**Socio-economic considerations, biosafety and decision-making in developing countries: Towards a Feasible regulatory system**

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**Introduction**

Article 26.1 of the Cartagena Protocol (see below) opened the possibility of including socio-economic considerations as part of the decision making process. Important issues to consider are that implementation of this article is **voluntary** and that it has a **limited scope**to those factors affecting biodiversity especially regarding its value to indigenous and local communities.

The Cartagena Protocol **does not mandate** the inclusion of socio-economic considerations, although countries have the sovereign right of doing so in their national laws and regulations, but being consistent with their international obligations.

Introduction of broader socio-economic considerations into GMO biosafety analysis and the decision-making process is controversial as there are many approaches an options for regulatory design, development and implementation, which in turn have implications in terms of costs, benefits, risks and tradeoffs in terms of technology use, safety, gains in knowledge and regulatory impact.

It is certainly prudent for countries to consider all of these issues, starting from the most basic question of why each country wants to include socio-economic considerations into their technology decision-making processes. Regardless of whether a country has made a decision in the matter, for transparency purposes, policy and decision makers have to have a clear response to this question. I will cover later in future posts, many issues, options and tradeoffs related to this policy issue.

***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.

**What do we know about the economic assessments' literature done in developing countries?**

In 2008, we conducted a literature review of 137 publications, which were chosen from an initial Google Scholar search that yielded more than 10,000 hits. We selected only those publications with an identifiable peer review process and a stated economic assessment method as a requisite for publication. We classified studies according to the unit of assessment studied, including measuring impacts on farmers/households, trade, industry/national, and consumers.

The literature review showed that:

* Bt cotton is the most-studied crop and trait combination
* Most studies were conducted in China, India, and South Africa
* On average, the adoption of Genetically Modified crops was profitable—but averages mask variability by agro-climate, host cultivar, and farmer
* This collection of studies concluded that too few traits have been studied and there are too few cases/authors implementing such studies. Taking this into consideration, generalization about all GM crops should not be drawn yet.
* Assessment methods need improvement, especially those dealing with household decision-making processes, risk and uncertainty, different types of selection bias, and endogeneity
* More time is needed to describe adoption and better methods to describe adoption in an ex ante setting.

Research in the next decade needs to focus on:

* Information and knowledge flows (to/from farmer )
* Gender, generational and other cross-cutting issues
* Impacts on poverty and inequality
* Externalities and other institutional issues

**Impacts on Farmers**

Our review of 137 published papers in the economics literature was disaggregated by the typical sampling levels used in field research that examines the adoption and impact of Genetically Engineered (GE) technologies. The levels include farmer, consumer, trade, and industry. Here we present salient notes from the impact on farmers.

Peer-reviewed research indicates that, on average, during the first decade of their use by smallholder farmers in developing economies, transgenic crops—and in particular Bt cotton—provide economic advantages for adopting farmers. There are several methodological limitations associated with the first generation studies which have been identified in most cases by the authors themselves. These limitations have implications for findings and for policy formulation. They should also be addressed (and are being addressed) in the next generation of studies.

* The majority of studies reviewed used primary field data collected from farmers, farm records, or field trials conducted by researchers
* Most ex post (after deliberate release) studies used methods such as partial budgeting/farm accounting and a specification of a model grounded on theoretical economics frameworks such as production functions or random utility models.
* Few studies have been ex ante (before deliberate release). Most of these use field data and an econometric estimation to then project potential economic impacts.
* Most studies focused on Bt cotton and were conducted in India, China, and South Africa.  This is not a surprising outcome as this was one of the first and most widely diffused technology in developing countries.
* A set of studies in Mexico and Argentina examined the implications of intellectual property rights on economic benefits earned by farmers.

Literature review caveats:

* On average, across all studies, farmers gained from the introduction and use of GM technologies. This does not mean that all farmers profited from its adoption. Furthermore, the magnitude of economic benefits varied widely across geography and the nature of the cropping season. These outcomes are neither surprising nor specific to transgenic technologies.
* The study period length had a dramatic impact on findings. The nature of adoption, technology impact, and innovation processes usually develops over time and, in some cases, it may take decades for such processes to completely unfold. This has major implications for technology assessments and for technology assessments within a regulatory process such as biosafety.
* Since the majority of studies were conducted early in the adoption process, they focused on first round impacts on yields, pesticide changes, and impacts on other inputs such as labor.
* Some attention has been paid to impacts on poverty, inequality, health, and the environment. Due to the time period during which the studies were conducted, the later assessments were done fairly simply, using mostly indicators rather than formal economic theory or frameworks.
* Few authors have studied few events to date. As a result, generalization about other events can’t be made.
* Most studies reviewed need to address selection, measurement, and estimation biases and thus endogeneity. Researchers have to consider such sampling and statistical issues when designing field surveys, especially in ex post studies and when using data collected for baselines and/or the basis to conduct projections/estimations in ex ante studies.

It is important to point out that the issues, methods, and analysis are intricately interconnected. The issues will determine the methods, which will be limited by the way in which the assessment is conducted within the regulatory system. If the assessment is conducted before deliberate release (ex ante), there is no adoption to measure and thus no data to be collected on adopters. This will reduce the portfolio of methods that can be used for the socio-economic assessment.

If the assessment is done after deliberate release (ex post) then the issue becomes designing appropriate data collection approaches that explicitly consider avoiding sampling and statistical bias. Note that practitioners can and have used survey data collected on the current producers using existing technologies in order to project potential benefits and all available secondary data.

Differentiating between a baseline and a counterfactual is critical. A baseline is a state of nature measured before the intervention by which to compare the state of nature after the intervention. A counterfactual is that state of nature that would have happened without the intervention. In social and economic analysis, we do not have the luxury of controlled experiments--though significant progress has been made in quasi-experimental approaches such as difference in difference approaches---by which to isolate the treatment from other confounding factors.

Most economists prefer using a counterfactual because of the limiting nature of social and economic baselines; other external factors may have also taken a role in explaining the observed state of nature with the intervention. Usually, the issue is then selecting or constructing a counterfactual as it is not observed in practice.

Here is a very partial list of methods that have been used for economic-based studies. Other lists compiled in different venue are available for broader social, anthropological, cultural, and ethical assessments.

*Farmers*

* Partial budget/accounting
* Econometric/statistical estimations

*Consumers*

* Willingness to Pay (WTP)
* Changes in consumer perceptions
* Impact on health
	+ Daily Life Year Adjusted (DALYs) lost
	+ Use of consumption patterns to project changes in fortified foods

*Sector*

* Economic surplus
* Stochastic economic surplus
* Real options
* Damage abatement
* Partial budgeting
* Stochastic partial budgeting
* Linear and non-linear programming methods
* Stochastic simulations
* Farmer decision models (lexicographic learning approaches)
* Applied Computable General Equilibrium (CGE) models – village, region, national and regional levels

*Trade*

* Trade models using GTAP (Generalized Trade Analysis Project)
* Applied CGE models
* Partial budget
* Partial equilibrium / economic surplus models

**bEcon: Economic assessments of Genetically Engineered Crops**

bEcon is a web-based bibliography developed by researchers at the International Food Policy Research Institute (IFPRI). It is a selective collection of peer-reviewed applied economics literature that assesses the impacts of genetically engineered (GE) crops in developing countries. The webibliography focuses on four major research questions addressed in the literature:

* What are the (potential, actual) advantages of genetically engineered crops for farmers?
* What are consumers willing to pay for non-GE products, and how will their preferences affect the market?
* What are the magnitude and distribution of the economic benefits resulting from the adoption of GE crops in a particular industry (sector)?
* What is the international distribution of economic benefits resulting from the adoption and trade of GE crops?

Consult online: <http://www.ifpri.org/publication/becon>

**Ex post vs. ex ante assessments**

Distinguishing between ex ante and ex post assessments is an extremely important distinction that needs to be discussed and understood. If countries introduce socio-economic assessments as part of the technology approval process before deliberate release (ex ante), this decision will have a different implications than the two alternatives: requiring only assessment for post deliberate releases (ex post), or requiring assessments for both ex post and ex ante.

In the case of ex ante assessments, there will be implementation limitations in terms of the type of methods and approaches that can be used for the assessments. These are mostly driven by the lack of the specific technology adoption and/or use data. Most of the data available will come from confined field or performance trials, expert opinion, or other secondary data. An element of best methodological practice will the addressing the lack of knowledge and uncertainty with regard to many parameters in the assessment. In fact, most of the methods in ex ante assessments  are a type of projection, simulation, or may use foresight approaches for implementation.

In the case of ex post assessments, there is quite a bit of experience in terms of implementation, although much more needs to be done in terms of methods (See Smale et al. 2010).

**Socio-economics and practical biosafety regulatory design**

The main objective in discussing regulatory design is to suggest to developing countries that it is prudent to carefully assess and define whether or not to include the socio-economics into the decision-making process and to define all of the steps in the process once the decision is made before attempting to implement such inclusion.

We think that it is critical to clearly define how socio-economic assessments will be used for decision-making in order to avoid having incongruities and to allow transparency so that everybody is clear about what will be expected in such a decision-making process. This will allow developers to assess whether they want to enter a market or develop a product for a specific market and for consumers understanding the rationale behind the decision rendered by the competent authority. Clarity can only introduce confidence into the system and help all stakeholders trust such decisions.

In the end, Countries have **many** choices in terms of how they can implement the inclusion of socio-economic considerations into decision-making. We can consider the following decision-making nodes for regulatory design. I will provide an expanded description of these in subsequent posts. In most countries, decisions related to the options presented here may be better and more flexibly addressed in implementing regulations rather than in laws or policies. This will ensure that changes can be made readily if the regulatory system considers potential alternatives to comply with inclusion of socio-economic considerations into decision-making.

**1.  Type of inclusion?**

* No inclusion
* Mandatory
* Voluntary

**2. Scope?**

* Narrow interpretation of  article 26.1
* Narrow set of socio-economic issues
* Broader set of assessments (Socio-Economic Impact Assessments or Sustainable Livelihoods)

**3. Approach?**

In contrast to the environmental and food/feed safety assessment, SEC assessment can be implemented:

* Concurrently but separately
* Sequentially
* Embedded

Which implementation entity?

* Independent (third party)
* Proponent
* Specialized full time unit within regulatory agency or government

Do you allow data from other countries with similar agro-ecological and/or social characteristics?

**4. Assessment trigger?**

* Each submission
* Event-by-event
* First proponent within an event class (i.e. insect resistant cotton or drought tolerant maize)

**5. When?**

* Laboratory/greenhouse
* Confined Field Trials
* Commercialization
* Post release monitoring

Commercialization and for post-release monitoring?

At all stages?

**6. How?**

* Choice of methods for *ex ante* assessments (before approval for deliberate release) is much more limited than for *ex post*
* Decision-making rules and standards
* Multi-disciplinary method integration, standards, and the decision-making process tolerance to errors

**Potential implications from the inclusion of socio-economics**

Here I present some of the potential implications from the inclusion of socio-economic consideration assessment in biosafety and biotechnology decision-making processes. Whether a specific implication applies to a specific country will depend on its regulatory context and status. Furthermore, the intensity level of each implication will also vary from country to country. Note that in many situations some implications listed here can be managed or mitigated through flexible and intelligent regulatory design.

* Regulatory costs of compliance with biosafety regulations will increase.

Conducting a socio-economic study will have a cost attached to its implementation. The more complex and broader the selection of issues to include in an assessment, the more expensive a specific study will be to any developer, other things kept equal. It is certainly not the same level of complexity to implement an economic study focused on a very specific topic (i.e. impact of exports /trade or impact on small scale producers) versus one that may examine impacts on biodiversity and long term sociological/anthropological issues.

Choice in terms of scope will have different cost implications. A broader set of issues incorporated into a study will likely require a multi-disciplinary team and is likely to need additional time and more resources than a narrow set of issues. This fact has clear implications for capacity strengthening in those countries who want to implement socio-economic assessments as part of a regulatory process.

Cost is usually not as important as time delays. The exception would be in those situations where cost is high enough that it becomes an insurmountable hurdle to a developer. I am thinking specifically on the public sector in developing countries that are likely to develop technologies of a public good nature. In essence, introduction of additional regulatory hurdles can impact national and international public investments in research and development.

Introduction of socio-economic considerations can have another important impact and that is a reduction in the number of potential technologies available to producers and society. This may be a result of additional regulatory complexity, cost implications and/or uncertainty (see below).

* Potential regulatory delays can have a major impact in terms of economic benefits to society.

In a paper that I co-wrote with Jessica Bayer and George Norton (Bayer, Norton and Falck Zepeda 2010) we showed in a simple experiment that delays can have a big impact on the net benefits from four LMO  applications in the Philippines.  In this paper, we showed that even small delays of three years compared to the baseline can decrease significantly net benefits to producers. Increases in cost of compliance had a very small effect on net benefits.

* Society does gain knowledge and information on technology impacts and potential issues that may affect such outcome.

The issue is then to compare the immediate costs of compliance with biosafety regulations -this does apply not only to socio-economic considerations but also to the environmental and food/feed safety assessment- with the delays in the onset of benefits, and both with the future gains in knowledge. The examination of these issues should consider the uncertainty surrounding these issues.

In a paper Kikulwe, *et al.* ( 2011) examined all some of  these issues and trade-offs within the scope of cost and benefit irreversibility in a real options model with an application to fungal (Black Sigatoka) resistant bananas in Uganda. Interestingly enough, the authors found out that even when considering all of these issues, every year that Uganda delays in approving such technologies, society loses 200-300 million US$.  Bananas are a staple crop in Uganda having large food security and poverty impact implications. The fungal resistant banana is being developed by the public sector.

Decision makers in practice may face two distinct set of situations with increased knowledge. One where additional knowledge may help weed out unsafe and/or undesirable technology or product, as is may have a negative socio-economic impact. Second, a situation may exist were a technology that has been deemed as “safe” by the biosafety assessment process can actually be not approved due to a "negative" *ex ante* socio-economic assessment. These two cases open a lot of discussions in terms of the reliability/verifiability of SEC studies and who is the appropriate entity to make decisions about technology (i.e. producers versus SEC assessors versus regulators/decision makers).

* Potentially introduce more uncertainty to the process

A workable system can be defined as one where all elements of society are able to define, describe and trust the process and its outcome.  Society actors can thus judge the system based on transparency, participation ability, predictability and robustness. These attributes are important for society actors’ decision making processes.

For example, if developers (be it public or private sector) face a predictable regulatory system, they can attach a value on outcome and the respective probabilities of success into their decision making process. If developers cannot attach such probabilities the likelihood is that they will not make investments in such jurisdiction. The potential impact of uncertainty on the public sector will be of relevance to many developing countries who have already invested in developing products of their own (See Atanassov 2003). Uncertainty is connected directly with rules and standards for implementation and decision making.

* Inclusion of SEC may lead to an unworkable system if rules and standards are not clear or are open ended and subject to many interpretations
* In most situations, the best alternative is to have rules and standards for implementation and decision making in implementing regulations. This is extremely important as the need may arise of changing procedures later on as the regulatory system gains experience and familiarity with products in the regulatory pipeline. Having an unworkable system, or one that cannot render a decision in a timely, cost efficient manner and whose decision is robust, protective and accepted by society; is not a desirable outcome and is a questionable use of scarce societal resources.

*Biosafety and public sector innovation*

IFPRI, as an international non-governmental organization, is particularly interested in those crops and traits of a public good nature where the public sector will take a large role in their development. Those products released to date, with a few exceptions such as those Bt cotton events developed by the public sector in India and China, have been private sector developed product for producers in industrialized countries. The opportunity arose to diffuse these technologies to farmers in some developing countries with outcomes such as the ones we have described in our literature review (Smale et al. 2009). This was an incidental development.

IFPRI focus is on the many public sector developed technologies by national research systems in developing countries and the international research community which are likely to address crops and traits of interest to farmers. We refer here to technologies such as the Black Sigatoka resistant bananas in Uganda, the Bt cowpea, the Bt eggplant, viral resistant cassavas and sweet potatoes, water efficient maize and sorghum, biofortified products, and others documented in Atanassov et al. (2003) and for Latin America in Falck Zepeda, et al. (2009) and Trigo et al. (2010). The consequences of regulatory development to the public sector and the budding domestic private sector in developing countries are an issue IFPRI is addressing currently.

**Summary**

1) The inclusion of socio-economic considerations under Article 26 of the Cartagena Protocol on Biosafety (CPB) is voluntary. It is not a mandatory requirement, thus countries have the freedom of choosing whether to make it voluntary, mandatory or not required at all.

2) The literal/strict interpretation of Article 26.1 of the CPB is that inclusion may consider impacts on biodiversity, especially on local and indigenous communities. The inclusion of broader socio-economic and other considerations may be done under national laws and regulations.

The issue of whether Article 26 allows the inclusion of food/feed safety and public health considerations as part of its scope is a bit vague. On the one hand, the CPB itself has mutated from a strict environmental treaty seeking to protect and enhance biodiversity while allowing the safe use of LMOs to one where it becomes a *de facto* risk assessment treaty for LMOs covering all general aspects in an evaluation system including environmental, food/feed safety and public health issues.

On the other hand, countries maintain the sovereign right within the scope of their international obligations to do what they want in terms of assessments. The question then becomes, what will the Parties choose: a narrow/strict versus a broader interpretation of Article 26?

3) Countries certainly have the sovereign right o make decisions in their national laws and regulations on:

a) Whether to include (or not) socio-economic considerations in their decision-making.

b) Expand on the narrow definition of the article to broader considerations.

c) Define any implementation and decision making process, scope, implementing agencies, and others. This implies that nations have the sovereign right to choose between a system with no requirement whatsoever and a system with broad assessments that include their choice of issues for considerations--or any system in between.

Participants in many discussions, have reaffirmed directly or indirectly these basic concepts. We hope that while making their decisions, countries take into consideration all potential development and implementation implications--both negative and positive.

4) Some countries that are party to the CPB are planning to include or have already included socio-economic considerations in their decision-making. Modalities vary from “narrow” economic impacts on trade and on their own export competitiveness to inclusion of broader social, ethical, and religious considerations.

5) Inclusion of socio-economic considerations has many implications that countries need to be aware in order to empower them in making an informed choice. Implications include:

a) Increased regulatory compliance costs.

b) Gains in knowledge about the potential technology in the hands of farmers.

c) Reduction in the number and type of technologies available for release if a cost increase is binding to developer’s budget. This is of special interest to the public research sector.

d) Potential for selecting the best technologies (and to compare with other potential alternatives) and to weed out those technologies that are not safe or may have a negative impact on biodiversity and other socio-economic issues.

Alternatively, the inclusion of socio-economics issues in the regulatory decision making process can cause the rejection of safe technologies. This fact calls attention to the question of how to judge socio-economic studies for quality and robustness. There is need to define how scientific peer review will be used in these situations.

6) Implementation issues include:

* Developing a list of socio-economic issues for inclusion without considering implementation procedures can lead to an unworkable system. One cannot disassociate legal/policy/regulatory development from implementation; experience has shown that these two factors need to be discussed simultaneously. Those of us who have been involved heavily with socio-economic assessments know the many limitations and issues that methods and approaches have in practice.
* Yes, there is a lot of experience dealing with relatively simple assessment procedures such as simple cost/benefit, with different regulated technologies and activities, and yet, as we discovered in our review of economic methods (see Smale et al. 2009), we need to further develop our methodological toolkit if we want to examine broader social and economic issues such as gender dimensions and impacts on poverty, food security, and public health.

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