

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.

Genetically modified organisms (GMOs)¹ have shown great promise in addressing specific farmer productivity constraints. Advances in molecular biology expanded the scope of genome manipulation in ways not envisioned before. The latter statement highlights the concerns on the riskiness of GM technologies earlier in the research process. The purported potential risks from GM products lead scientists, regulators, and policy-makers to develop procedures for proper risk assessments.

The regulatory experience with science-based risk assessments of pesticides, pharmaceuticals, and other products provided guidance to the initial risk assessment of GM crops. Parties to the Cartagena Protocol on Bio-

safety, an implementing agreement of the Convention on Biological Diversity (CBD), provided additional incentives to adopt these procedures when the protocol entered into force. Furthermore, biosafety risk-assessment procedures are now an established prerequisite for transboundary movements of GM materials, as well as research, development, and release of these materials into the environment.

Although the Cartagena Protocol focused on the potential effects of GMOs on the environment, as this is the scope of the CBD, the Protocol allows the possibility of including other considerations such as food safety and socio-economics. Furthermore, the Cartagena Protocol is not the only guidance document with regard to the risk assessment of GMOs, as other treaties and agreements, such as Codex Alimentarius, exist (Quezada, 2008, personal communication). Nevertheless, most Cartagena Protocol parties and non-parties have indeed broadened the narrower environmental scope of the Protocol. In some cases, the Protocol may have been the basis for some countries choosing to include food and feed safety and other public interest issues, such as socio-economic considerations.

Introduction of broader socio-economic considerations into GMO biosafety analysis and the decision-making process is, however, controversial. Even though Article 26.1 (see below) of the Cartagena Protocol does open the possibility of including socio-economic con-

1. Article 2 of The Convention on Biological Diversity defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." This definition includes products arising from both traditional and modern biotechnology. Traditional biotechnology would include products of tissue culture, micro-propagation or those used to eliminate diseases. Modern approaches would consider use of DNA diagnostic probes, recombinant DNA, functional and structural genomics, and other methods for genetic modification. Only products of genetic modifications—designated as "living modified organisms"—are subject to biosafety assessments under the Cartagena Protocol on Biosafety.

siderations as part of the biosafety assessments, some authors such as Jaffe (2005) argue that the Cartagena Protocol limits its scope to factors affecting biodiversity.

Article 26 of the Cartagena Protocol on Biosafety

Socio-Economic Considerations

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.
2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Source: Cartagena Protocol on Biosafety as part of the Convention on Biodiversity.

This article discusses relevant issues and implications resulting from the inclusion of socio-economic considerations in biosafety assessment procedures. Discussions in this article center on the timing, scope, elements of best practice, the potential consequence of the inclusion of socio-economic considerations for technology decision-making and their potential relationship to the WTO rules, and other obligations. By definition, socio-economic assessments are *ex-ante*—before-the-fact procedures—for those products in the regulatory approval process. There may be some cases where some biosafety regulatory systems may require post-release monitoring and evaluation of socio-economic impacts, but this instance clearly falls under the realm of *ex-post* assessments, where there is a long and well-established literature and experience for assessments. Nevertheless, very few regulatory systems have requested socio-economic assessments after environmental release. One example is the European Union (see Table 1).

We argue in this article that although socio-economic assessment of new and emerging technologies,

including GM products, are an invaluable tool in supporting decision-making, they may constitute an unworkable hurdle if the assessment procedure is not clearly defined up front. Therefore, inclusion of socio-economic considerations may become an obstacle that in some cases may delay or even block the release of potentially valuable products. This outcome is of special interest to the public sector in developing countries, as they initially face higher barriers in terms of biosafety regulatory compliance due to resource constraints.

The implication of this policy outcome is that there is the need to define clearly the ‘how,’ ‘when,’ and ‘under what decision-making rules’ will developers or decision makers consider socio-economic issues and its assessments for those products undergoing regulatory review. In essence, the rules of the game for the inclusion of socio-economic considerations into biosafety and biotechnology decision-making need to be transparent, well defined, protective, and understood by all actors and stakeholders. The latter are the characteristics that define a functional biosafety system (Jaffe, 2005).

We organize the article as follows. In the next section, we discuss the conceptual issues related to biosafety assessments, followed by a discussion on the international context. Then we proceed to discuss the broad spectrum of country choices for inclusion of socio-economic considerations, followed by a discussion on what the issues are and what is at stake, while presenting some practical guidance to socio-economic evaluators. We conclude with a summary discussion of policy implications for developed and developing countries.

What are Biosafety Assessments Anyway?

The text of the Cartagena Protocol on Biosafety refers to biosafety as “the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology” (CPB, p.1). Biosafety can be defined as the regulatory systems and risk analysis procedures designed to perform proper risk assessments, mitigation, and communication of GM products’ risk profile in order to ensure their safe use. The previous definition of biosafety is very general as there is no “best” approach to biosafety analysis (McLean, Frederick, Traynor, Cohen, & Komen, 2002). The broad definition should apply to a wide-ranging spectrum of countries and decision-making processes. Yet, the biosafety processes that emerge in implementing countries, reflect their national, environmental, political, financial, and scientific capacities. Therefore,

Table 1. Biosafety protocols and socio-economic considerations in relevant regulatory laws and regulations.

Country	Party CBD/ CPB ^a	CFT/ CO ^b	Language of relevant text considering socio-economic considerations	Relevant law and regulations for socio-economic considerations
Argentina	Y/N	Y/Y	Decision on the convenience of the commercialization the genetically modified material over its impact on markets, in charge of the National Market Directorate, so as to avoid potential negative impacts on Argentinean exports.	Resolution n° 656/92 of SAGyP and Resolutions n°39/03 and n°57/03 SAGPyA
Brazil	Y/Y	Y/Y	Article 48, Paragraph 1. The National Biosafety Council—CNBS shall: II—analyze, upon request by CTNBio, in the context of convenience, socio-economic opportunity and national interest, requests to grant license on the commercial use of GMO and GMO derivatives.	Decree NO. 5,591, of November 23, 2005
Honduras	Y/Y	Y/Y	Socio-economic considerations will be conducted through partial studies that should include different social and economic impacts.	Honduras draft policy
Kenya	Y/Y	Y/N	“in reaching a final decision, the Authority shall take into account ... (e) socio-economic consideration arising from the impact of the GMO on the environment.”	Kenya draft policy
Uganda	Y/Y	Y/N	“no approval shall be given unless the GMO will not have adverse socio-economic impacts.”	Uganda draft regulations of 2005
Nigeria	Y/Y	N/N	The decision-making procedures shall take into consideration risk assessment, which involves scientific, socio-economic, cultural and ethical considerations.	Nigeria National Biosafety Framework, 2005
R.S. Africa	Y/Y	Y/Y	“The Council may in performing its function in terms of sub regulation (8), consider the socio-economic impact that the introduction of a genetically modified organism may have on a community living in the vicinity of such introduction.”	GMO Act 1997 (Act No. 15 of 1997)
Philippines	Y/Y	Y/Y	“Socio-economic, cultural and ethical considerations. Impacts on small farmers, indigenous people, women, small and medium enterprises, and the domestic scientific community to be taken in to account.”	Executive Order 514 (EO514)
Indonesia	Y/Y	Y/Y	“The utilization of GEAP originating from both domestic and foreign products must pay attention to and take into consideration the religious, ethical, socio-cultural and esthetical norms.”	Regulation 21 of 2005
India	Y/Y	Y/Y	India’s biosafety system provides for evaluation of the economic benefits of LMOs through systematic evaluation of agronomic performance.	Not included or mandated by the Environmental Act or Biosafety Guidelines
United States	N/N	Y/Y	Voluntary/additional information	None
Canada	Y/N	Y/Y	Voluntary/additional information	None
EU	Y/Y	Y/Y	European Commission requires preparing a report on the socio-economic impact of GM crops every three years. Definition of socio-economic considerations is unclear in current legislation and associated guidelines, no provision for a risk-benefit analysis.	None

Note. Compilation by author from National Biosafety Frameworks, laws and regulations posted at the Biosafety Clearinghouse (Convention on Biological Diversity, 2008).

^a CBD/CPB=Party to the Convention on Biological Diversity/Cartagena Protocol on Biosafety

^b CFT=Conducted confined field trials, CO=Has made approval for commercialization

^{a,b} Y=Yes, N=No

there is the need to analyze biosafety regulatory capacity within the individual implementing institution and national context and be contrasted to well-known principles of risk analysis and regulatory experiences globally.

Biosafety procedures, common to most biosafety systems, provide a systematic and logical (science-

based) framework to address consumer and other stakeholder safety issues while addressing trade-offs within the decision-making process. Risk analysts and decision makers face trade-offs between stricter regulatory regimes and a reduction in the approval of new products or activities. Furthermore, most risk assessors conceptu-

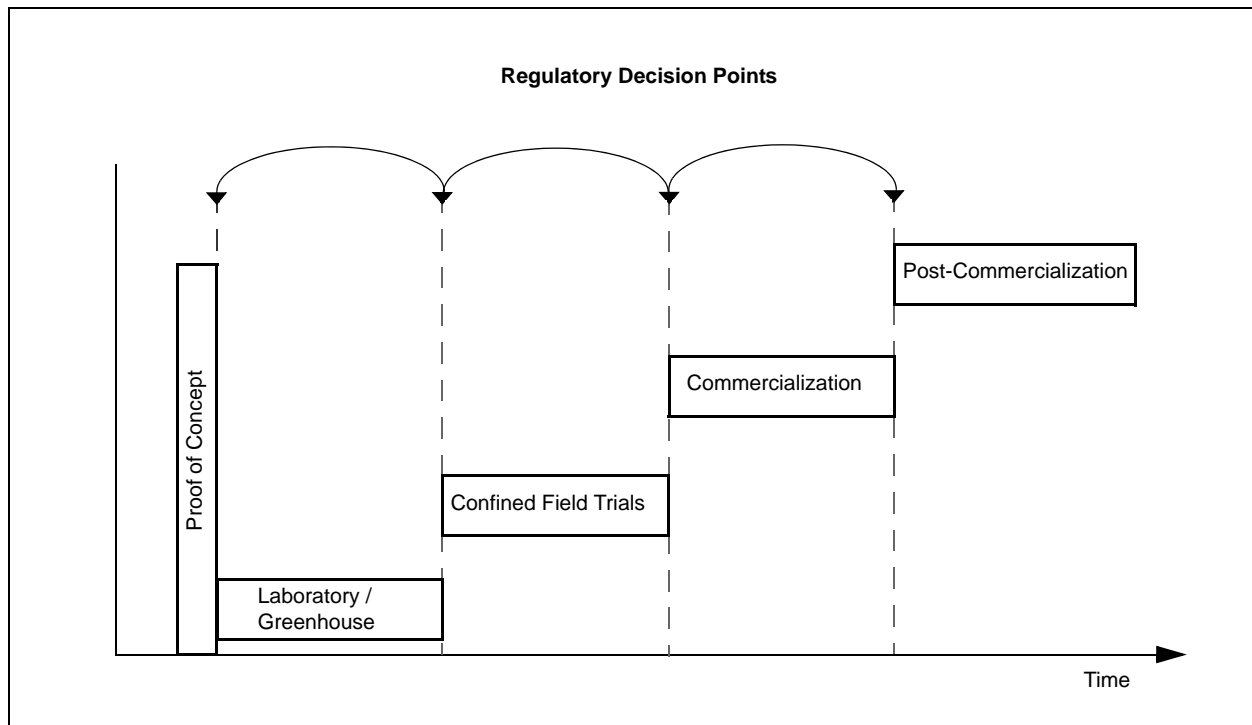


Figure 1. Regulatory stages in a functional biosafety system.

Note: Author's own design.

ally recognize that there are risks, benefits, and costs associated with product approval after regulatory review, including the opportunity costs of regulatory decisions. Nevertheless, in some jurisdictions, laws and regulations may not allow regulators to consider other issues besides risk.

In most countries, biosafety regulatory assessments build upon a sequential set of steps and approvals by a regulatory authority (see Figure 1). The regulatory authority may be an institutional, regional, and/or national biosafety authority, or a combination of all of the above. Furthermore, there may be a single regulator (e.g., Australia) or a combination of agencies (e.g., United States or Canada) who evaluate proposals. Decision-making may be complex as there may be different combinations of science and technical bodies only, or those that are intermingled with a policy and political process, such as the system in the European Union. For discussion purposes in this article, we will refer to a "regulatory authority" with the provisos discussed before. This linear sequence of events assumes that each regulatory step builds upon the knowledge accumulated in previous steps and/or from other regulatory assessments done in or outside the evaluating country.

The regulatory authority assesses information submitted by the developer/proponent in an application

dossier. The dossier includes information on several safety issues or attributes. The safety attributes normally considered include risk descriptors for the parent crop, the transformation method, the gene construct, and the GM crop. Issues of concern include food safety, health, and environmental impacts from potential use.

A typical set of sequential steps may include laboratory experiments, glasshouse/greenhouse (contained) trials, confined field trials, step-up extended or multi-locational field trials, and commercialization. Each stage in the regulatory process requires a set of activities that have an attached cost. Additional activities, especially those that are redundant or not needed to demonstrate safety or a specific outcome, increase the cost of compliance with biosafety regulations, while additional time to comply with biosafety regulations extends the starting date for the onset of the cost and benefit flows to society. The time value of money lost from regulatory approval delays tend to be larger than the cost of compliance itself (Beyer, Norton, & Falck-Zepeda, 2008).

The additional time and cost beyond what is necessary to demonstrate safety may constitute a disincentive to innovators, especially those in the public sector who may be developing national and international public goods, that is, on crops and productivity limitations of interest to resource-poor farmers. The private sector

may not have an interest in crops of a public-good nature, given their low commercial benefit (Atanassov et al., 2004; Cohen, 2005). Public sector organizations, already constrained by budgeting limitations, may not pursue potentially valuable technologies, especially when they face uncertain biosafety compliance costs and outcomes from risk assessments.

Risk and cost considerations bound biosafety assessments and biotechnology decision-making processes (Viscusi, Vernon, & Harrington, 2000). In terms of risk, society has a maximum level of risk that it is willing to tolerate while using GM products. The biosafety regulatory and decision-making process is at the same time bounded by cost considerations due to limited societal budgets for biosafety and biotechnology review processes. Different combinations of potential regulatory procedures with risk and cost trade-offs—a regulatory policy frontier—are therefore achievable. Risk and cost combinations offering society the same level of risk at a lower cost or the same level of cost but with a lower level of risk may represent policy options in a decision-making framework. Furthermore, all investments and time spent during the regulatory process have opportunity costs, as these resources could be better spent elsewhere. The opportunity costs increase the total cost of development and may reduce the number of technologies offered to society (DiMasi, Hansen, & Grabowski, 2003). These trade-offs highlight the need for societies to define a decision-making pathway that will guide their actions in terms of defining timing, scope, methods and techniques, and decision-making rules. These are critical issues that need to be brought back to the attention of all stakeholders in their decision-making process.

Assessing risk, benefits, and cost trade-offs of biosafety and biotechnology regulatory processes are conceptually elegant and simple processes. In practice though, the assessment of biosafety and biotechnology regulatory processes is a complex task. The safety profile of a particular GM biotechnology in practice consists of a portfolio of risk attributes and the potential pathways by which they may affect overall risk. Risk analysis defines hazard identification as the process of isolating the specific risk attributes of a specific technology. Examples of risk attributes include allergenicity, toxicity, and impact on non-target organisms.

Concrete examples of risk-assessment decisions include the decision made by the Australian Office of Gene Technology Regulation (OGTR) for the case of delayed-ripening papaya (OGTR, 2003). Each risk attribute has itself a safety profile that may require a tailored decision-making process. The fact that countries may

place different weights to each attribute further complicates the multiple-attribute/multiple-decision-making processes characteristic of most modern biotechnologies. Individual or societal risk preferences determine the weights attached to each attribute. Regulators may deem unacceptable the risk of a specific attribute (i.e., potential for allergenicity), whereas regulators may judge other attributes (i.e., weediness or impact on non-target organisms) as acceptable or manageable through risk mitigation procedures.

The Regulatory Agencies Structure and the Decision-making Process

There is wide variation in terms of biosafety regulatory structures, systems, and implementation procedures. These are quite complex in practice as they respond to specific country needs and capacities. For example, some countries have a single regulator who makes the assessment and shares responsibility of risk management with the proponent, such as Australia and South Africa. Other countries may have coordinated frameworks where several agencies may intervene in the assessment process based on the type of product being evaluated. This is the case of the biosafety regulatory system in the United States and Canada. In some countries, there may be a centralized risk-assessment process, but multiple agencies share the risk management. This is the case of the European Union, where the European Food Safety Authority and related institutes have the sole responsibility of risk assessment, whereas member states, the European Commission, and the European Council share risk management responsibilities. It is worthwhile noting that the EU decision-making process is quite complex, as the technical risk assessment becomes part of a broader technology decision-making approach that may include political aspects in its implementation.

The main lesson here is to understand how biosafety systems developed as a response to national needs, but also to international demands for these approaches. Whether a particular biosafety system responds more to national needs or to international demands may help explain the history and performance of a particular biosafety system.

The International Biosafety Context

As described earlier, Article 26.1 of the Cartagena Protocol opened the possibility of including socio-economic considerations as part of biosafety decision-making processes. Several authors and other stakehold-

ers (i.e., Jaffe, 2005) have pointed out that under a strict interpretation of the Cartagena Protocol, the scope of socio-economics is only on those impacts on biodiversity, especially on indigenous communities.

Inclusion of broader socio-economic considerations into the GMO biosafety analysis process continues to be controversial and is an ongoing discussion within international agreements and other international forums. The formal agenda at the Protocol's Conference of the Parties/Meeting of the Parties (COP9/MOP8) in May 2008 included discussions on socio-economic considerations, focusing on information exchange between parties. At the conclusion of the COP9/MOP4 meeting, Cartagena Protocol parties decided to postpone any decision with regard to socio-economic considerations to get further technical guidance. This issue has been a highly debated point amongst parties and non-parties to the Cartagena Protocol and will continue to be a major discussion issue, as countries essentially diverge into two major opposing views.

One view is of those countries whose opinion is that socio-economic considerations have little to do with a GM product's safety profile, except in very specific instances in which they may play a role in influencing biosafety management efforts. The latter would be the case, for example, in helping to make decisions about insect-resistant management strategies.² The rationale is that biosafety decision-making has to pursue a strict interpretation of the article 26.1 of the Cartagena Protocol, where environmental risk assessments need to guarantee a reasonable level of safety to society only.

The underlying argument under this view is that end-users are the decision makers entitled to make their own socio-economic assessments, determine technology viability and implement decision-making processes. Moreover, socio-economic assessments (or marketing studies) can be a voluntary and supplementary information package that may be included in the application

dossier for commercialization. In this sense, socio-economic assessments help understand the potential implication of technology use, however, biosafety regulatory bodies should not be mandated to use socio-economic information. In some instances, unless clearly spelled in existing regulations, there may be incompatibilities between risk assessments and cost/benefit analyses and, thus, clear and transparent decision rules may not be applicable for regulatory decision-making.

The most powerful argument against the inclusion of socio-economic considerations seems to be that countries that do include such considerations in their decision-making processes may appeal to these considerations as a blanket justification to reject GM technologies without having a clear statement or reason by which this decision was made in the first place. In this regard, socio-economic considerations may follow the regulatory development pathway where some countries have implemented the precautionary principle in such a way that allows them not to make a regulatory decision and/or to justify the pre-emptive rejection of GM technologies. Paarlberg (2008) presents similar arguments to this line of thought.

A broad and undefined inclusion of socio-economic considerations will, in the end, cause major disruptions and thus become a major limitation to technology development and transfer. Clearly, sovereign nations can decide what policies they want to pursue. As the possibility exists that GM products or technologies may at least benefit some stakeholders, and to ensure that society makes the best decision, having full information and a clear justification of why a nation pursues a specific policy becomes critical.

In contrast, the second view maintains that socio-economic considerations are vital to protecting indigenous and local communities and users against any potential negative impact of GM products (La Viña & Fransen, 2004). In the strictest interpretation of this view, this may include even hypothetical and uncertain impacts of GM products. This point of view strongly affirms that any proper assessment of a GM product should include not only biosafety risk assessments, but also broader socio-economic considerations, including any potential ethical, philosophical, and religious concerns. This position potentially aligns itself with the precautionary principle embodied in the Cartagena Protocol.³

Both positions described above align themselves well to the scientific and social approaches to regulatory paradigms described by Isaac (2002, 2004). Isaac discusses the strikingly different approaches of the Unites

2. *We will abstract from other types of risk that may be borne by adopting producers, including financial, credit, production, and social or community risks. These risks directly relate to vulnerability and the livelihood of poor farmers in developing countries. However, we cannot emphasize enough the need to bring back these issues into the discussion, as they are critical to the process of deciding whether a technology is appropriate or beneficial for a particular country. Of course, this opens other discussions such as who makes the technology adoption decisions; is it farmers, regulators, policy makers, civil society, all? How does society decide amongst competing alternatives?*

States and the European Union, including other nations aligned to one approach or the other, or combinations of both regulatory frameworks. It is interesting to note that because of the differences between both *trajectories* (Isaac's own terminology), there are significant differences in approaching risk analysis and other regulatory approaches. This in turn will affect how regulatory and decision-making bodies consider socio-economic considerations and potential outcomes.

According to Isaac, the fundamental difference between the scientific and social rationalities is the fundamental belief about the role science and technology has in society. Scientific rationality posits that innovation and technology are vital to enhancing productivity and maximizing efficiency. The outcome of an innovative process is the maximization of society's welfare. If food and environmental safety regulations are pre-requisites for the approval of innovations, then scientific approaches to their assessment become a natural consequence of the scientific rationality approach. Thus, countries that follow the scientific rationale for regulation tend to implement regulations based on science only and tend to support or encourage innovations.

A strong support of science, technology, and innovation tend to yield regulations based in the scientific method and in risk analysis processes. This approach requires compiling existing data to estimate objective risk, or if data is not available, the use of subjective risk estimates—usually by a community of experts. The regulatory evaluation and decision-making process uses substantial equivalence as a starting point. If a new GM product is deemed as 'substantially equivalent' and a posterior risk analysis indicates that the products have the same—or lesser—level of risk as existing products in the market, then the GM product is approved for commercial distribution. If the GM product is deemed as 'not equivalent,' regulators consider it as novel and, thus, extensive testing is required to evaluate safety. In this approach, there is an inclination to estimate short- and medium-term effects on health and the environment, usually through estimation of probabilities of occurrence. Thus, scientific-rationale-based regulatory

systems will tend to downplay the inclusion of socio-economic assessment for biosafety regulatory approval.

In contrast, the social rationality approach views technology and innovation in a completely different way. Science, technology, and innovation are a mere component of the societal dynamics that govern humanity. In this approach, decision makers examine not only the relationship between science and technology, but also its effects to humans and the environment. As there is greater inclusion of societal concerns within the regulatory process, this process tends to favor approaches that are precautionary in nature. This is a consequence of the cognitive conclusion that science and technology cannot explain all the reality of the human experience. Therefore, in this trajectory's view, there is the need to examine social, ethical, and philosophical concerns within the risk analysis framework.

Although the tension between these opposing views can lead to international disagreements and further delay in the establishment of functional biosafety systems in many developing countries, what is imperative at this point is to first understand all the potential trade-offs from a required inclusion of socio-economic considerations. For those countries who, after a careful evaluation of these tradeoffs, still want to pursue inclusion, then the issue becomes identifying methods and techniques, timing, scope, decision-making rules, and other implementation procedures that will ensure reducing costs, which maximizes the efficiency and benefits of such a policy approach. Furthermore, the need will arise to judge whether the chosen approach for the inclusion of socio-economic considerations *does* contribute to the establishment of a functional biosafety system.

We can define a functional biosafety system in several ways. Perhaps it is more fruitful to focus on a set of descriptors for functional biosafety systems, such as those introduced by Jaffe (2004a, 2004b, 2005). In these articles, Jaffe shows that functional biosafety systems can be analyzed and described in terms of (1) comprehensiveness; (2) adequate legal authority; (3) clear safety standards; (4) proportionate risk-based reviews; (5) transparent and understandable processes; (6) participatory; (7) flexible and adaptable; (8) efficient, workable, and fair; and (9) post-approval oversight. These descriptors can be used to evaluate how functional a particular system is, but does not necessarily imply that *not* having a fully functional individual descriptor makes a system non-functional. Quite to the contrary, this list should be, in our opinion, viewed as an evalua-

3. *Countries that do not require or oppose inclusion of socio-economic considerations as a formal requirement for regulatory approval tend to be innovators, developers, and/or broad users of GMO technologies. In contrast, many countries that favor inclusion of socio-economic considerations in decision-making tend to be potential receptors of foreign GM technologies and/or have limited investments in GM innovation.*

tion tool to help develop regulatory systems in their quest to achieve functionality.

Each descriptor is necessary but not sufficient to describe the functionality of a particular system and, thus, decision makers have to evaluate the regulatory system as a whole. Therefore, there is the need to evaluate these contrasting positions within a stated country position, the scope of the Biosafety Protocol, and the World Trade Organization's (WTO) Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS) agreements, and other considerations (e.g., Jaffe, 2008). Note that the design—and also implementation—of biosafety regulations can consider public participation (Fransen et al., 2005).

What are Countries Doing in Terms of Socio-economic Assessments and Biosafety?

Table 1 shows a small group of developed and developing countries to showcase the broadness of approaches and positions with regard to the inclusion of socio-economic impact assessments in laws, regulations, or the national biosafety frameworks developed under the United National Environment Program-Global Environmental Facility (UNEP-GEF).⁴ A common thread amongst countries who have indicated their intentions to include socio-economic considerations is the tenuous guidance on how, when, and which rule decisions to use for decision-making. Furthermore, there is no guidance with regard to how the narratives and estimations resulting from the socio-economic assessments will be used, vis-à-vis results from the risk assessment evaluations.

For example, Argentina requires a socio-economic assessment but limits its implementation to impacts on Argentine's exports, while a country like The Philippines details whose impact will be assessed, but not when, how, and for how long before a decision is made. In the Republic of South Africa, Article 5(9) of the GMO Act 15 of 1997 limits the scope of the socio-economic assessments for experimental trials to those communities living closely to the planned introduction sites for the GM crop. Although a review of the available South African regulatory documents do not include a reference for socio-economic assessments of products that may be approved for commercialization, these have

been used in the past to support regulatory decision-making (Jaffe, 2008).

Proponents in countries that do not have a mandatory socio-economic requirement, such as the United States or Canada—who are not parties to the Cartagena Protocol—may include socio-economic studies as supplementary material along with the application dossiers. In the European Union, socio-economic studies may also be included as supplementary material, but current directives mandate a socio-economic assessment of products given regulatory approval every three years (see Table 1).

A closer look at specific legislations, guidance documents (including the National Biosafety Frameworks developed under the UNEP-GEF programs), and other legal documents—for example, the case of Nigeria, Honduras, and Bangladesh as in Table 2—show that these countries have included significant requirements related to the scope and issues considered. Once we reconcile these apparent high requirements with the fact that, by definition, socio-economic assessments for biosafety regulatory approval purposes are mostly ex-ante estimations, then we can expect that potential conflicts may arise if provisions are not included in laws and regulations to allow flexibility with regard to requirements and issues discussed in the socio-economic assessments.

One country that does not have a formal mandatory requirement for the inclusion of socio-economic studies is India. Although there are no mandatory requirements, the biosafety system has the flexibility for the regulatory authority—The Genetic Engineering Approval Committee (GEAC)—to request a socio-economic study for current applications in the regulatory pipeline. Two recent examples of such requests were the insect-resistant cotton and eggplant expressing the Bt gene (Sharma, 2008). There is still no clarity on how these studies have been or will be used in the future for technology decision-making, and if they will set a precedent for future technology evaluations. Clearly there is quite a bit of scope in terms of developing elements of best practice, methods, and policy guidelines and capacity-strengthening efforts to guide socio-economic evaluation and decision-making processes in India and in most countries implementing biosafety regulations.

What are the Issues for Socio-economic Considerations and Biosafety?

Literature on the analysis of socio-economic considerations and impact assessments is well established. However, questions are still pending on how to accomplish

4. *There was no explicit criterion to select countries in Table 1, except for highlighting the broad variability across countries, continents, economic development status, and biosafety system approaches.*

Table 2. Three examples describing inclusion of socio-economic considerations included in drafts policies done at the UNEP-GEF country projects.

Nigeria	Honduras	Bangladesh
(a) Anticipated changes in the existing social and economic patterns resulting from the introduction of the GMO or product thereof;	Article 41. Socio-economic considerations will be conducted through partial studies that should include:	(i) Factors such as the potential impact on trade, labor, food security, gender, small business development, sustainable development, and poverty alleviation would be taken into consideration in the evaluation process;
(b) Possible threats to biological diversity, traditional crops or other products, and, in particular, farmers' varieties and sustainable agriculture;	(a) Estimation of changes in social and economic patterns as a result from the introduction of GMO and their products;	(ii) The impact on food security, impact on livelihood of communities, and ethical issues and the right to choice would be identified as key socio-economic factors that need to be considered;
(c) 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;	(b) All those impacts related to the potential substitution of traditional crops and indigenous technologies through modern biotechnology outside their agro-climatic zones;	(iii) Ethical issues and the right to choice—The right to choice could be addressed by having an effective labeling system;
(d) 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 GMO or product thereof;	(c) Anticipate the social and economic costs resulting from losses resulting from labor reductions, market opportunities, and in general, the community livelihoods potential affected by the introduction of GM crops and its products;	(iv) Where genes of certain animals or human genes have been inserted to produce GM crops, livestock, or food, it is necessary to identify and incorporate the relevant socio-economic factors in the protocol for risk assessment. Detailed environmental impact analysis including socio-economic impact analysis will be the responsibility of the applicant/notifier/proponent and the competent authority concerned or NCB/MoEF would undertake a detailed review of this analysis with the technical support of BCC.
(e) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare;	(d) Identify potential communities affected in terms of disruptions to their economic and social welfare;	
(f) Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the GMO or product thereof.	(e) Identify potential effects that are contrary to communities' social, cultural, religious, ethical values; due to the introduction of GM crops and its products.	

Note. Text is from National Biosafety Frameworks of Nigeria, Honduras, and Bangladesh. Extracted from the Biosafety Clearinghouse (Convention on Biological Diversity, 2008).

the mandate of including socio-economic considerations into biosafety and biotechnology assessments and decision-making process. In this section, we discuss issues related to socio-economic assessment inclusion and suggest potential alternatives for addressing them in developing and developed countries.

When to Require Socio-economic Assessments

The main concern is to determine at what stage of the regulatory process is inclusion most useful, while maximizing the functionality of the biosafety system. Keeping in mind the determinants of functional biosafety systems proposed by Jaffe (2005), we argue here that the inclusion of socio-economic considerations and the data and knowledge collected in order to address socio-economic impact will be most useful in the final regulatory stage of commercialization or propagation. This approach has the added advantage of using some of the

basic knowledge generated—including the relative effectiveness of the technology vis-à-vis conventional technologies—during the laboratory and confined field trial stages, and thus these studies may reduce parameter uncertainty to some degree. Socio-economic data is least useful—and can even become a waste of valuable resources—if done during the laboratory, confined field trial, and multi-locational stages, as most GM product candidates will not make it to the commercialization stage.

The argument could be made that socio-economic assessments can help reduce the possibility of selecting products that do not have a market potential or may have a negative socio-economic impact. However, regulatory and impact assessment experience does not fully support this argument. There are relatively well-established procedures for setting R&D priorities, or for selecting amongst competing projects that do not require a full socio-economic assessment but are rigor-

ous enough to render a decision. Demanding a broad assessment of a product that has a limited market potential to producers can be a waste of scarce resources.

Unified Versus Alternate Decision-making Processes

The second critical issue is the decision to include socio-economic considerations in the biosafety decision-making process or, alternatively, to have a separate but concurrent process. In the first option, the regulatory authority evaluates both biosafety and socio-economic considerations and renders a decision. In the second option, a decision-making authority considers the outcomes of the separate risk and socio-economic impact assessments and then renders a decision.⁵ The main advantage of the latter approach is that it minimizes political interference from interest groups (both pro and con), while assessments center on elements of best practice and disciplinary rigor. Furthermore, this approach does not force biosafety regulatory bodies to deal with issues they are usually not prepared to deal with.

How Should Countries or Society Resolve Competing Assessment Paradigms?

Countries need to define how socio-economic considerations will be included in the decision-making process. Furthermore, countries need to decide what the decision-making rules are that will incorporate outcomes from different decision-making processes (i.e., risk assessment versus socio-economics versus ethical issues). For example, countries need to decide whether they will conduct a cost/benefit or a cost/benefit/risk analysis and how. Furthermore, countries need to identify and address the potential trade-offs involved with such estimations and to define clear rules to guide decision-making.

Special situations may arise in which developers may propose products with very high benefits relative to costs, but with an identifiable risk potential. This is the situation (albeit hypothetical) that a specific country may face with a product that generates very high net benefits relative to costs, but which may incur a significant risk (e.g., high income variability or negative impacts on non-target organisms).

5. A variation of the second option is that of a tiered system, where risk analysis determines a product to be "safe" based on a set of decision-making rules, and then allows socio-economic impact assessment as needed on a second round of decision-making.

What is Necessary Versus Sufficient Knowledge for Decision-making?

The issue is to determine how much (and what) knowledge is necessary or sufficient to demonstrate an outcome such as socio-economic impact or safety. The information set submitted by the proponent or, alternatively, the one required by the regulatory authority, may differ from the minimum information set needed to demonstrate an outcome.⁶ Furthermore, the regulatory community and policy makers need guidance in terms of identifying the minimum information set, discriminating amongst studies with competing claims, and to identify the rules and decision-making standard that will signal achievement of an accepted level of social welfare.

Inclusion or Exclusion in Democratic Society's Decision-making Processes⁷

Democratic societies reach decisions on technology and policy issues through popular consensus or vote, or by delegating decisions to a regulatory body. Most nations have decided to delegate biosafety decisions to a regulatory authority. The regulatory authority needs to have adequate legal authority with national laws and regulation *and also* international commitments. A practical problem is how and who will finance biosafety assessments. In many biosafety systems, the proponent performs most of the procedures needed to demonstrate safety or uses existing knowledge. In essence, the proponents undertake the burden of financing the biosafety process. However, this may introduce questions as to the data verifiability and reliability, while at the same time influencing negatively the public sector and small private (domestic) firms who may be developing public

6. *The medical field, particularly the analysis of clinical trials, provides ample examples of methodologies and approaches to defining the minimum information requirements necessary to make a regulatory decision. Examples include the discussion of "Evidence-Based Medicine and Value of Information Analysis" made by Claxton, Cohen, and Neuman (2005) and the "Expected Value of Perfect Information" described in Claxton, Sculpher, and Drummond (2002). In other disciplines, formal Bayesian-based approaches to examining evidence and sufficiency of information have been used in this type of analysis. These include Carpenter and Ting (2005), Benaroya and Kosciusko-Morizet (2001), Gollier, Julien, and Treich (2000), and others.*
7. *We thank one of the anonymous reviewers of this article for pointing out this issue, which was not as completely discussed as needed in previous versions of the article.*

goods and are constrained by limiting budgets. This instance does fall into broader discussion on how society finances science, technology, and innovation in their respective countries.

Socio-economic and Biosafety Assessments in Practice

The issues discussed previously describe how regulators and decision makers evaluate and decide on the relative value of information and knowledge submitted for consideration in a biosafety/biotechnology decision-making process. As indicated previously, the need arises for a process that determines a socially acceptable process to evaluate socio-economic considerations and sets clear rules to make a decision. These elements are well known and have been used as descriptors of disciplinary excellence.

The process needs to be agreed upon by all stakeholders and there is the need to address all trade-offs that are inevitable in the implementation of socio-economic impact assessment studies in practice, including budget constraints. There is the need to evaluate the cost of implementing socio-economic considerations and the gains from performing such studies and relate this to the ability of socio-economic assessors to simulate or project impacts based on imperfect information and even more imperfect assumptions and methods.

As seen in Table 3, some stakeholders are requesting quite broad data and analysis, which is hard (in some cases even impossible) to estimate in a meaningful and rigorous manner, in an ex-ante study. We hypothesize that broader requirements for socio-economic assessments, as included in Table 3, are the result of confusion about what is feasible with socio-economic impact assessment methods in an ex-ante setting. Of course, methodological limitations and/or available budget to collect information and data for analysis also curtails ex-post analysis.

The issues and potential conflicts with regard to the inclusion of socio-economic considerations and the potential introduction of a GM crop in a country need to be resolved. Such resolution will consider the issues and trade-offs by allowing all relevant stakeholders and other participating actors to agree upon the assessment process for new technologies, as well as define a socially acceptable level of safety and institutional and governance mechanisms to implement this biosafety process. Therefore, any procedure that considers inclusion of socio-economic considerations needs to include a clear decision-making standard, be comprehensive and

transparent, and be the result of participatory processes, while at the same time incorporate flexibility and adaptability, while being efficient, workable, and fair. This of course brings us back to Jaffe's (2005) descriptors of a functional biosafety system.

What is at Stake?

The main issue at stake is the impact from the inclusion of socio-economic considerations in decision-making processes that may affect access to promising technologies. This is the case especially when inclusion is not transparent or participatory. Consequently, from the implementation of the Cartagena Protocol on Biosafety, biosafety risk assessments and decision-making processes will exist regardless of the inclusion of socio-economic considerations. Nevertheless, countries need to address thoroughly the issues, questions, and trade-offs involved with this policy choice in order to ensure that it is feasible, functional, enabling, and protective (Jaffe, 2004a).

From this standpoint, if the biosafety process is not sufficiently robust, the possibility exists that a particular technology introduced in a country may indeed prove to be welfare-reducing. In the case of developing countries where there are existing structural problems along with poverty issues, we have to be more careful how we do things. The decision-making rationale in developed countries of allowing farmers to weed out the worthless technologies may not be entirely appropriate in developing countries. The latter statement needs to be qualified because most companies have a reputation and a long-term business perspective to guard, thus the possibility that a company will market a product that is not at least as good as the existing products is probably low. Markets in most countries take time to clear competing productive options—time that developing country farmers usually do not have.

The inclusion of socio-economic considerations without a clear and transparently defined process upfront can lead to an unworkable system. This is true especially in those situations where the lack of rules may hide political decisions or other considerations, such as protecting local producers from external competition. Socio-economic considerations may mask protectionism or other considerations apart from biosafety. Of course, inclusion of political decisions into any technological decision-making process is a prerogative of all sovereign nations. Stakeholders need clear and transparent processes that are understood from the start. It is important to know if the process is a scientific approach

Table 3. Economic considerations suggested for inclusion within biosafety regulatory approval by the Third World Network.

Issues	Questions and issues raised by the TWN briefing paper
Control over tools and relations to production	<ul style="list-style-type: none"> • Will the dissemination of GM seeds provide opportunities for poor farmers to have some control over the tools of production? • Will dissemination increase control by certain sectors?
Income security	<ul style="list-style-type: none"> • Cost of GM seeds and other required inputs (share of total production). • Expected potential net income or losses. • Consideration of hidden costs such as environmental and health effects.
Income and wealth distribution	<ul style="list-style-type: none"> • Assumption is that since GM seeds are more expensive, they will be bought by richer farmers. Question is then whether GM adoption aggravates income inequality in rural areas.
Rural labor	<ul style="list-style-type: none"> • Does the introduction of herbicide tolerance aggravate the “perennial” problem of rural unemployment?
Markets	<ul style="list-style-type: none"> • Developing countries, whose economies are particularly dependent on a specific crop, may be affected by production increases in other countries, i.e., Bt cotton expansion in India may affect resource-poor farmers in West Africa.
Trade	<ul style="list-style-type: none"> • When deciding to plant GM crops or not, questions arise about the ability to compete with commodities of bigger and wealthier countries in export markets as they have to meet high international standards such as sanitary and phytosanitary standards, thus jeopardizing export prospects.
GMO contamination and organic cultivation	<ul style="list-style-type: none"> • Proven cases of “GM contamination” poses serious threats to biodiversity and genetic base for long term food security. • Damage to organic agriculture where farmers may lose organic status and premium prices.
Food security	<ul style="list-style-type: none"> • Most GM crops sold today are intended for animal feed and not usually considered for food crops. • If change occurs to GM crops, then a change from food crops to commodity crops for industrial use and export. • Examine overall food security of communities.
Food aid	<ul style="list-style-type: none"> • Countries will be confronted with the decision whether they should accept or reject food aid under emergency situations.
Intellectual Property Rights (IPRs)	<ul style="list-style-type: none"> • GM crops are IP protected and thus raises concerns over corporate control of agriculture. • IPR may hamper free flow of information, knowledge and genetic materials that are the basis of R&D in public universities. • Limit potential public research to pursue research that serves the interest of the poor.

Note. Adapted and summarized by author from Yoke Ling (2008).

(evidence-based), a political decision-making process, or sequential process having a biosafety assessment, and then submit for a political technology decision.

Certainly, the inclusion of socio-economic considerations increases the cost of development. There is a cost attached to every assessment. Increased cost may aggravate the situation of public-sector and small private-firm developers that are struggling even to meet risk assessment requirements. In the latter case, the issue should broaden to how society finances public goods, especially those relevant to resource-poor farmers in developing countries.

Non-inclusion of socio-economics may impair democratic processes for decision-making, as relevant information for decision-making may not be available. Certainly, socio-economic considerations rarely have biosafety implications per se. However, from the standpoint of developing countries, issues presented in this article are magnified as there are significant questions about the capacity to do risk assessments, clarity and

transparency about laws/regulations and thus scope of strategic environmental assessments (SEA), and political power and influence of stakeholders and pressure groups. The special case of developing countries demands further study to support the development of functional biosafety and decision-making processes.

Decision-making Guidance for Socio-economic Evaluators

From a practical standpoint, socio-economic evaluators or biosafety regulators must make decisions on data submitted by the proponent. Proponents may submit socio-economic data and estimations from public and private sources (perhaps peer-reviewed), but also from self-generated estimations of socio-economic impact in the biosafety regulatory dossiers. The data and analysis generated will likely come from such sources as internal experiments, confined field trials, or laboratory and feeding tests that will shed light in terms of yield and cost differentials, as well as other productivity param-

ters, compared to the conventional counterfactual. The issue is then for the evaluator to decide whether the data and estimations are reliable and sufficient to be a valid indicator of a socio-economic impact for the *potential* introduction of the GM product into the country as in ex-ante studies or *actual* introduction for post-release monitoring of socio-economic impacts in ex-post studies.

What are the parameters by which a regulator can make this judgment? We present and discuss some general guidelines to judge the quality of the submitted data and socio-economic impact assessment studies. Decision makers can use the same qualitative value determinants to judge the quality of risk assessment and other scientific processes. Issues to consider are:

1. *Gradient from opinion editorials to peer-reviewed publications:* Peer-reviewed literature is usually considered the most credible of all publications. The least credibility can be assigned to opinion editorials and personal opinions. Evaluators can further disaggregate publications by quality perceptions and by using impact indicators for peer-reviewed journals.
2. *One-year/one-location study vs. multi-year/multi-location studies:* One-year/one-location studies may not capture outcome inter-temporal and geographical variations as well as compared to multi-year/multi-location studies. However, as the socio-economic impact assessment studies are likely to be ex ante, it will be important to attempt to capture variability (yield and cost distributions) and/or uncertainty about model parameters in the simulation studies or projections done for regulatory approval.
3. Use of generally accepted best-practice indicators for statistical analysis:
 - *Sample size:* The need to have a sufficient number of observations per sample and treatment to ensure statistical significance of baseline surveys.
 - *Reliability:* Practitioners should be able to replicate results using the data and/or models used in the study.

- *Experimental design and randomization:* The protocol used to conduct the experiment should be clear and available to the regulator.
- *Statistical analysis/significance of results:* The methodology used for the study should be explicitly presented and available to the regulator. The raw data, data used for quantitative analysis, and the routines/programs and models for quantitative analysis should also be readily available.
- *Statistical and sampling problems such as self-selectivity, simultaneity, and bias:* These problems in ex-ante studies are a direct result of using data collected without considering biases in the experimental design and protocol used to collect baseline data for the ex-ante estimations. In practice, there is no formal inclusion into existing evaluation methodologies, or a theoretical background backing considering such issues, for ex-ante estimations. Practitioners, therefore, must carefully use baseline data and consider the potential impact on outcomes if indeed baseline data is biased.

In ex-post studies, the issues of self-selectivity and simultaneity may be inherent in the behavior of actors. For example, when examining populations in which there are adopting and non-adopting members of a particular GM product, the individual self-selects his/herself to be part of a specific group by choosing to adopt or not. At the same time, in many countries the decision to use a GM product is simultaneous with the decision to use pesticides (see Fernandez-Cornejo, Klotz-Ingram, & Jans, 2002).⁸ If practitioners do not address these issues for socio-economic assessments, they may severely affect the outcome of such studies.

- *Who conducts the studies?* Regulators or decision makers may put a greater weight on those studies conducted by independent entities versus those done by the proponent. Regulators or decision makers need to address whether the study implementer has a vested interest in

8. *In many developing countries, the use of a particular biotic control product may be limited as there is a great degree of limitation to use inputs in general.*

the outcome of the study. The implication is that there needs to be an overall assessment of how to conduct a socio-economic study and decide whether proponents followed elements of best practice.

- *Relative risks ratios:* Relative risk (RR) is the ratio of the probability of the event occurring in the exposed group versus the control (non-exposed) group in a random experiment. Most statisticians will normally not accept an RR of less than three, almost never an RR of less than 2, and never an RR less than 0.5. The relative risk closely relates to the concepts of randomness, statistical significance, sample size, and addressing sampling issues.
4. *Statistical significance:* Most researchers use a P value of 5% as a critical value for hypothesis testing. By definition, this represents the possibility that the purported treatment or effect could be random (this is the so-called “1 in 20 lottery”). Note that if the critical P value is set at 10%, there is a significant chance that this is due to a random effect (in effect, becoming the 1 in 10 lottery). Therefore, for those studies that include a statistical analysis, the preference should be to demand a stricter significance standard and statistical power for accepting results as statistically true.⁹

Statistical issues discussed above have practical implications in terms of decision-making. European and US regulators are discussing two related issues: the inability to detect differences between GM and non-GM products, and the ability to prove that GM and non-GM

9. *A very provocative article in the medical literature by Ioannidis (2005) concluded that there is distinct probability that most published research findings are actually false. This conclusion is drawn after taking into consideration the studies' power, bias, the number of existing studies for the same issue, the probabilities of the true-versus-not-true relationships between putative parameters, and the mistakes made during interpretation and consideration of Type I and II errors. In more recent articles, Djulbegovic and Hozo (2007) and Moonesinghe, Khoury, Cecile, and Janssens (2007) have derived procedural alternatives for improving the interpretation and acceptance of false results mostly by suggesting replication and by deriving thresholds by which society may accept false results, that is, for results to become sufficiently true in order to gain societal acceptance.*

products are equivalent (Quemada, 2008, personal communication). Similar discussions are happening with detection of the adventitious presence of GM products in the EU.

Relationship to the WTO and Other International Agreements

Text in the Cartagena Protocol preamble indicates that the inclusion of socio-economic considerations has to be consistent with obligations arising from international agreements signed by parties, and that they have to be mutually supportive in their quest for sustainable development. There is, however, a significant difference between the Cartagena Protocol on Biosafety and the SPS and the TBT of the WTO in terms of what these agreements allow regarding the inclusion of socio-economic considerations.

As can be seen in Table 4, the WTO rules tend to emphasize decision-making procedures that rely on rules and regulations that center around scientific risk assessments, while limiting decision-making based on non-safety issues. The strict emphasis on scientific risk assessments under the WTO, are sometimes relaxed within implementation agreements, such as the SPS agreement. The SPS agreement indicates that the basis of risk assessments should be the relevant international standards, guidelines, or recommendations. However, the SPS agreement allows its members to take economic factors into consideration.

Article 5.3 of the SPS agreement states that

“In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk. Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.”

As can be seen from the text, article 5.3 narrowly defines inclusion of economic considerations and, in reality, mostly considers cost/benefits analysis of SPS implementation decisions.

Table 4. A summary comparison between international agreements.

Issue	Cartagena Protocol	WTO	
		Sanitary, Phytosanitary Measures (SPS) agreement	Technical Barriers to Trade (TBT) agreement
Scope: Commodities, living organisms	Both, subject to different regimes	Both, no difference in regimes	Mainly commodities
Precaution/science	Can be described as co-equal core values	Science-based requirement pre-eminent, precaution minimized	Science-based requirement pre-eminent, precaution minimized
Advanced informed agreement	Required for GMOs unless exceptions apply; notification of AIA requirement by importing states needed for it to apply to commodities	Not required, use controlled by trade disciplines	Not required, use controlled by trade disciplines
Requirement for assessment	Yes, content set out in Annex, including role of precaution	Yes, content requirements from cases, minimize precaution as input	Yes in some cases, contents not clear yet
Responsibility for assessment	Can be placed on exporter, or costs paid by exporter	State taking measure	State taking measure
Decision-making parameters	Science-based risk assessment, precaution, least trade restrictive, socio-economic factors, impact on trade	Full scope of trade disciplines including science-based assessments, least trade restrictive, non-discrimination as between foreign and other domestic-like products, non-discrimination as between similar risks and national treatment	Full scope of trade disciplines including science-based assessments, least trade restrictive, non-discrimination as between foreign and other domestic like products, non-discrimination as between similar risks and national treatment
Subsequent review of assessment or management decisions	Responsibility on potential exporter if permit not granted or subject to conditions; responsibility on importing state if to reduce imports or increase conditions	Responsibility on state taking measure (but can download to potential exporter if specific in doing so); additional constraints subject to justification	Responsibility on state taking measure; additional constraints subject to justification
Labeling	Ongoing process, cooperation with other agencies	Mandatory labels subject to disciplines	Mandatory labels, subject to disciplines; less clear for voluntary labels
Capacity building	Significant coverage, including reference to financial mechanism, absence can impact on choice among possible measures	Never applied in practice in regulatory issues	Never applied in practice in regulatory issue
Liability	Subject to future negotiations	Not included, efforts to impose subject to trade disciplines	Not included, efforts to impose subject to trade disciplines

Note. Table is from Mann (2000).

The potential for conflict between the WTO and the Biosafety protocol exist. The WTO agreements pre-date the Cartagena Protocol on Biosafety and may take precedence over the latter agreement. However, as discussed previously, language included in the Biosafety Protocol of not changing obligations and being mutually supportive with existing treaties, leaves the door open for conflict. There has not been so far a ruling under the WTO or the Cartagena Protocol that would shed light unto how this apparent conflict may be resolved. We can

speculate that pursuing the directives of the Cartagena Protocol of allowing compliance with other international agreements, countries may attempt to implement Article 26.1 for biosafety decision-making in a manner that is consistent with WTO agreements. The implication of this decision will be a narrow interpretation of Article 26.1 that includes impacts on biodiversity for those indigenous communities affected by the introduction of a particular GM crop. This leaves the door open for countries to consider broader socio-economic con-

siderations within the scope of national legislation that deals with technology decision-making for approval, but not within the scope of biosafety risk assessments.

Concluding Comments

Article 26.1 of the Cartagena Protocol on Biosafety allows the inclusion of socio-economic considerations into biosafety regulations for GM crops. A strict interpretation of the text in the Cartagena Protocol seems to show a narrow implementation scope that is limited to effects on biodiversity. However, countries can—and have—included socio-economic considerations in their decision-making utilizing national legislation.

Inclusion of socio-economic considerations for biosafety decision-making has a set of advantages and disadvantages. National policies may enhance benefits or complicate—or even worsen—disadvantages of inclusion depending upon objectives pursued. Inclusion of socio-economic considerations may help avoid release into the environment of ineffective or unsafe technologies. Furthermore, socio-economic impact assessments may help identify promising technologies for deployment and institutional issues that may curtail technology adoption and success in farmers' fields. Socio-economic impact assessments, if done properly, following elements of best practice and disciplinary rigor, can be an invaluable tool for supporting environmental and food risk assessments in terms of understanding the trade-offs between cost, benefits, and risk.

On the other hand, if biosafety regulations do not clearly spell out data and analysis requirements, decision-making rules and other procedures may lead to unintended consequences including unnecessary regulatory delays and increases in the cost of compliance, which may ultimately lead to less technologies released to farmers. In addition, uncertain regulatory requirements may become a disincentive for biotechnology innovators to develop appropriate technologies. This effect may be particularly poignant in the case of public-sector and small private firms that may develop products with a public good nature for resource-poor farmers in developing countries. Biosafety regulations need to describe clearly outcome indicators, methods, timing and scope, and decision rules. These regulatory processes need to be transparent, negotiated, and agreed-upon by all stakeholders in the process. Requirements for socio-economic impact assessments need to be known in advance and clearly understood by developers and all other stakeholders.

If a country, after careful considerations of the pros and cons, decides to include socio-economic considerations as part of the biosafety decision-making process, then it is prudent to design carefully appropriate regulations that will ensure a functional system. Rules and regulations should clearly spell out procedures for inclusion of socio-economic considerations to avoid blanket or unsupported regulatory decisions that other members of society may challenge legally. In essence, evaluation procedures need to comply with elements of best practice or disciplinary rigor. By following this approach, countries may indeed make use the advantages of socio-economic impact assessments while reducing the disadvantages.

There is quite a bit of scope of supporting developing countries in analyzing the trade-offs for the inclusion of socio-economic considerations and to allow the appropriate implementation of socio-economic considerations within biosafety decision-making so as to overcome disadvantages of doing so. In this process it is necessary to consider the descriptors of a functional system, suggested by Jaffe, in order to ensure that the inclusion of socio-economic considerations do lead to a functional biosafety system, which will approve safe and valuable products that may reach producers while not approving unsafe and/or worthless products. Perhaps one of the most difficult issues to overcome is that of competing assessment outcomes. Society and countries need to define how they will decide between potentially conflicting outcomes from a biosafety and a socio-economic assessment. This decision-making process will require extensive participation and transparency for its design and implementation. In this sense, developing countries will need much more guidance in terms of deciding between alternate policy options than what international research and policy organizations have done so far. Countries are likely to confront the same issue when the issues of trade, environment, and biodiversity collide in the biotechnology policy and decision-making arena. The latter is a developing story that will need proper attention in the near future.

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