Biotech Approvals in Key Markets

Canadian Seed Trade Association Annual Meeting, Vancouver

July 11, 2016

BIOTECHNOLOGY COMMITTEE

Ian Affleck
Managing Director, Science and Regulatory Affairs, Plant Biotechnology
CropLife Canada

www.croplife.ca
Representing the Canadian developers, manufacturers and distributors of pest control products and products of modern plant breeding.
CropLife Canada’s role

- **Communication** - increase awareness and acceptance of the benefits, safety and sustainability of plant science innovations
- **Advocacy** - secure legislation, regulation and policy that encourage science and industry innovation
- **Stewardship** - be world-leaders in lifecycle stewardship of pest control products and plant biotechnology traits
- **Outreach** - forge and lead alliances with stakeholder groups to help achieve the industry’s vision and sound public policy

**Facilitate introducing new choices for farmers and producers**
Outline

• Recent events in biotechnology

• Regulatory approvals:
  – China
  – Europe
Recent events in biotechnology

• “Genetically Engineered Crops: Experiences and Prospects”
  – National Academy of Sciences reaffirms the scientific consensus on the safety of biotech crops

• “Laureates Letter Supporting Precision Agriculture (GMOs)”
  – 107 Nobel laurates publish a letter on the importance of biotech crops, focus on Greenpeace opposition
China: Trade relationship

• Canada’s top five 2015 agri-food exports to China (total is $5.6 billion):
  – Canola seeds, $2 billion
  – Soybeans, other than seed for sowing, $595 million
  – Canola oil, $546.9 million
  – Non-durum wheat, $333 million
  – Peas, dried, shelled, $314 million

• Canada’s top five 2015 agri-food imports from China (total is $946 million)
China: Approvals continue to be a challenge

- Approvals are a two-step process
  1. Full application and in country field trials (China requires in country field data)
  2. Submission of in country field data and final review

- Historically questions have not been received during step 2, however, recently that has changed

- China is not following its published rules around submission and approval windows

- Result: approximately a 6 year delay for Canadian farmers
China: Recent developments

• China has proposed amendments to its “GMO safety assessment measures” which include:
  – Removal of timelines
  – Inclusion of economic and social factors into the decision making process
  – Comments were submitted via the WTO notification system and an official response is expected soon

• China’s 13th 5 year plan outlining a “roadmap for genetically modified crops”
  – including the possibility for the cultivation of insect resistant corn
China: Recent developments

- **2\textsuperscript{nd} Meeting with Chinese embassy to Canada**
  - CropLife and valuechain stakeholders
  - Discussed the importance of biotechnology in China’s ag future

- **CropLife International G20 mission**
  - G20 Agricultural ministers meeting in China June 1-3
  - CL Staff from likeminded countries attended in support of their respective government delegations
  - Included meetings with MoA, AQSIQ, MOST
• Continue to build relationships
  – Additional meeting with the Chinese embassy in Canada
  – Take advantage of opportunities, like the G20, to hold neutral information sharing sessions

• Support Government of Canada activities
  – Potential agricultural trade mission to China in November
  – Hold a second “Biotech Dialogue” during the trade mission
  – Further develop the “MoA/AAFC Agricultural Action Plan”
  – Additional opportunities for CFIA/MOA technical dialogues
  – Look for opportunities to work with likeminded countries whenever possible
Europe: Trade relationship

- Canada’s agri-food exports to the European Union (EU) totalled $2.8 billion in 2015
  
  - Canada’s top five 2015 agri-food exports to the EU (total is $1.6 billion):
    - Durum wheat, $600 million
    - Soybeans, other than seed for sowing, $445 million
    - Non-durum wheat, $246 million
    - Canola seeds, $172 million
    - Lentils, dried, shelled, $147 million

- CETA is expected to be signed in 2016 and in force in 2017 (parallel letter on Biotech)
Europe: Approvals continue to be a challenge

• EU decisions typically science based, but they take too long

• EU is averaging 6.5 years to complete an authorization
  – Up from under two years (in 2006)
  – Delays are unnecessary and not based on science
  – EFSA risk assessments becoming more complex
  – Growing number of guidance documents
Europe: Recent developments

- Opt outs for cultivation and import/use
  - In October 2015, 19 of the EU’s 28 Member States notified their intention to opt out of cultivating GM crops
  - April 2015 Commission proposal to allow Member States to opt out of use for food and feed
    - Rejected by Parliament (Oct/15)
    - Still to be discussed by the European Council

- EU Ombudsman: “Clear maladministration” of the system (January/16)
Europe: Recent developments

- Canada-EU Biotech Market Access Dialogue
  - AAFC/GAC has accelerated these meetings to twice a year
  - GoC working closely with the value chain to develop approaches to the dialogue meetings
  - CropLife organizations in likeminded countries coordinating advice
  - 7th/8th dialogues - December 8th, 2015 and June 10th, 2016

- During the 8th meeting
  - EU committed to making process improvements to better the client experience
  - Indicated commitment to following established timelines
  - Refused to discuss the current outstanding soy approvals
Europe: Outstanding soybean approvals

• Three soybean products:
  – Final committee approval Jan 11/16
  – Global industry and government bodies have pressured the EU to finalize the approval

• Over 1 million acres planted in the US
  – Due to trade concerns has not been made available in Canada

• Delay is unofficially tied to the re-review of glyphosate
  – With glyphosate extension granted there is new hope
  – EU has indicated the approval is in the “final stage” and approval should be before the end of July
Europe: Next Steps

• Continue to leverage all points of communication
  – EU/Canada Biotech Market Access Dialogue
  – CETA negotiations

• Enhanced cooperation between likeminded countries
  – Industry groups in those countries are working closer together
  – International associations are speaking up as well
  – Canadian Government is coordinating likeminded government approaches to the dialogues

• Consider other more direct methods to challenge the EU system?
Questions or Clarifications?