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Economic Cooperation

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Low Level Presence: Overview

Purpose: Information
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INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE
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A partnership program for biosafety capacity development

Low Level Presence: Overview

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Organization of this Talk

I. What is Low Level Presence?
II. Increasing Importance in Agricultural Commodity Trade and in APEC
III. How does LLP Occur?
IV. Can it be avoided?
V. Multilateral initiatives dealing with LLP
VI. What about thresholds/tolerances?
VII. LL 601 A Case Study

I. Low Level Presence (LLP)

The unintentional or inadvertent mixing of a grain commodity with small, insignificant quantities of another (transgenic) variety of grain

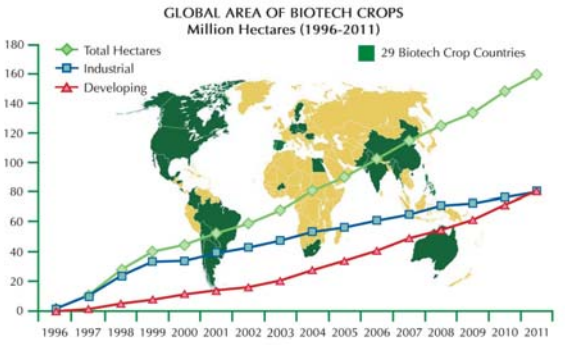
I. Low Level Presence (LLP)

1. Biotech events that have been approved in the exporting economy, but have not yet been approved in the importing economy become mixed in with grain approved in both exporting and importing economies. (asynchronous approval).

2. Biotech events that have been approved in the exporting economy, but for which approval is not being sought in the importing economy become mixed in with grain approved in both exporting and importing economies (asymmetric approval).

II. World-wide Importance

An increasingly important issue in South East Asia, and the world as,



A record 16.7 million farmers, in 29 countries, planted 160 million hectares (395 million acres) in 2011, a sustained increase of 8% or 12 million hectares (30 million acres) over 2010.

Source: Clive James, ISAAA

1. Area planted with biotech crops is steadily increasing
2. Number of economies growing Biotech crops is increasing

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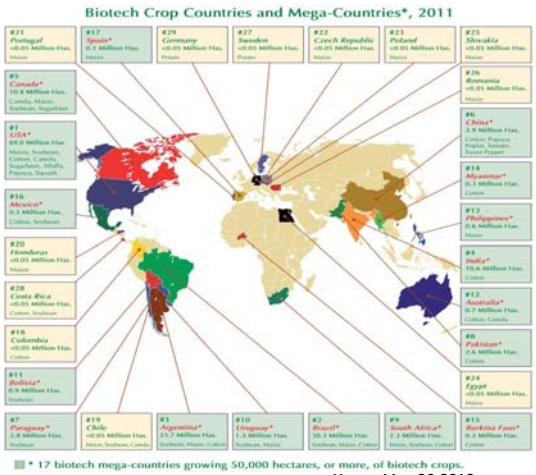

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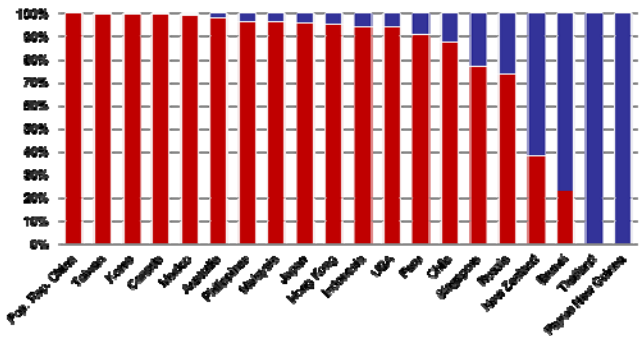
Source: Clive James, ISAAA

Kazan May 26 2012 6

II. Importance in APEC

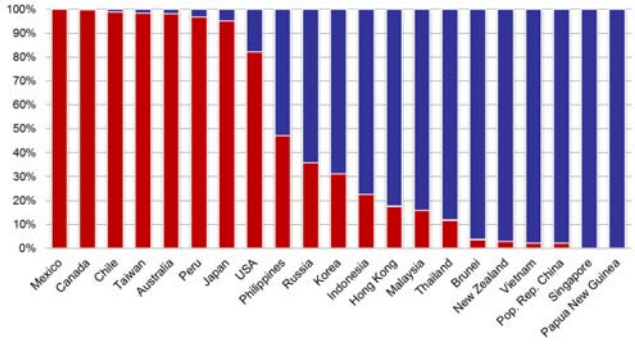
Percentage of Soybean Imports that have have potential LLP problems



Source: G. Gruère, IFPRI

II. Importance in APEC

Percentage of Maize Imports that have have potential LLP problems



Source: G. Gruère, IFPRI

II. World-wide Importance

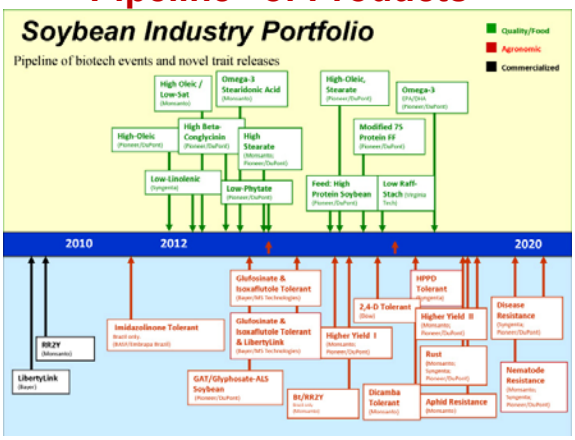
Number of Biotech Events Approved

	Biotech Events Approved
USA	122
Japan	114
Canada	99
EU	45

Source: N. Kalaitzandonakes, Univ. Missouri

II. Increasing Importance

"Pipeline" of Products

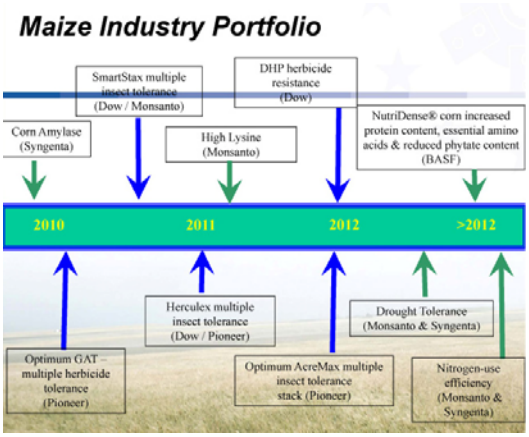


Source: American Soybean Association

Increasing numbers of new Biotech Soybean varieties under development

II. Increasing Importance

"Pipeline" of Products

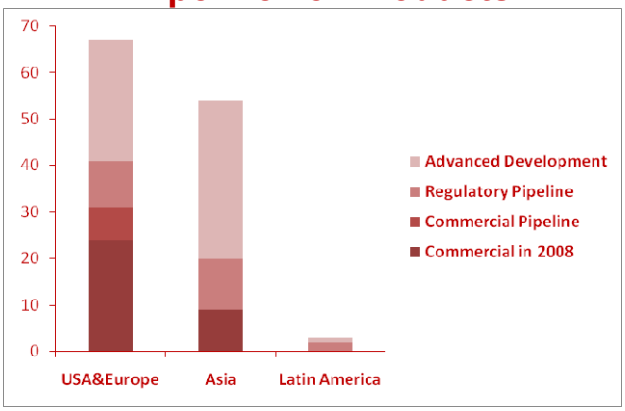


Increasing numbers of new Biotech Maize Varieties under development

Source: J. Piçarra

II. Increasing Importance

"Pipeline" of Products



Increasing numbers of new Biotech varieties under development

Source: Stein & Rodríguez-Cerezo 2009

II. Increasing Importance

"Pipeline" of Products

Current Situation in the USA

Crop	Events Awaiting Approval
Corn	6
Soybean	8
Other	8
Total	22

Source: http://www.aphis.usda.gov/biotechnology/not_reg.html

II. Increasing Importance

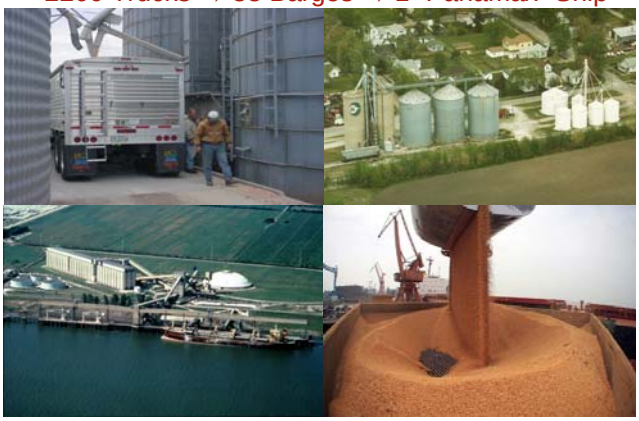
Asynchronous Approvals

As the number of new GM crop varieties increases, so will the problem of asynchronicity

III. How does LLP occur?

How grain is shipped

2200 Trucks → 38 Barges → 1 "Panamax" Ship



Source: R. Giroux, Cargill

IV. Can LLP be avoided?

Yes, theoretically but this would involve:

- Cleaning silos, trucks, barges and ships
- Maintaining harvests from individual farms separate (Identity Preservation)
- Possible delays in shipping
- Testing to verify nature of the commodity
  - Setting up Laboratories, buildings, equipment, personnel
  - Costs of the tests
- Physical Isolation of the non-Biotech Crop being grown (no gene flow)

All this will involve considerable costs and unlikely to achieve practically

V. Multilateral Initiatives: Codex Annex

Annex to Codex Guidelines for LLP

- **Adopted July 2008 For Crops Authorized according to Plant Guidelines, but not Authorized in Importing Economy**
- **National Authorities Determine when Annex is Appropriate**
  - **Low Level (Threshold) not defined, but below nutritional significance**

V. Multilateral Initiatives: Codex Annex

What the Annex Covers

- Safety of New Substances (Toxicity, Allergenicity)
- Molecular Characterization (to enable identification of new substances)
- For foods eaten in whole individual units (e.g., fruits, potatoes), evaluate potential changes in levels of key native toxicants and allergens
- Nutritional composition considered not relevant for low level presence

Abbreviated Risk Assessment – but not by much

VI. Thresholds/Tolerances

Can we use thresholds/tolerances as a practical solution to the issue of LLP?

VI. Thresholds/Tolerances

What a low threshold means

- 0.01% of an unapproved GM variety means 66 beans in 100kg (~667,000 beans)
- Have to test ~3,000 beans to have a 95% chance of picking one or more that is GM
- Assumes homogeneous distribution of the GM beans in a cargo. Non-homogeneity means sample size should be much larger – to be determined empirically

VI. Thresholds/Tolerances

Cost analysis for LLP issues similar to Labeling, but the consequences of an LLP incident are potentially much more serious…

Rejection of an import Commodity Shipment rather than a labeling change

VI. Thresholds/Tolerances

Why are they important?

1. Quality Issue
2. Influence the costs of segregated trade
3. Effective exposure to human or animal population
   - Important if risk assessments identify potential risks
   - Tolerances/thresholds could then be different for each LLP situation

VI. Thresholds/Tolerances

Maize International Quality Standard Codex Stan 153-1985

Maximum tolerances

	%
Diseased grain	0.5
Grain attacked by pests	2
Other grains	2
Foreign matter	2
Inorganic material	0.5
Filth	0.1

VI. Thresholds/Tolerances

Wheat: International Quality Standard ISO 7970: 1989

Maximum tolerances

	%
Unsound grain	1
Grain attacked by pests	2
Other cereals	3
Extraneous matter	2
Inorganic material	0.5
Harmful/toxic seeds, bunted grains and ergot	0.5

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VI. Thresholds/Tolerances

Annual Costs for testing for LMOs in the USA and Argentina

Samples Tested	Cargos Tested	Contain LMOs (US$)	Identify LMOs (US$)	Quantify LMOs (US$)
1 /Cargo	3575	936,650	2,342,900	4,356,900
20/Cargo	3575	18,733,000	46,858,000	87,138,000

Source: N. Kalaitzandonakes, Univ. Missouri

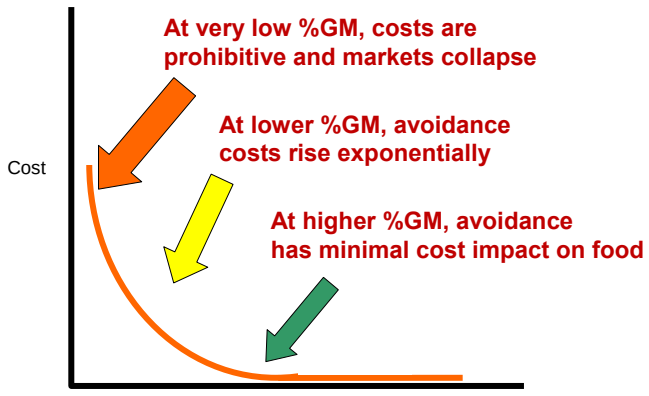
VI. Thresholds/Tolerances

Effect of Different Threshold levels (additional costs)

Threshold Level	0.9%	5%
Soybeans	US$14.9/ton	US$8.3/ton
Maize	US$ 8.3/ton	US$2.9/ton

Source: N. Kalaitzandonakes, Univ. Missouri

VI. Thresholds/Tolerances



VI. Thresholds/Tolerances

Adoption of most stringent thresholds (<1%) will

- Increase the cost of food and feed
- Cause costs to fall disproportionately on smaller importers (often developing economies)
- Discourage investments in research into the next generation of crops
- Be effective technical barriers to trade

VI. Thresholds/Tolerances

Adoption of a threshold of 0% (zero tolerance) moreover is

- **Unreasonable and unattainable practically**
- **Is inconsistent with statistical concepts intrinsic to the interpretation of sampling and testing data**

VI. Thresholds/Tolerances

Why are they important?

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NOTE: A wealth of data indicates that there is no food safety risk for all events tested so far

VII. LL ("Liberty Link") Rice

Herbicide ("Liberty®") Tolerant Rice Varieties

Developed by Aventis Crop Science (acquired by Bayer Crop Science in 2002)

VII. LL ("Liberty Link") Rice

3 Transformation events

LL Rice 06, LL 601, LL 62

- Trait: Herbicide Tolerance specifically Glufosinate ammonium.
- Contains a bacterial gene encoding the PAT protein (phosphinothricin acetyl transferase), that provides tolerance to Liberty® herbicide
- The amount of PAT protein in LL601® is very low; 0.000034%, or 3 parts per 10 million, of all the protein in a Liberty Link rice grain

VII. LL ("Liberty Link") Rice

LL Regulatory Approvals

LL 06, LL62

- US 1999/2000
- Canada 2006
- Mexico 2007
- Australia 2008

LL601

- US 2006
- Colombia 2008

VII. LL ("Liberty Link") Rice

LL601

- Commercialization initiative halted in 2001
- Detected in harvests in the US in 2005 and 2006

VII. LL ("Liberty Link") Rice

LLP cases with LLP 601

In 2006 Low Levels of LL 601 were detected in Commodity Shipments to

1. **Europe**
   - **29% of US Rice imports to EU in 2005**
   - Level reported to be at the limits of detection (that is, trace level)
2. **The Philippines**
   - Greenpeace sends samples of US Rice from a Philippine Grocery to Japan for testing – reports tested positive for LL 601
3. **Australia and New Zealand**
   - **<1.5% of Rice imports to Australia,**
   - **<0.5% of Rice imports to New Zealand**

VII. LL ("Liberty Link") Rice

1. EU Consequences

Rice millers had to:

- Test for LL601 Rice in stocks awaiting processing/milling, in stocks of milled rice and in derivative products containing rice
- Notify customers that products may need to be tested
- Remove and destroy all stocks and products containing LL601
- Recall milled rice and other LL601 products supplied to customers
- Seek assurances from US suppliers that future supplies of rice would not contain LL601
- Seek alternative supplies of long grain rice from other economies

VII. LL ("Liberty Link") Rice

1. EU Consequences: Costs Incurred by 15 European Rice Millers

Cost Category	Value (Millions of Euros)	
Equipment Testing and Cleaning	€ 0.3 – 0.6	
Product Withdrawals	€ 9 - 12	Returns, disposal and destruction of stock
Replacement of affected stock	€ 6 - 9	Identification and costs of alternative supplies
Legal	€ 0.3 – 1.5	
Adverse impact on Brands	€ 15 – 37.5	
Total	**€ 52 - 1,000**	

Source: Brookes 2008

VII. LL ("Liberty Link") Rice

2. Consequences: the Philippines

- Recall of affected Rice from the Domestic Market
- One year delay in Rice importation
- Additional Costs to Philippine Government
  - Higher Prices
  - Oversight costs
  - Cost for Failed Bids
    Bidders added a premium of 15% to undertake testing
- Delay in monetization of Rice Imports
- Delay in funding for PL-480 projects
- But - Stimulated the Philippine Government to enact a LLP Policy

VII. LL ("Liberty Link") Rice

3. Consequences Australia/New Zealand

FSANZ (Food Safety Australia and New Zealand)

- applies conventional risk management strategy (e.g., hazard x exposure)
- gathers information of LL 601 and novel protein involved (PAT)
  - USDA and US-FDA reviewed data: concluded no health, food safety or environmental concerns associated with LL610
- Determines that protein had been scientifically reviewed and used safely in food in ~12 economies including Australia and New Zealand
- FSANZ had assessed and approved the use of other LL GM crops (cotton, canola corn)
- No novel hazard identified, determined that risk was negligible

Спасибо за внимание

Thank you for your attention

Les agradezco su atención

谢谢您的关注

Terima kasih

ご清聴 ありがとうございました

Спасибо за внимание

제 발표를 경청해주셔서 감사합니다

Terima kasih atas perhatian anda

Salamat sa iyo para sa iyong pansin

ขอบคุณ

Cảm ơn quý vị đã lắng nghe