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“Socioeconomics, Biosafety, and Biotechnology Decision-making: Implications for Developing Countries”

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Core message from this presentation

The assessment of socio-economic considerations as related to the adoption of genetically engineered crops, provides extremely useful knowledge for decision makers.

However, within the scope of a biosafety regulatory process that leads to a decision whether to release a GE technology

-and if a decision has been reached as to the usefulness/desirability of SEC assessments to a country-

then proper implementation and inclusion of such procedures is critical for achieving the goal of a functional biosafety system.

Content

- I. Discuss socio-economic consideration (SEC) assessments as related to biosafety regulations
- II. SEC assessments: What do we know?
- III. SEC inclusion in decision making: Country experiences
- IV. Practical considerations for regulatory design

What are socio-economic considerations (SEC) assessments?

- Diverse research focus
 - Household, Farm, Communities, Industry, Consumer, Trade
 - Gender, health, age, institutional issues
- May be done before (*ex ante*) or after adoption of the technology (*ex post*)
- Contrast effects of intervention against an alternative



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

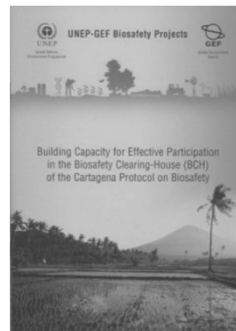
A paper by Gruere and Pal suggests

Well conducted socio-economic assessments can

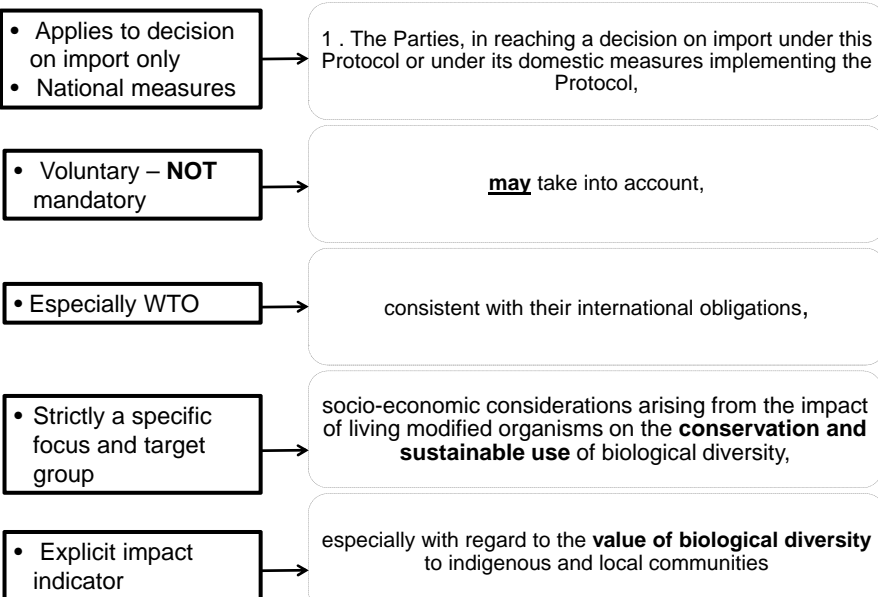
- Objectively weigh benefits and cost for better decisions
- Provide useful lessons that may avoid costly mistakes
- Suggest management practices to increase benefits from use
- Support economically beneficial applications and pave the way for promising new tech

What drives SEC inclusion?

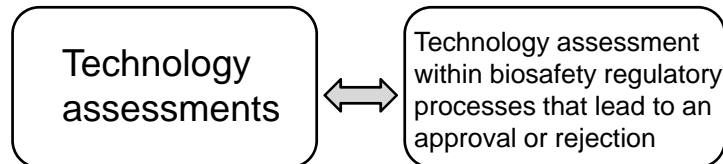
- Knowledge creation
- Understanding role of technology
- Regional considerations
- National laws and regulations
- International agreements
- Other political, institutional and stakeholder interests



Socio economic considerations and Article 26.1 of the Cartagena Protocol on Biosafety



Objective driving socio-economic consideration assessments



- For biosafety regulatory processes one needs to understand:
 - the **impact of** the inclusion of socio-economic issues in decision making
 - The relationship / interaction with the risk assessment process

Consider impacts on
innovation,
opportunities lost
due to additional regulatory
hurdles and
who
is impacted more by regulatory
actions and technology
decisions

Biosafety regulatory design
implies establishing a balance
between

Democratic societies' right to know

vs.

Freedom to operate

vs.

Freedom to choose

Important distinction

An impact assessment during the biosafety regulatory stage needs to be **ex ante**



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

- What are the goal and objectives for socio-economic assessments as related to biosafety or technology decision making?

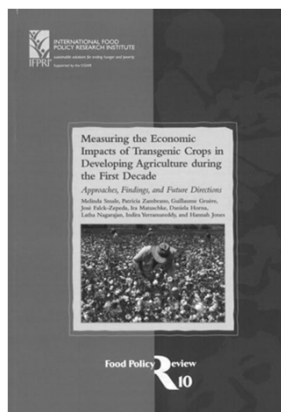
Specific questions about potential socio-economic consideration inclusion

Feasibility	Can all socio-economic considerations be assessed ex ante and/or ex post?
Fit with decision making process	How are assessment outputs going to be used in a decision making process?
Utility	Does inclusion of socio-economic considerations improve society's welfare?
Regulatory impacts	Are we considering all benefits, costs, risks and potential outcome from the inclusion of socio-economic considerations

II. Socio-economic assessments: What do we know?

What do we know from the economic impact assessment literature to date? –

- A review of 137 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 profitable — but averages mask 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**

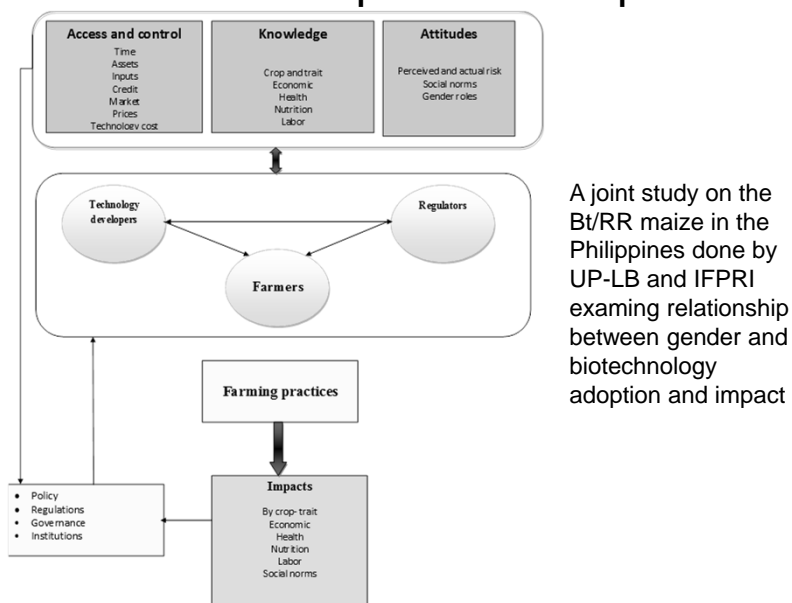


Food Policy Review 10 conclusions

- Next decade
 - Cross cutting issues for further study including impacts of poverty, **gender**, public health, generational
 - Need improved methods to examine broader issues



Relationship between gender differentiated adoption and impact



Impact on Farmers / Household / Community

Potential issues for a socio-economic assessment

Value of biodiversity to indigenous communities

Value of biodiversity to individual farmers, households, and communities

Profits and benefit/cost ratios

Net income

Use of productive inputs (pesticides,...)

Production practices

Gender differentiated access and control, knowledge and/or attitudes

Health impacts

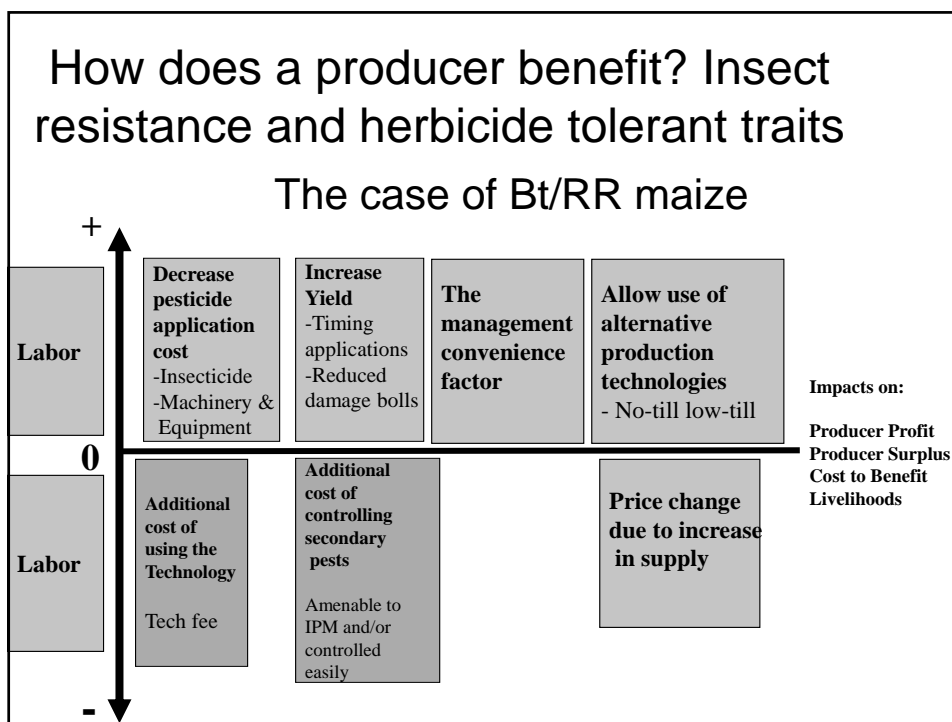
Safety first, downside risk, minimum production for survival

Irreversible costs and benefits

Freedom of choice and freedom to operate

Lists of potential issues should not
be viewed as check lists

Prudent to carefully choose which
issues are relevant to the technology
decision making process



Black Sigatoka Resistant Bananas in Uganda: An *ex ante* study

- 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. Publication Forthcoming 2011.

Bt maize in the Philippines: An *Ex post* study

- Growing Bt maize significantly increases profits and yields
- Significant insecticide use reductions
- Adopters tend to:
 - 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

Bt maize in Honduras: Ex post study

- Excellent insect control
- Bt yield advantage 893-1136 Kg ha⁻¹ yield (24-33%)
- Bt maize yields preferred even by risk averse producers
- 100% higher seed cost than conventional hybrid
- Institutional issues important



Photos credit: © Sanders and Trabanino 2008



"Small "Resource-Poor" Countries Taking Advantage of the New Bioeconomy and Innovation: The Case of Insect Protected/Herbicide Tolerant Maize in Honduras." Jose Falck Zepeda, Arie Sanders, Rogelio Trabanino, Oswaldo Medina and Rolando Batallas-Huacon. Paper presented at the 13th ICABR Conference "The Emerging Bio-Economy", Ravello, Italy June 17-20, 2009.

III. Biosafety and socio-economic considerations inclusion: Countries' experience

Argentina vs. Brazil

Issue	Argentina	Brazil
Type of inclusion	Mandatory	Only if a socio-economic consideration(s) identified during the scientific biosafety assessment
Scope / What	<ul style="list-style-type: none"> • Economic impacts on trade and competitiveness • Considering expanding to impacts to producers 	<ul style="list-style-type: none"> • Not clear / open
Who	Minister of Finance and Trade – special unit	<ul style="list-style-type: none"> • Two separate bodies <ul style="list-style-type: none"> • CTNBio: biosafety assessments • National Biosafety Council: decision making • Rationale for dual bodies was to separate technical assessment from the “political” assessment” • NBC commissions a third party to do SEC assessments
When	Commercialization	Commercialization

European Union vs. USA/Canada

Issue	European Union	USA / Canada
Type of inclusion	Mandatory (?)	<ul style="list-style-type: none"> •Not required. Proponents may submit study with application dossier but regulators are not mandated to consider socio-economic considerations •Legal philosophy used to be to leave consideration of socio-economic considerations to the marketplace (and courts)
Scope / What	<ul style="list-style-type: none"> • Not clear – still negotiating 	None
Who	<ul style="list-style-type: none"> • Proponent (?) 	None <ul style="list-style-type: none"> • proponent may include report on socio-economics in application dossier • Regulatory agency does not have an obligation to consider SEC assessment
When	<ul style="list-style-type: none"> • Approvals and Post-release monitoring (?) 	None

The Netherlands Commission on Genetic Modification (COGEM 2009) proposal: Issues for consideration of SEC

Benefits to society – e.g. yield increase or food quality improvement

Economics and prosperity – such as increased employment and productivity

Health and welfare – for workers, the local population and consumers

Local and general food supply – these should remain at the same level or improve

Cultural heritage – if desired, specific elements of cultural heritage or local customs should be preserved

Freedom of choice – both consumers and producers should be able to choose between GMO and GMO-free products

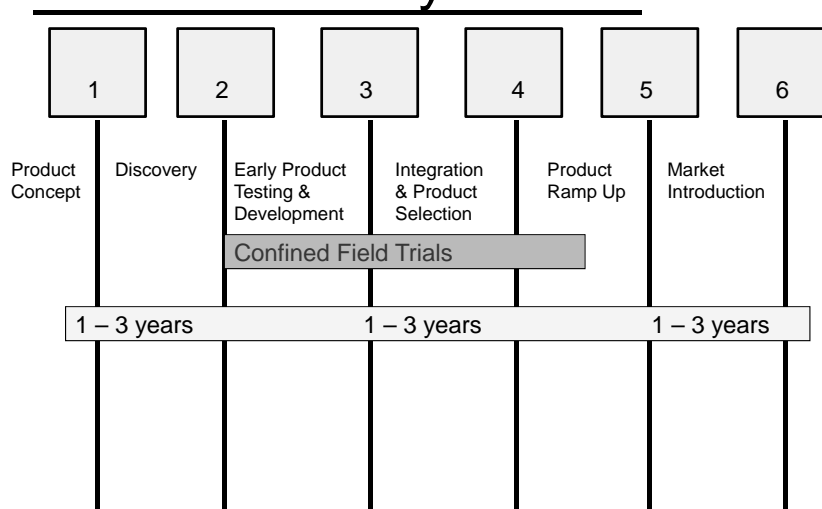
Safety – in terms of both personal and the environment

Biodiversity

Environmental quality

IV. Practical considerations and options for biosafety regulatory design

R&D and product development life cycle



Author: Ramaeker-Zahn

Considerations for regulatory design

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

Socio-economic Considerations in Biosafety and Biotechnology Decision Making: The Cartagena Protocol and National Biosafety Frameworks

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Abstract

Article 26.1 of the Cartagena Protocol on Biosafety left open the possibility for member countries to include in their biosafety regulatory processes the assessment of socio-economic considerations. Countries may also decide to include such assessments as part of their national legislation or regulations for the approval and deliberate release into the environment of genetically engineered technologies. Countries are debating if and how to implement assessment of socio-economic considerations. This paper contributes to the ongoing policy dialogue by discussing issues related to socio-economic assessment including scope, timing, inclusion modalities, methods, decision-making rules and standards, and the integration of

Paper presented at the Fourth World Congress of Environmental and Resource Economists (WCERE 2010) in Montreal, Canada, June 28- July 2, 2010.

The Current Status of the Debate on Socio-Economic Assessments and Biosafety Highlighting Different Positions and Policies in Canada and the US, the EU and Developing Countries

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Abstract

Article 26.1 of the Cartagena Protocol on Biosafety has the option of considering socio-economic issues in biosafety regulatory approval processes related to genetically engineered (GE) organisms. National laws and regulations in some countries have

Socio-economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake?

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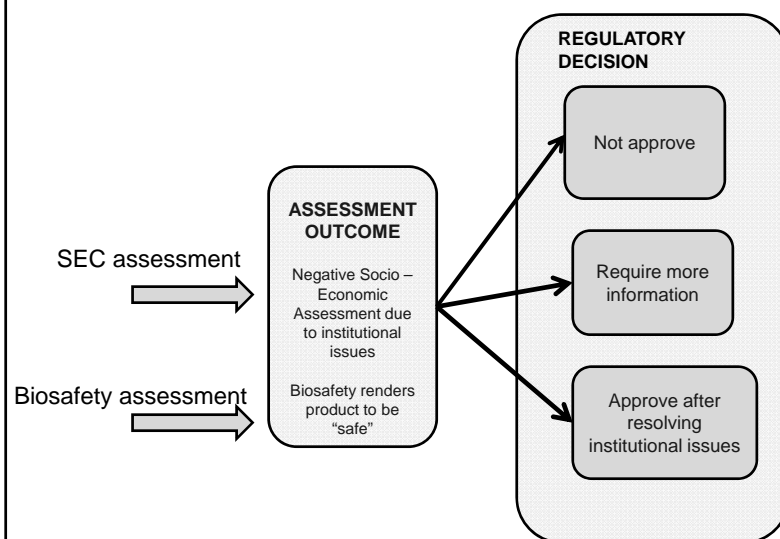
The Cartagena Protocol on Biosafety allows the possibility of including socio-economic considerations in biosafety regulatory approval processes and decision making for genetically modified products. Divergent opinions about the desirability of including socio-economic considerations have polarized the debate. For biosafety approval processes, assessment of socio-economic considerations will likely be before the fact, as the genetically modified product has not reached commercialization approval processes. This implies that there is a limited scope as to methods and approaches for assessments. To ensure that socio-economic assessments will not become an obstacle to the development and transfer of safe and efficacious products to farmers, all stakeholders need to understand clearly all regulations governing inclusion of socio-economic considerations. Furthermore, the decision-making process needs to clearly define decision-making rules and standards by which to guide approval processes.

Key words: socio-economic considerations, developing countries, biosafety, biotechnology, trade, risk assessments, genetically modified organisms.

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
- What to do with SEA results?

What can a decision maker do with the results a socio-economic assessment?



Potential implications from SEC inclusion into decision making (cont..)

- Cost of compliance will increase
- Time to completion may increase
- Reduction in the ability for the country to innovate
- Consider impacts on public sector and crops and traits of interest to Philippines
- Difficulties for private and public sector investments

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
Impact on net benefits due to an increase in the cost of compliance with biosafety				
75% higher	0%	-1%	0%	0%
200% higher	-2%	-3%	0%	0%
400% higher	-5%	-7%	-1%	-1%
Impact on net benefit due to an Increase regulatory time lag				
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.

Key messages

- Countries need to clearly articulate:
 - Why they want to include socio-economics?
 - Does inclusion improve society's welfare?
 - Additional regulatory burden and innovation
 - Clear decision making rules and standards

Key messages

- Careful evaluation of benefits, costs, risks and outcomes from inclusion of SEC assessments
 - No approvals carry risk.... there is also risk in the *status quo*
- Countries have many options and choices
- Worst possible outcome is a process with a mandate but with no implementation guidance

Key messages

- In the end, SEC inclusion needs to contribute to a functional biosafety assessment and decision making process
 - Predictable
 - Transparency
 - Assessment hurdle proportional to risk
 - Cost and time efficient
 - Explicit rules and decision making standards
 - Maximize the benefits