

Regulation of Plants with Novel Traits

**William Anderson Ph. D.
National Manager, International and Import Protocols
Plant Biosafety Office
Canadian Food Inspection Agency
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1. Broad Overview – History, Responsibilities and Principles

2. Environmental Safety Regulation of Agriculture Biotechnology

Broad Overview – History, Responsibilities and Principles

What is Biotechnology?

Broad **Government of Canada** definition including various technologies, e.g., rDNA, mutagenesis, traditional breeding:

“ 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”

Uses of Agricultural Biotechnology

- plants (horticultural plants, trees, crops)
- livestock feeds & feed additives
- biopesticides (e.g. disease & pest control)
- biofertilizers (e.g. fertilizer additives)
- veterinary drugs & biologics (e.g. rabies vaccine)

Canadian Regulatory Approach

The Canadian Federal Regulatory Framework for Biotechnology (1993):

- Transparent, consultative
- Science based, consistent with national and international standards,
- Foster a climate for investment and innovation

Canada is unique!

- Focus on **product**, not process used to create the product
 - for plants, this may include: conventional breeding, genetic engineering, mutagenesis, etc.

Determining What Products Need to be Regulated

- Many methods used, but **novelty** serves as a regulatory trigger
 - Novel Risk necessarily
- Product may be considered **novel** if:
 - new trait(s) or characteristic(s)
 - changed trait(s) or characteristic(s)
 - new use (e.g. as a food or livestock feed)

Determining What Products Need to be Regulated (2)

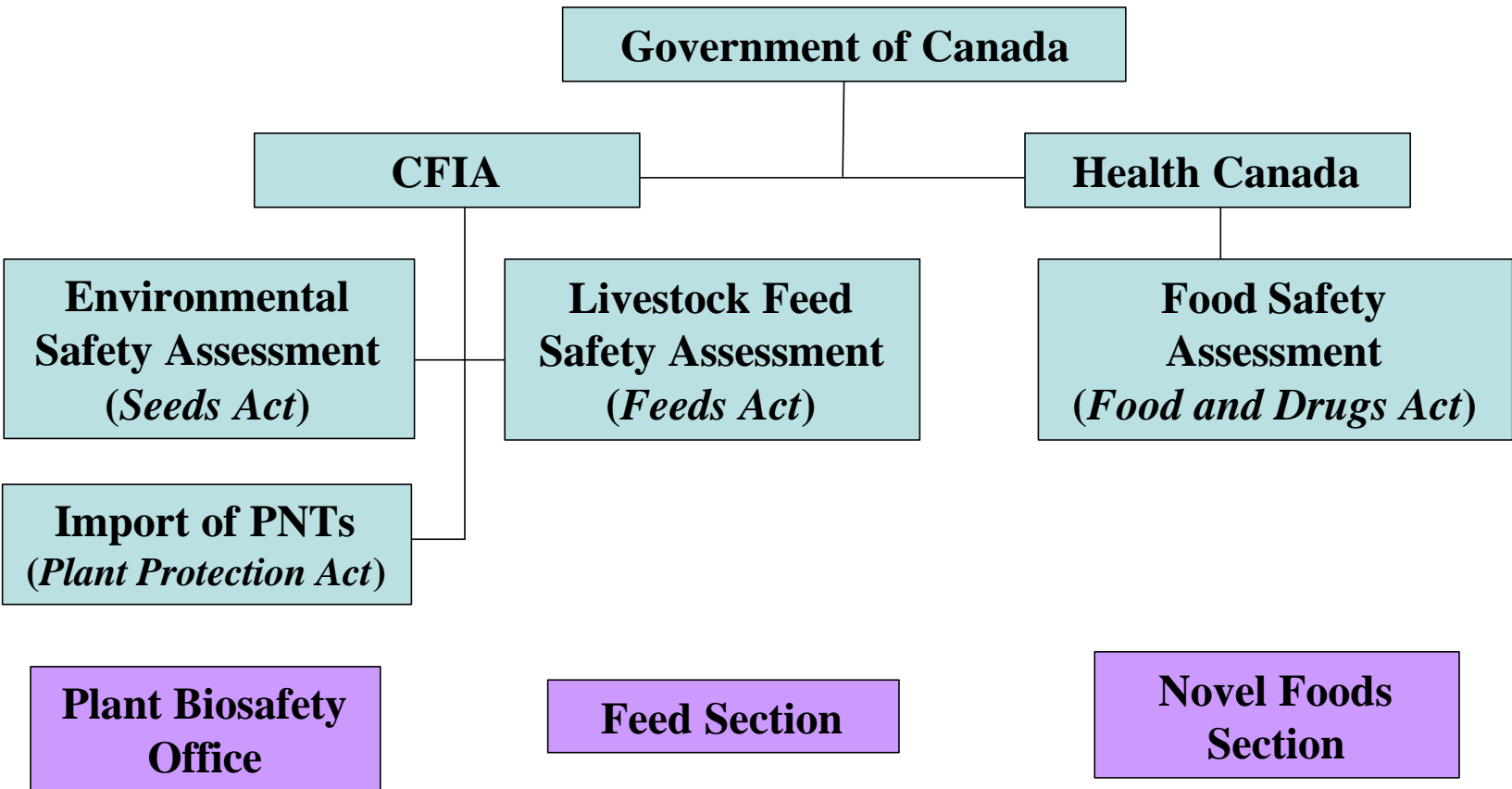
- Mandatory, pre-market safety assessments required by government regulators before novel product can be:
 - used as a **food**
 - used as a livestock **feed**
 - unconfined release into the **environment**

Canadian Regulatory Approach

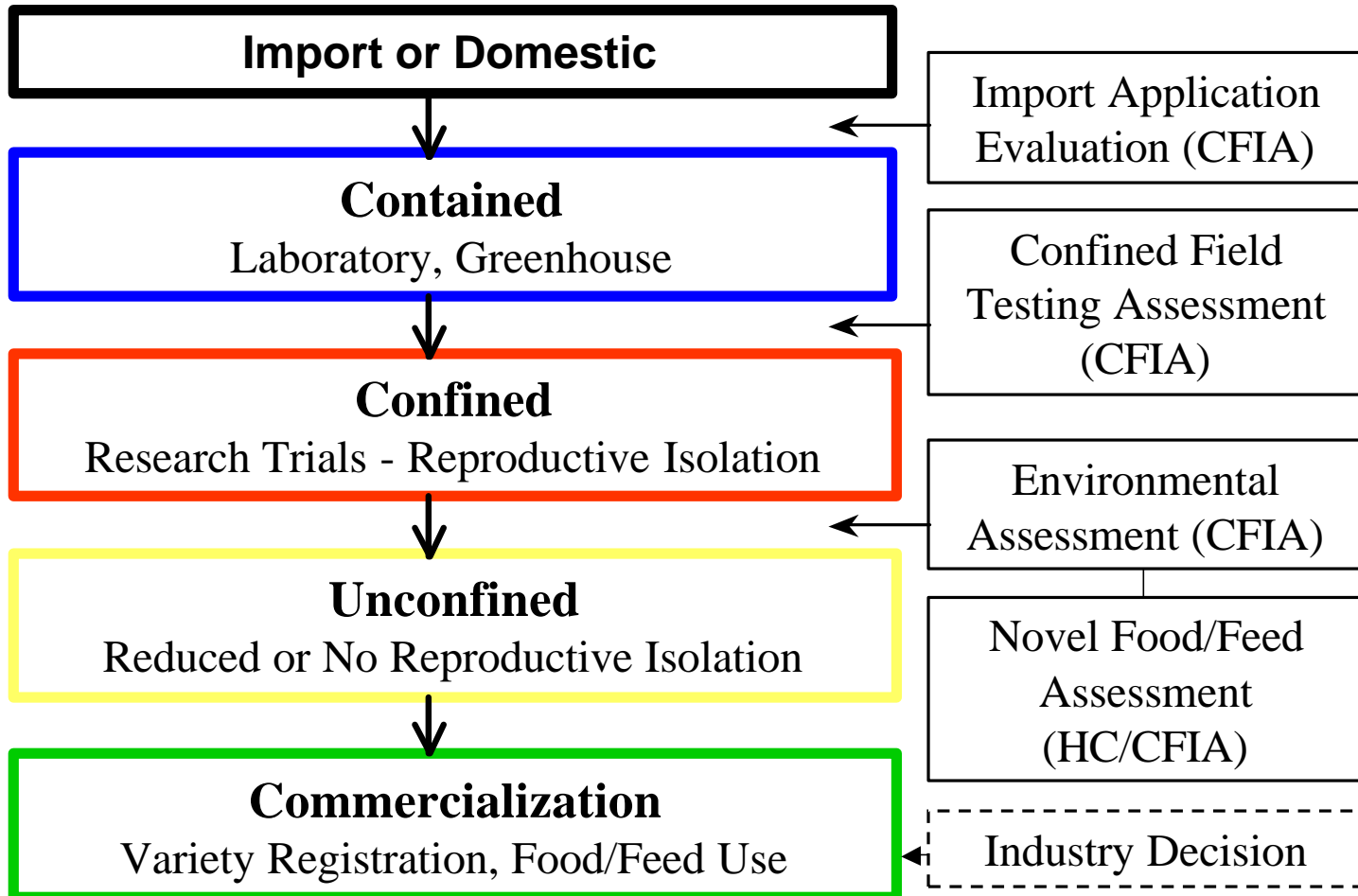
The Canadian Federal Regulatory Framework for Biotechnology (1993) – Key Element:

- Use existing legislation and regulatory institutions
- No “Gene Act” or “Biotechnology Agency”

Canadian Biotechnology Regulation - *Plants* -



Regulatory Approval Process for Products of Biotechnology





Canadian Food Inspection Agency

Canadian Food Inspection Agency

- Canada's largest science-based regulatory agency
- Began operations on April 1, 1997
 - food inspection activities of 4 Departments consolidated
- Mandated to safeguard Canada's food supply and the plants and animals upon which safe and high-quality food depends

Main Concepts for the CFIA's Regulations of Biotechnology Products

- Science-based & Product-based
- Case-by-case
- Regulatory transparency
 - Openness through decision documents & consultations
- Harmonized approvals between Canadian regulators
 - Bilateral initiatives with U.S. (i.e. data requirements)
- Research in support of regulatory system

What do CFIA safety assessments determine?

Depending on their intended use, novel agricultural products are assessed based on:

- Potential impact on the environment
- Potential impact on livestock health
- Potential impact on human health
 - via worker or bystander exposure

Plant Biosafety Office

- The Plant Biosafety Office of the CFIA is responsible for the regulation of the environmental release of plants with novel traits (PNTs).
- CFIA responsibilities include:
 - approval and inspection of confined field trials of PNTs
 - approval of unconfined release of PNTs
 - assessment of import applications for PNTs

Plants with Novel Traits (PNTs)

Canola with a novel herbicide tolerance has been produced by:

- recombinant DNA techniques- *Liberty Link, Roundup Ready etc.*
- mutagenesis- *Imidazolinone tolerance*
- conventional breeding- *Triazine tolerant*

Similar environmental risk issues whether derived from rDNA, mutagenesis or traditional breeding

What is a PNT?

- A PNT is a plant containing a trait not present in plants of the same species already existing as stable, cultivated populations in Canada, or is present at a level significantly outside the range of that trait in stable, cultivated populations of that plant species in Canada.
- All PNTs are subject to an environmental safety assessment.

How to Define Novelty? (1)

- Different contexts for novelty
 - Trait introduction –
 - Trait modification –
 - Incremental increase -

How to Define Novelty? (2)

- Different contexts for novelty

Trait introduction - the plant in question contains a trait that was not previously expressed in a stable cultivated population in Canada e.g., Herbicide tolerance, insect resistance

How to Define Novelty? (3)

- Different contexts for novelty

Trait modification - the plant in question contains a trait that has been identified in a stable cultivated population in Canada but is expressed at levels that are significantly outside the range of that stable population, e.g., disease resistance was present previously but the new plant has a level of resistance that significantly outside the range of normal variation within that species in Canada.

How to Define Novelty? (4)

- Different contexts for novelty

Incremental increase - if the trait in question has a history of selection for increase (e.g., yield) in that species, and the increase of that trait for the plant in question was significantly greater than the historical increase.

Novelty as a Regulatory Trigger in Practice

- Most products of breeding programs would not be considered PNTs
- Many products of mutagenesis may not be considered PNTs (e.g. trait changes within normal ranges)
- Could be substantially equivalent with respect to potential environmental concerns

Environmental Release Approvals

- Confined Environmental Release
- Unconfined Environmental Release

Confined Environmental Release Approval

- Confined Environmental Release
 - Risk mitigation measures
 - Inspection and monitoring

Environmental Risk Assessment Principles

- Environmental assessment uses a “familiar” counterpart as a comparator
- It relies on “substantial equivalence” to define the threshold of risk
- It’s a comparative, qualitative assessment

Risk Assessment

Authorizations

- Food, Feed and Environmental Release are “linked”
- 62 PNTs (52 LMOs) authorized for Environmental Release
- Canola, Maize, Cotton seed, Potato, Soybean, Squash, Sugar beet and Tomato

Unconfined Environmental Release Authorizations:

- **62 PNTs (52 LMOs) authorized for release**
- Crops include canola, corn, flax, soybeans, potatoes, wheat (non-LMO)
- Traits include herbicide tolerance; insect pest and virus resistance, hybrid systems, oil compositional changes
- *Actual release is a commercial decision*

Future Challenges (1)

- Develop clear guidance on interpretation of novelty that can be applied to all types of plants, e.g., crops, ornamental plants, trees
- Develop guidelines for molecular farming
 - Confined research field trials
 - Commercial production
 - Includes plants producing industrial compounds

Future Challenges (2)

- Regulatory streamlining
 - Import vs. domestic
 - Plants with novel traits vs. novel plants
- How to evaluate long-term and non-target effects
 - suitable indicator species
 - acceptable protocols
- How to regulate new classes of biotech products, e.g., biodiesel in canola

THANK YOU

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