



AgEcon SEARCH
RESEARCH IN AGRICULTURAL & APPLIED ECONOMICS

The World's Largest Open Access Agricultural & Applied Economics Digital Library

This document is discoverable and free to researchers across the globe due to the work of AgEcon Search.

Help ensure our sustainability.

Give to AgEcon Search

AgEcon Search

<http://ageconsearch.umn.edu>

aesearch@umn.edu

*Papers downloaded from **AgEcon Search** may be used for non-commercial purposes and personal study only. No other use, including posting to another Internet site, is permitted without permission from the copyright owner (not AgEcon Search), or as allowed under the provisions of Fair Use, U.S. Copyright Act, Title 17 U.S.C.*

“The Status of the Inclusion of Socio-Economic Considerations in Biosafety Regulations and Biotechnology Decision Making Processes in Southern and East Africa: Practical Implications and Consequences for Innovation Governance”

Jose Falck-Zepeda, Doreen Shumba Mnyulwa, Dorothy Mulenga, Marnus Gouse, Patricia Masanganise¹

JEL classification codes

O32 - Management of Technological Innovation and R&D

Q16 - R&D; Agricultural Technology; Agricultural Extension Services

L50 - Regulation and Industrial Policy - General

Corresponding Author Postal Address and Email

Jose Falck Zepeda

IFPRI

2033 K Street NW

Washington, DC 20006-1002

USA

j.falck-zepeda@cgiar.org, j.falck@gmail.com

Abstract

The paper discusses the current status of the inclusion of socio-economic considerations into biosafety and biotechnology decision making processes, laws and regulations in Botswana, Malawi, Swaziland, Tanzania, Zambia, Zimbabwe, Uganda, Kenya and South Africa. The discussion includes relevant issues related to the biosafety and socio-economic assessment processes while comparing and contrasting national regulatory developments with obligations subscribed by parties to the Cartagena Protocol on Biosafety in Southern and Eastern Africa. The paper also discusses the conceptual issues related to socio-economic assessments relevant to biosafety regulatory procedures including those considered in *ex ante* assessments for regulatory approval procedures and *ex post* for post-release monitoring or conventional technology evaluator procedures. The paper discusses practical considerations for the inclusion of socio-economics in biosafety regulatory processes including inclusion options, scope, timing, implementing body, methods, decision making rules and standards, and integration of technical biosafety research and socio-economic into a cogent decision making process. The paper concludes with a discussion of potential implications and positive and negative consequences from the inclusion of socio-economic considerations in biosafety decision making and for the governance of biotechnology innovations in developing countries.

Keywords: biosafety, biotechnology, socio-economic assessment, regulation, Southern Africa, Eastern Africa, developing countries

¹ Jose Falck-Zepeda is a Research Fellow IFPRI. Doreen Shumba Mnyulwa is the Regional Director, RAEIN Africa Namibia. Dorothy Mulenga is the Leader Policy Group, RAEIN Africa Namibia. Marnus Gouse is a Researcher, University of Pretoria South Africa. Patricia Masanganise is a Consultant, Agriculture, Food Security and Livelihoods Development, South Africa.

“The Status of the Inclusion of Socio-Economic Considerations in Biosafety Regulations and Biotechnology Decision Making Processes in Southern and East Africa: Practical Implications and Consequences for Innovation Governance”

The decision making process for the experimentation and deliberate release of regulated products such as genetically engineered crops meant that developing countries faced new (sometimes unfamiliar) policy choices in areas related to modern biotechnology. The policy choice portfolio included areas such as intellectual property rights, biosafety regulatory issues, trade, food/feed and environmental safety, consumer choices and public participation. The policy choice portfolio was further complicated due to the interactions of biotechnology innovations with the political, ethical, cultural, social and economic imperatives’ context for developing countries and the implications of such interactions on policy choices.

A major policy choice was the decision to frame the biosafety assessment process in an international protocol where parties agreed to a common process regulating genetically engineered crops and other organisms. The international protocol, the Cartagena Protocol on Biosafety, is supplementary agreement to the Convention on Biological Diversity. The Cartagena Protocol was adopted by the Conference of the Parties to the CBD on January 2009. The Protocol entered into force September 2003 and now has 158 countries deemed parties to the Protocol.

The objective of the Cartagena Protocol is to provide a common framework to ensure an adequate level of protection related to the safe transfer, handling, and use of “living modified organisms resulting from modern biotechnology” that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health with a specific focus on transboundary movements (Article 1 of the Protocol, Secretariat

of the Convention on Biological Diversity, 2000). The initial focus of the Cartagena Protocol on Biosafety was environmental. This focus was later expanded to include food/feed safety and other public health concerns. The Protocol contains Article 26 that gives countries the option to include socio-economic considerations in their decision making, but the Protocol does not provide any guidance in terms of how to implement such assessments.

This paper is organized as follows. First, the paper provides a basic understanding of Article 26. Second, we describe the current status of biosafety frameworks in Southern African countries and expand on the status of the inclusion of socio-economic considerations in decision making in the region. Third, we discuss practical considerations that Southern African countries will likely face if they want to include socio-economic considerations in their decision making. Finally, we conclude with some region specific recommendations to ensure that the inclusion of socio-economic considerations contribute to the establishment of a feasible, transparent, efficient and protective biosafety regulatory system.

Article 26 of the Cartagena Protocol on Biosafety

Box1 contains the full text of Article 26 of the Cartagena Protocol on Biosafety. To assess the potential implementation issues and consequences, it is useful to split the Article into its parts (As shown in Figure 1). We will focus on Article 26.1 as it is the implementing component of the article, whereas 26.2 relates to information exchange which is a non-controversial issue.

The first part of Article 26.1 indicates that implementation can follow the minimum floor established by the Protocol which deals with transboundary movements. However, this option can be expanded by domestic laws and its requirements. The second part is an indication that application of Article 26.1 is not mandatory leaving countries the option to decide what is the

appropriate course of action to regulate products in their jurisdiction. The third part indicates that application of socio-economic considerations in a specific country has to comply with all international obligations. The obvious treaty related to transboundary movements is the WTO. There is no clear indication of whether socio-economic considerations can be legally included in a biosafety assessment under the provisions of the WTO. A definitive resolution will probably have to wait until a country's decision in a biosafety regulatory process is challenged by another under the WTO court ruling mechanism.

The fourth part introduces a scope for the socio-economic assessment. A strict interpretation of the scope in this part of the article limits the socio-economic assessment to the impact from the use of a genetically modified organism on conservation and sustainable use of biological diversity. Depending on how the user interprets this scope, this may allow inclusion of socio-economic benefits derived from the use of genetically modified organisms themselves, which is the traditional focus of most socio-economic benefit assessments. The final part of article 26.1 seems to describe an impact parameter and target stakeholder group for the socio-economic assessments. As indicated previously, we can think of the strict interpretation of Article 26.1 of the Cartagena Protocol as the minimum floor for a socio-economic assessment, if countries laws and regulations do require such assessment. This Article certainly leaves open the possibility for countries to go above and beyond this floor if they decide to do so in practice.

Box 1. 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.

Certainly in democratic societies the need exists to perform socio-economic assessment to measure the consequences from the adoption of GM organism innovations and its distribution across different agents/stakeholders, the environment and other areas of social concern. To establish a complete assessment of all social consequences, countries are advised to include in such assessments the costs and benefits of the biosafety regulatory system and its impact on the innovation system. In this sense, the impact assessment of technology adoption and regulations allows society to make informed decision that may improve society's welfare.

Status of National Biosafety Frameworks in Southern Africa

The Biosafety Clearinghouse defines a National Biosafety Framework (NBF) as those regulatory systems that may include a combination of policy, legal, administrative and technical instruments that are set in place to address safety for the environment and human health in relation to modern biotechnology. Understanding the current status of National Biosafety Frameworks in Southern African countries will help value the current status of the inclusion of socio-economic considerations into biosafety decision making processes.

To understand the degree of development we have grouped Southern African countries into four groups. The first group is composed of those countries with a “Functional” NBF. These are countries that have approved policies and bills, and their regulations. The second group is those with an “Advanced” development stage. These are countries where policy and legislation have been drafted and approved by their governments and may have draft regulations. Countries listed as “Partial Development” have a draft Policies and bills, and have initial work completed on regulations. The final group are those countries where “No action taken”. These countries are those where there has not been any identified progress in terms of policies, bills or regulations.

Note that this classification system is a somewhat subjective and has some limitations. Certainly having policies, laws and regulations may be necessary but not sufficient to ensure a

functional biosafety system. Furthermore, some countries around the world do not have explicit biotechnology and biosafety policies or bills, basing their regulatory framework on existing laws and regulations. We can view this classification as an indirect measure of status, not necessarily of regulatory performance. With these caveats in mind we can tentatively distribute Southern African countries into these categories.

Based on this classification the only countries with a “Functional” NBF are South Africa and Zimbabwe (Table 1). In turn those countries defined as “Advanced” include Namibia, Malawi and Zambia (Table 2). Countries with a “Partial Development” NBF include Botswana, Democratic Republic of Congo, Lesotho, Mozambique, Swaziland, Seychelles, and Tanzania (Table 3). In turn, the only country where no identifiable action has been taken to date is Angola (Table 4).

The potential limitations of the previous classification can be shown when one lists the stages of the biosafety regulatory process that have occurred to date. As can be seen in Table 5, the only country that has implemented all biosafety regulatory stages from approvals for experimentation to commercialization in practice is South Africa. The only other country that has had an approval for confined field trials is Zimbabwe. In turn the rest of countries in the region do not have approvals for experimentation, confined field trials or commercialization. In essence, countries may have all legal regulatory instruments by which to regulate new technologies. In practice until countries undergo and complete a regulatory approval process, they can be ensured that their biosafety system is indeed feasible and functional.

Socio-economic inclusion status in Southern Africa

Table 6 considers the status of socio-economic inclusion in biosafety policies, laws, or regulations in Southern African countries. Most countries in the region have already incorporated the need to include socio-economic considerations in their biotechnology and/or biosafety

decision making processes through policies, laws and/or regulations, but none has specific implementation guidance for such inclusion. Note that even in a country such as South Africa, where commercialization approvals has occurred, guidelines do not give guidance in terms of implementation. This is important because if countries do not establish a system that is clear, feasible and fair, to include socio-economic considerations in decision making, the distinct possibility exist of rendering the whole biosafety system inoperable and thus becoming an insurmountable hurdle for innovation and thus denying farmers the possibility of accessing potentially valuable technologies.

An interesting development is the inclusion of a decision making standard in Swaziland's National Policy. This country national policy describes that "A positive decision based on scientific risk assessments can be overturned on the basis of negative socio-economic risks, whilst a negative decision based on scientific risk assessment cannot be overturned on the basis of socio-economic reasons."

Issues with Regard to the Inclusion of Socio-Economic Issues in Biosafety

Policy makers and regulators in Southern Africa and in other regions, who intervene in designing a biosafety system and who may consider inclusion of socio-economic considerations into biosafety and/or biotechnology decision making, need to address a set of concerns before settling into a specific approach. Discussion of the following issues will emphasize those concerns for *ex ante* evaluations although the discussion for *ex post* assessments in a post-release monitoring situation is likely to face similar issues.

Scope

The procedure for inclusion of socio-economic considerations must define whether the standard or operating procedure will follow a strict interpretation of Article 26.1 of the Cartagena Protocol

or will consider a broader mandate under national regulations. Furthermore, inclusion procedures need to define whether inclusion is mandatory (i.e. required by national regulations or procedures) or voluntary for the developer. Finally, inclusion procedures need to define whether to include socio-economic issues only, or if they should be broadened to include, as some countries seem to suggest, ethical, philosophical, or religious considerations.

Inclusion of broader considerations will expand the range of questions and thus the range of methods to be used for the evaluation, while at the same time, increasing the importance of defining method feasibility especially for *ex ante* evaluations. Assessment practitioners can describe the potential ethical, religious and philosophical impacts from the adoption of a GE crop by using qualitative and participatory approaches for evaluation. Incorporating results from broader-type assessments to regulatory processes might be hard to accomplish for decision-making as it incorporates judgment values, difficult to incorporate in a biosafety assessment.

Timing

Inclusion procedures need to define when is the appropriate stage for the proponent to include socio-economic considerations assessment for review by the regulatory body. In those systems where inclusion is mandatory, policy makers in Southern Africa need to raise several questions. Will inclusion procedures require (or consider) socio-economic considerations during laboratory/greenhouse, confined or multi-locational field trials, or during commercialization applications? Will the biosafety system consider only those assessments after deliberate or general release? For example, socio-economic assessment can be considered a requirement for renovating temporary commercialization permits customarily given to proponents in most countries as done by the European Union.

The timing decision has many issues and trade-offs to consider. As the technology progresses through the regulatory pipeline, developers may gather additional information regarding the product's field performance –although in most cases practitioners have to be cautious with the interpretation as it is experimental data- of the technology and thus may be worthwhile waiting for later stages of the regulatory process. In addition, spending scarce resources in products that the developer will not release to farmers (or the environment) is indeed a waste of money and resources. The implication of this issue is that policy makers in Southern African countries need to set clear guidelines about the appropriate assessment for each of the development stages, from laboratory/greenhouse, passing through confined field trials and finally, general/deliberate release.

Implementation modalities of the socio-economic inclusion process

Southern African countries have several options on how to implement the inclusion of socio-economic considerations into biosafety regulatory processes. The decision on which approach to follow will likely be based on the language of the policy, laws and regulations requiring such assessment, but also (hopefully) on a consensus amongst stakeholders.

No inclusion

The first option is no inclusion of socio-economic considerations in the decision making process. The regulatory system relies only on the risk assessment for approvals for confined field trials and general/deliberate release. The rationale behind this alternative is that developers screen the technologies for efficacy, regulators for safety, while allowing farmers to decide what the best technology for their context is. Certainly, the possibility exists that developers may volunteer a socio-economic assessment as part of the application dossier, but in this regulatory option, it is not mandatory for the developer to include such assessment or for the regulatory bodies to

consider the assessment itself. This is the current approach followed both in the U.S., Canada and others.

Concurrent but separate

A second option is to have concurrent but separate processes for risk and socio-economic assessments preferably by different assessors. In this regulatory process option, a technology decision-making entity later puts together both assessments and renders a decision. This option has the benefit of potentially reducing time delays and limiting the influence of politics (as opposed to fact gathering) in the assessment process. Examples of countries who have implemented this approach include Brazil and to a certain degree India.

Sequential

A third option is a sequential approach where proponents or professional evaluators perform the risk assessment first and only if the technology demonstrates its safety, then the technology proceeds to a socio-economic assessment before approval. An example of a country that follows this approach is Argentina, although the socio-economic assessment only considers impacts of the potential adoption on trade, specifically the competitiveness of Argentinean exports. A variation of this option is the approach followed by the European Union who now requires a post release monitoring for those temporary approvals of commercialization. Similar to the concurrent approach, this option isolates the risk assessment from politics while leaving the option open of considering politics in the technology decision-making process. At the same time it poses the risk of unnecessarily delaying the approval process.

Embedded

A final option is that of a socio-economic assessment that is embedded and perhaps inter-twined with the risk assessment. In this option, the risk assessment is done at the same time as the socio-

economic assessment. Depending on the specific process, the competent authority, full time assessors, commissioned to external experts, or by the proponent, may conduct both assessments. There is no strict separation between this option and the concurrent but separate option described previously. The difference lies only in the fact that the implementing agency conducts both assessments. The risk here is that this authority might have further difficulty in advancing the process given the multiple objectives it's pursuing and potentially conflicting methods how it should carry this process.

Implementation entity

Options available for discussion by Southern African policy and decision makers include the proponent, third entities commissioned by regulatory agencies, or professional assessors within the regulatory system. The choice of who will conduct the assessment will largely depend on the overall design of the biosafety regulatory system. As McLean et al. (2002) points out each one of these options have tradeoffs in terms of resources and capacities and will directly relate to the country's inventory of national capacities, the complexity of technologies being reviewed and the volume of regulated technologies under review.

The Methods – How?

The timing of the socio-economic assessment will largely drive the choice of methods that may be available to practitioners. Data and information availability, as well as the research questions and maintained hypotheses to answer or test, will define the type of methods that practitioners may use for socio-economic assessments. *Ex ante* assessments will be largely used during the biosafety regulatory approval purposes for decision-making purposes. In contrast, *ex post* methods will be used for post-release monitoring, for example in the case of products given

temporary regulatory permit pending further monitoring or in the case of conventional technology assessment procedures.

As described by Smale *et al.* (2009), for *ex post* evaluations assessors may need to use multiple methodological approaches to address multiple research questions but also to untangle many of the sampling and statistical biases that arise during adoption. Furthermore, practitioners may need to conduct assessments during multiple years to capture production variability and responses to abiotic and biotic constraints. The choice of methods will hinge on the data availability and assessment resources and capacities.

Each one of the potential assessment methods has specific data requirements and thus varies in terms of feasibility. For example, econometric/statistical adoption models require actual data and thus are of limited use for *ex ante* assessments. Certainly, the scope exists for using econometric/statistical methods for *ex post* assessments, where the limitation is the time and resources to collect the adequate volume of data. If the purpose of the socio-economic assessment is to evaluate adoption and technology impact *ex post*, then practitioners can follow the elements of best practice and lessons learned from accumulated assessment experience as described by Smale *et al.* (2009), Qaim (2009), Maredia, Byerlee and Anderson (2000) and Alston, Norton and Pardey (1995).

Decision making rules and standards

The biosafety regulatory framework in Southern African countries will need to define clearly methods, decision making standard and procedures used to assess socio-economic considerations in biosafety regulatory frameworks. This implies setting elements of best practice not only for conducting the assessment but also for decision-making. The standard and decision-making process needs to be transparent and predictable so that participants in the biosafety regulatory

process know what to expect during all stages of the biosafety regulatory process. For example, all stakeholders need to know in advance whether the socio-economic assessment should consider risks only, or will also include cost/benefits and risk. In addition, developers and assessors need to know the evaluation criteria including the standard for evidence, quality and sufficiency (Falck Zepeda 2009a).

Furthermore, the decision-making standard and assessment procedure need to be feasible and cost effective, while ensuring that the overall process is protective and efficient (Jaffe 2006). This implies that regulators and policy makers in Southern African countries need to conduct periodical Regulatory Impact Assessment (RIA) reviews, which may help streamline the process. Finally, as mentioned in the discussion of Article 26.1, inclusion of socio-economic considerations in national frameworks and biosafety regulations, need to consider its compliance with binding international treaties especially the World Trade Organization. This is extremely important as countries need to avoid being liable to violations to the terms of signed international agreements.

Integrating biosafety/biotechnology technical issues with socio-economics

This is perhaps one of the most contentious issues and difficult issues to resolve from a regulatory standpoint. Regulatory decision-making needs to consider inputs from different disciplines, methods and issues considered in a biosafety assessment. A typical application dossier for commercialization approval will have information on environmental, food/feed safety and perhaps socio-economic impacts and other considerations. Environmental impact assessments may consider for example gene flow assessments and impacts on non-targets, which in turn may have different considerations of their own. In its review, a regulator will need to consider a set of potential risk issues and formulate a decision, which balances all considerations.

It is important to underline the fact that much of the environmental and food safety assessment are expressed as likelihoods or probabilities of occurrence, and thus the possibility exists of having conflicting evaluations from socio-economic and from environmental risk assessment expressed in differential units of measurement.

Implications Derived from Inclusion of Socio-Economics

Compliance with regulatory regimes and a reduction in the number of new products released to farmers

The possibility of non-compliance with biosafety regulations increases when a biosafety regulatory system considers socio-economic considerations and there is no clarity in terms of methods and decision making standards. The consequence of such regulatory outcome will likely be a reduction in the number of technologies that may be released to farmers and consumers after regulatory review. This is especially true for those systems that make socio-economic assessments mandatory but which do not provide guidance in terms of assessment approaches nor clarity on how will the decision making will be implemented. Alternatively, excessively complicated rules and regulations for socio-economic inclusion which demand complicated assessments that may not be even feasible, especially *ex ante*, will achieve the same regulatory outcome.

Cost of compliance will increase – focus on the regulatory lag delays

Direct costs of compliance with biosafety regulations will increase with additional regulatory requirements including socio-economics. Furthermore, depending on the timing and scope, inclusion of socio-economic assessments may increase the time needed for completion of a biosafety regulatory assessment. Higher compliance cost may reduce investment in the development of regulated products such as GE crops. Depending on the relative contribution to

society welfare, this may represent a loss if regulatory systems do not release valuable and safe technologies to farmers. Furthermore, higher compliance costs may translate into higher social and/or private rates of return for regulated products and thus penalize public good technologies. This may be of particular interest for developing countries who may have crops and traits of particular interest due to their high social and economic value, but where there is very little regulatory experience elsewhere and where public sector R&D may have financial limitations for product delivery to resource poor farmers (Falck-Zepeda and Cohen, 2006).

We can differentiate the impact of higher regulatory costs by sector. Higher costs may force public research to invest more on non-regulated approaches. As cited in Falck Zepeda *et al.* (2009b), this may be happening already in Brazil and other places. For public goods the question of cost will connect directly to who will pay for development costs. In turn, the private sector may need to focus their research efforts on products with higher “private” returns. As seen in James (2008) although there has been an increase in the adoption over time of GE crops, this has been largely limited to four crops (cotton, maize, soybeans and canola) and two traits (insect resistance and herbicide tolerance). The importance of this fact is that almost all adoption in this limited set of crops and traits developed by the private sector may be a consequence of increased cost of compliance with biosafety regulations. Although the R&D pipeline is expanding the number of products that will be available in the market will still be mainly from these four crops plus rice (Stein and Rodriguez-Cerezo 2009), although the R&D pipeline in developing countries has many products for specific needs of developing countries (Atanassov *et al.* 2004)

If socio-economic considerations increase the time lag needed to complete the biosafety assessment, then the time value of money becomes important. In fact, cost of compliance with biosafety regulations may not be as important when compared to the total benefit stream derived

from adoption over time. Delaying the benefit stream is important to the technology's value for society as earlier returns are more important to the present value of benefits (Bayer, Norton and Falck-Zepeda 2010) and can be of significant social value to developing countries (Kikulwe, Wesseler and Falck-Zepeda 2008). In summary, when considering the inclusion of socio-economic considerations, policy makers need to consider not only the direct cost of such inclusion, but also the time for completion, method feasibility and the potential value of technologies entering the regulatory process.

Entry barriers and regulatory uncertainty

Inclusion of socio-economic considerations may render a biosafety regulatory process a non-functional process if it becomes an insurmountable regulatory hurdle. This is especially true if regulations, regulators or the biosafety assessment process require activities beyond those needed to demonstrate a socio-economic impact based on the decision making standard. This may be a result from inclusion of political processes that may cloud the assessment process by requiring answers to questions which may not be even feasible answering in an *ex ante* regulatory framework. In both situations, where socio-economic considerations increase the cost and time to complete a regulatory assessment process, this may constitute a barrier to entry for smaller organizations and the public sector as they may be less capable of complying with a cumbersome or unworkable regulatory process.

Human and financial capacity requirements for assessments

Socio-economic assessments of GE crops are not easy to implement. They require a degree of skill and experience dealing, with not only the socio-economic methods and approaches, but also require knowledge of the bio-physical sciences and the regulatory considerations that are

relevant to the assessment. Furthermore, GE crops add a series of challenges which are not typical of other agricultural innovations in the past, including intellectual property protection and imperfectly competitive input markets, differentiated markets, institutional limitations, and the fact that they are knowledge technologies (Falck Zepeda 2000, Smale et al. 2009). The methods and approaches need to reflect the increased complexity that these technologies face for adoption and use, tend to be more complex. The experts needed to evaluate GE crops will need to address this complexity especially for those assessments done in an *ex ante* frameworks as there is very little data to base assessments.

Conclusions

Our assessment of the current status of National Biosafety Frameworks in the Southern African region shows that only two countries have what can be considered as functional. These two countries are South Africa and Zimbabwe. Of these two, only South Africa has completed all regulatory review stages leading to the commercialization of a GE crop technology. In turn, our assessment of the current status of socio-economic considerations in biosafety decision making shows that the policies, laws and/or regulations in many countries in Southern Africa have a requirement to consider socio-economic issues but none has clear guidelines on how to implement such process into a feasible and functional biosafety system. This is a major gap in legal and regulatory development.

The gap in legal and regulatory development of not describing how to implement inclusion of socio-economic considerations has introduced much confusion at the country and regional level starting even from the basic issue of whether implementation is voluntary, all the to o explicit implementation questions such as those related to scope, timing, methods and others. Socio-economic considerations need to be assessed within clearly defined standards and

guidelines including methods, timelines, decision making standards vis-à-vis risk assessments. If socio-economic considerations are done within these standards they can be a powerful tool for the valuation of upcoming new technologies especially GE crops. On the other hand, if biosafety regulatory frameworks do not clearly define the inclusion of socio-economic considerations or such consideration become an insurmountable hurdle the result will be the reduction of potentially valuable technologies to farmers and consumers. Unreasonable regulatory delays affect negatively the stream of societal benefits derived from the adoption of GE crops. This has to be weighed against the potential damage from those technologies that are indeed harmful and regulatory approval errors with positive and negative impacts.

Inclusion of socio-economic considerations in a biosafety assessment in any of the modalities discussed in the paper, especially when the process does not clearly define the modality of inclusion, can increase the cost of compliance with biosafety regulations. If this is the case, then inclusion of socio-economic considerations may become a significant “barrier to entry” for some developers. This development is of interest especially to those developing pro-poor technologies including international agricultural research centers and the public and (domestic) private sectors in developing countries.

Finally, policy makers need to address the issue of regulatory predictability. Regulatory uncertainty can become a disincentive for R&D investments. In this scenario, the public sector or those interested in developing technologies with a public good nature are likely to be impacted more than technologies with a private nature. Furthermore, impact of regulatory uncertainty on R&D and tech transfer investments will be critical for future technologies not only GE crops but for other technologies in the agricultural research pipeline.

References

- Atanassov, A., A. Bahieldin, J. Brink, M. Burachik, J. I. Cohen, V. Dhawan, R. V. Ebor, J. Falck-Zepeda, L. Herrera-Estrella, J. Komen, F. C. Low, E. Omaliko, B. Odhiambo, H. Quemada, Y. Peng, M. J. Sampaio, I. Sithole-Niang, A. Sittenfeld, M. Smale, Sutrisno, R. Valyasevi, Y. Zafar, and P. Zambrano. (2004). *To Reach The Poor: Results from the ISNAR-IFPRI Next Harvest Study on Genetically Modified Crops, Public Research, and Policy Implications*. EPTD Discussion Paper 116. Washington, D.C.: International Food Policy Research Institute
- Alston, J.M., G.W. Norton and P. G. Pardey. (1995). *Science under scarcity: Principles and practice for agricultural research evaluation and priority setting*. Ithaca, New York: Cornell University Press.
- Bayer, J.C., Norton, G.W., Falck-Zepeda, J. (2010). Cost of compliance with biotechnology regulation in the Philippines: Implications for developing countries. *AgBioForum*, 13(1), 53-62. Available on the World Wide Web: <http://www.agbioforum.org>.
- Falck-Zepeda, J. (2009a). Socio-Economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake? *AgBioForum* 12(1):90-107.
- Falck-Zepeda, J., C. Falconi, M. J. Sampaio-Amstalden, J. L. Solleiro Rebolledo, E. Trigo, J. Verástegui. (2009b). La biotecnología agropecuaria en América Latina: Una visión cuantitativa. IFPRI Discussion Paper 860SP. Washington, D.C. International Food Policy Research Institute (IFPRI). Retrieved March 1, 2010 from <http://www.ifpri.org/sites/default/files/publications/ifpridp00860sp.pdf>
- Falck Zepeda J, and Cohen J. (2006). Biosafety Regulation of Genetically Modified Orphan Crops in Developing Countries: A Way Forward. In Richard Just, Julian Alston, and David Zilberman (Eds.), *Regulating Agricultural Biotechnologies and Policy* (pp. 509-534). New York:Springer Editors.
- Falck-Zepeda J, G. Traxler, and R. G. Nelson. (2000). Surplus distribution from the introduction of a biotechnology innovation. *American Journal of Agricultural Economics* 82: 360 - 369.
- Jaffe, G. (2006). Regulatory slowdown on GM crop decisions. *Nature Biotech* 24:748–749
- James, C. (2008). *Global Status of Commercialized Biotech/GM Crops: 2008*. ISAAA Brief 39. Ithaca, New York: International Service for the Acquisition of Agri-biotech Applications.
- Kikulwe, E., J. Wesseler, J. Falck-Zepeda. (2008). Introducing a genetically modified banana in Uganda: Social benefits, costs, and consumer perceptions. IFPRI Discussion Paper 767.

Washington, D.C. International Food Policy Research Institute (IFPRI).
<http://www.ifpri.org/pubs/dp/ifpridp00767.asp>,

- Maredia, M., D. Byerlee and J. R. Anderson,. (2000). Ex Post Evaluation of Economic Impacts of Agricultural Research Programs: A Tour of Good Practice. In *The Future of Impact Assessment in the CGIAR: Needs, Constraints and Options*. Rome, Italy: CGIAR Technical Advisory Committee Secretariat, FAO.
- McLean, M. A., R. J. Frederick, P. L. Traynor, J. I. Cohen, and J. Komen. (2002). A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity, and Regulation. International Service for National Agricultural Research (ISNAR) Briefing Paper #47, The Hague, The Netherlands.
- Qaim, M. (2009). The Economics of Genetically Modified Crops. *Annual Review of Resource Economics* 1:665-694.
- Smale, M. P. Zambrano, G. Gruère, J. Falck-Zepeda, I. Matuschke, D. Horna, L. Nagarajan, I. Yerramareddy, H. Jones. (2009). Measuring the economic impacts of transgenic crops in developing agriculture during the first decade: Approaches, findings, and future directions. *Food policy review* 10, Washington, D.C.: International Food Policy Research Institute (IFPRI) 107 pages.
- Stein, A.J. and E. Rodríguez-Cerezo. (2009). The global pipeline of new GM crops: implications of asynchronous approval for international trade. European Commission, Joint Research Centre, Institute for Prospective Technological Studies. Seville, Spain. Retrieved March 1, 2010 , from <http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=2420>

Tables

Table 1. List of Countries with a Functional National Biosafety Framework

Country	Status in Cartagena Protocol on Biosafety	Additional information
South Africa,	Acceded 2003	<ul style="list-style-type: none"> • The Genetically Modified Organisms Act No.15 of 1997 has been implemented since 1999. • The National Department of Agriculture (NDA), mainly the Biosafety Division houses the registrar of GMOs and is responsible for implementing the GMO Act. • The Act makes provision of the Advisory Committee and the Executive Council
Zimbabwe	Ratified 2005	<ul style="list-style-type: none"> • National Policy on Biotechnology (2005), the National Biotechnology Authority Act, the National Biotechnology Authority, and Biosafety Guidelines were all in place. • The Biotechnology Authority is the implementing entity • NBF is being implemented through the National Biosafety Board

Table 2 List of Countries with an Advanced NBF Development Level

Country	Status in CPB	Additional information
Namibia	Ratified 2005	<ul style="list-style-type: none"> • National Policy (1999), Biosafety Act (2005) & draft Regulations & technical guidelines. • Act establishes the Biosafety Council (decision making body) • Ministry of Education, Dir. of Research, S&T is the National Biosafety Authority –to implement the Act
Malawi	Ratified 2009	<ul style="list-style-type: none"> • National Biotechnology and Biosafety Policy - June 2008, Biosafety Act (2002-2007), Biosafety Regulations and Guidelines (June 2007) • The National Commission for Science and Technology (NCST) -biotech promotion and Environmental Affairs Department (EAD)- biosafety and biotechnology regulation, serves as secretariat to National Biosafety Regulatory Committee (NBRC)
Zambia	Acceded 2004	<ul style="list-style-type: none"> • Biotechnology & Biosafety Policy (2003): Biosafety Act (2007), draft Biosafety regulations and guidelines • Ministry of Science, Technology and Vocational Training is the National Biosafety Focal Point

Table 3 List of Countries with a Work in Progress NBF

Country	Status in CPB	Additional info
Botswana	Ratified 2002	<ul style="list-style-type: none"> • Currently using CPB, Draft Policy & Biosafety bill before Cabinet, • Department of Agriculture is the National Biosafety Focal Point
DRC	Acceded 2005	<ul style="list-style-type: none"> • <i>Updated Information not available</i>
Madagascar	Ratified 2003	<ul style="list-style-type: none"> • Director General of Environment is the National Competent Authority. • Working finalising NBF have draft law .
Mozambique	Ratified 2001	<ul style="list-style-type: none"> • Draft Biosafety Bill in place • Biosafety Focal Point is the Ministry of S&T • Country has an interim National Biosafety Working Group (GIIBS) coordinating the process for development of the NBF. • Regulation on GMOs, approved 2007
Swaziland	Acceded 2006	<ul style="list-style-type: none"> • National Biosafety Bill 2009 – currently in parliament awaiting approval into law. • National Biotechnology and Biosafety Policy in place. • The Swaziland Environment Authority (SEA) is National Biosafety Focal Point. • The Bill further establishes the National Competent Authority, the Swaziland Environment Authority Board - a decision making body, & the National Biosafety Advisory Committee
Tanzania	Acceded 2003	<ul style="list-style-type: none"> • National Biosafety Frameworks produced in 2005. • Tanzania does not have an independent Biosafety Act, rather the biosafety issues are a component of the Environmental Management Act of 2004 • Has a draft Environmental Management (Biosafety) Regulations
Lesotho	Acceded 2001	<ul style="list-style-type: none"> • <i>Updated information not available</i>
Seychelles	Ratified 2004	<ul style="list-style-type: none"> • <i>Updated information not available</i>

Table 4. List of Countries with a No action Yet on its NBF

Country	Status in CPB	Additional information
Angola	Signed the in 2005 was process of ratification in 2009.	<ul style="list-style-type: none"> • Angola Ministry of Environment is the National Focal Point. • Currently uses the Act of Ministerial Council 92/04 of 14/12/04 • Importation of GMOs implemented under the Ministry of Agriculture and Rural Development & a Law of Aquatic Biologic Resources, Law n° 6 – A/04 – which regulates importation of genetic modified species

Table 5 Status of National Biosafety Framework Implementation and Decision Making

Country	Party to the Cartagena Protocol on Biosafety	Approvals for experimentation / confined field trials	Approvals for deliberate release (Commercialization)	Commercialization effective
South Africa	Yes	Yes	Yes	Yes
Tanzania	Yes	No?	No	N/A
Malawi	Yes	No (1 application in process)	No	N/A
Namibia	Yes	No	No	N/A
Zimbabwe	Yes	Yes	No	N/A
Zambia	Yes	No	No	N/A
Angola, Botswana, DRC, Lesotho, Mozambique, Mauritius Swaziland, Seychelles,	Yes	No	No	N/A

Table 6 Status of Socio-Economic Considerations in National Biosafety Processes

Country	National Provisions of the Article 26 of the CPB	Implementation Mechanisms
Angola, DRC, Lesotho, Mauritius, Tanzania	Information not yet available	Information not yet available
Botswana	<p>Economic considerations: Focus on assessments of benefits of biotechnology and their relevance to Botswana development and environmental needs, Identification of potential niche markets, effective management of scientific research.</p> <p>Socio considerations focused on development of agriculture for food security at household, national and export levels to enable Botswana to cushion itself and compete within global market.</p>	Mechanisms not elaborated
Madagascar	Provisions requires that before imports of GMO and /or derived products of GMO in the country, a study of ethic and socio economic impacts on local population must be done. The study should include effects on: traditional markets and exports, systems of production (food security), socio ethic and moral issues, effects economic value of traditional species and effects on health of the communities	A study of ethic and socio economic impacts on local population, to be done before imports of GMO and /or derived products of GMO into the country. Does not provide guidance on the tool/methodology/approach to be used in doing the study.
Malawi	The Biosafety Regulations provides that in addition to the scientific risk assessment the NBRC shall consider socio-economic impact of the general release of GMOs on a community living in the proposed area for release.	The methodologies/tool on how to conduct a socio-economic assessment will be provided in the guidelines issued under the regulations.
Mozambique	Apart from scientific risk assessment report public contribution and other socio economic considerations have to be carried out.	Not clear on what and how – assumption this will be provided for in the regulations
Namibia	Biosafety Act Article 25 in paragraph 4 (b) makes provision for socioeconomic considerations, it states that “permission will not be given unless the Minister is satisfied that the GMO dealing being applied for is in the public interest” (meaning any issues of interest and concern, to the Namibian society).	The details of the implementation mechanisms and approaches to be clarified in the Regulations.

Table 6 Status of Socio-Economic Considerations in National Biosafety Processes (cont...)

Country	National Provisions of the Article 26 of the CPB	Implementation Mechanisms
South Africa	Provisions in the NDA function states “Facilitate a compliance system for assessing potential risks (scientific, economic, social and trade etc.) associated with the application of genetically modified organisms.	Clear scientific risk assessment, economic risk assessment and trade procedures to be carried out, but not clear on socio-economic issues.
Swaziland	<p>Adopted the protocol’s text when dealing with socio-economic issues in making her decisions. The government believes socio-economic considerations are vital to protecting the indigenous and local communities and users against any potential negative impact of GM products.</p> <p>According to the National Policy “A positive decision based on scientific risk assessments can be overturned on the basis of negative socio-economic risks, whilst a negative decision based on scientific risk assessment cannot be overturned on the basis of socio-economic reasons”</p>	No guidance in draft regulations
Zambia	The Biosafety Act has provisions for socio-economic consideration (Article 19 1(c)) as part of other issues to be considered in addition to scientific risk assessment	No guidance in draft regulations
Zimbabwe	<p>The national policy on science and technology states that “reproductive technologies in human beings shall be subjected to broad public debate, ethical discussion and possible regulation or restriction, keeping in mind cultural and religious feelings prevalent in the country and the necessity of not exploiting women.”</p> <p>The National Policy on Biotechnology provides for the inclusion of socio-economic considerations in biosafety decision making.</p> <p>Section 3(2)b of the National Biotechnology Authority Act states that “the Act shall apply to the import, export, contained use, release or placing on the market of any product of biotechnology that is likely to have adverse effects on human health, the environment, the economy, national security or social norms and values.”</p>	Existing regulations do not give details or guidance on how socio-economic issues are to be implemented in biosafety decision making. However section 22 of the Act empowers the Biosafety Board to develop standards and guidelines including those on socio-economic considerations.

Figures

Figure 1 Article 26.1 of the Cartagena Protocol on Biosafety

SOCIOECONOMIC CONSIDERATIONS

