

Socioeconomic considerations in biosafety decision making

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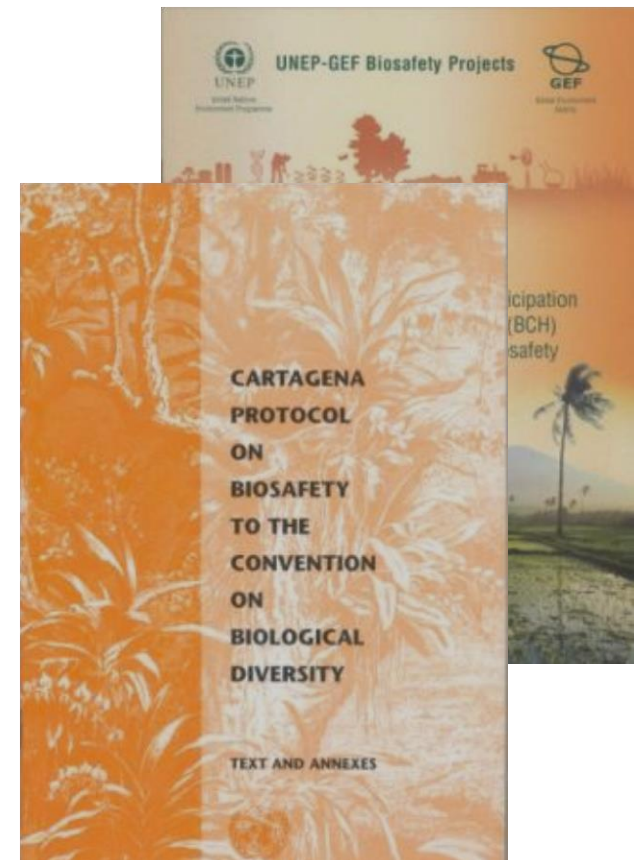
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What has driven the inclusion of socioeconomic considerations in biosafety decision-making?

- International agreements
- Regional considerations
- Stakeholder interests
- Special interest groups



The Cartagena Protocol on Biosafety to the Convention on Biological Diversity - adopted in 2000

Article 26.1 states

“The Parties, ...**may** take into account, consistent with their international obligations, socio-economic considerations.....”

Despite the limited scope

There is now the **perception that countries have to include SEC** in their regulatory process


GMOs and Socioeconomic Considerations SEC

The preference among many environmental risk assessors, regulators, and economists would be to **exclude socioeconomic considerations (SEC) from the regulatory process or the regulatory decision-making process**

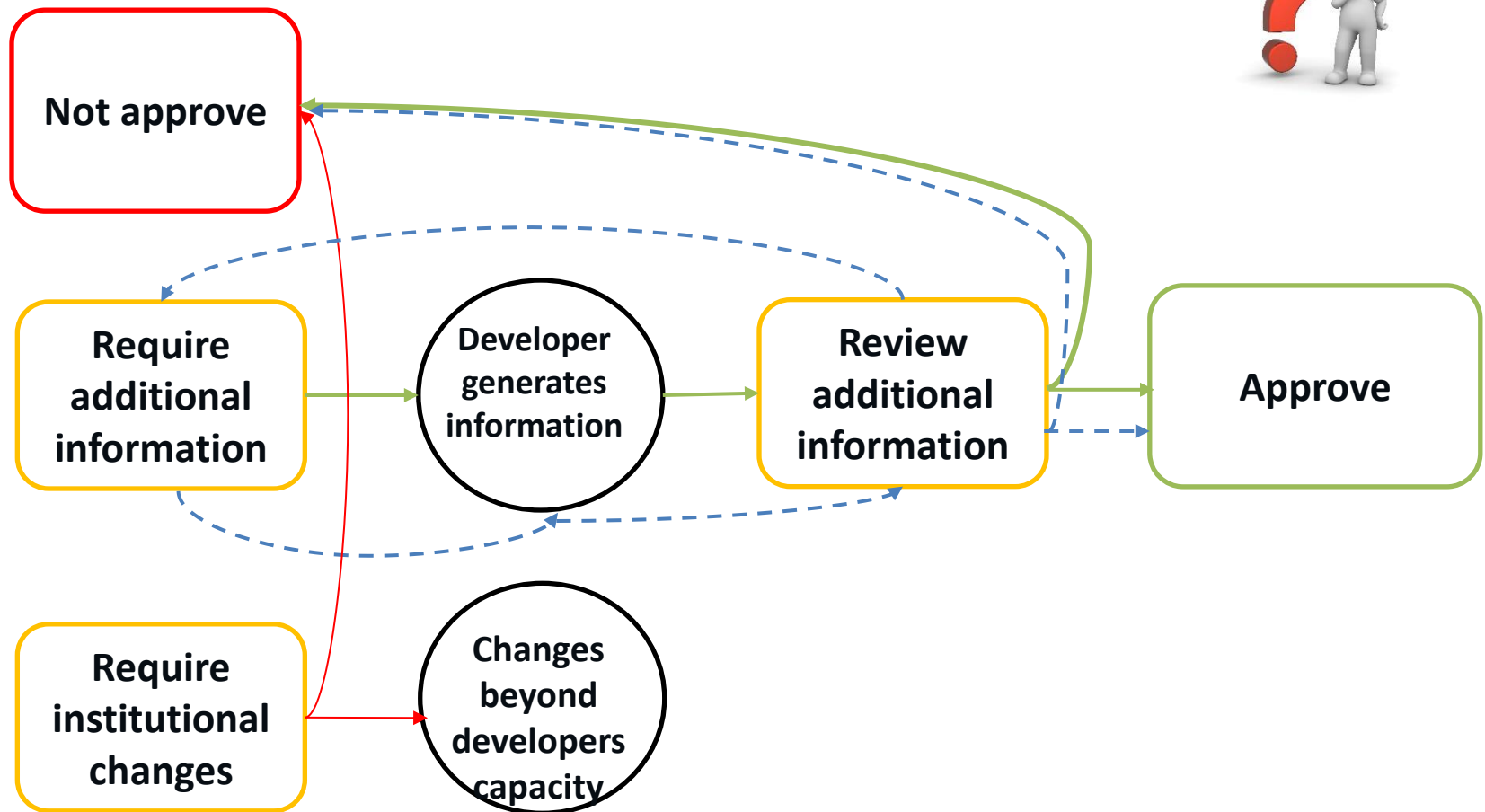
Why?

- Introduces **uncertainty** in the regulatory decision making process
- Can result in **subjective** rejection of safe technologies
- Has an negative impact in the stream of benefits due to approvals' **delays**

Regulatory decision under SEC

| | | Socioeconomic considerations | |
|---------------------------|----------|------------------------------|---|
| | | Positive | Inconclusive |
| Biosafety Risk Assessment | Safe | Approve |  |
| | Not Safe | Not approve | |

Regulatory decision for a safe technology with inconclusive SEC



SEC

Scope: The broader the costlier, and least robust
SEC become

- Economic considerations: Rely on actual data (control) but also many subjective assumptions as products/technologies have not been released/commercialized (treatment)
- Social considerations such as ethical, religious, philosophical: Rely in qualitative and participatory approaches

SEC

Timing: At what stage(s) are they included and when should the regulator review them

➤ Laboratory, field, commercialization

SEC

Inclusion process: How are SEC included in biosafety decision process

- Voluntary: No mandatory SEC inclusion
- Parallel: SEC running concurrent but separate
- Sequential: SEC start after technology is proven to be safe
- Embedded: SEC are part of the regulatory authority functions

Examples of countries including SEC in biosafety decision making

| | | Type of Inclusion | |
|-----------|---------|--|--|
| | | Voluntary | Mandatory |
| SEC Scope | Limited | Brazil China Colombia India South Africa | Argentina Kenya Honduras Ghana Uganda |
| | Broad | Swaziland | Indonesia Nigeria Philippines Samoa Tanzania |

SEC in Biosafety laws, and regulations

Argentina [Resolucion SAGyP No 510 2011](#)

Brazil [Law No. 11.105 of March 24, 2005 \(Biosafety Law\)](#)

II –analyze, at the request of CTNBio, requests to release GMOs and their derivatives for commercial use, with regard to the desirability, suitability in social and economic terms, and the national interest;

Burkina Faso [LOI N° 005-2006/AN JO N° 18 DU 04 MAI 2006](#)

Article 34 : Avant toute utilisation des organismes génétiquement modifiés dans l'environnement, une étude **des impacts d'ordre éthique, social et économique** sur les populations locales ou riveraines doit être menée par l'autorité nationale compétente en collaboration avec les autres administrations concernées

Colombia [DECRETO 4525 DE 2005](#)

Identificar y valorar los potenciales efectos directos e indirectos sobre la salud humana, el ambiente y la biodiversidad, la producción o productividad agropecuaria y **cuando se requiera**, los potenciales efectos socioeconómicos que puedan derivarse

Indonesia [Government Regulation \(PP\) No.21 of 2005 regarding Biosafety](#)

ensuring environmental safety, food safety and or animal feed safety based on an accurate scientific method by considering **religious, ethic, socio-cultural and esthetic norms**.

Ghana

SEC: Mandatory but limited scope

Ghana Biosafety Act, 2011

Biosafety Act, 2011

Article 21

In reaching, a final decision on an application, the Board **shall** take into account

(d) socio-economic considerations arising from the **impact of a proposed activity** and of the genetically modified organism on the **environment**

Nigeria

SEC: Mandatory and broad scope

National Biosafety Law 2015

Sections 25 (3) and 32 (2)

Covers socio-economic consideration in risk assessment.

“Ensure environmental, human and socio-economic safety while harnessing the benefits associated with the practice of modern biotechnology and its outputs, Ensure that the use of the genetically modified organism does not have undesired impact **on socio – economic and cultural interest** either at the community or National level.”

Nigeria Biosafety Law 2015

SEC

Parameters to be taken into consideration

79. Anticipated **changes in the existing social and economic patterns** resulting from the introduction of the genetically modified organism or products thereof.
80. Possible threats to **biological diversity**, traditional crops or other products and in particular, farmers' varieties and sustainable agriculture.
81. Impacts likely to be posed by the possibility of **substituting traditional crops**, products and indigenous technologies through modern biotechnology outside of their agroclimatic zones.
82. Anticipated **social and economic costs due to loss of genetic diversity, employment, market opportunities and in general, means of livelihood** of the communities likely to be affected by the introduction of the genetically modified organisms or products thereof.
83. Possible countries and communities to be affected in terms of disruptions to their **social and economic welfare**.
84. Possible effects which are contrary to the **social, cultural, ethical and religious values** of communities arising from the use of release of the genetically modified organism or the product thereof.

Tanzania

SEC: Mandatory and broad scope

Tanzania Environmental Management (Biosafety) regulations, 2009

“26. (1) Prior to any deliberate release of GMOs into the environment, a thorough study of-

- a) their ethical and social-economic impact on the local population; concerned;
- b) the traditional market and export earnings;
- c) health;
- d) production systems;
- e) ethical, moral and social considerations;
- f) the actual economic value of traditional species likely to be affected by introduction of the GMOs,

shall be conducted by the competent authority in collaboration with the service

Tanzania SEC:

When, who, and what

“VII. Socio-economic considerations

In parallel to and simultaneous with the **scientific risk assessment**, an evaluation of the socio-economic risks shall be undertaken in consideration of the following, but not limited to:

Under ‘Risk assessment parameters’

“1. **The applicant** shall carry out an assessment prior to the use or release of genetically modified organisms or products thereof as regards the risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies”

1. Anticipated **changes in the existing social and economic patterns** resulting from the introduction of the genetically modified organism or product thereof;
2. Possible threats to **biological diversity**, traditional crops or other products and, in particular, farmers’ varieties and sustainable agriculture;
3. Impacts likely to be posed by the possibility of **substituting traditional crops**, products and indigenous technologies through modern biotechnology outside of their agro-climatic zones;
4. Anticipated social and economic **costs due to loss of genetic diversity, employment, market opportunities and, in general, means of livelihood** of the communities likely to be affected by the introduction of the genetically modified organisms or products thereof;
5. Possible countries and/or **communities to be affected** in terms of **disruptions to their social and economic welfare**;
6. **Possible effects which are contrary to the social, cultural, ethical and religious values of communities** arising from the use or release of the genetically modified organism or the product thereof.”

Uganda

SEC: Mandatory and limited scope

National Biotechnology and Biosafety Bill

Bill No. 18 National Biotechnology And Biosafety Bill 2012

Section 20 Form 3

Application for approval to make a general release of GMOs in Uganda

PART I – SOCIO-ECONOMIC CONSIDERATIONS

- 9.1 List any **potential positive or negative socio-economic effects** of the proposed general release activity in Uganda **or within the target population**
- 9.2 Identify any **possible bio-ethical aspects** of the general release activity
- 9.3 **Suggest** measures to limit any potential negative socio-economic or ethical considerations

The Philippines

SEC: Mandatory and ~~broad~~ scope

DOST -DA-DENR-DOH-DILG joint Department Circular No.1, series of 2016

Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology

Article II - Section 3

D. Socio-economic, Ethical and Cultural Considerations. In making biosafety decisions for the commercialization of a regulated article concerned departments **shall take into account socio-economic, ethical and cultural considerations** arising from the impact of regulated articles on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

Article V - Section 11

E. The STRP shall evaluate the application particularly the risk assessment and risk management strategies based on the risk assessment conducted by the IBC. Based on the information submitted by the applicant, **the BPI may require expert evaluation of any socio-economic, ethical or cultural considerations**

Everything can fall under SEC

- Economic impact – farmers, consumers, industry, trade
- Environmental impacts
- Biodiversity impacts
- Intellectual property rights
- Health impacts
- As well as many other possible impacts :
 - Ethical, bioethical
 - Cultural, religious
 - Human rights
 - Farmers' rights
 - Livelihoods
 - Aesthetic norms

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



Potential roadmap

CHANGE

1. Evaluate tradeoffs with socioeconomic considerations into decision making
2. Focus on the inclusion and implementation process
3. Consider having a basic requirement of a standard economic review/assessment with a defined evaluation criteria similar to Argentina
 - Impact on producers' net income
 - Impact on smallholder net income
 - Impacts on production/financial risk
 - Impacts on trade

Potential Roadmap (continued)

CHANGE

4. Critical allowing completion of biosafety risk assessment/analysis process
5. Ensure there are no authority conflicts between regulatory agencies – maximize collaboration synergies
6. Ensure having a decision making standard/rules, process to evaluate evidence quality, validation and review process based on quality standard
7. Define a transparent, feasible, fair and time/cost efficient and protective process

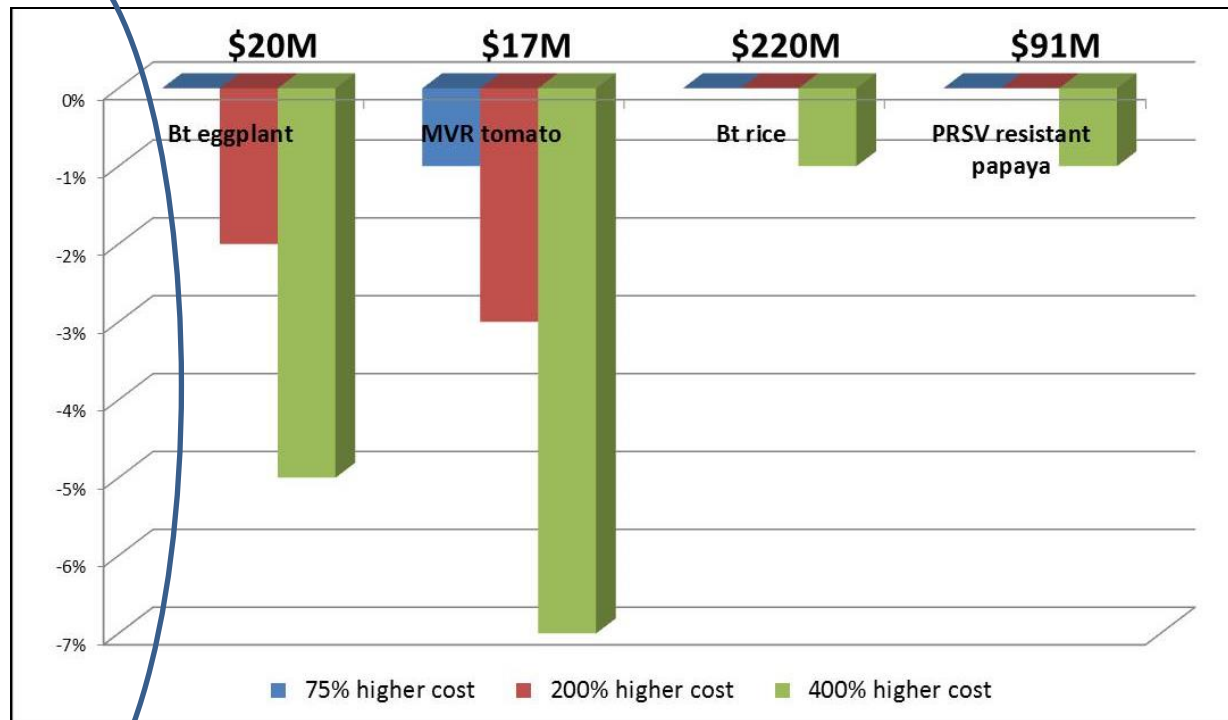
Potential implications from SEC inclusion into decision making

- **Positive:** May gain **more and/or better** information about technology impacts for decision making - may support valuable technologies
- **Not so positive:** May introducing uncertainty that can lead to an **unworkable system** especially if rules and standards are not clear
- **Balance:** gains in information (costly: financial and time wise) that can negatively affect innovation

Potential implications from SEC inclusion into decision making

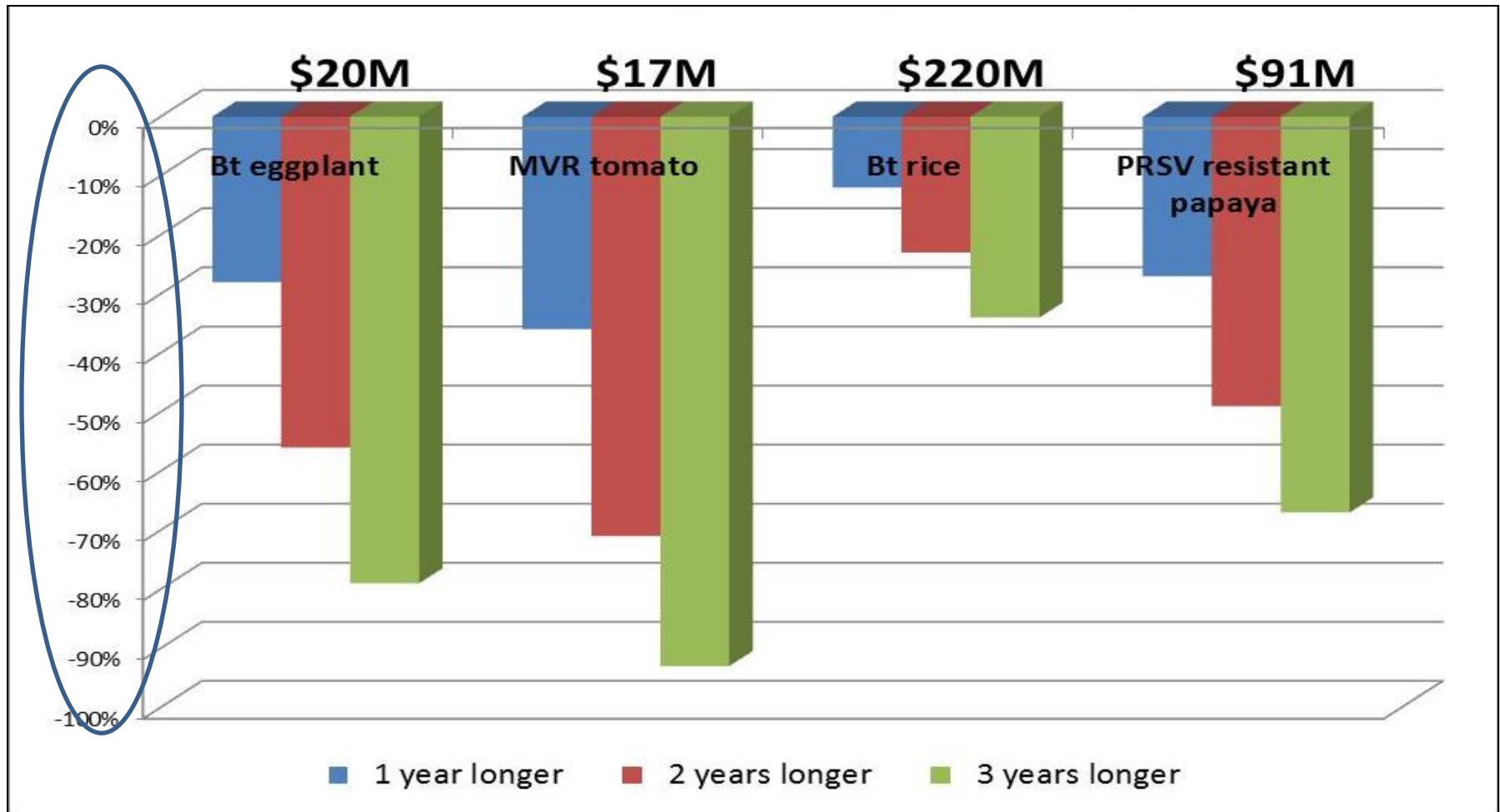
- **Cost** of compliance will **increase**
- Potential regulatory **delays**
 - Reduction in the number of technologies **especially** those released by the **public sector** and crops/traits of a public good nature
 - Some public sector institutions may not be able to deploy technologies due to fixed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

Contrasting GMO benefit levels with **increasing costs of compliance,** 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 GMO benefit levels with **increasing regulatory lags**, 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.

Draft PBS Template questionnaire for SEC evaluation to start a conversation

Suggested focus of quantitative and/or qualitative assessment of:

- Impacts on income, profits, economic returns and/or wealth
- Yield, labor and/or productions costs
- Specific target trait (ifor example: impacts on nutrition)

-

Draft PBS Template questionnaire for SEC evaluation to start a conversation

- Qualitative response checklist (Yes, No, Maybe, Not applicable, No existing evidence) to following questions including how and under what conditions
 - Does the proposed event contribute to food security and sustainability?
 - Is the proposed event affordable/accessibly to farmers? Low and middle income farmers? Who is the target user?
 - Are there any foreseen market or consumer issues?
 - Are there any cultural, ethical and social issues?
 - Are there any other foreseen benefits derived from the event?
- Proposed ways to address/mitigate SEC issues (if any) by the developer

A product from the September 2016 IFPRI/PBS workshop: a draft proposal for socioeconomic indicators

| ISSUES | INDICATORS | METHODOLOGY |
|---|-----------------------------|---|
| <p>Type of qualitative and quantitative data needed to estimate socioeconomic indicators</p> <p>Not all applicable to all cases</p> | Productivity | <ul style="list-style-type: none"> • Ex ante methodology can be done using secondary/experimental data, experiences of other countries • Ex post methodology after commercialization • Can consult literature to respond questions |
| | Cost Efficiency | |
| | Profitability | |
| | Food Security | |
| | Global Cost Competitiveness | |
| | ROI | |

A product from the September 2016 IFPRI/PBS workshop: draft recommendation for cultural issues

| ISSUES | QUALITATIVE QUESTIONS | METHODOLOGY |
|---|-----------------------|--|
| <ul style="list-style-type: none">• Is the crop cultivated by the local communities/IP?• Autonomous governance vs self determination | | <ul style="list-style-type: none">• Review of secondary resources• Community based monitoring?? |
| | | |
| | | |
| | | |
| | | |
| | | |

A product from the September 2016 IFPRI/PBS workshop: Draft recommendation for addressing ethical issues

| ETHICAL PRINCIPLE | PUBLIC POLICY |
|--|---|
| <ul style="list-style-type: none">• Respect for Persons (esp the vulnerable): dignity, welfare and rights.• General welfare | <p>Do public consultation. Consider cultural issues. Disseminate accurate, relevant information. Ensure consumer choice</p> |
| <ul style="list-style-type: none">• Beneficence• Non-maleficence | <p>Ensure social value. Avoid harm to health. Mitigate risks. Balance harms/benefits.</p> |
| <ul style="list-style-type: none">• Justice | <p>Support small farmers Ensure sharing of burdens and benefits</p> |

Based on questions and procedures used at ethical review boards

Proposal for dealing with Socioeconomic Considerations in partner countries

- Develop two distinct set of documents:
 - Roadmap to SEC implementation with a focus on process for implementation to define decision making
 - Template questionnaire for SEC evaluation. Minimum information set is the economic assessment

Main points

- Critical need for using robust socioeconomic evidence in decision making
- Essential to achieve a systematic understanding of the possible implications of the issues that may affect the adoption and diffusion of GMOs
- We want to ensure that socioeconomic assessments supports decision making

Concluding comments

- Biotechnology and GMO have played and can play an important role in meeting current and future food production challenges
- Similarities and differences with other technologies
- SEC have to be clearly defined and delimited, if included in the decision-making process.
- Assessments have to be based in comparison with conventional or traditional

...

Need to address socioeconomic considerations. This is an issue that ***will not go away*** and one which has the **potential to derail** biosafety progress.



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Despite the ongoing controversy over their use, genetically modified (GM) crops have progressively grown in popularity and are now planted in approximately 160 million hectares in 29 countries. In the discussions of biosafety regulations for GM crops and whether to approve such crops for commercialization, many countries, including some African nations, have gone beyond environmental assessments and are now introducing socioeconomic considerations as part of their decisionmaking process. There are, however, very few guidelines as to how to ensure that this inclusion of socioeconomic considerations results in a robust and efficient decision-making process. *Socioeconomic Considerations in Biosafety Decisionmaking: Methods and Implementation* provides guidance to professionals involved in assessing the ex ante impact of a GM crop in the context of an approval process. Using the case of GM cotton in Uganda, the authors illustrate the evaluation of socioeconomic impact on farmers, the national economy, and trade.

The authors identify three crucial steps in making socioeconomic assessment part of a biosafety regulatory process, decisionmaking process, or both. First, select appropriate research tools and methods that yield robust results but that also take into account time and budget constraints. Second, evaluate the institutional setting of GM technology deployment. Third, allow for the uncertainties inherent in the assessment by using ranges of values for the parameters under evaluation, including yield, technology efficiency, and prices. These and other conclusions should provide useful guidance to policymakers and development researchers in countries that opt to incorporate socioeconomic considerations into their biosafety regulations, as well as their decisionmaking process for GM crop approval.

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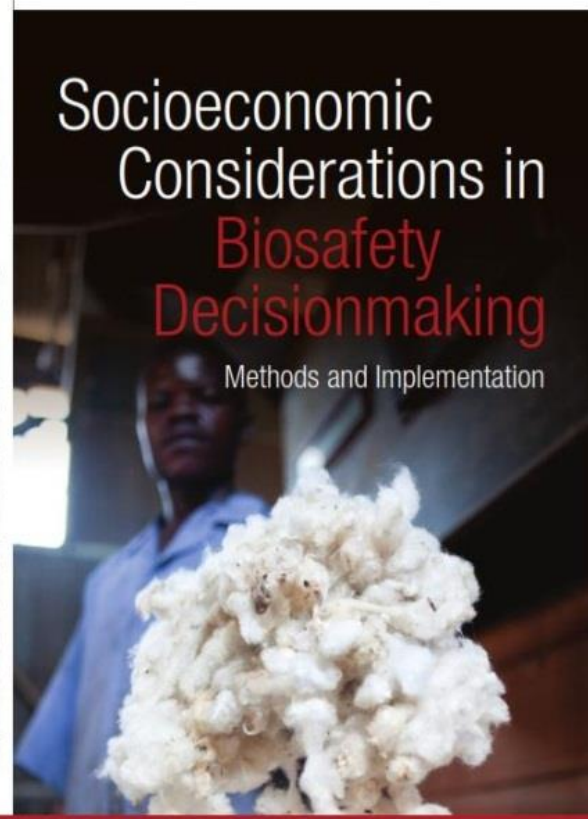
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Methods and Implementation

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