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PROGRAM FOR BIOSAFETY SYSTEMS

A partnership program for biosafety capacity development

“Socio-economic considerations of GM crops in the context of the Cartagena Protocol on Biosafety-CBD and National Regulations”

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Outline

- Biosafety regulations in practice
- SEC and the Cartagena Protocol on Biosafety
- Socio-economic assessments in a biosafety regulatory process
- Practical considerations and options for implementation
- Concluding comments



Why regulate Living Modified Organisms (LMOs)?

- Two relevant issues

Safety: Prevent the introduction of (potentially) harmful technologies to the environment and public health.

Efficacy: Prevent the introduction of unimportant or inefficacious technologies

- Currently, most biosafety systems are science-based focused on safety only
- Science based risk evaluation approaches provide a logical framework for decision making it a **preferred approach**



Regulatory design implies establishing a balance
between...

Societies' democratic right to know

VS.

Freedom to operate

VS.

Freedom to choose



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Biosafety as a process...

Regulatory decision points

X Familiarity

Learning

**Contained Use
Experiments**

**Confined
Field Trials**

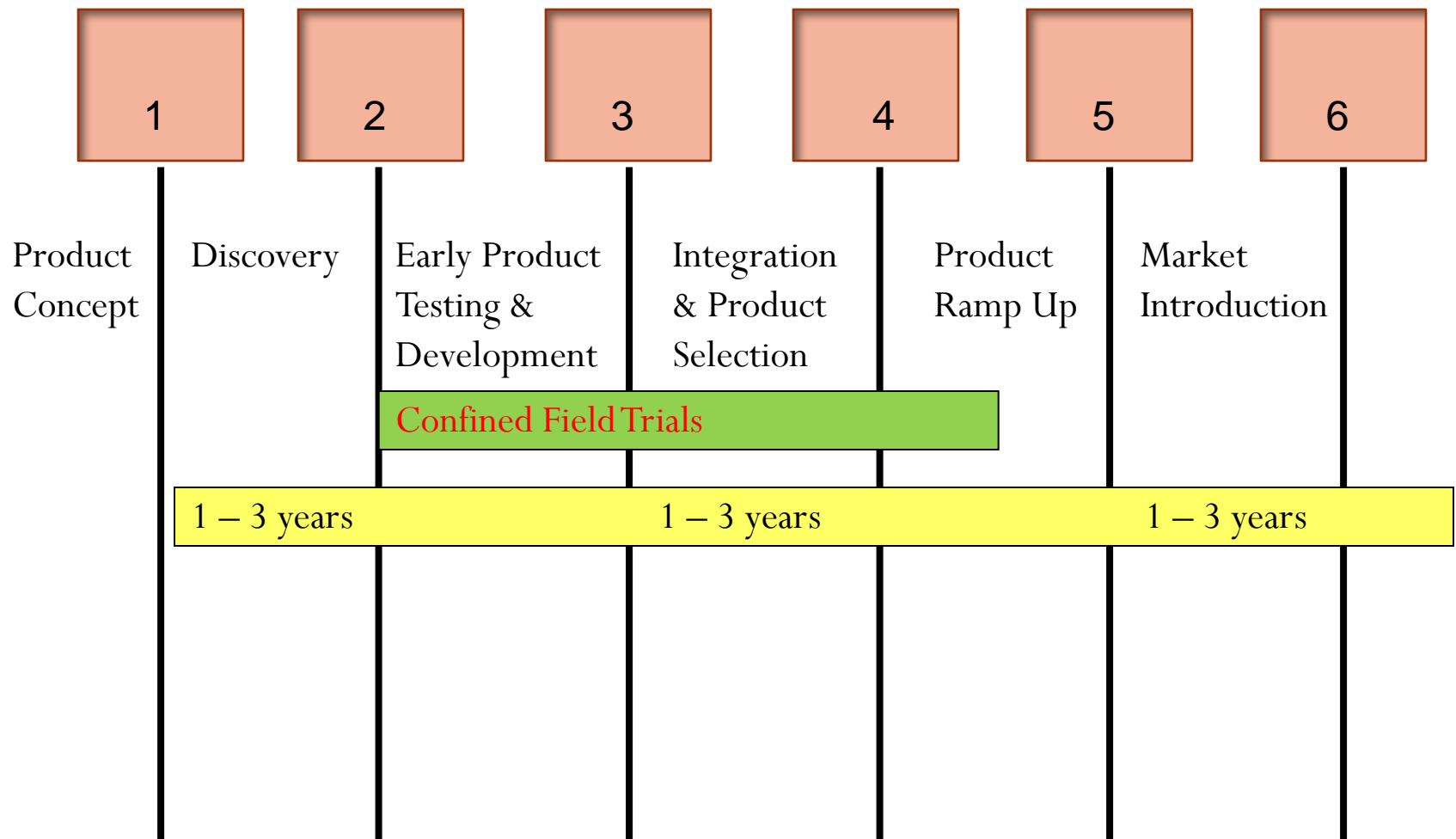
**Deliberate
Release**

**Post
Release**

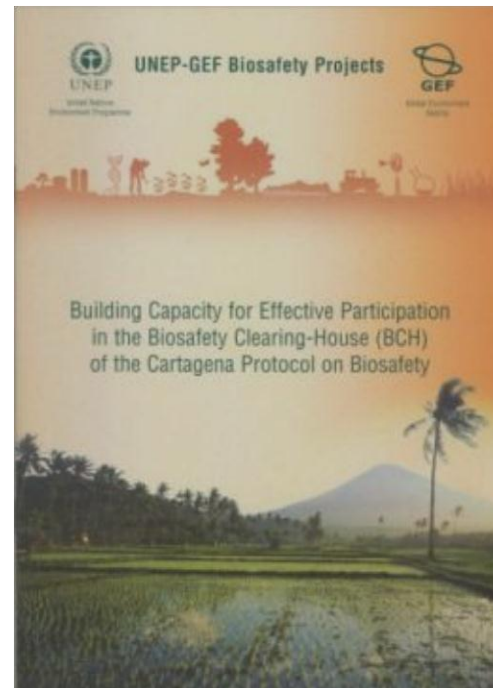
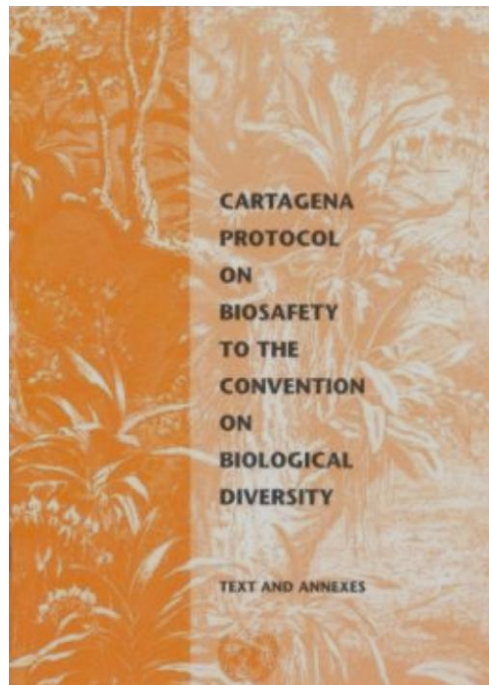
Deregulation



R&D and product development life cycle

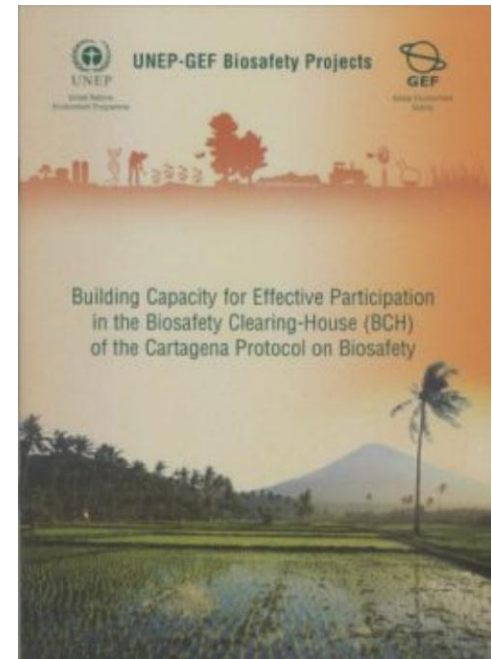


2. Socio-economic assessments and the Cartagena Protocol on Biosafety and national laws and regulations



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

- Applies to decision on import only, or
- National measures



1 . The Parties, **in reaching a decision on import** under this Protocol or under its domestic measures implementing the Protocol,

- Voluntary – **NOT** mandatory



may take into account,

- Especially WTO



consistent with their international obligations,

- Strictly a specific focus and target group



socio-economic considerations arising from the impact of living modified organisms on the **conservation and sustainable use** of biological diversity,

- Explicit impact indicator

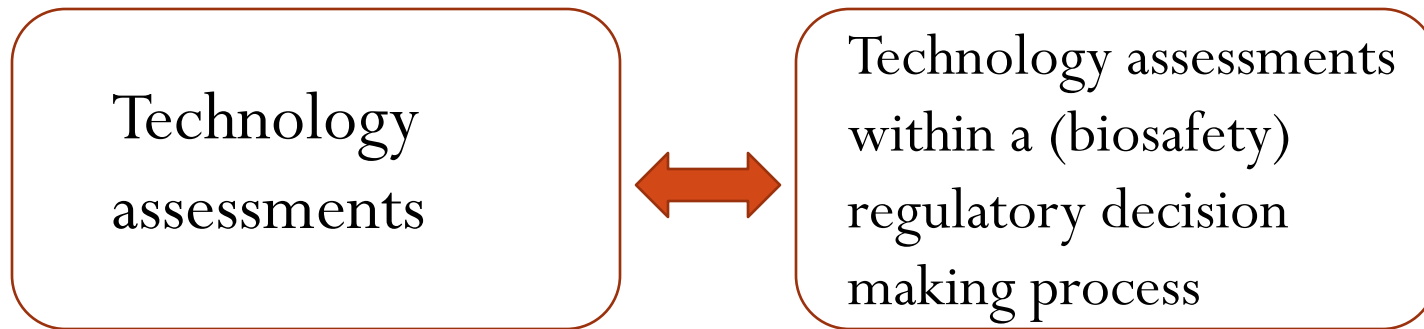


especially with regard to the **value of biological diversity** to indigenous and local communities

3. Socio-economic assessments in a biosafety regulatory process



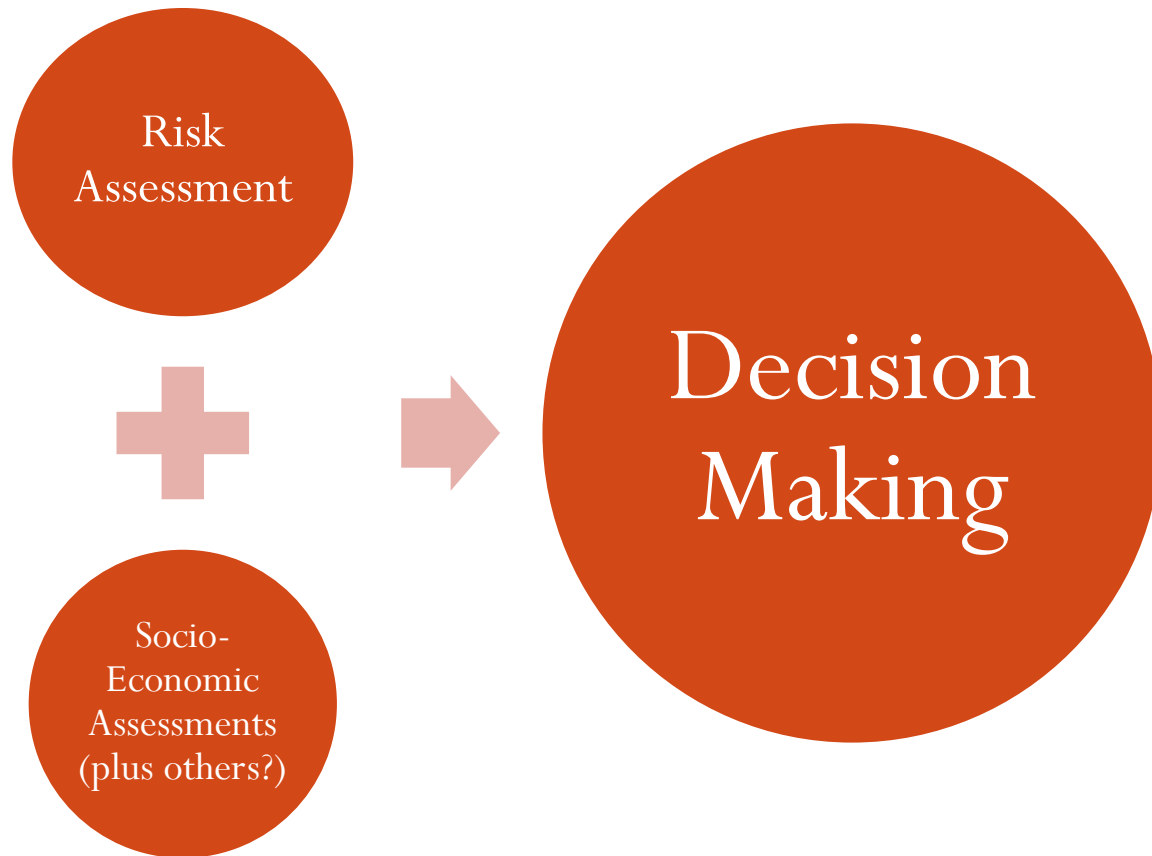
Motivations for the assessment of socio-economic considerations



Biosafety regulatory processes are:

- Time delimited
- Mandated to render a **decision** or outcome
- Moderators of technology flows
- Sensitive to trade-offs between decisions and alternatives
- Respondent to stakeholders
- Subject to regulatory error impacts

Decision making and assessments



Beyond knowledge generation on biosafety and socio-economic considerations – decreasing returns to biosafety investments?

Necessary or sufficient knowledge to determine a product as “safe” or beneficial to society

- Food/feed safety
- Environmental safety
- Socio-Economic impacts

Other motivations

- Liability
- Marketing
- Science and curiosity
- “Excessive” precaution
- Others?

Setting a precedent

- 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



Ex ante studies completed by IFPRI and partners

Country/Region	Crop	Trait	Method
Uganda	Cotton	Bt / RR	<ul style="list-style-type: none"> • Stochastic economic surplus • Stochastic budget • Stochastic dominance • Damage abatement
Uganda	Bananas	Black sigatoka resistance	<ul style="list-style-type: none"> • Real options • Choice experiments
West Africa	Cotton	Bt	<ul style="list-style-type: none"> • Stochastic economic surplus • Stochastic budget
Ghana	Vegetables, Cassava	Viral resistance, insect resistance	<ul style="list-style-type: none"> • Economic surplus • Damage abatement
Colombia	Potatoes	Bt	<ul style="list-style-type: none"> • Stochastic economic surplus
India, China, Philippines and other Asian countries	Rice	Bt	<ul style="list-style-type: none"> • CGE model (MIRAGE)
Kenya, Uganda, Malawi (in progress)	Cotton	Bt	<ul style="list-style-type: none"> • Stochastic economic surplus • Real options • Damage abatement • Control models

Ex post studies completed by IFPRI and partners

Country	Crop	Trait	Method
Colombia	Cotton	Bt	<ul style="list-style-type: none">• Gender analysis• Stochastic economic surplus
Philippines (ongoing 2 nd study)	Maize	Bt/RR	<ul style="list-style-type: none">• Damage abatement• Economic surplus• Gender analysis
Honduras (will start 2 nd study)	Maize	Bt/RR	<ul style="list-style-type: none">• Robust regression• Stochastic dominance (SDRF, SERF)
Burkina Faso	Cotton	Bt/RR	<ul style="list-style-type: none">• Gender analysis
Bolivia	Soybeans	RR	<ul style="list-style-type: none">• Institutional analysis• Treatment model

4. Practical considerations and implications for implementation



Considerations for regulatory design

Issues	Options
Type of inclusion?	<ul style="list-style-type: none"> • No inclusion vs. Mandatory vs. Voluntary
Who?	<ul style="list-style-type: none"> • Developer vs. Dedicated unit within Government vs. third party experts
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 vs. class of events
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

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/or competitiveness. Other impacts being 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 Plus institutional biosafety committee	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”. Mexico has a similar approach	Use of advanced assessment methods

Attributes of functional biosafety regulatory process

- Assessment hurdle proportional to risk
- Risk assessment is science based
- Predictable process
- Transparent
- Feasible
- Cost and time efficient
- Fair
- Explicit rules and decision making standards

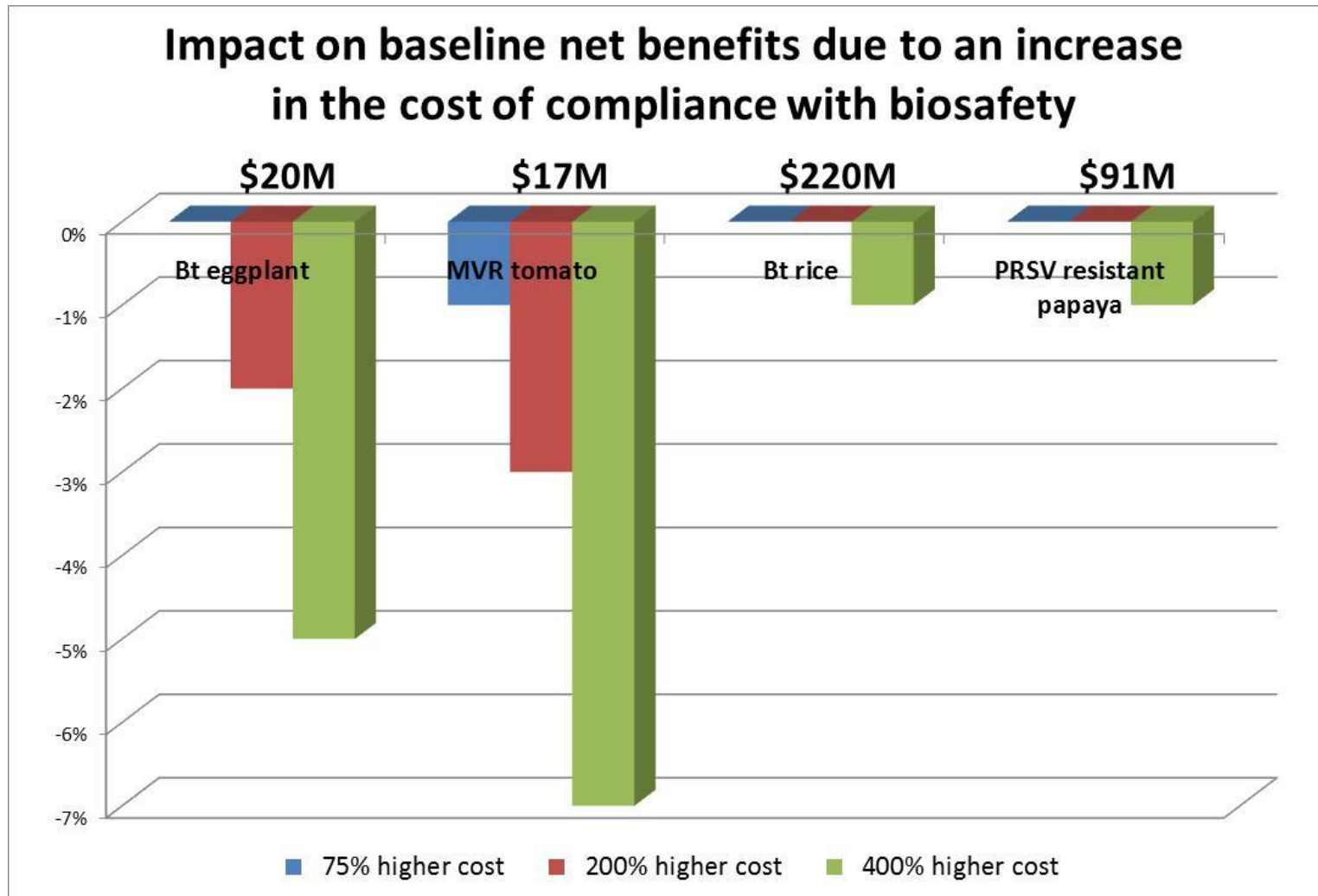
Potential implications from SEC inclusion into decision making

- 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 implications from the inclusion of socio-economic considerations into decision making

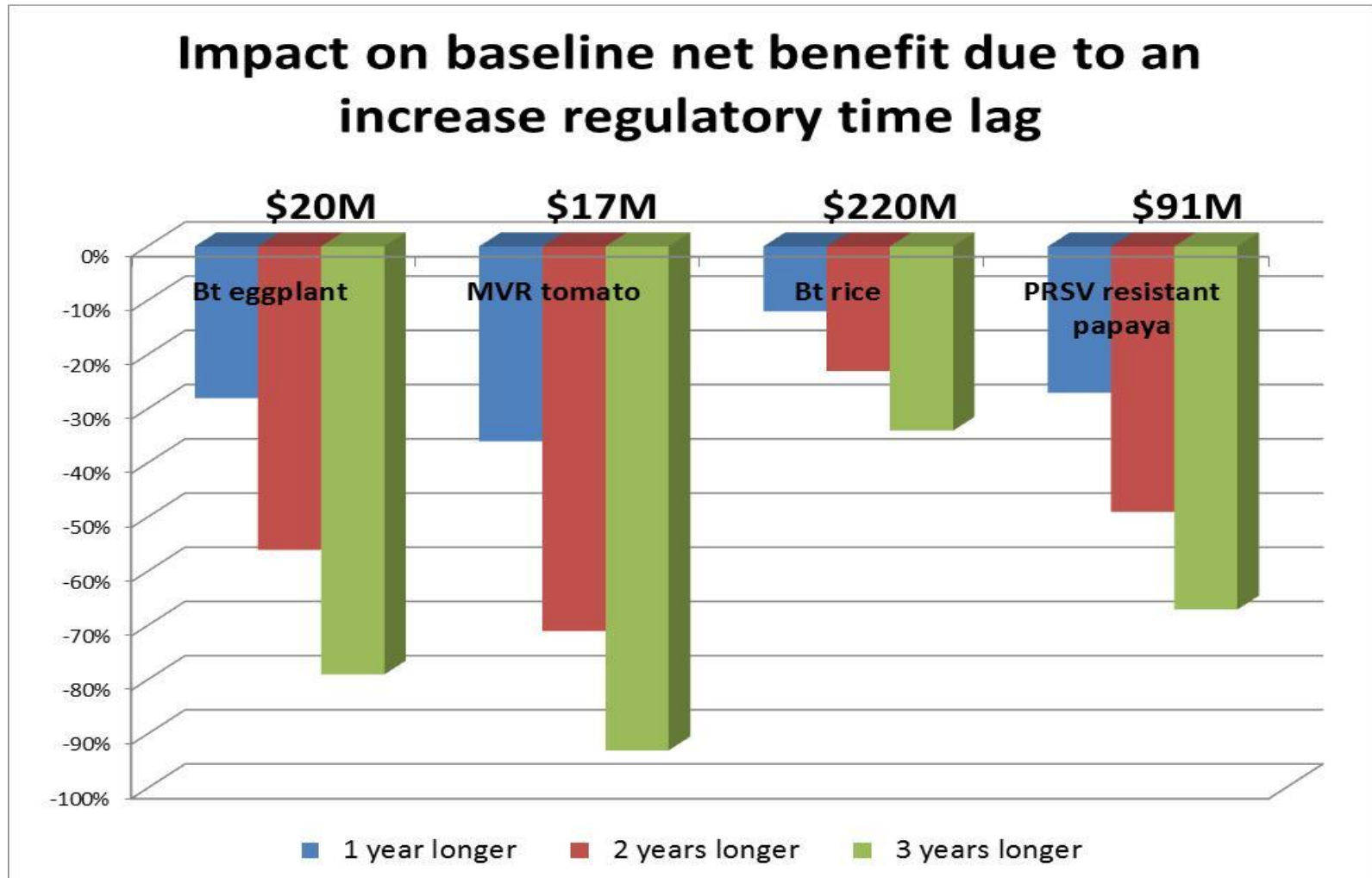
- Potential for a **unworkable** system if rules and standards are not clear
- **Cost** of compliance costs will **increase**
- Potential regulatory **delays**
 - Reduction in the number of technologies **especially** those released by the **public sector** and crops/traits of a public good nature
 - Some public sector institutions may not be able to deploy technologies due to fixed costs necessary to enter market

Contrasting baseline net benefit levels from GE crop adoption with higher costs in the Philippines



Notes: 1) Source: Bayer, Norton and Falck Zepeda (2008), 2) Baseline values for each technology expressed in millions US\$ using a discount rate for the estimation of Net Present Value = 5%, 3) Change in Net benefits defined as the total benefits estimated using the economic surplus minus total regulatory costs.

Contrasting benefit levels from GE crop adoption with larger regulatory lags in the Philippines



Notes: 1) Source: Bayer, Norton and Falck Zepeda (2008), 2) Baseline values for each technology expressed in millions US\$ using a discount rate for the estimation of Net Present Value = 5%, 3) Change in Net benefits defined as the total benefits estimated using the economic surplus minus total regulatory costs.

Concluding questions about potential inclusion of socio-economic issues

- Does inclusion of socio-economic considerations improve society's welfare?
- Can all socio-economic considerations be assessed *ex ante* and/or *ex post*?
- Are we considering all cost, benefits and outcomes of regulatory processes?
- How are assessment outputs going to be used in a decision making process?

My answers to these questions: "It's a mixed bag of outcomes", "probably no", "no" and "I am not sure yet, but will need an answer"

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bEcon

**Economics Literature about the Impacts
of Genetically Engineered Crops in Developing
Economies**



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