Representing the Canadian developers, manufacturers and distributors of pest control products and products of modern plant breeding.
Overview

- Supporting Innovation in Plant Breeding
  - CFIA Plant Biosafety Office Directive 94-08
  - April 2018 Industry/government forum on plant breeding innovation
  - Seed and grains roundtable letter / Minister’s response

- International Update
Supporting Innovation in Plant Breeding

- Current efforts supported by a significant body of work
- Reinforced by enhanced collaboration across industry
- Aligned with international push to coordinate regulatory approaches
TOWARDS MORE CONSISTENCY

Consistent, science-based criteria

- Common endpoints
- Common scopes of regulation
- Predictable decisions
Revisions to Directive 94-08

- Inconsequential changes: streamlined text and reduced redundancy
- Stewardship plans for disease resistant plants
- Modernized information requirements for similar PNTs
Modernized information requirements: Impetus for Change

• Appropriate allocation of resources based on potential risk
• Appropriate regulatory burden on applicants based on potential risk
• Provide support for risk assessors making recommendations in pre-submission consultations
• USDA is increasingly using their ‘extension process’
  – See: USDA Guidance for petitioners
A Policy Spectrum

Increasing information requirements

Self-Monitor
- Remutation
- Intraspecific cross

Notification
- Retransformation
- Stack

Reduced
- Similar PNT

Full
- All other PNTs
Forum on Plant Breeding Innovation

- Joint forum led by CropLife Canada in partnership with CSTA and CGC, April 2018

- Attended by over 20 HC, CFIA and AAFC staff, including executive directors

- Open and frank discussion on what the challenges are and possible solutions

- Informed both industry and government of respective pressures and challenges
Joint Seed and Grain Roundtable Letter

Industry collaborations supported the development of a joint roundtable letter to Minister MacAulay, April 4th

- Improved guidance and clarity for Canadian innovators on the interpretation of Canada’s novelty-based regulatory trigger for plant breeding innovations (PBI)
- Greater predictability and transparency of data requirements and product review time-frames
- Removal of unnecessary complexities among separate review offices which assess food, feed and environmental safety
- Reduce unintended barriers to domestic and international market entry for plant breeding innovations
Joint Seed and Grain Roundtable Letter

- In the Minister’s June 1st response
  
  - Acknowledged the importance of plant breeding in the success of the agriculture sector and ambitious government growth targets
  
  - Commitment to working with industry to address concerns
  
  - Highlighted the importance of the forthcoming Economic Strategy Table advice
  
  - Signaled that the Treasury Board led “Regulatory Review” would be key
Joint Seed and Grain Roundtable Letter

As a result of this coordinated effort:

- CropLife Canada, CSTA and the CGC are working with AAFC, HC and CFIA to form a working group to address the four elements of the letter

- Co-chaired by CropLife Canada and AAFC

- Frequent meetings aimed at proposals for change in fall 2018

- Working through the existing biotech sub working group of the grains roundtable with linkages to the seed roundtable
Plant Biotech Network

North America
- CBI U.S.
- CropLife Canada

Latin America
- AgroBIO Mexico
- AgroBioColombia (Bolivia, Ecuador, Peru)
- ArgenBio (Argentina, Paraguay, Uruguay)
- ChileBio
- CIB Brazil
- CropLife Latin America (Costa Rica, Guatemala, Honduras, El Salvador)

Europe
- EuropaBio (Belgium, France, Germany, Hungary, Italy, Netherlands, Portugal, Romania, Spain, UK)

Asia-Pacific
- CBI Japan
- CropLife Asia
- CropLife Australia
- CropLife China
- CropLife Indonesia
- CropLife Korea
- CropLife Pakistan
- CropLife Philippines
- CropLife Taiwan
- CropLife Vietnam
- FSII (India)

Africa
- AfricaBio
- African Seed Trade Association

Import Geography

Cultivation Geography
The case for Regulatory Harmonization

Many countries are making food safety decisions – often about the same products or proteins with many years of safe use.

There have been than 1,260 food safety decisions across 28 countries on biotech crops – never with a differing conclusion.

ILSI Research Foundation/CropLife International
Helping Farmers Grow
Positive Momentum

Simplified registrations for familiar traits

Safety assessment sharing

Stack streamlining

Safety assessment sharing for food/feed to reduce asynchrony

Simplification of registrations for stacked-trait products

CropLife International
Helping Farmers Grow
Coordination by Geography
The E.U.

2016

2017

Post Brexit

Post Comitology

Conclusion:
One of France, Germany, or Italy at minimum required to maintain (a broken) approvals process
Signs of Progress

Start of 2017

End of 2017

• Stay the course.
• Engage broader group of countries in the effort where appropriate.
• Opportunities for Canadian/European collaboration via CETA working groups
China

- Continued challenges with approvals and regulatory requirements
  - Establishment of new field trial protocols = further delays
  - Last Chinese approval was in June of 2017
  - Minister MacAulay raised the issue during November 2017 trade mission and May 2018 visit to China
  - NBC meeting held in June however no indication of approvals

- Prepare for upcoming engagements
  - Potential Canada/China bilateral in September
  - Ministerial trade mission in November
Questions?