

THE CANADIAN REGULATORY SYSTEM and NEW AGRICULTURAL TECHNOLOGIES

April 13, 2011

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Outline

- Canadian regulations
- Current threats
- Opportunities

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The History of Novelty - Canada

- 1992- Novel Foods Regulation was enacted under the Food and Drugs Act
 - Covers introduction of foods not previously available in the Canadian marketplace.
 - Responding to:
 - Globalization of food supply
 - Rapid advances in food science and technology



The History of Novelty - II

- 1996 - Seeds Regulations, Part V and Feeds Regulations on Novel Feeds came into effect.
- 2001 - The Seeds Act and the Feeds Act were scheduled under CEPA
 - Formally transferred regulatory risk assessments to CFIA



Novelty Assessment of Plants With Novel Traits and Feed/Food Derived From Them

Plant in question

E1) Is there a history of the use of the germplasm prior to 1996 in the Canadian Environment?

No

E2) Was germplasm from outside of Canada used that contained traits that were not previously observed in Canada, or were not observed at those levels?

No

E3) Are there any new characteristics/traits that were not previously observed within a stable cultivated Canadian population of this species ?

No

E4) Has a significant change occurred in characteristics / traits that were previously observed within a stable cultivated Canadian population of this species ?

No

Exempt

Yes

No

F1) Is there a history of food use or Canadian feed use?

Yes

F2) Are there any potential food/feed concerns surrounding any species used during the development of this product?

No

F3) Are there any new characteristics/traits that were not previously observed in this species ?

No

F4) Has a significant change occurred in characteristics / traits that were previously observed in this species ?

No

Novelty Likely

Yes

Yes

Yes

Yes

Yes

Yes

Novelty Not Likely

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Canada's Regulations Are Science-based

- Canada recognizes global regulatory bodies (i.e. WHO, FAO, Codex, OECD)
- Canada regulates the product - not the process (not only rDNA regulated).
- Novelty is the trigger (moving towards inclusion of new risk).
- Regulatory system is predictable
- Fosters innovation



Current Threats to Innovation-1

- **Bill C-474:** “an analysis of potential harm to export markets be conducted before the sale of any new genetically engineered seed is permitted.”
 - Bill is contrary to Canadian regulations
 - Industry already ensures new technologies are approved in key export markets (voluntary)
 - Would not have prevented issues with flax, mustard

Focus on implementing Codex guidance for LLP

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Current Threats to Innovation-2

- **Labeling Initiatives:**

- NGOs/consumer groups demanding GMO labeling based on “right to know”
- Contrary to FDA regulations - labeling for health & safety information
- NGO goal is to stigmatize GMO products
- Many regions already have GMO labeling laws that are costly, inefficient, and serve no reasonable consumer need

There is a voluntary labeling standard from CGSB to address the issue



Current Threats to Innovation-3

- Legal challenges to regulatory systems
 - Have already seen repeated challenges to RR sugar beet, alfalfa authorizations in the US, and the battles continue
 - No similar actions in Canada as yet, but Canadian regulators very aware of US developments
 - Perceived goal of the challenges is not to bring clarity to the decisions, but to delay and muddle regulatory progress

Canadian legal climate not as litigious as US
- regulatory challenges less likely

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Current Threats to Innovation -4

- PMRA crop tolerance and efficacy data
 - Additional requirements compared to U.S.
 - Creates technology data gap for Canadian growers
 - Trade irritant (i.e. MRLs)

Opportunity to harmonize through
NAFTA

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Current Threats to Innovation -5

- **Regulatory Capacity**

- Budget cutbacks straining review capacity/policy development
- New product pipeline expanding every year
- Canadian regulatory system world-class, but there is still room for improvement
- Tracking of product reviews remains an issue

Need to find a balance between amount of data submitted and required to optimize review efficiencies

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Current Threats to Innovation -6

- **New interpretations of existing regulations:**

- EC proposed regulations under Schedule I of New Substance Notification: Notification required for introduction of micro-organism anywhere in Canada.
- Micro-organisms (pathogens being studied) are not new to Canadian environment!

Perhaps consider only micro-organisms new to Canada

- Prevention of import of insect pest eggs for research
- Impact on Bt corn research - change without consultation

Regulators need to do a better job analyzing potential impacts of their decisions



Opportunities

- Enhanced Variety Registration
- Lead implementation of Codex guidance for LLP and expand to feed
- Accelerate framework for LLP in seed
- Reduced data packages based on familiarity, risk
- Learn from chemistry and drive Joint Reviews and/or Work-Shares for products of biotechnology



Summary

- Canadian regulations are science-based and support innovation
- Threats to current science-based system are present, but have not caused significant interference to date
- Canada has opportunity to maintain scientific integrity and lead

