

# **CropLife Update**

## **ASTA Innovation & Policy Committee**

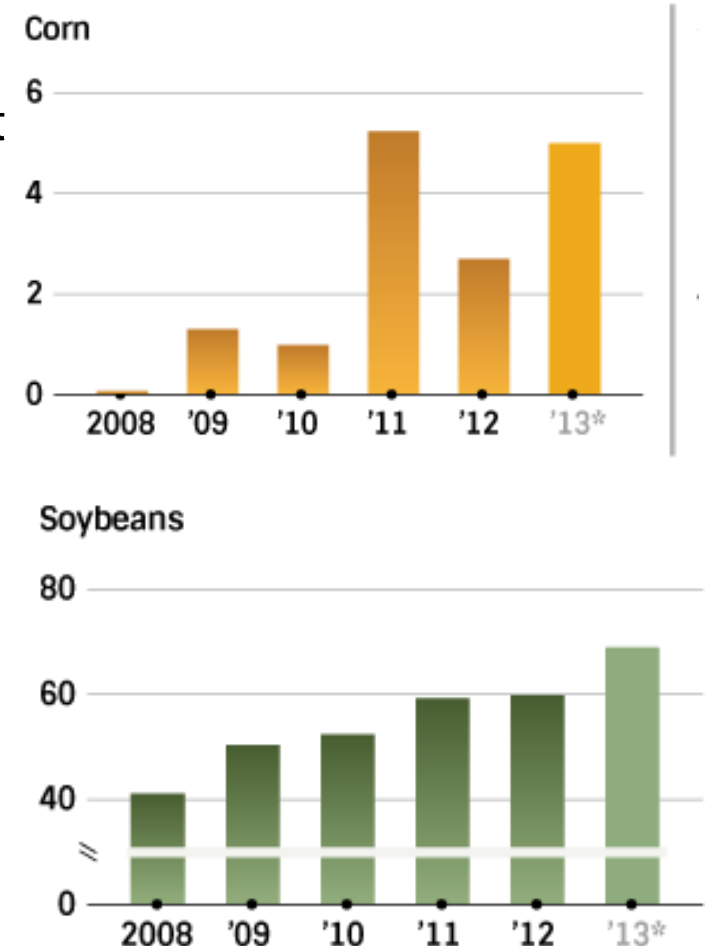
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# Priority Focus: China

## Environment Overview

- **Trade** China remains a significant importer of biotech products, particularly from the United States
- **Local Production** China is the sixth largest producer of biotech plants based on total area (mainly cotton) and may become an exporter of biotechnology in the medium to long term;
- **Government Position** The central government supports the ag biotech industry and invests in R&D of indigenous products, while regarding MNCs as threats
- **Public Acceptance** Consumer opinion remains mixed and cautious toward biotech products, which impacts political decision-making

China's grain imports; in millions of tons



# Policy and Regulatory Challenges

Current regulations and policies present market access impediments

## Regulatory Challenges

- Asynchronous approval, which requires that a product be approved from an exporting country before an approval application can be filed in China;
- A restrictive low-level presence threshold of zero percent
- No clear policy on stacked events, and
- Approval process fails to comply with official announced timeline; lack of transparency and predictability

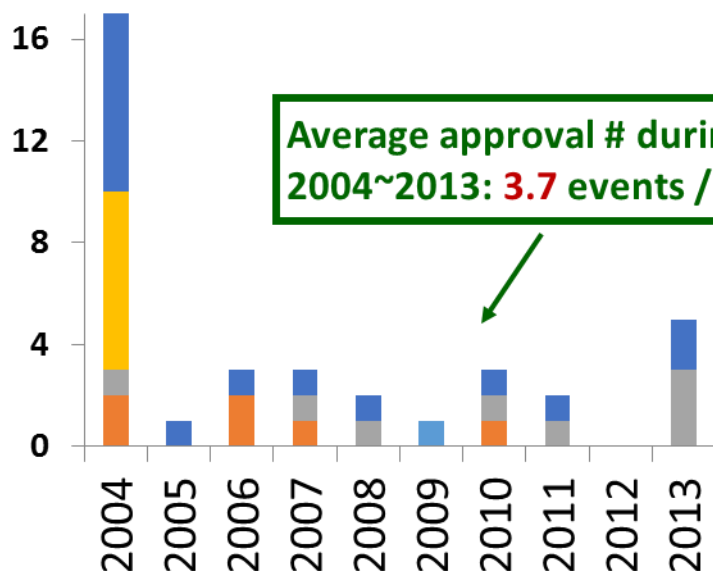
## Seed Policy

- Foreign companies are prohibited for biotech R&D and biotech seed business;
- Inadequate protection for intellectual property rights;
- Lack of guideline on variety registration for biotech varieties

# Regulatory Approvals

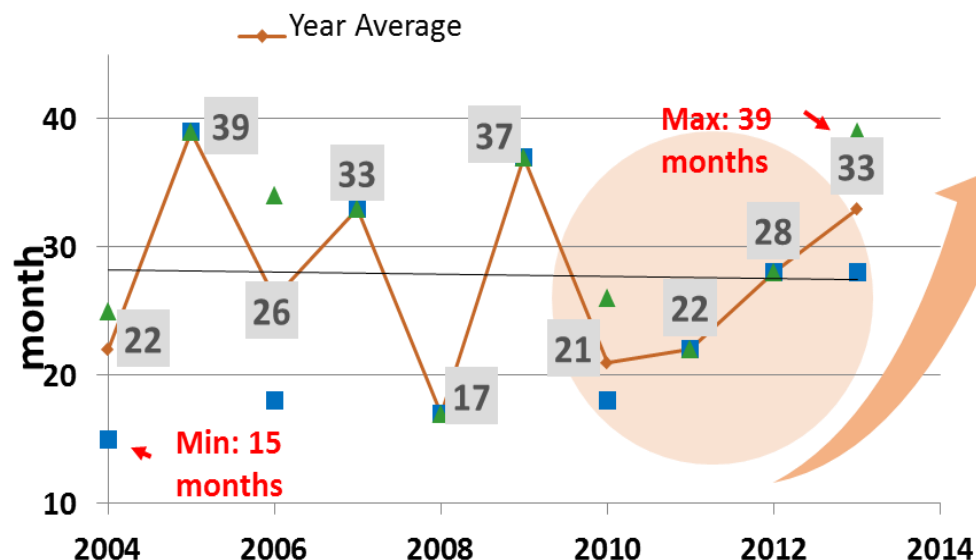
## 2014

- Two cotton events approved for import (May)
- Five events approved for local study (May-July)
- Two soybean events for import rejected with not-science-based reasons (August)
- Applications for local cultivation purposes no longer accepted



Average approval # during  
2004~2013: 3.7 events / year

Time cost for 1 approval:



# 2014: “GMO Deadlock”

## Increasing pressure from public opinion

3 safety certificates of self-developed events issued in 2009 expired

Media reports on illegal cultivation of Bt rice

Biotech scientists corruption

Wide spread anti-GM voice throughout social media

## More cautious approach adopted

NBC only provides technical consultation to MOA once a year (2 preview meetings + 1 final feedback)

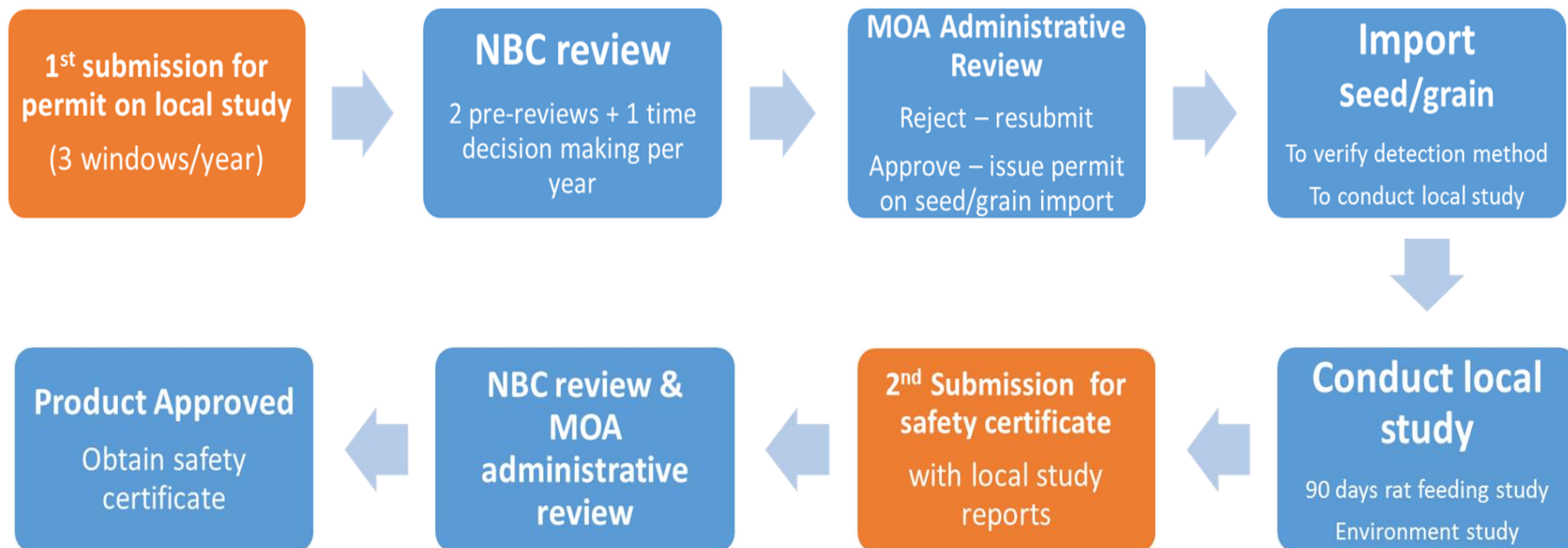
Minister makes decisions once a year ( the next year of NBC feedback)

Taking social acceptance into consideration

**One Step Forward:  
MOA plans to launch large scale media campaign to improve public perception**

# Regulatory Review Process

## Import as FFP



This process is based on an ideal scenario. In practice, the following situations might prolong the timeframe of approval:

- 1) NBC requires additional data/information;
- 2) MOA issues a rejection for the product; and/or
- 3) Miss cultivation season during local study.

# MOA Administrative Review

## Factors to consider:

- Technical consultation from NBC safety assessment based on science and risk assessment principles
- Impact on agriculture production, food security and industry security
- Impact on economy and international grain trade
- **Social acceptance**
- Evaluation of IPR status

The above factors apply to both products for import purposes and for local production (such as Bt rice)

# China Strategy

## Goal:

- Allow for timely market access in China of new innovative technologies developed by CropLife International members

## Oversight:

- Creation of a North Asia Task Force to provide oversight of resources, strategy, timelines and metrics for success; ensure coordination across CropLife committees and coalitions

## Focus:

- Emphasis on trade challenges vs. regulatory reform needs



# Five Pillar Strategy

## Process the Backlog

- Regulatory systems function as designed



- Regional & National Associations
- Regulatory Committee & Project Teams

## LLP

- Thresholds
- Minimize short-term trade disruption



- GAABT
- China LLP Coalition
- Regional & National Associations

## Regulatory Reform

- Predictable regulatory system
- Compress timelines



- Regional & National Associations
- Regulatory Committee

## Synchronous Approvals

- Concurrent multilateral submissions



- EMA Committee
- GAABT
- China LLP Coalition
- Regional & National Associations

## Harmonization

- Harmonize food and feed approvals



- Regulatory Committee
- Emerging Regulatory Systems Project Team

# Outcomes to Date

- Coordinated advocacy effective in outreach with the four targeted governments to date.
- MOA indicates the authorization process will transition to a system with three submission windows, but only one approval time period per year.
- US exports of DDGs stopped due to MIR162
- Rejection of 2 soybean submissions non-science based
- President Obama met President Xi - commitment that “United States and China reached consensus to intensify science-based agricultural innovation for food security. The United States and China commit to strengthen dialogue to enable the increased use of innovative technologies in agriculture.”
- December JCCT meeting in Chicago next week, where industry is pressing for a comprehensive framework agreement with a schedule of commitments to ensure that the U.S. and China are working to resolve the issue in the near term.

# GAABT – Low Level Presence

# Global Alliance for Ag Biotech Trade

## “Farm to fork” industry coalition

- Focuses on LLP as a potential “shorter term” solution to asynchronous approvals issue
- Includes global organizations and coordinated country teams
- Benefits from close engagement from producer groups and traders

# Global LLP Activities

## Focused on Global LLP Initiative

- Canadian-led initiative to gain agreement on a harmonized approach to manage LLP and asynchronous approvals
  - Argentina, Australia, Brazil, Canada, Chile, China\*, Colombia\*, Costa Rica, European Commission, Indonesia, Korea\*, Mexico, Paraguay, Philippines, Russia, South Africa, United States, Uruguay, Vietnam
- Goal: GLI maintains its momentum and progresses toward establishing a harmonized approach to handling LLP and minimizing asynchronous approvals
- GAABT is lead industry contact point, lead industry voice at meeting, and organizer of industry day

## GAABT-led Solutions

- GLI not coalescing around a specific solution or set of solutions
- GAABT Coordination Committee leading GAABT effort to evaluate national, regional and multilateral options and select “best” approaches:
  - “National approach: Five percent threshold applied for LLP for products approved in at least one country for food use in accordance with the Codex Food Safety Guideline
- End products:
  - White papers elaborating solutions in detail
  - Clear set of principles and criteria
- Support from Canadian government and willingness to share with GLI member at 4<sup>th</sup> GLI (Guadalajara, Mexico – March 2015)