

Sustaining and expanding global trade  
Challenges and opportunities in crop  
biotech regulation and innovation

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2nd Decade of Crop Biotechnology

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# Outline

- International Biotech Regulation  
Challenges/Hurdles
- Report on Progress Made
- Remaining Challenges
- Lessons Learned

# Objective

Harmonization of international regulatory systems to facilitate trade

Science based risk assessment implemented with science based risk management schemes

# Hurdles in International Grain Trade

- Impracticality of Zero tolerance
- Perception of US/Western Hegemony
- Undeveloped Regulatory Systems
- Stewardship Gaps/Failures
- Multilateral Organization Uncertainty

# Strategies for Success

- **Give Purchaser Alternatives-**  
Biotech or non-biotech
- **United industry approach-**  
International Grain Trade Council- Formed 2000  
Global AP (Adventitious Presence) Coalition
- **Focus on prevention of trade disruption**  
Importer and exporter interests aligned  
Domestic industries have more influence than  
outside interests/governments

# Zero is a very small number

In regulatory regimes capable of testing to parts per billion or greater, zero or below the limits of detection are not practical (dare we say unsustainable?).

# What is Adventitious Presence?

## Grain Perspective

- Unintentional
- Low level presence of a transgenic event(s) authorized in one or more countries but not in country of import
- Reasonably be expected to be present consistent with generally accepted agricultural and manufacturing practices

# Zero Threshold AP Policies

- Zero threshold AP risk management policies currently employed by countries for events authorized in one or more countries but not in country of import, create the most disruptive issue facing the international grain trade today
- Zero Tolerance of such events impossible even while employing sophisticated quality management systems: Not a question of whether or not such events will appear, only question is when such events will appear



# Impact of Zero Threshold AP Policy Upon Grain Industry

- Zero threshold AP policies expose grain industry to exceptionally high risk: (demurrage, additional handling/storage costs/ disposal costs) leads to:
  - Exporters stop offering product: trade stops; loss of export opportunity impacts entire export value chain; worst case leads to industry downsizing
  - Importers must seek alternative, usually higher cost replacements e.g. EU feed industry estimates potential Herculex AP in corn gluten feed imports this past year cost feed industry between 2 - 4 billion euros; worst case leads to industry downsizing

# Low Level Thresholds

- Low level thresholds are much superior to zero thresholds BUT raise questions:
  - What is low level? Lower the threshold, higher the cost to farmers and down stream value chain members
  - Who pays higher costs? Traditionally low level thresholds were negotiated between seller and buyer as threshold level represented end use processing benefits; hence the lower the threshold the higher the premium; higher premiums enabled members of value chain to be compensated for higher cost Identity Preserved handling systems . But who pays added costs including liability exposure to downstream members of value chain to keep an unwanted product out of the normal market stream when no end use marketing premium is available?

# Update on Multilateral Fora

## CODEX

- **Codex Alimentarius Low Level Presence Task Force approved Risk Assessment Guidelines**

Covers Low level presence of a transgenic event(s) authorized in one or more countries but not in country of import

Still needs to be approved by the Codex Council, but can provide countries with alternatives to deal with AP

# Update on Multilateral Fora

## Cartagena Protocol on Biosafety

- Individual Parties to the protocol beginning implementation
- Implications of restrictive policies becoming clearer to importers
- Global AP Coalition engaging nations individually  
Liability and Redress remains a disturbing and unclear risk

# Remaining Issues

- Asynchronous Approvals
- Rogue Events
- Corporate Responsibility/Stewardship-  
BIO Stewardship-
- Liability and Redress
- Discontinued Events

# Proactive Use of Codex Low Level AP Risk Assessment Guidelines

- Most governments currently expect to use the new Codex Low level AP Risk Assessment Guidelines when an event is detected at unload that has been authorized in one or more countries but not in country of import.
  - Costly: Ship unloading may be delayed until low level risk assessment is completed, creating additional unnecessary costs
- Grain industry urging governments to perform low level AP risk assessment as soon as information on the event is posted to the new FAO data base (when the event has been authorized in one or more countries) and upon successful completion of low level AP risk assessment announce a marketing tolerance.
  - Less costly, marketing tolerance known in advance of shipment

# Lessons Learned

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Thank you