



Promoting Seed Business in the Americas | September 5-7 2017 - Colombia Cartagena de Indias

PBI Country Experience: Canada

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Value of Canadian Agriculture

- **Agriculture & Agri-food System (AAFS)**

- Generates \$108.8 billion annually, 6.6% GDP (2014)
- 1 in 8 jobs linked to the sector
- Canada is the 5th largest exporter of agri-products globally

- **Horticulture**

- \$5 billion in direct farm receipts (2015)

- **Ornamental/nursery**

- \$14.5 billion in economic output (2009)
- Employees 110,750 full time equivalent jobs

- **Seed Industry**

- \$5.6 billion in economic output (2014)
- \$120 million private sector annual investment plant breeding (2017)

CROP DOMESTICATION

Farmers select the best wild species to create crops



Domestication of wheat

10,000 BC



HYBRID BREEDING

Crossing two genetically different individuals to develop better performing hybrid



More vigorous hybrid corn

1926

PLANT BREEDING
BASED ON

CROSS BREEDING

Development of improved varieties by combining good characteristics from two parents



1940



MUTAGENESIS

Developing new genetic diversity by exposing crop plants to chemical agents or radiation

Blast-resistant rice



Insect-resistant cotton

GMO

Introducing foreign genes into the DNA of a plant

1994



Barley resistant to yellow dwarf virus

MARKER-ASSISTED SELECTION

Locating desirable traits in a plant for efficient selection and breeding



Waxy corn

TARGETED BREEDING

Using modern tools such as genome editing for more targeted breeding

PLANT BREEDING BASED ON
GENETIC INFORMATION



now

future

Established Safe Track Record: The scrutiny breeders routinely apply to new variety development is the foundation for a safe, nutritious and diverse food supply.

Products approved in Canada

- Herbicide Tolerant
- Insect Resistance
- Virus Resistant
- Compositional changes

rDNA
20
years
~100

~20
↓

Products which fall outside the scope of a pre-market review

Mutagenic
~100
Years
>3200
varieties

Selective breeding

1000s of varieties
over 1000s of years

- Disease Resistant
- Insect Resistant
- Herbicide Tolerant
- Virus Resistant
- Higher Yield
- Compositional changes

New Plant Breeding Innovations (PBIs)

All deemed to be safe with no altered risk, and no safety concerns to date

Understanding Canadian Novelty Triggers

- **Canada system is product rather than process (case by case).**
 - Trigger can be “newness” or “newness” + “(potential) risk”
- **Novelty is defined differently in the Seeds, Feeds and Novel Foods regulations.**
- **Current risk assessment process is primarily based on confirming a lack of hazard, where the use and safety of the plant/food is not changed**

PNT Strengths and Weaknesses

Predictability:

- **Strength:**

- General submission requirements are described in guidance documents and are usually followed and predictable
- Familiar traits (insect and herbicide tolerance) in familiar crops (soy, corn, canola), introduced via rDNA or mutagenesis, have had a high degree of regulatory predictability
 - Now moving through system faster 14-20 months
 - Applicants have high degree of comfort based on precedence

PNT Strengths and Weaknesses

Predictability:

- **Weakness:**

- Familiarity has hindered modernization and level of predictability does not apply to new crop/trait combinations
- Regulators modify data requirements (not described in guidance documents) and precedence changes (sometimes abruptly)
 - Even for traits that are familiar, e.g. pesticide residue requirements, and
 - Growing data set requirements for mutagenesis – not based on policy, but regulatory creep

PNT Strengths and Weaknesses

Case by Case:

- **Strength:**

- Provides space for scientific discussions with regulators to determine when oversight is required and what data is necessary
- Supports predictability when cases are similar

- **Weakness:**

- Regulator is by default the judge/jury/executioner on what is required creating a climate where it can be difficult for a developer to truly defend their position
- Allows for deviations from precedence for the regulator and room for unpredictability, difficulty in business planning

PNT Strengths and Weaknesses

Cost:

- **Strength:**

- Application fee is currently very low and is not a barrier to innovation

- **Weakness:**

- Although cost is low there are no formal service standards in place (HC has informal standards) so, review time is unknown
- Overall cost and size of the data package has increased over the last 20 years while knowledge and safety would indicate that burden should have decreased

PNT Strengths and Weaknesses

Regulatory Capacity:

- **Strength:**

- Regulators are world class and very capable of completing the reviews
- CFIA/HC have a strong collaborative relationship
- Publication: A comparative analysis of insertional effects in genetically engineered plants (Schnell *et al.*, 2015)
- Canadian approach avoids the need for unique legislation

PNT Strengths and Weaknesses

Regulatory Capacity:

- **Weakness:**

- Lack of resources dedicated to modernizing the system i.e. integration of 2015 publication into policy
- Three regulatory groups creates duplication and opportunity for delay if one group has a backlog (no split approval policy)

PNT Strengths and Weaknesses

Self-Determination of Novelty:

(developers must self-identify to government if they are regulated)

- **Strength:**

- Places responsibility on the industry to be vigilant and reduces unnecessary expenditure of government resources

PNT Strengths and Weaknesses

Self-Determination of Novelty:

- **Weakness:**
 - Challenges with determining potential risk
 - Triggers are hard to interpret, leading to uncertainty about when, exactly, developers need to notify regulators
 - Regulators feel required to review any submission submitted therefore no feed back mechanism to say “this is not novel, thank you for your submission but we will not be reviewing”

FUTURE OF PLANT BREEDING OVERSIGHT IN CANADA:

PRESENTED
BY:



Future of Plant Breeding Oversight

Workshop objectives:

1. Clarify the current industry/government oversight system, including regulation (how it works currently);
2. Take stock of its strengths and weaknesses;
3. Identify drivers for change in the Canadian system (including regulation)—what change if any is required;
4. Begin to conceptualize principals for change and potential options and;
5. Clarify the next steps toward placing Canada as a leader in both industry and government oversight systems for plant breeding.

Future of Plant Breeding Oversight

INDUSTRY WORKSHOP

FUTURE OF PLANT BREEDING OVERSIGHT IN CANADA:

MAY 30, 2017
OTTAWA
DRAFT AGENDA

OBJECTIVES

To facilitate a value chain conversation aimed at ensuring a safe and predictable industry/government framework for the oversight of plant breeding in Canada which attracts investment, research and innovation while enabling trade by:

- Clarifying the current industry/government oversight system, including regulation (how it works currently);
- Taking stock of its strengths and weaknesses;
- Identifying the drivers for change in the Canadian system (including regulation) – what change if any is required;
- Beginning to conceptualize principals for change and potential options and;
- Clarifying the next steps toward placing Canada as a leader in both industry and government oversight systems for plant breeding.

ROADMAP

07:30	Arrival, Coffee	
A. GETTING STARTED/TAKING STOCK – LOOKING INTERNAL – OUR SYSTEM TODAY		
08:00	Welcome/Opening Remarks	President – CropLife Canada
	Purpose of the meeting	
	Process after today	
	Agenda Review	Facilitator
	Expectations	
	How we will work together, introductions, Rules of Engagement	
08:20	Remarks from the Government of Canada	TBD
08:30	Panel 1: How the Canadian system for plant breeding oversight works today: perspectives on the strengths and weaknesses of the current system	
	Presenters	
	TBD	
	Stephen Yarrow, Vice President of Plant Biotechnology, CropLife Canada	
	Graham Scoles, Professor of Plant Sciences, University of Saskatchewan	
	Open Forum – Discussion	
	Questions of Clarification?	
09:30	Discussion # 1 – Taking Stock – Plant Breeding Regulatory System Today	Facilitator
	What are the key strengths and weaknesses of the current system?	
	Who are the key stakeholders of the regulatory system and what do they expect?	
10:15	Health Break	

- Attended by over 60 stakeholders
 - Government
 - Commodity groups
 - Grain trade
 - Academia
 - SMEs and LMNs
 - International experts
- 9 presentations by leading experts
- Half day deliberation on change

PRESENTED BY:



Future of Plant Breeding Oversight

Outcomes:

- **Need for a modernized system that addresses true risk**
 - Tiered model worth exploration
 - Focus of risk assessment needs to move toward intended changes
- **Opportunity to establish a regulatory regime which ensures safety, fosters innovation and maintains trade**
- **Canada is well positioned to be a global leader in rational regulation**

Where do we go from here?

Potential Options:

- **Maintain the product based approach but where**
 - Newness is no longer the key trigger
 - Potential risk is more clearly defined (equivalence in terms of use and safety)
- **Develop a tiered approach to the administration of the oversight model**
 - Potential risk of the trait triggers oversight, while familiarity of the product & breeding technique informs administration and tier placement
- **Develop more focused safety assessment**
 - Focused on investigating the intended change, and the corresponding appropriate risk assessment that should be required

Concluding Thoughts

- Canada well positioned: Plant with Novel Traits framework is good but requires more predictability and transparency.
- How do we ensure transparency for both consumers and the value chain?
- While the goal is international harmonization, there is a good chance that there will likely be different regulatory approaches in different markets. Need to keep trade considerations in mind and align where possible.

Thank you for your attention!



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