and RMs, both must impart same novel trait(s) to a plant as previously authorized PNT of same species
 - Novel trait(s) is/are expressed within a similar range to that of authorized PNT
 - Based on characterization, RT/RM does not display additional novel traits (substantially equivalent regarding specific use, safety for the environment, and for human and animal health, to authorized PNT)
 - Novel food and livestock feed requirements are met as appropriate
- RT/RM products meeting these criteria are included in the original authorization, subject to same conditions as previously authorized PNT
- **RT/RM products require notification to the PBO of the CFIA, include unique identifiers**

Regulatory overview of novel feeds

Regulatory Responsibility

- Regulatory oversight of novel feeds according to the *Feeds Regulations* (under the *Feeds Act*)
- Administered by the Canadian Food Inspection Agency (CFIA)
 - Animal Feed and Veterinary Biologics Division
 - Biotechnology and Microbiology Section conducts pre-market assessment of novel feeds, policy and guidance development for novel feeds, etc.

Novel Feed Guidance for Products of Plant Breeding

- Updated May 2024
- Five criteria that determine a Novel Feed
 1. Ingredient that is not listed in Schedule IV or V
 2. Ingredient that is listed in Part II of Schedule IV or V
 3. Ingredient that is listed in Part I of Schedule IV or V, however it does not meet the ingredient description
 4. Ingredient that is listed in Part I of Schedule IV or V, however it contains a **novel trait**
 5. Ingredient with a claim
- **If an ingredient meets any one of these criteria, a pre-market evaluation is required**

Novel Feed Guidance for Products of Plant Breeding

Ingredient that is listed in Part I of Schedules IV or V, however, it contains a **novel trait**

1. Ingredient from a plant **containing foreign DNA**
 2. **A new nutrient is expressed** in the plant
 3. The **level of an endogenous nutrient is outside the documented range** for that plant species such that:
 1. Change in endogenous nutrient level results in Maximum Nutrient Values being exceeded; and/or
 2. Change in endogenous nutrient level affects the usage rate of the ingredient, and/or
 3. Change in endogenous nutrient level impacts foods of animal origin
 4. The **bioavailability of an endogenous nutrient is changed** such that:
 1. Change in nutrient bioavailability results in Maximum Nutrient Values being exceeded; and/or
 2. Change in nutrient bioavailability affects the usage rate of the ingredient such that it differs from that of the conventional ingredient; and/or
 3. Change in nutrient bioavailability impacts foods of animal origin
 5. **A new secondary metabolite is expressed** in the plant, or the **level of an endogenous secondary metabolite is increased**, impacting the safety or use of the ingredient
 6. The genetic modification to the plant alters an endogenous protein in a way that introduces or increases similarity with a known **allergen** or **toxin** relevant to animal or human health
 7. **A new toxin, allergen or anti-nutrient is expressed** in the plant, or the **level of an endogenous toxin, allergen or anti-nutrient is increased beyond the documented range** for that plant species
- **If an ingredient meets any one of these criteria, including the criteria 1, 2, 3, 5 (previous slide), a pre-market evaluation is required.**

Novel Feed Guidance for Products of Plant Breeding

For inquiries regarding which plant-derived feed ingredients require a pre-market evaluation, please contact the Animal Feed Program email box:

cfia.afp-paa.acia@inspection.gc.ca

Feed program

- **Apply through My CFIA:** [1.3.1 My CFIA online livestock feed applications](#)
- **Pre-market Evaluation Process**
 - Submission via MyCFIA, fee/application varies depending on request (typically \$341.85). Fees increase each year on March 31 with Consumer Price Index
 - First come, first served review queue
 - **Outcome:** Authorization Letter
- **Relevant Guidelines**
 - [RG-1 Regulatory Guidance: Feed Registration Procedures and Labelling Standards](#)
 - [RG-1 Chapter 2.6 Guidelines for the Assessment of Novel Feeds: Plant Sources](#)
 - [2.8 Guidance on bridging an application to data from publicly available literature and previously approved feed applications](#)
 - [3.1 Guidance on data requirements to complete Sections 9, 10, 11 and 12 of the feed approval or registration application](#)
 - [Tables of Maximum Nutrient Values for Feeds](#)
 - [Tables of Maximum Contaminant Levels for Feeds](#)
 - [Decision Documents - Determination of Environmental and Livestock Feed Safety](#)

Feed derived from stacks, retransformants, remutations

- Stacks

- Notification required (at least 60 days prior to intended feed use)
- Animal Feed and Veterinary Biologics Division will issue letter within 60 days of notification
- Additional information and assessment required if:
 - Stacking traits incompatible with management requirements, possible negative synergistic effects, feed use is altered that would require further assessment (e.g., an additional novel trait)

- RTs/RMs

- Same definitions as for environmental program
- Feeds derived from RTs/RMs may not require pre-market assessment if:
 - Method of development is identical to that used previously
 - Intended uses are similar
 - No additional novel traits and are substantially equivalent
 - Previously assessed traits expressed at similar levels to the previously authorized plant

Regulatory overview of novel foods

Regulatory Responsibility

- Regulatory oversight of novel foods according to the *Food and Drug Regulations* (under the *Food and Drugs Act*)
- Administered by Health Canada
 - Novel Foods Section
 - Co-ordinates pre-market assessment of novel foods, policy and guidance development for novel foods, etc.

Novel Food Guidance for Products of Plant Breeding

- Updated in May 2022
- Foods are not considered novel if they are derived from products of plant breeding with genetic modifications that:
 1. 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. 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. Do not have an impact on **key nutritional composition and/or metabolism**;
 4. Do not intentionally change the **food use** of the plant; and
 5. 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**

Novel Foods Program

- **Guidelines**

- [Food Directorate's Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods](#)
- [Guidelines for the Safety Assessment of Novel Foods](#)

- **Pre-Market Safety Assessment**

- 410-day service standard
- No fee for assessment
- Assessment conducted by Directorate science bureaus: Bureau of Chemical Safety, Bureau of Microbial Hazards, Bureau of Nutritional Sciences
- Positive outcome: **Letter of No Objection**

- [**List of Completed Safety Assessments**](#)

- Plain language and technical summaries

- [**Novelty Determination Process**](#)

- [List of Non-novel determinations for food and food ingredients](#)

- [**Transparency Initiative Process**](#)

- [List of non-novel products of plant breeding for food use](#)

Transparency for Gene-Edited Products of Plant Breeding for food use

- 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.

Food derived from stacks, retransformants, remutations

- Stacks
 - No notification required for stacks if:
 - No additional traits/characteristics in stack compared to previously assessed parental plants
 - No significant change in existing characteristics in stack compared to previously assessed parental plants
- RTs/RMs (same definitions as environment and feed)
 - [Health Canada Guidance on the Pre-Market Assessment of Foods Derived from Retransformants](#)
 - 120-day service standard
 - Complete molecular characterization + scientific rationale for other endpoints
 - Positive outcome: **Letter of No Objection**

Thank you

Questions?