

International Experience in Biosafety in Agriculture

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Conferencia Regional Sobre Bioseguridad
Cartagena de Indias, Colombia

8 June 2012

International Experience in Biosafety in Agriculture

1. Elements of Functional Biosafety Regulatory System
2. Global Implementation Status of Biotechnology and Biosafety in Agriculture
3. Current Perceptions of Agricultural Biotechnology
4. Agriculture and Biosafety in the World Bank Experiences and Lessons Learned
5. Recommendations on Future Work

Elements of a functional biosafety regulatory system

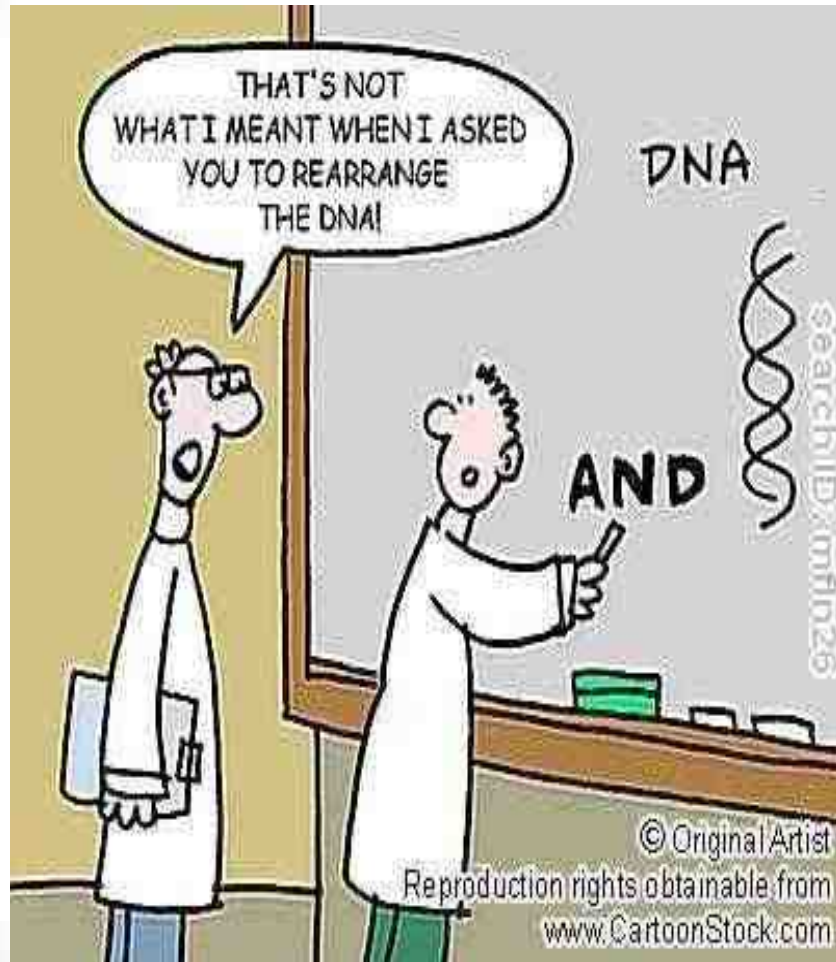
- No best model
- Influenced by the social, cultural, economic and environmental context of a country
- However, there are a number of common issues to consider when **establishing or revising** a biosafety regulatory system



- Elaboration of a national **biosafety policy consistent** with objectives related to 1) economic, social, and rural development; 2) natural resource management and environmental sustainability

- An **assessment and gap analysis** of the national development priorities, policies, and existing regulatory regimes.





- Building a strong base of **scientific knowledge** in support of the regulatory system and developing **core competencies** in biotechnology product evaluation



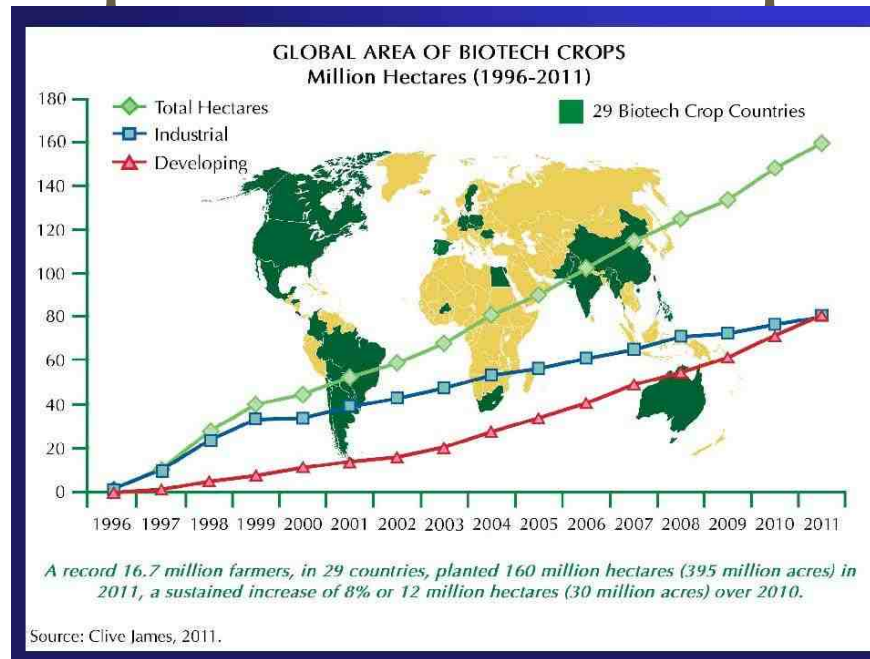
- Regulation not an end in itself
- Key to move towards implementation of regulations and building functional biosafety regulatory system.

- Addressing cross-cutting issues :
 - Public information, communication & participation
 - Long term national/regional commitment to provide human, financial and infrastructure resources to biosafety.



2. Global Implementation Status of Biotechnology and Biosafety in Agriculture

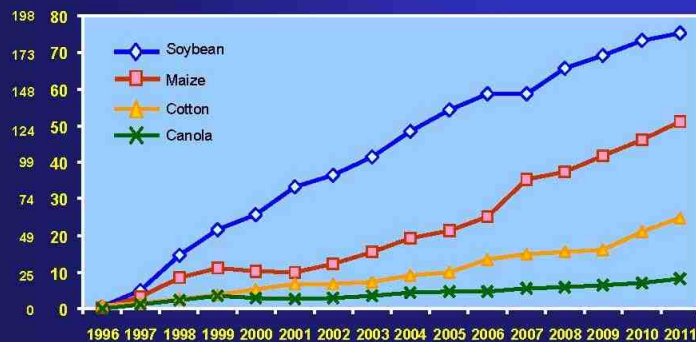
Global adoption of GM crops



**Global Area of Biotech Crops, 1996 to 2011:
By Crop (Million Hectares, Million Acres)**



M Acres

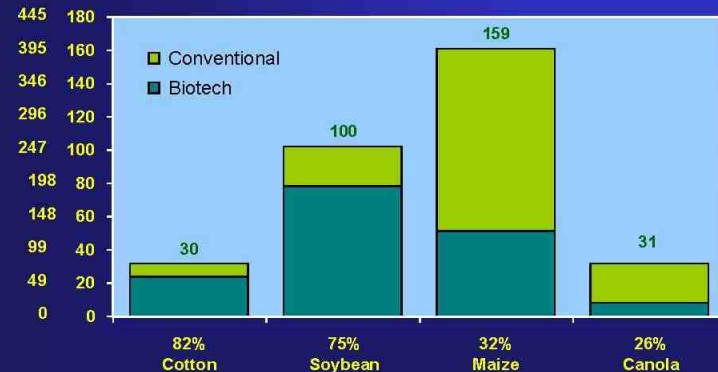


Source: Clive James, 2012

**Global Adoption Rates (%) for Principal
Biotech Crops (Million Hectares, Million Acres), 2011**



M Acres

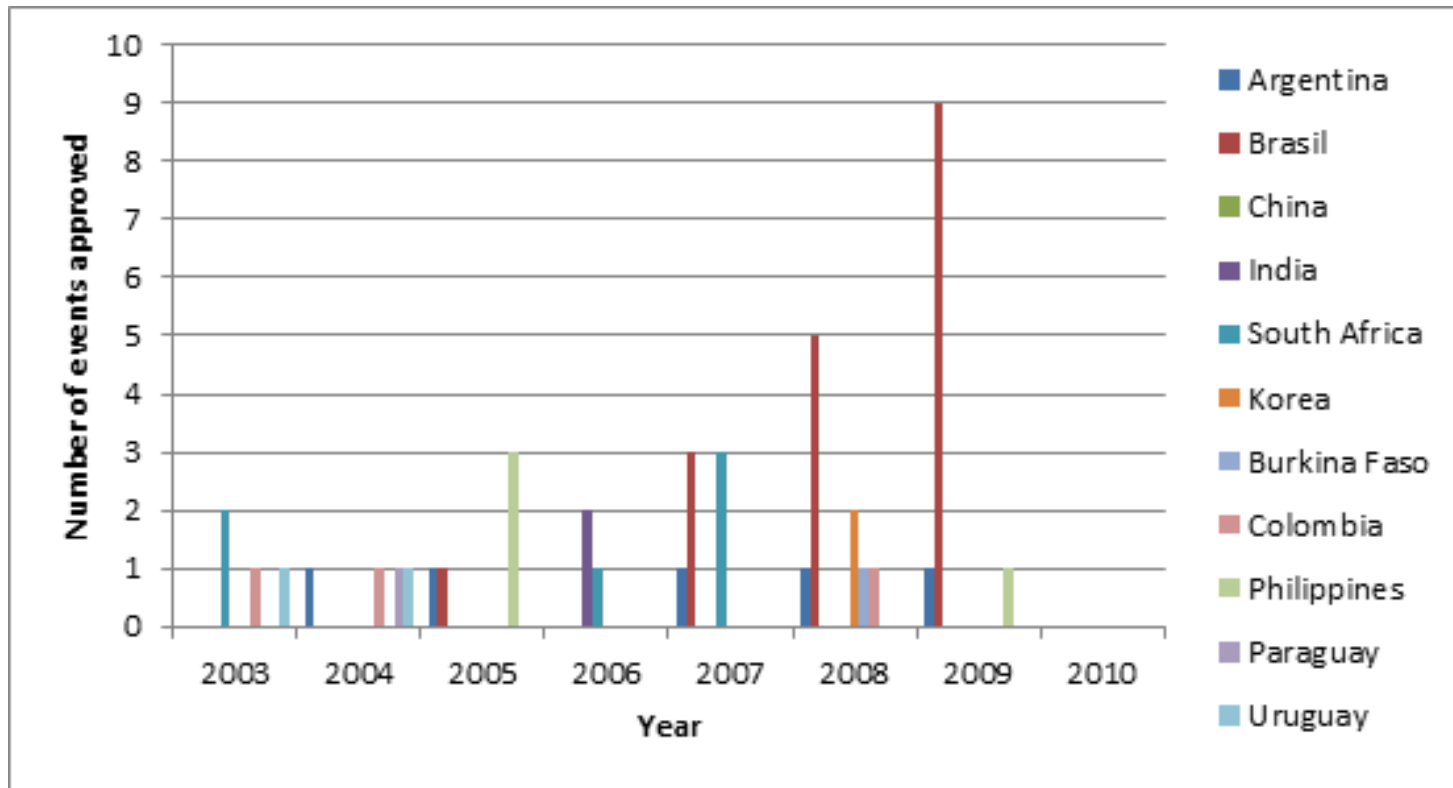


Source: Clive James, 2012

Global implementation status of biosafety

- GEF-funded projects as an indicator in developing countries (since 2001):
 - 123 countries with GEF projects on Development of National Biosafety Frameworks
 - 4 multi-country/regional capacity-building projects to promote compliance with the Protocol.
 - 54 country-specific projects for the implementation of national biosafety frameworks
 - Capacity Building to multiple countries for Effective Participation in the CPB Biosafety Clearinghouse
- GEF grants total approx. US\$105 million with an additional US\$94 million of cofinancing
- Example of extent of use of NBFs: Out of 38 African countries, 3 have taken decisions on GE plants beyond confined spaces

Approvals of GE events by developing countries since 2003



3. Current Perceptions of Agriculture Biotechnology

CONSUMER SURVEYS

International Food Information Council (IFIC) 2005 survey of US consumers

- “Are there any foods or ingredient that you have avoided or eaten less of?”
- If yes, what foods or ingredients did you avoid or eat less of? (Open ended, multiple responses allowed, n = 478)



Almost ½ consumers are avoiding some food or food ingredient.



Food / ingredients avoided:

58% Sugar / Carbohydrates
37% Fats / Cholesterol
34% Animal products
14% Salt / Spices
11% Snack foods
<½% Biotechnology

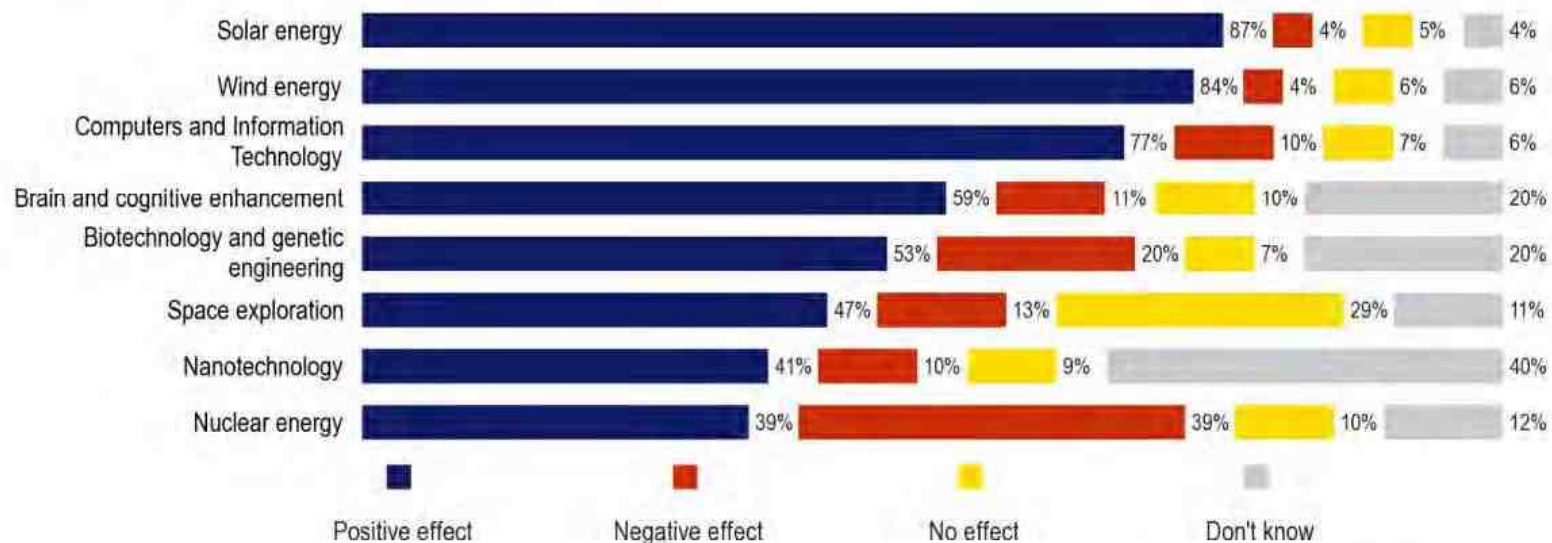


Read more: IFIC survey

SURVEYS TELL US

...(CONT.)

- EuroBarometer, 2010
- For each technology respondents were asked:
 - *“do you think it will improve our way of life in the next 20 years, it will have no effect, or it will make things worse?”*



EU27

Read more: EuroBarometer 73.1 survey

- South African Association for Science & Technology Advancement (SAASTA), Public Understanding of Biotechnology (PUB) program 2004 survey



What do you think of when you hear the word Biotechnology?



8 out of 10 (82%) individuals did not know what they thought when they heard the word 'biotechnology'
The rest had varied responses, ranging from negative to positive

Read more: SAASTA consumer survey report

AFIC CONSUMER RESEARCH ASKS IN SELECTED **ASIAN COUNTRIES** ...



- Food biotechnology was not indicated as a safety concern in Japan, China, India and the Philippines.
- Awareness of biotechnology is relatively high in the Philippines.
- Consumer perceptions of the technology show two different patterns among the surveyed countries:
 - Consumers in China, India and the Philippines, the food producing countries, are more positive
 - More negative in food importing countries of Japan and South Korea.

Read more: AFIC consumer survey 2008

BASIC RULES FOR EFFECTIVE RISK COMMUNICATION

- Be honest, frank and open; don't keep secrets
- Listen to, and acknowledge, people's concerns
- Accept and involve the public as a legitimate partner; treat adversaries with respect
- Don't expect to be trusted – plan carefully
- Coordinate and collaborate with other credible sources



*Source: e-learning course in biosafety,
soon available in Spanish by CIAT*

4. Agriculture and Biosafety in the World Bank: Experiences and Lessons Learned

Agricultural Biotechnology and Biosafety at the World Bank

- Core objective of the World Bank:
Sustained poverty reduction
- **Agriculture**
 - World Development Report 2008, 2010
 - Agriculture Action Plan 2009, 2012
 - Research project support since 1985 *e.g.*,
NATPs-India, Regional Productivity Programs in Africa

• Environment

- World Bank's new 2012-22 Environment Strategy: *Lending program for biodiversity, including biosafety – will be expanded as per client country demand.*
- Assistance for the implementation of multilateral environment agreements (incl. the Cartagena Protocol on Biosafety)

- GEF-World Bank Projects

- India and Columbia: Capacity Building for CPB Implementation
 - 2 of 12 demonstration projects under GEF's Initial Strategy
 - Completed in 2007
- Ongoing regional/multi-country projects for 9 countries in 2 regions
 - West Africa Regional Biosafety Project (5 countries);
 - Multi-country Capacity-Building for CPB Compliance in Latin America (4 countries);
 - Medium-sized project on regional communication and public awareness to complement the Latin America project

Colombia and India GEF supported Projects: Lessons Learned

- Attention to the specific country context in project design (existing legal framework, institutional set-up; capacity needs among stakeholders)
- Vision beyond environmental risks to the role of biotechnology in the agricultural sector (bring in Ministries of Agriculture, Finance, Trade and Commerce, the private sector, producer organizations, etc. to the project sphere)
- Emphasis on public information provision and awareness building
- Led to the idea of regional support to rationalize resource use

Experiences and Lessons Learned applied to ongoing biosafety projects

1. Build Consensus/Promote Information Sharing

- Parallel Track: Inter-institutional Coordination Mechanism and technical working groups
- Utilizing existing channels for dialogue and cooperation
- Stock-taking and needs assessment
- Building relationships between stakeholders and keeping them engaged throughout implementation as a way to ensure sustainability

2. Explore convergence of Interests to Achieve Country Commitment to Biosafety

- Shared centers of biodiversity
- Common crops/commodity
- National development priorities and development assistance strategies
- Cross-sectoral synergies
- Coordination among environment and development agencies; and between public and private sectors.

3. Maximizing Resources and Capacity

- Centers of Excellence
- Common risk assessment/management methods
- Information sharing with public/policy-makers
- Complementarity

5. Recommendations on Future Work

Opportunities for advancing agricultural innovation by competent biosafety regulation

- “Effective and enabling national biotechnology policies and science-based regulatory frameworks can facilitate the development and appropriate use of biotechnologies in developing countries”

ABDC-10/FAO (2010)

Revisit the context for biosafety regulation of GE crops

- Environment has led biosafety work because of being the **focal point for GEF grant funding** for developing countries
- Regardless of the main regulatory authority, **inter-ministerial coordination** at political and technical levels is essential
- Decisions to be defined by **environmental protection goals and by development priorities**: improving agricultural productivity, food security, climate change resilience, and rural development

Rationalize risk assessment

- **Change is good:** key regulatory functions like risk assessment should be continually re-evaluated and improved
- **Risk assessment** (and associated decision making) needs to be **commensurate with the actual level of risk** associated with GE crop production
- $\uparrow$ data + $\uparrow$ stringency = $\uparrow$ \$\$\$\$
- $\uparrow$ data + $\uparrow$ stringency **not necessarily** $\uparrow$ safety

Rationalize risk assessment

- Improved and cost-effective approaches to risk assessment can be pursued without compromising environmental protection and management goals
- This will benefit SMEs, and
- **The public sector**

Regulatory approvals for large scale production of public sector gm-crop/trait combinations since 1995

Crop	Developer	Description	Approvals (country and year)	Commercially available in 2012
Flax (linseed)	University of Saskatchewan (Canada)	Herbicide tolerance	Canada, 1996 USA, 1999	No
Papaya	Cornell University (USA)	Virus resistant	USA, 1996	Yes
	University of Florida (USA)	Virus resistant	USA, 2008	No
Plum	U.S. Department of Agriculture (USA)	Virus resistant	USA, 2007	No
Soybean	Embrapa ^a (Brazil)	Herbicide tolerance	Brazil, 2009	No
Bean	Embrapa	Virus resistant	Brazil, 2011	No

a. Developed jointly with BASF.

Consider risk and benefit assessment

- Potential adverse environmental impacts are addressed in risk assessments
- Potential environmental benefits are usually not considered

Harmonize biosafety risk assessment regionally

Why?

- **Improved access to the technology** for
 - Rural development
 - Food security
 - Agricultural adaptability
- **Problems with asynchronous approvals**
 - Low-level presence
 - Trade disruptions
- **Larger critical mass** for risk assessment
 - Centers of excellence
 - optimize resource use

What do we mean by regulatory harmonization?

- Policy and process harmonization
 - Inter-governmental (e.g. West Africa project)
- Technical harmonization
 - Experimental protocols
 - Information and data sharing and requirements (e.g. LAC biosafety project)

To conclude.... World Development Report 2008: Key messages on Agricultural Biotechnology

- **Biotechnology is a tool** in sustainable production of food, feed, and fiber; and environmental protection;
- Biotechnology **not a magic solution, but underutilized** to address poverty alleviation and environmental protection
- Strengthening the **role of public research in agricultural biotechnology** is crucial;
- Coordination and co-financing with the **private sector and civil society** is needed
- There is a need for **further development and rationalization of biosafety regulation** as it co-evolves with biotechnology research and large scale production.
- **Effectiveness and efficiency through regional biosafety capacity development.**

“If you want to go fast, go alone, if you want to reach far, go together”

African proverb