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## “Socio-economic consideration and biosafety”

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From left to right: a) Damage by Asia corn borer and b) Bt maize plot in Barangay Conel, Mindanao, The Philippines, c) Transgenic Garden, UP-LB Los Baños, Luzon, Philippines

## Outline

1. Biosafety as a process
2. SEC, the Cartagena Protocol on Biosafety and national laws
3. Socio-economic analysis and biosafety
4. Practical considerations, options and implications
5. What do we know from the economic impact assessment literature to date?
6. Concluding comments



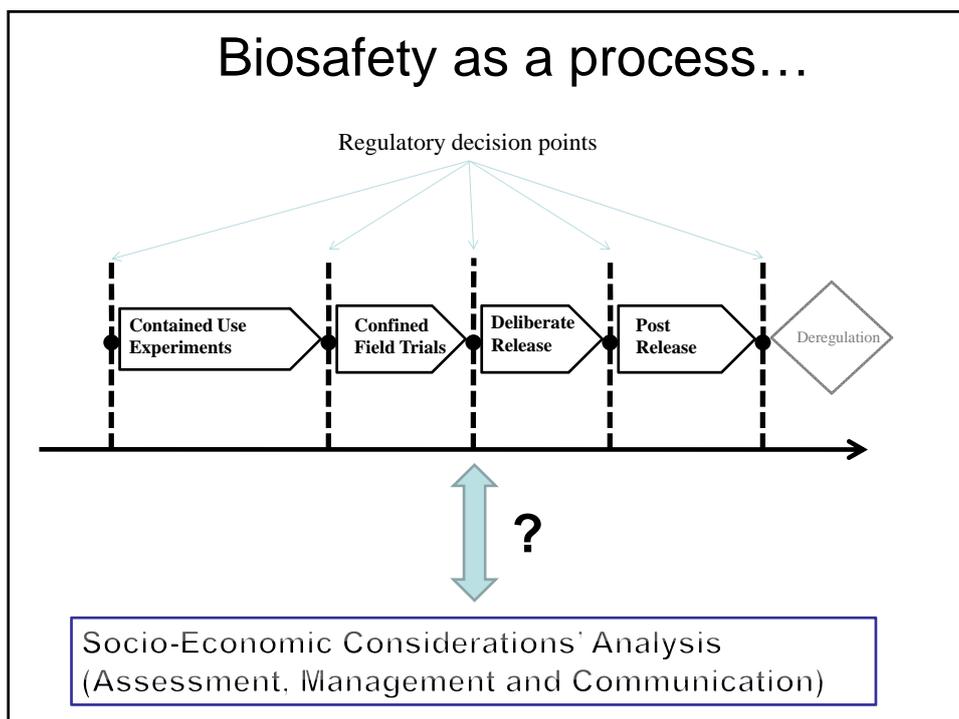
## The Program for Biosafety Systems (PBS)

- Led by IFPRI
  - 2004-2013
  - Funded by USAID, USAID missions, core and national partners, regional bodies
  - Core countries
    - Kenya
    - Indonesia
    - Malawi
    - Nigeria
    - Philippines
    - Uganda
    - Vietnam
  - Regional Efforts
    - Common Market for East and Southern Africa (COMESA)
    - Asia strategy
- Core Consortium
    - IFPRI
    - BIGMAP – Iowa State University
    - Donald Danforth Plant Sciences Center
    - University of Minnesota
  - National partners
  - Regional partners
  - International programs and research centers

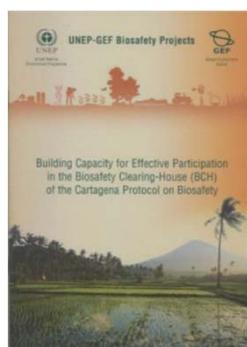
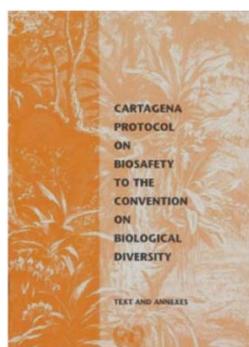
## Biosafety assessment observations

- Decision making considering risk – no technology is 100% safe
- Remarkable safety track record
- No instance of a failure or demonstrated (actual) damage to date by a regulated product approved for deliberate release
  - Instances of purported regulatory failures relate more to deficiencies of standard operating procedures for biosafety management



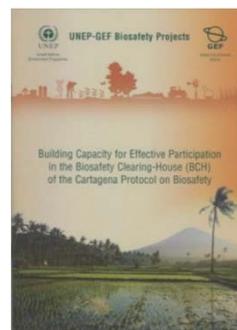


## 2. Socio-economic analysis and the Cartagena Protocol on Biosafety and national laws and regulations

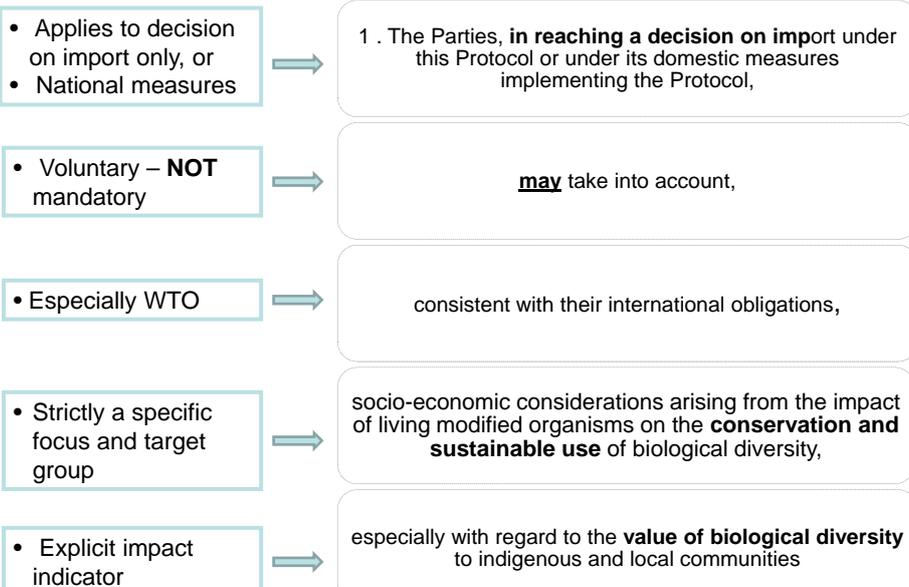


## What drives SEA inclusion

- International agreements
- Regional considerations
- National laws and regulations
  - National Biosafety Frameworks
  - Implementing regulations, directives, administrative acts



## Article 26.1 of the Cartagena Protocol on Biosafety



## SEC Discussions in the Protocol

- MOP5 issue introduced in capacity building discussions
- Some countries seem to propose:
  - Creation of an AHTEG on socio-economics
  - Modification of “science based” and “scientific method” definitions to a broader and perhaps an ill-defined concept
  - Broadening of assessment scope beyond socio-economics
  - Tying SEC issue to liability and redress
- Parties negotiations yielded consensus that
  - Too early thus the need for further discussions and thus the issue of an SEC AHTEG was put on hold
  - Norway tabled US\$70,000 to hold discussions
  - Online expert discussion
  - Regional online expert and parties discussions
  - Meeting on capacity building and SEC in India November 2011
- Substantive issue in MOP6



### 3. Socio-economic assessments and biosafety



## What are socio-economic impact assessments?

- Examine benefits, costs, and risks from technology adoption and use
- Diverse research focus
  - Household, Farm, Communities, Industry, Consumer, Trade
  - Gender, health, age, institutional issues, poverty, biodiversity, food security
- May be done before (*ex ante*) or after adoption of the technology (*ex post*)



## Science and/or art?

- Impact assessment is a scientific process that significantly incorporates art in its implementation
- The practitioner has to in many cases subjectively address many problems with data, assumptions, models and uncertainties



## Working towards a conceptual framework on SECs

- Prudent to describe rationale for inclusion
- Many policy options and choices
- Detailed evaluation of costs and benefits of SEC inclusion (***Regulatory Impact Assessment***)
- Clear decision making rules and standards
- Decision that incorporates environmental and food/feed safety AND socio-economic assessments

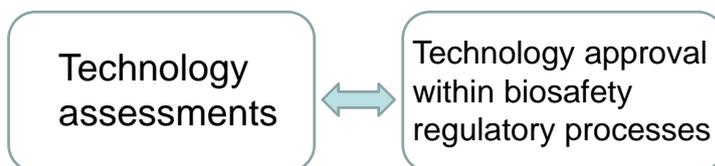
*Socio-economic consideration inclusion introduces one more layer of complexity to decision making*



Consider  
**innovation and opportunities lost/gained**  
 due to additional regulatory hurdles  
 and  
**who**  
 is impacted more by regulatory actions and technology decisions



## Motivations for the assessment of socio-economic considerations



Need to consider that biosafety regulatory processes:

- Time delimited
- Render a decision or outcome which controls technology flows to farmers
- Examine trade-offs between decisions and alternatives
- Process subject/respondent to stakeholders pressures
- May face regulatory errors and their impacts



## Socio-economics and biosafety / biotechnology decision making

An impact assessment during the biosafety regulatory stage to decide on the approval of a technology needs to be **ex ante**

For monitoring purposes or for standard technology evaluation purposes this is a conventional **ex-post** assessment

## 4. Practical considerations, options and implications



### Considerations for regulatory design

Issues	Options
Type of inclusion?	<ul style="list-style-type: none"> <li>No inclusion vs. Mandatory vs. Voluntary</li> </ul>
Who?	<ul style="list-style-type: none"> <li>Developer vs. Dedicated unit within Government vs. third party experts</li> </ul>
Scope?	<ul style="list-style-type: none"> <li>Narrow interpretation article 26.1</li> <li>Narrow set of socio-economic issues</li> <li>Broader set of assessments (SIA or SL)</li> </ul>
Approach?	<ul style="list-style-type: none"> <li>Concurrent but separate vs. Sequential vs. Embedded</li> <li>Implementation entity</li> </ul>
Assessment trigger?	<ul style="list-style-type: none"> <li>Each submission vs. Event-by-event vs. class of events</li> </ul>
When?	<ul style="list-style-type: none"> <li>Laboratory/greenhouse vs. CFTs vs. Commercialization</li> <li>For post release monitoring</li> <li>At all stages?</li> </ul>
How?	<ul style="list-style-type: none"> <li>Choice of methods for <i>ex ante</i> assessments is much more limited than for <i>ex post</i></li> <li>Decision making rules and standards</li> <li>Method integration, standards, tolerance to errors</li> </ul>



## Different approaches to SEC inclusion

Issue	Argentina	Brazil	China
Type of inclusion	Mandatory	Only if an SEC identified during the scientific biosafety assessment	Not included in current guidelines and regulations
Scope / What	Economic impacts on trade and competitiveness. Other impacts considered.	Not clear / open	Not clear
Who	Minister of Finance and Trade – special unit	Two separate bodies CTNBio = biosafety assessments, and National Biosafety Council: decision making. NBC commissions a third party	Third parties
When	Commercialization	Commercialization	Commercialization
Comments	For a while..policy of only approving those already approved in trade sensitive markets	Rationale for dual bodies was to separate technical assessment from the “political” assessment”. <b>Mexico</b> has a similar approach	Use of advanced assessment methods

## Attributes of functional biosafety regulatory process

- Transparent
- Feasible
- Cost and time efficient
- Fair
- Explicit rules and decision making standards
- “Maximizing the benefits...”

Will our decision for each design option make the overall biosafety and technology decision making process better?



### Potential implications from SEC inclusion into decision making

- Potential for introducing uncertainty that can lead to an unworkable system if rules and standards are not clear
- Gain **more and/or better** information about technology impacts for decision making
- **Balance** gains in information, additional costs & effort, and innovation



### Potential outcomes from SEC inclusion into decision making

- Impact on national innovative capacity
  - Consider impacts on public sector and crops and traits of interest to developing countries
- Difficulties for R&D investment decisions
- Cost of compliance will increase
- Time to completion may increase
  - Time value of money important



## Contrasting benefit levels from GE crop adoption with higher costs and regulatory lags in the Philippines

	Bt eggplant	MVR tomato	Bt rice	PRSV resistant papaya
Net Benefits baseline (NPV US\$)	20,466,196	16,748,347	220,373,603	90,765,793
<b>Impact on net benefits due to an increase in the cost of compliance with biosafety</b>				
75% higher	0%	-1%	0%	0%
200% higher	-2%	-3%	0%	0%
400% higher	-5%	-7%	-1%	-1%
<b>Impact on net benefit due to an increase regulatory time lag</b>				
1 year longer	-28%	-36%	-12%	-27%
2 years longer	-56%	-71%	-23%	-49%
3 years longer	-79%	-93%	-34%	-67%

Notes: 1) Source: Bayer, Norton and Falck Zepeda (2008), 2) Discount rate for the estimation of NPV = 5%, 3) Change in Net benefits defined as the total benefits estimated using the economic surplus minus total regulatory costs.



## A paper by Gruere and Pal suggests

Well conducted socio-economic assessments can:

- Objectively weigh benefits and cost for better decisions
- Provide useful lessons that may avoid costly mistakes
- Suggest management practices to increase benefits from use
- Support economically beneficial applications and pave the way for promising new tech



## SEC and capacity building/strengthening

- Focus on implementation and ensuring a functional biosafety system
- Activities have to address existing needs
  - Avoid building capacity when not needed
  - Focus on country status in relation to applications
- Inventory of existing human, financial and institutional resources
- Identify target audiences, key issues and activities



## IFPRI/PBS proposed SEC expert's assessment knowledge support platform

- Literature database – IFPRI's bECON
- Depository of secondary and primary datasets, computer routines, procedures
- Expert discussion platforms at the national/regional level
- Training on advanced methods and approaches
- Network with internationally recognized experts in the field  
=> International Consortium of Agricultural Bioeconomy Research (ICABR)
- Developing communication and policy outreach capacity
- Development of quality protocols/standards to conduct research (for experts)



## 5. What do we know from the economic impact assessment literature to date?

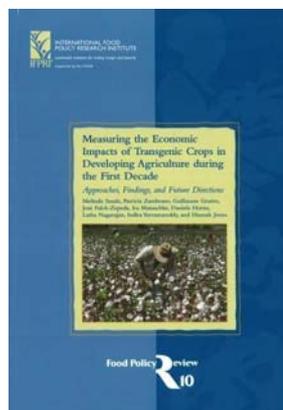


## Objectives

1. Give a sense of the experience to date
2. Give a flavor on how SEC assessments are done in practice
3. Showcase SEC communication issues
4. Discussion on SEC issues related to its inclusion in decision making

## IFPRI's review of the economic impact literature

- A review of 187 peer reviewed studies
- Examined studies with a focus on:
  - Farmers, household and community
  - Industry and markets
  - Consumers
  - Trade



Citation: Smale, Melinda; Zambrano, Patricia; Grùère, Guillaume; Falck-Zepeda, José; Matuschke, Ira; Horna, Daniela; Nagarajan, Latha; Yerramareddy, Indira; Jones, Hannah. 2009. Measuring the economic impacts of transgenic crops in developing agriculture during the first decade: Approaches, findings, and future directions. (Food policy review 10) Washington, D.C.: International Food Policy Research Institute (IFPRI) 107 pages



## Food Policy Review 10 conclusions

- On average LMO crops have a **better economic performance** — but averages do not reflect the variability by agro-climate, host cultivar, trait, farmer
- Too few traits, too few cases/authors—generalizations should not be drawn yet...need more time to describe **adoption**



These conclusions are no different than those for most technologies released to date...



## Food Policy Review 10 conclusions

- Address cross cutting issues for further study including impacts of poverty, gender, public health, generational
- Develop improved methods and multi-disciplinary collaborations to examine broader issues



## Ex ante - Black Sigatoka Resistant Bananas in Uganda

- Consider irreversible and reversible cost and benefits by using the Real Option model
- One year delay, forego potential annual (social) benefits of +/- US\$200 million
- A GM banana with tangible benefits to consumers increases their acceptance for 58% of the population



Photos credits: Kikulwe 2009 and Edmeades 2008



Kikulwe, E.M., E. Birol, J. Wesseler, J. Falck-Zepeda. A latent class approach to investigating demand for genetically modified banana in Uganda Agricultural Economics 2011.



## Ex ante - Bt cotton in Uganda

- Positive yield impacts and net benefits
- Smaller rate of return probably explained due to low base yields
  - Need to improve overall cotton productivity
- Probability of a negative return can be as high as 38% with a technology fee as charged elsewhere



Photos credit: © Horna 2009



Horna, et al. (2011). "Economic Considerations in the Approval Process of GM Cotton in Uganda: Designing an Ex-ante Assessment to Support Decision-making." IFPRI Policy Note, Under review.



## Ex post- Bt maize in the Philippines

- Growing Bt maize significantly increases profits and yields
- Significant insecticide use reductions
- Adopters tend to be
  - Cultivate larger areas
  - Use hired labor
  - More educated
  - have more positive perceptions of current and future status



Change in economic surplus (mill pesos)	
Producer Surplus	7906
Seed Innovator	703
Total Surplus	8609
Producer Share (%)	92
Innovator Share (%)	8

Bt maize studies in Philippines led by Dr. Jose Yorobe Jr. with 466 farmers in 16 villages Isabela Province, Luzon, South Cotabato Province, Mindanao



## Ex post - Bt cotton in Colombia

- Evidence of yield enhancement rather than pesticide reductions
- Bt farmers benefited where the target pest is economically important
- Sampling bias important: adopters were better-off farmers
- Institutional context critical



Photos credit: © Zambrano 2009



Source: Zambrano, P., L. A. Fonseca, I. Cardona, and E. Magalhaes. 2009. The socio-economic impact of transgenic cotton in Colombia. In *Biotechnology and agricultural development: Transgenic cotton, rural institutions and resource-poor farmers*, ed. R. Tripp. Routledge Explorations in Environmental Economics 19. London: Routledge. Chapter 8. Pp. 168-199



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