



Regulation of Living Modified Organisms in the United States, Canada and Mexico

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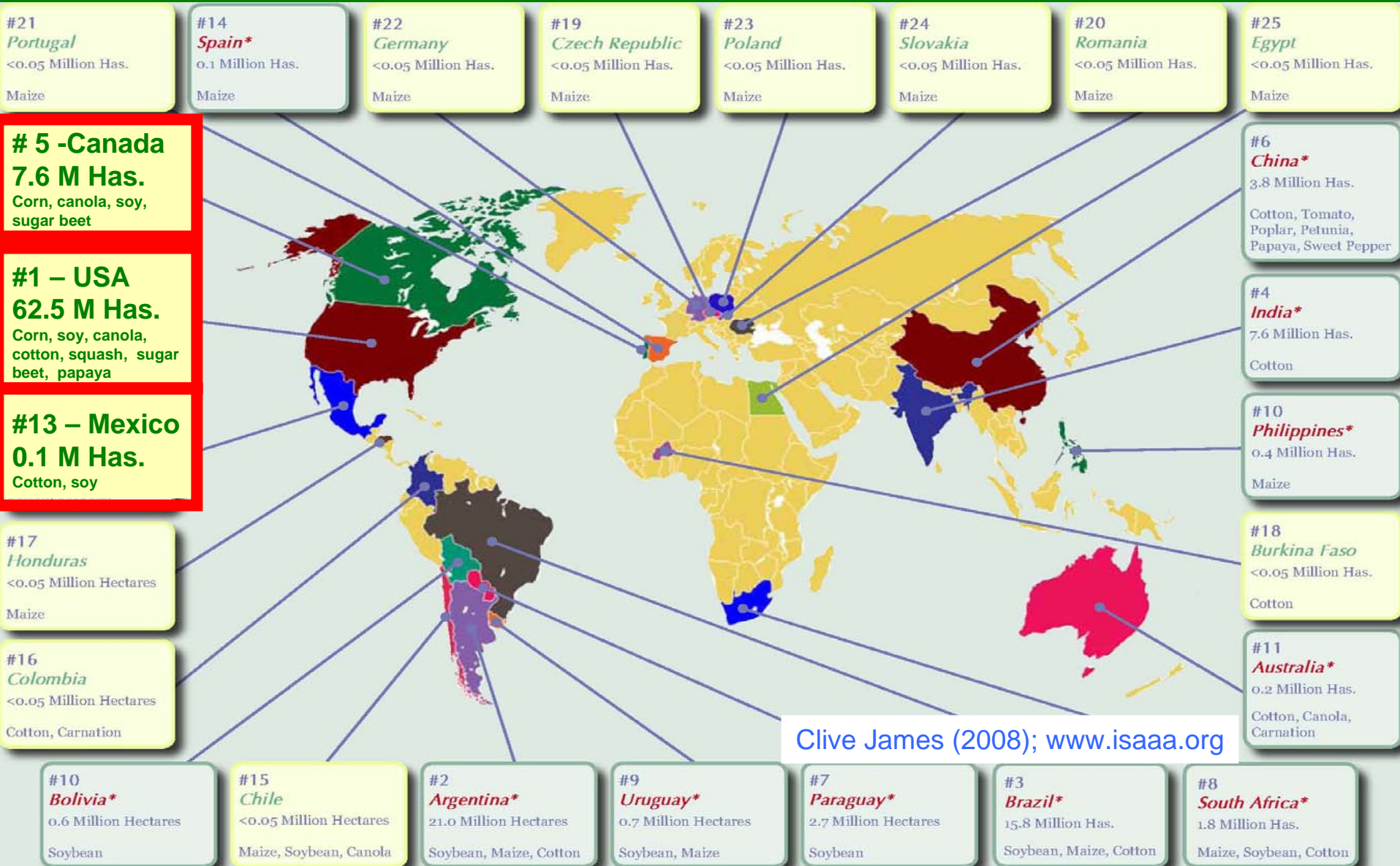
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Introduction

- Canada and Mexico are 1st and 3rd largest trading partner of U.S. for total imports and exports of agricultural products
- Phytosanitary regulations and procedures are in place to prevent spread of pests and diseases that could harm agriculture or the environment
- Food safety regulations to ensure safety of products for food and feed

Global Status of Commercialized Biotech Crops - 2008



Clive James (2008); www.isaaa.org

Overview

- In 2008 – percent of genetically engineered (GE) varieties planted
 - U.S. – soybeans 92%, corn 80%; cotton 86%
 - Canada – canola 30%; soybeans 60%; corn 45%
- Other GE varieties in development, including fruits and vegetables, coffee, wheat that are traded within North America
- Need for regulatory oversight to ensure safety and provide confidence that GE products moving between countries in North America are safe for humans and animals and the environment

Outline

- General regulatory principles and implementation
- Areas of mutual concern
- Regulatory harmonization in NAPPO countries

Regulation of GE organisms by NAPPO Countries

- Review of new genetically engineered organisms to assess whether the modification could result in that organism posing an unacceptable risk to the environment or human or animal health
- Comparison to non-engineered counterpart

Regulatory oversight

- Regulatory oversight shared between agencies
 - U.S. - USDA, FDA, EPA
 - 1986 - Coordinated Framework
 - Canada – CFIA, Health Canada, Environment Canada
 - 1993 – Framework for regulation of biotech products
 - Mexico – SAGARPA, SEMARNAT, SALUD
 - CIBIOGEM (Inter-ministerial Commission for Biosafety of Genetically Modified Organisms)

Regulation – general principles

- Risk assessments are science-based, and conducted on a case-by-case basis
- Level of oversight is determined by the intended use, e.g.,
 - Field trials vs large scale or commercial release
 - Food and feed only vs environmental release
- Special consideration for impacts on threatened and endangered species
- Transparency
 - Public consultations
 - Websites

Field trials – regulated organisms

- Permits required for environmental release (field trials)
- Conditions imposed to minimize gene flow and the likelihood of establishment and spread of the regulated organism
- Subject to inspections, monitoring; penalties for non-compliance
 - Canada – limits size of field trials to 1 hectare
 - Mexico – “Tiered” permits for experimental, pilot or commercial releases

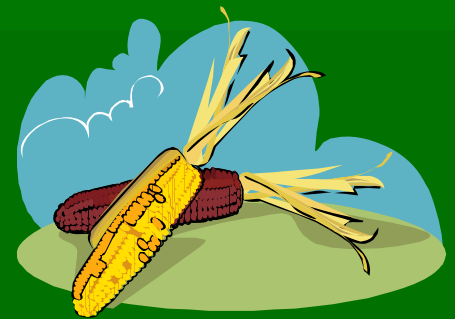
Large Scale or Commercial Cultivation

- Decision based on data supplied by developer demonstrating the new GE organism does not pose a risk to agriculture, environment, human or animal health
 - Risk assessment consistent with Annex III of ISPM-11
- U.S. and Canada – “deregulation” or approval allows for growth, importation without additional permits
- Mexico – commercialized products would be grown under commercial release permits
 - Decision to commercialize based on market demand



Mexico – special considerations for maize

- Mexico is a center of origin and a center of biodiversity for maize
- Maize also has a major cultural significance in Mexico, and there are additional sensitivities related to use of GE varieties
- No maize field trials allowed since 1998
 - March 2005, Mexico promulgated a new comprehensive Biosafety Law, and in March 2008, they published the implementing regulations.
 - Under the new regulation, in 2009, Mexico published a special regime for maize field trials designed to protect maize biodiversity, including no planting in centers of origin
 - Mexico currently considering over 25 new applications for maize field trials



Regulatory Harmonization

- Areas of mutual concern
 - Shared borders, unintended cross-border movement of unapproved varieties
 - “Low level presence, LLP”
 - Possible environmental or food safety consequences
 - Socioeconomic concerns
 - E.g., presence of GE traits in maize landraces, organics
- Trade within North America
- Concern for export markets
- One goal – synchronous approvals

Regulatory Harmonization: trilateral activities

- **NAPPO – Biotechnology Panel**
 - RSPM-14: Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries (October 2003)
 - RSPM-27: Guidelines for Importation and Confined Field Release of Transgenic Arthropods in NAPPO Member Countries (October 2007; collaboration with Fruit Panel)



North American Biotechnology Initiative (NABI)

- Established in 2002 as a forum for information exchange and policy discussions on agricultural biotechnology
- Establish relationships with regulatory counterparts
- Scientific and regulatory information exchange, risk communication, coordination for work in international fora, special topics
- Meets once per year, plus special topics
 - November 2008 – field trial workshop in Mexico
 - November 2009 – risk communication workshop in Mexico

Technical Working Group

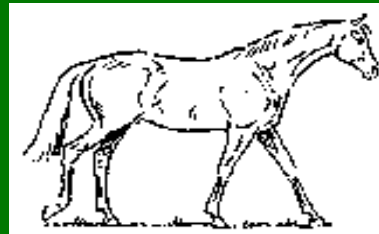
- **Technical Working Group**
 - U.S. and Canada have held regular discussions on new product reviews, risk assessment criteria since mid-1990s
 - Mexico has become full partner in trilateral discussions
 - Bimonthly conference calls; meetings once or twice per year

Technical Working Group

■ Current projects

- Revising U.S./Canada bilateral documents on molecular characterization and environmental review of new biotech products
 - To encompass Mexico's new regulations
 - Update for consistency with current research and experience
- Joint review Pilot Project
 - Concurrent review of new GE drought tolerant maize
 - Share reviews, collaborate on assessments
 - Goal – synchronous approvals to prevent trade disruptions

Any Questions?



<http://www.aphis.usda.gov/brs>

<http://www.inspection.gc.ca/english/sci/biotech/bioteche.shtml>

<http://www.cibiogem.gob.mx>