Regulation & Stewardship of Plant Biotechnology

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- Industry association representing developers & distributors of plant science innovations
- Crop Protection & Plant Biotechnology
- Member Companies include: BASF, Bayer Dow, Dupont, Monsanto, Pioneer, Syngenta, Agricore United, Cargill, JRI, Sask Wheat Pool, etc.
- Industry founded on Safety & Innovation

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Why Biotechnology?

- "Input" traits – HT crops, IR crops
- Reducing the "environmental footprint" of agricultural production
- "Output" traits – nutritional enhancements, bio-materials
- Canola Council study found:
  - In 2000 over 80% of growers chose transgenic varieties and planted them on 55% of the 12 million canola acres
- Benefits in weed management, yield, reduced tillage

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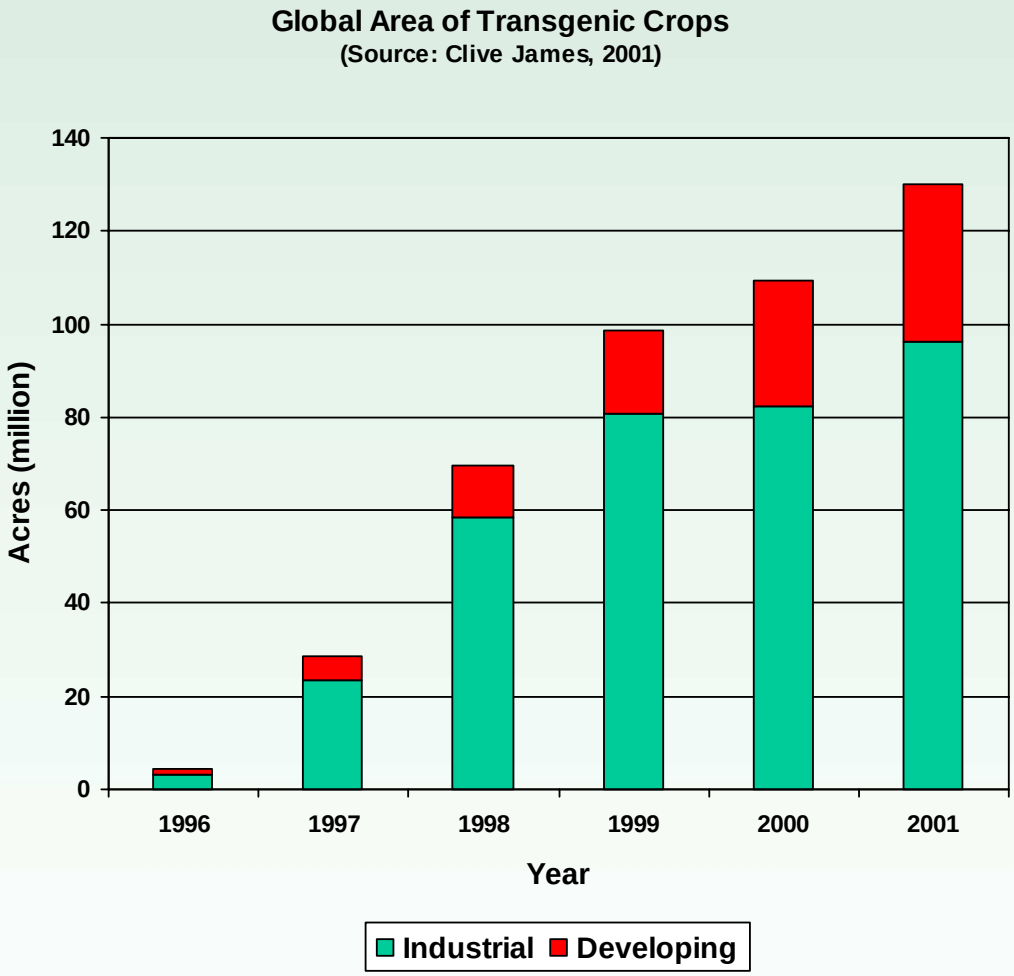
Continued Growth in Global Crop Area



- Since 2000, an additional 5.5 million farmers, mostly in developing regions, are growing transgenic crops
- Significantly, the rate of adoption is higher in developing regions (26% between 2000 and 2001) than in developed countries (17%)

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Are these Crops Safe? - A Historical Perspective

- Biotechnology has been a focus within the Canadian federal government for 20 years
- 1983 – National Biotechnology Strategy – a business strategy to promote R&D, investment, and consumer acceptance
- 1990 – review of NBS recommended increased focus on regulation in advance of commercial applications
- Strong regulatory framework would **protect** health and safety, provide a **predictable** environment for industry, and build consumer **confidence**

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Canadian Regulatory Framework

- Announced in 1993 following extensive public consultation
- Guiding principles
  - Use **existing legislation** and regulatory institutions
    - coordinate activities to reduce duplication
  - **Product based** approach
    - risk is related to properties of the product, not the technology used to produce it
  - **Evidence-based** risk assessment
    - Not the “precautionary principle” but a “precautionary approach”

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Regulatory Authorities

- **Health Canada** has sole responsibility for evaluating the human health safety of all foods
  - Legislative power – Food and Drugs Act
    - Novel Foods Regulations (1999)
    - Guidelines for the safety assessment of novel foods (1994)

- **Canadian Food Inspection Agency (CFIA)** regulates the importation, environmental release, and use in livestock feeds of plants with novel traits, which includes transgenic plants
  - Seeds Act, Feeds Act, Fertilizers Act, Plant Protection Act, CPLA, Health of Animals Act, F&DA.

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Key Assessment Areas

- While each product is evaluated on a case-by-case basis, generally the evaluation focuses on these key areas:
  - **Molecular Characterization**
    - Description of the donor and host organisms, modification process, genetic stability, expressed proteins
  - **Nutritional and Compositional Analysis**
    - Altered levels of nutrients and anti-nutrients
  - **Toxicology**
    - Changes in levels of naturally occurring toxicants, potential toxicity of novel protein
  - **Potential for Allergic Reaction**

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Food & Feed Safety Assessment

- Dietary exposure by the average consumer & population subgroups, such as children
- Differences identified in the comparison are subjected to further studies as appropriate
- Assessment considers impact of new trait or component in the modified organism, and the final food

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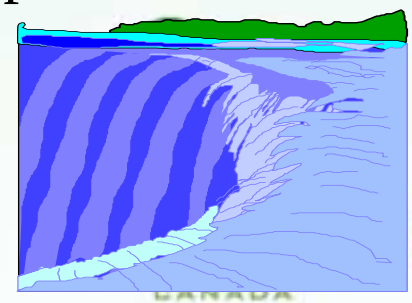
Environmental Safety Assessment

- Examination of the biology of the PNT as well as its environmental impact.
- Potential for movement of the novel trait from the PNT to related plant species
- Whether the novel plant could become a plant pest
- Impact on non-target organisms including insects, birds & mammals
- Whether the introduced trait could make the plant more “weedy”
- Impact on biodiversity



Authorizations

	Canola	Corn	Cotton	Potato	Soybean	Others
Herbicide Tolerance	Glufosinate (6) Glyphosate (2) Imidazolinone (1) Oxynil (1)	Cyclohexanone (1) Glufosinate (3) Glyphosate (4) Imidazolinone (3)	Glyphosate (1) Oxynil (1)		Glyphosate (1) Glufosinate (1)	Flax (1) Wheat (1) Sugarbeet (1)
Insect and/or Virus Res.		ECB (1) ECB + glufosinate (3) ECB + glyphosate (2)	CBW (1)	CPB (2) CPB+PVY (1) CPB+PLRV (1)		Squash (2) Tomato (1)
Quality Traits	High laurate (1) High oleic (2)				High oleic (1) Low linolenic (1)	Tomato (3)

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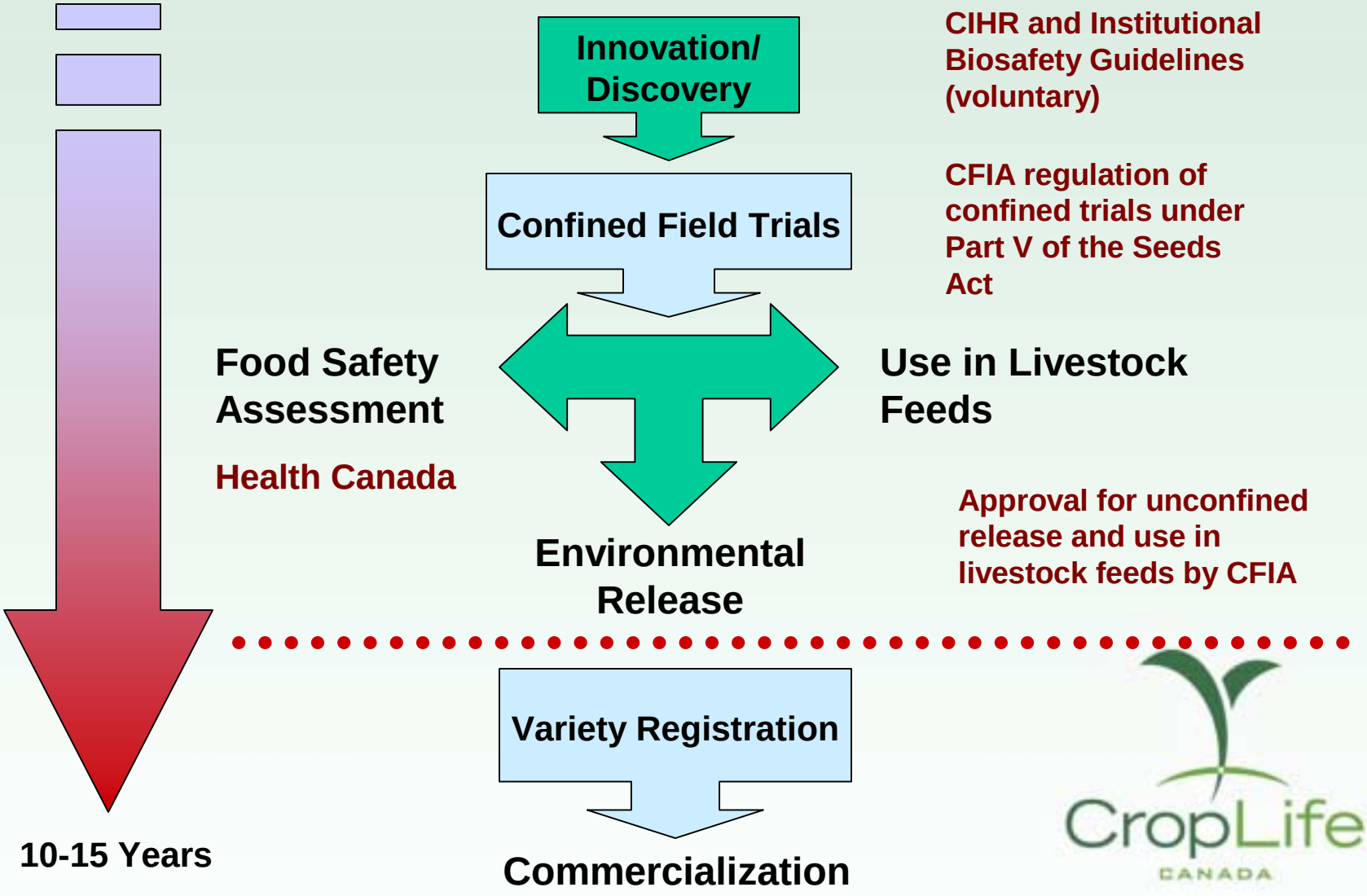
The Innovation – Commercialization Path



Industry's Role – Responsible Product Management

- Stewardship - "Working responsibly to protect people and the environment" - ***stewardship*First™**
- Contribute to sustainable agricultural practices – maximize benefits/minimize risk
- A long-term vision
- Full circle product life cycle management
- Series of industry led initiatives - proactive

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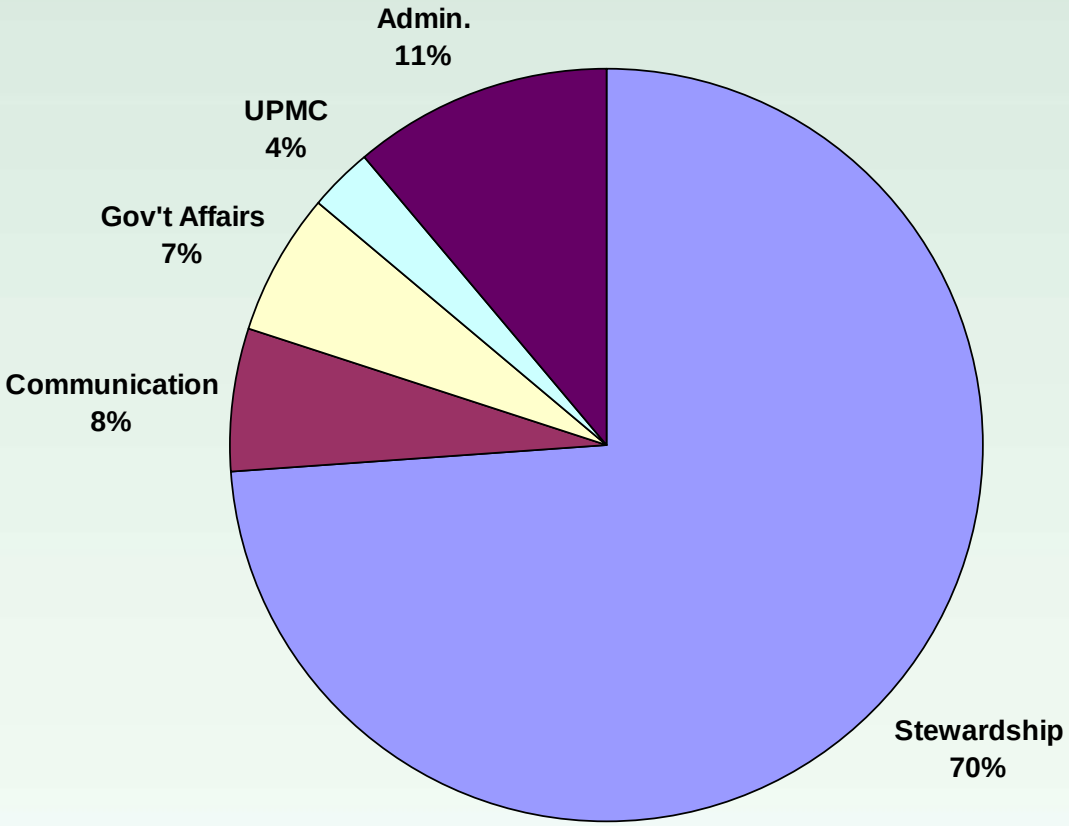
Membership Commitment



* Excluding Conference

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Plant Biotechnology Stewardship

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representing the plant science industry

Bio-stewardship Initiatives

- Industry Code of Practice
- Marketing & Commercialization Commitments
- **Compliance Management Program for Conducting Confined Field Trials**
- **HT Stewardship Program**
  - BMP for controlling HT volunteers
  - SOP for handling calls related to AP
- **Notice of Submissions Pilot Project**
  - Transparency of the regulatory system

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Compliance Management Training – What?

- Training for managers &researchers working with PNTs (plants with novel traits)
- To ensure compliance with CFIA requirements for conducting confined field trials
- Overview of regulatory system
- Understanding of approval system
- Understanding of trial requirements
  - Before, during and after conducting the trial

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Compliance Management Training – Why?

- Due diligence for field trial managers
  - Demonstrate responsible management
- Audit and inspection compliance
  - by creating a framework for monitoring, documentation, and reporting
- Prevent unintended releases
- Identify and close any gaps/risks
- Outline best practices for safe management

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Progress To Date

- Pilot project in 2000
- Official program launch in 2001
- Trained > 200 researchers
  - Public & private sector
  - Canada & US
- Since program launch CFIA reports improved compliance
- New Modules in 2004

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Stewardship of HT Crops

Why

Improving industry and grower management of HT crops

Elements of the Program

1. ***BMP Guides – HT Volunteers, others?***
2. FAQs – Seed Purity, HT Crops/Volunteers, others?
3. ***Handling Enquiries for AP of HT traits in Crops***
4. Work with partners to refine seed production
5. Ongoing support for research activities
6. Member company stewardship of products

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Best Management Practices Guide

Purpose

To develop a practical guide for growers on managing **HT volunteers**

Highlights

General recommendations followed by crop specific recommendations, non-chemical recommendations and a focus on **rotation**

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Guidelines for Handling Enquiries Related to Adventitious of HT traits in Crops

- **Objectives**
  - Industry resolution of enquiries related to **adventitious presence** of HT traits in crops
  - Avoid calls to the CFIA, industry will manage customer concerns
  - Dispute resolution through CropLife if companies cannot resolve – NOT through the regulator

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Improving Transparency of the Regulatory System

- CBAC & Royal Society state
  - **"There is insufficient emphasis on transparency. The communication of information related to the regulation of GM and other novel foods has not been highly effective."**
- No legislative ability - worked with CFIA & HC
- Notice of Submissions – opportunity for public review & comment
- Confidence in the regulatory system = confidence in the safety of our products

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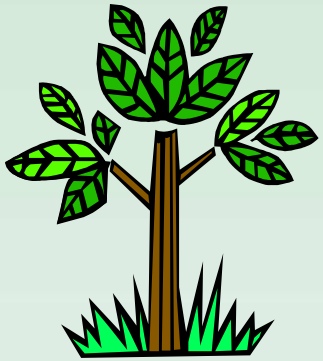
Summary



- Benefits – **farmer and consumer**
- Environment – untold good news story
- **Rigorous testing, safety assessment and government approval**
- Industry doing its part to address the concerns

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