Volume 17 Number 2 2016/pp.117-136 www.usask.ca/esteyjournal

The Estey

Journal of International Law and Trade Policy

Zen and the Art of Attaining Conceptual and Implementation Clarity: Socio-economic Considerations, Biosafety and Decision-making

José Falck-Zepeda
International Food Policy Research Institute, Washington, DC, USA
Stuart J. Smyth
Department of Agricultural and Resource Economics, University of Saskatchewan, Canada
Karinne Ludlow
Faculty of Law, Monash University, Australia

Several countries have included socio-economic considerations (SECs) into domestic regulatory frameworks for biosafety and approval of genetically modified crops. Numerous others are contemplating such inclusion. This article addresses the conceptual design for including SECs in domestic regulatory frameworks, as well as related implementation issues and tradeoffs, highlighting the challenges through actual examples from countries that have already made that inclusion.

Keywords: biosafety, decision-making, regulations, socio-economics

1. Introduction

The October 2014 Conference of the Parties Serving as the Meeting of the Parties (COP-MOP 7) of the Cartagena Protocol on Biosafety in South Korea and other international and national policy forums have included considerable discussions about the role and relevance of socio-economic considerations (SECs) as related to biosafety and biotechnology regulation. The Cartagena Protocol on Biosafety (CPB) states that SECs may be a voluntary part of regulatory decision-making. In principle, this means that countries have the option of including socio-economics in their decision-making as an expression of their national sovereignty. Yet several parties to the CPB, as well as a number of environmental non-governmental organizations (eNGOs) and other civil society groups opposed to biotechnology and other agri-food innovations, are lobbying for SECs to become a mandatory part of regulatory decision-making.

Given that there is no formal definition of SECs in the CPB, socio-economic assessments can include examination of a variety of social and economic factors affected by biotechnology research, development, adoption, diffusion and impacts on society. The objective for the potential inclusion of SECs would be to better understand the potential impacts of relevant interventions – such as agricultural innovations – on people and communities. This article provides conceptual clarity to countries debating whether to include socio-economics in their decision-making, as well as implementation assistance to those that have decided already to implement this policy decision. Our intention is to provide information and insights into the potential issues arising from the inclusion of socio-economics in decision-making while addressing potential options for countries' consideration.

To accomplish this, the article is structured as follows. First, an examination of the drivers of inclusion of socio-economics in decision-making as related to GM biotechnology is provided, followed by examination of a selected group of countries with experience in the formal or informal inclusion of SECs in decision-making processes. Section 4 discusses potential policy implications for regulatory design and options that may be pursued by countries in their deliberations. A potential roadmap is provided for the inclusion of SECs in decision-making by countries that make the policy decision to include such matters. We conclude by summarizing experiences and lessons learned from the countries discussed.

2. Drivers for Inclusion of Socio-economic Considerations

Global Agreements

The CPB includes Article 26 on SECs. As seen in figure 1, the inclusion of socio-economics in decision-making, as allowed in Article 26.1 of the CPB, is a reflection of a desire by a number of countries to understand the broader impacts of regulated technologies on relevant stakeholders and society in general. The purported objective is to contribute to the protection of producers, consumers, biodiversity and the environment. SEC inclusion under Article 26.1 is not mandatory, leaving countries to determine their own policies in deciding what options to pursue. In this sense, inclusion of SECs in decision-making as allowed under Article 26.1 is a reflection of national sovereignty.

As also shown in figure 1, Article 26.1 needs to be qualified in terms of consistency with international obligations, scope, causality, impact indicators and potential target groups. From the standpoint of defining the scope, and since the CPB is a sub-agreement within the Convention on Biological Diversity, socio-economic discussions may need to be related to biodiversity-related impacts from genetically modified organisms (GMOs).[1] This, of course, does not necessarily preclude broader considerations beyond biodiversity in national legislation and domestic measures for implementation of the protocol or for decision-making processes. However, these in turn will need to be consistent with countries' international obligations (Ludlow, Smyth and Falck-Zepeda, 2014).

Inclusion of socio-economics (and Article 26 of the CPB) was not meant to be an impossible regulatory barrier to overcome nor a mandatory step in the decision-making process for implementation. Inclusion of SECs is neither a "fuzzy" approach to slow down or prevent the flow of technologies to producers and consumers nor a platform to resolve socio-economic problems in a country. The need therefore exists to balance socio-economic and diversity protection with regulatory, policy and decision-making impacts on innovation and technology flows.

Regional and National

Policy discussions at the global level may have augmented discussions at the regional and national levels. For example, the African Union drafted the African Model Law, which pursues a precautionary approach to regulation and which includes socio-economics as an important issue for consideration in decision-making. Further, as part

of the efforts supporting implementation of the CPB, multiple projects funded through the United Nations Environmental Program and its Global Environmental Facility (UNEP-GEF) promoted the development of national biosafety frameworks, which in turn led to efforts focused on the development of national laws and regulations. Most of the national biosafety frameworks produced as a result of this program include socio-economics as an issue for discussion.

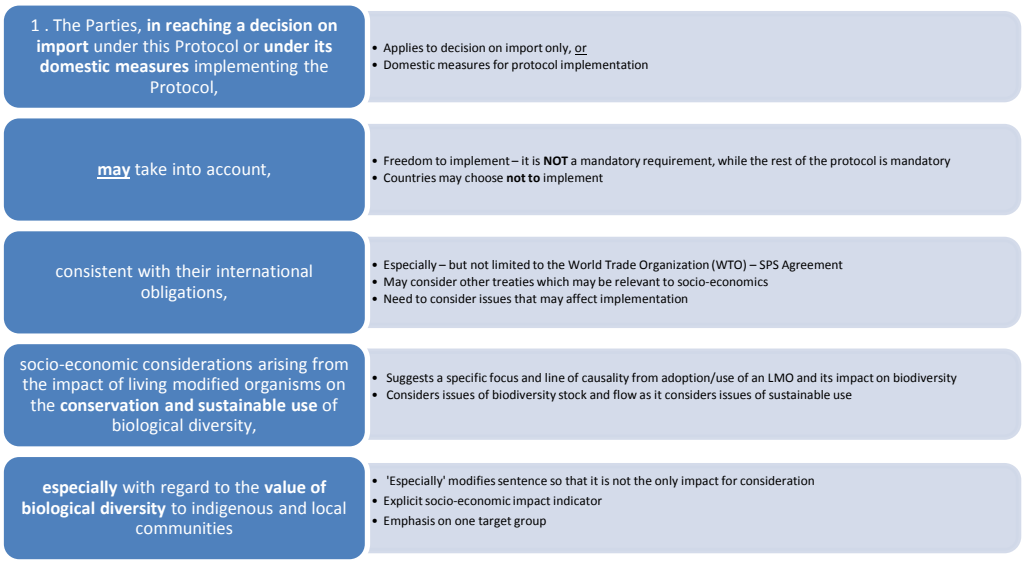

Figure 1 Article 26.1 of the Cartagena Protocol on Biosafety.
Source: Authors, based on Article 26.1 of the Cartagena Protocol on Biosafety

3. Country Experiences with SEC Inclusion in Decision-making

We describe the experience with the inclusion of socio-economics in a set of countries with actual regulatory experience up to commercialization. The following is not meant to be an exhaustive list of countries; rather, the discussion tries to highlight issues related to implementation, which necessitates actual regulatory experience with regulated articles.

Brazil

The new Biosafety Law approved in 2005 (Law 11.105) and a change in the voting regime for making decisions within the competent authority implied a major change in Brazil's biotech regulatory landscape. Previous iterations of the biosafety system appeared to be quite complex and chaotic. Under previous regulatory systems, applications lagged in the system without resolution, and for a while the illegal

planting of herbicide-tolerant soybeans occurred in the country. The emergence of lawsuits brought by a number of pressure groups, and decisions made by individual states (some states declaring themselves "GMO Free"), further complicated the regulatory process.

Brazil's biosafety system now pursues a dual format, with both technical and policy decision-making bodies. The technical bodies, known as the Institutional Biosafety Committees (CIBios) and the Technical Council on Biotechnology (CTNBio), oversee, along with the proponent, the technical risk assessment and communication processes. CTNBio is a large, multidisciplinary body composed of 54 members. The policy decision-making body, the National Biosafety Council (CNBS), is composed of 11 ministries which follow government policy. The regulatory design objective of Brazil's new framework was to clearly assign risk processes (assessment, communication and management) to well defined regulatory bodies and agencies.

Socio-economics can come into play during the risk communication/public consultation procedures. In these procedures if a socio-economic issue is identified as relevant, only the CNBS can commission a socio-economic study by a third party. After Brazil's regulatory approach was clearly defined by the new law, there was a major expansion of the number of events approved for commercialization, including the first public sector release of a food crop in Brazil, the viral-resistant bean from the Brazilian public sector research organization EMBRAPA. The viral-resistant bean is a food security crop in the country.

Argentina

By design the biosafety regulatory system in Argentina is a well defined and routinely streamlined process. There is a single coordinating regulatory agency with recommendation power for applications. This agency, called the National Advisory Council for Agricultural Biotechnology (Comisión Nacional Asesora de Biotecnología Agropecuaria or CONABIA), works in close collaboration with other government agencies.

CONABIA is in charge of agricultural and environmental assessments based on field trials and information and knowledge developed during research and development processes. This is the first step in the process. Once CONABIA gives the clearance, the application proceeds to the second step, which is carried out by the National Service for Agrofood Safety and Quality (Servicio Nacional de Sanidad y Calidad Agroalimentaria or SENASA) and the Technical Advisory Committee on the Use of GMOs (Comité Técnico Asesor en el Uso de OGM or CTAUOGM), which conducts food safety assessments. The third step is socio-economic assessment.

Socio-economic assessment is mandatory in Argentina, but until now has focused on impacts of the potential adoption of the technology under regulatory consideration on the competitiveness of Argentinian trade, specifically exports. This assessment is conducted by the Agricultural Markets Directorate of the Ministry of Agriculture, Livestock and Fisheries (Dirección de Mercados Agrícolas del Ministerio de Agricultura, Ganadería y Pesca). The last step in Argentina's regulatory process is a final report summarizing recommendations, done by CONABIA. The final decision on approval resides in the Ministry of Agriculture, Livestock and Fisheries.

United States of America

In the United States, decisions on import and/or release are based solely on environmental and food/feed safety issues. A developer may submit socio-economic data, but the regulatory bodies are under no obligation to review such data. This regulatory process is for the most part science and technology–based, and adoption and diffusion decisions are left to the market. There have been some indications that the system may change to consider socio-economics, as described in the U.S. National Environmental Policy Act (NEPA). However, NEPA is a procedural statute, because it does not provide the power to stop an action that may impact the environment, although mandated for all U.S. Federal Government agencies' projects and actions.

NEPA has a set of graduated procedural steps with different information and knowledge generation and assessment requirements. These steps include, ordered here from less to more information required: 1) Categorical Exclusion; 2) Environmental Assessment (EA) and a Finding of No Significant Impact (FONSI); and 3) Environmental Impact Statement (EIS) and Record of Decision (ROD).

Categorical Exclusion applies to a list of actions that the implementing agency has determined do not, individually or cumulatively, affect the quality of the human environment. If a proposed action does not fall within those contemplated in the Categorical Exclusion list, then the agency must prepare an EA. If the proposed action does not fall within the Categorical Exclusion list and it does not qualify for a FONSI, then the agency must undertake an EIS. An agency may undertake an EIS without conducting an EA first if it determines significant environmental impact. These graduated procedural steps are an interesting option that introduces the concept of proportionality; that is, the inclusion of socio-economics is proportional to the expected or probable socio-economic impact that a technology may have. Although there has been some pressure by interest groups to conduct EIS procedures under NEPA for GMO applications in the United States, courts ultimately rejected the

eNGOs' arguments to ban GM alfalfa and sugar beets based on economic arguments (Bryson, forthcoming).

South Africa

In South Africa, biosafety regulation is based upon the Genetically Modified Organisms Act 1997 (Act No. 15, 1997) and the Genetically Modified Organisms Amendment Act (Act No. 23, 2006). There are several components to the system. The registrar administers the GMO Act, while the Directorate of Biosafety at the Department of Agriculture, Forestry and Fisheries administers its implementation. The Technical Advisory Committee, composed of scientists with a diverse range of expertise, advises the Executive Council on the risk assessment and management processes. The Executive Council is the decision-making body and may take into consideration other issues, such as socio-economics, in decision-making.

India and China

The experiences in India and in China are similar to each other. In both countries, current versions of laws or regulations do not include SECs, although ongoing reviews may change existing laws and regulations to modify this state of affairs. In both countries, socio-economic assessments and studies have been conducted for applications for commercialization of products in the regulatory pipeline. However, to date it is unclear if socio-economics played a role in their final decision-making. In China in particular, socio-economic assessments have been conducted for applications for commercialization and for other purposes, and China has one of the most solid track records in conducting a large number of technical risk assessments of GM crops and of socio-economic assessments, especially of Bt cotton (Qiao, 2015; Huang, 2014; Smale et al., 2009).

Lessons Learned

Practical lessons can be drawn from the experiences of the countries considered above. First, the experience in Argentina and Brazil shows that it is important and beneficial to complete the technical risk assessment process before considering socio-economics in the decision-making process. Further, the experience of these countries highlights the importance of considering socio-economics at the final stage of decision-making on applications for deliberate release. This avoids spending resources on applications which may not make it through the risk assessment process. Maintaining the independence of the technical risk assessment and the socio-

economic assessment, unless there is a major issue where they intersect, helps avoid confusion and regulatory paralysis.

Second, the experience in Argentina, Brazil and South Africa shows the importance of clearly defining what is expected in terms of socio-economic assessment, including defining the scope and approach of such assessment and defining relevant SECs and issues. Unclear approaches, such as the existing ones in India and China, seem to lead to confusion about the process itself and how decisions are made. The experience in Argentina and Brazil also shows the contrast between a voluntary/flexible and a mandatory approach to SEC assessment. If a country desires to pursue a mandatory approach, it is prudent to have a defined set of issues for a socio-economic assessment; however, if a country has a particular socio-economic concern arise with respect to a particular application, such a case could require a much more extensive review and assessment. The choice of SECs to include is important and suggests a need to set up priority-setting and ranking exercises with relevant stakeholders.

Finally the experience in all countries highlights the importance of clearly defining the process, lines of responsibility, approach and coordination between all regulatory activities. It must also be carefully considered how socio-economics may fit into the decision-making process in order to ensure transparency and cost and time efficiency, and to provide adequate protection and gain the trust of all relevant stakeholders. In the next section we discuss practical policy implications for policy and regulatory design.

4. Policy and Regulatory Challenges and Limitations

There are multiple issues relevant to the design and implementation of processes for taking SECs into consideration in decision-making. Issues include defining the what, who, assessment scope, approach, triggers, when and how. These issues are critical in creating a proper decision-making process. From the standpoint of countries it is important to achieve conceptual clarity, especially with regard to clearly framing SECs in the context of biodiversity as defined in Article 26.1 of the CPB and/or in national laws and regulations, as well as other broader societal concerns.

Table 1 considers multiple issues and summarizes the potential alternatives and tradeoffs involved with policy and regulatory implementation efforts based on implementation options chosen by countries. This is an overtly complex list of options and potential combinations for policy and regulatory design. Implementing a decision-making process that is functional will, in many countries, include the examination of a

set of challenges and limitations that are relevant not only for the biosafety regulatory process in general but also for the potential inclusion of SECs in particular. We now proceed to discuss such challenges and limitations arising from the issues highlighted in table 1. The following section provides a roadmap for countries seeking help to achieve a functional decision-making process while responding to the issues discussed in this section.

Unclear Decision-making Framework

Countries which do not have clear guidelines and standard operating procedures for the inclusion of SECs in decision-making run the risk of introducing confusion by having a process that is not transparent (Ludlow, Smyth and Falck-Zepeda, 2014). Adequate guidelines and/or standard operating procedures would describe in some detail issues identified in table 1 by each country as relevant. Countries may want to leave some items out of such guidelines to preserve flexibility for compliance with SEC inclusion if required. The decision-making process will need to describe the issues, decision-making standards, potential approaches and lines of responsibility, as described in more detail below.

Defining Relevant Socio-economic Issues

An important issue is the critical need to identify relevant SECs at each level of analysis (local, country, regional) and a proper ranking of the importance of such considerations using robust priority-setting criteria and methods. This is critical because clearly defined review or research questions and hypotheses are needed to conduct an assessment. This implies delimiting the scope of inclusion on a case-by-case basis.

The case-by-case basis would in principle apply at the country-by-country and for the event-by-event application levels. However, it is prudent to leave some flexibility to allow using performance and other data generated in countries and/or agro-ecological niches to conduct such assessments, especially in *ex ante* assessments where such data may not exist.

Defining which SECs are relevant to society will also help socio-economic reviewers/assessors and those defining regulatory and policy processes to map SECs and review/research questions to research methods and approaches and to define decision-making standards and procedures. The latter need to clearly define how socio-economic assessments relate to technical risk assessment processes such as environmental and food/feed safety assessments.

Table 1 Design and Implementation Issues and Tradeoffs

Issues	Options	Alternatives and Tradeoffs
Type of inclusion?	No inclusion vs. mandatory vs. voluntary	• Mandatory and voluntary options increase cost of compliance but obtain information and knowledge about the technology
What?	SEC issues for review	• Multiple issues possible for review • Need to rank and prioritize which issues are relevant for society
Who?	Developer vs. dedicated government unit vs. third party experts	• Developers likely have the most information about a specific technology • Dedicated government unit and third party experts likely to be perceived as credible and independent • Dedicated government unit implies a policy reform allocating budget for operation
Scope?	Narrow interpretation Article 26.1 vs. narrow set of socio-economic issues vs. broader set of assessment approaches	• Narrow interpretation of Article 26 focuses on biodiversity and SECs derived from LMO impact on biodiversity • The more issues included the more complex the research and/or assessment process and the higher the cost associated with compliance • Method limitations with broader set of assessments
Approach?	Concurrent but separate vs. sequential vs. embedded	• Preference towards allowing completion of risk assessment procedures first, in part to ensure the potential viability of the technology itself. • Focus on technical risk issues first; redirect attention to more quantifiable SEC issues • Potential for gaining some information about the technology from risk assessment procedures
Assessment trigger?	Each submission vs. event-by-event vs. class of events	• More general categories such as class of events tend to focus on a differential approach by identifying what is different for GM technologies • General approaches may reduce cost of compliance
When?	Laboratory/greenhouse vs. confined field trials vs. commercialization vs. post-release monitoring	• Many events that enter the regulatory pipeline do not finish due to market, efficacy and/or safety issues. Waste of resources to require extensive data or assessments before commercialization • No adoption and use data available before release • Need to define for how long and how often to review in a post-release setting
How?	Review of existing data vs. rapid assessments vs. *de novo* study?	• Choice of methods limited for releases before commercialization • Complicated process to define decision-making rules and standards, evidence standards and tolerance for errors

Defining Standards for Decision-making

A major issue for decision-making is to devise standards to guide decisions. This is one of the most difficult – in some cases impossible – issues to resolve. Finding standards by which to guide decisions implies defining the metrics and parameters guiding decision-making. Economists tend to focus on such parameters as cost/benefit or gains in economic surplus or positive net present values to guide decisions. These approaches may work well if the SEC has an economic connection. However, for broader social, ethical and cultural considerations this may not be the case.

Relation to Risk Assessment Process

In most cases, a further major issue will be finding appropriate decision-making procedures that balance two seemingly different assessments: the environmental and food/feed safety assessment and the socio-economic assessment. As can be seen in figure 2, a decision-making body will likely have two distinct sets of assessments and will need the capacity to balance both biosafety and socio-economic assessments. Some countries, including South Africa, have in practice applied an approach where if there is any concern affecting biodiversity or food/feed safety, the application is not allowed to proceed in spite of the potential socio-economic benefits to society.

As illustrated, perhaps a more problematic scenario is that of a technology that has gone successfully through the biosafety review, but which may receive a negative SEC review. Taking into consideration the inherent result variability, methodological and data limitations, and the lack of actual adoption and performance data for a technology that has not made it to the field, one may need to carefully weigh the decision-making process by understanding the strengths and limitations of all SEC review/assessment approaches.

Balancing Different Stakeholders' Needs

Many stakeholders with conflicting perceptions and positions exist in the arena of GM crops and other organisms. The debate regarding GM crops in particular has become extremely polarized. The undue influence of pressure groups may have been critical in defining policy outcomes in some countries (Wesseler and Zilberman, 2014). From the standpoint of a decision-making process, appropriate steps are needed to ensure proper public consultation while at the same time protecting the rights of different stakeholders and ensuring that pressure groups do not unduly influence the inclusion of SECs in decision-making. This is not an easy task, but it is one where the existence

of transparent processes can make an important difference, especially with regard to issues for consideration, approaches and decision-making standards.

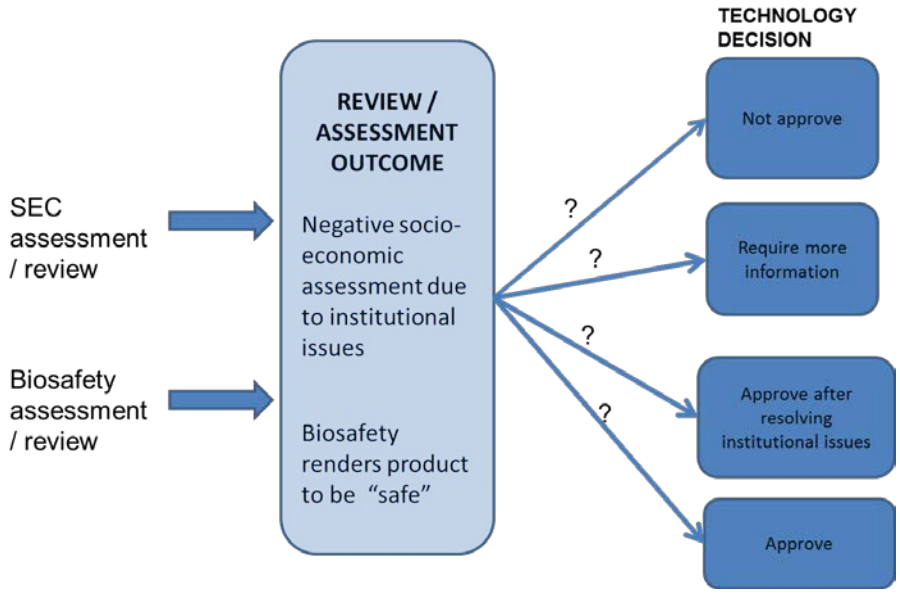

Figure 2 Hypothetical scenario of a process contemplating risk and socio-economic assessment.

Note: Institutional issues refer to those derived from failures related to the existing "system of social rules that structure social interaction" (Hodgson, 2006). Here we may consider such issues as failure in access to credit, fertilizer, pesticides, knowledge and information about the technology, and others

Cost of Compliance

Inclusion of SECs in decision-making will increase the cost of compliance with regulations. Regardless of the approach pursued, from a simple qualitative assessment or review to a full-fledged assessment study that includes research, this will have time, human and financial resources implications. The more complex the assessment or review, the higher the cost involved. This is true even in those countries where socio-economic assessments may be commissioned from third parties and/or public sector researchers on a pro bono basis, formally as part of their current work duties. The latter approach does introduce an opportunity cost for these human resources, as they could be doing other activities.

The Tension between Regulatory Delays, Innovation Flows and Benefits to Society

Bayer, Norton and Falck-Zepeda (2010), Smyth, McDonald and Falck-Zepeda (2014) and others have shown unnecessary regulatory delays introduce the potential for negative impacts on innovation flows. Regulatory delays may reduce the types and number of technologies that enter the regulatory and product development pipeline. The tension is partly due to the time value of money, where longer time periods before the onset of benefits from adopting a technology tend to reduce benefits due to time discounting. Special care will need to be taken to ensure that inclusion of socio-economic considerations does not impact innovation flows even further by introducing unnecessary delays in the decision-making process.

Inclusion of SECs in decision-making will contribute knowledge and information that may improve the quality of decision-making and help reduce the possibility of introducing ineffective technologies to farmers. These benefits need to be weighed against the increases in cost, the impact of unnecessary regulatory delays and the option of pursuing alternate investments (Ansink and Wesseler, 2009).

Building Socio-economic Assessment/Review Capacity

Assessing and/or reviewing the socio-economic impacts from GM crops is not an easy task (Smale et al., 2009; Ludlow, Smyth and Falck-Zepeda, 2014). There are multiple research limitations, including data availability, cost of conducting research, and the choice between multiple research approaches that may be used, amongst others. These challenges and limitations interact with the procedure defined for the inclusion of SECs into decision-making.

From the standpoint of assessment expertise, GM crops and other biotechnology innovations have some special traits or characteristics which may require an upgrade in existing capacity to evaluate socio-economic impacts. Considerations include protection of intellectual property, imperfect markets and competition, attribution, interactions with biotech technical characteristics, and others. From the standpoint of decision-makers this implies gaining an understanding of how assessments and/or reviews are made when such traits are present, the limitations of their results, and how to interpret such results.

Methodological and Practical Challenges for SEC Assessments and Reviews

Smale (2012), Smale et al. (2009) and Gouse (2012) have highlighted the multiple challenges and limitations for conducting field research for the assessment of SECs. These publications identify there has been an evolution of economic methods used in the assessment of GM crops in developed and developing countries. The need still exists to address other methods for broader social issues, as described in Ludlow, Smyth and Falck-Zepeda (2014). There is a need to invest financial resources to improve human and technical capacity to conduct SEC assessments and to further conduct research in institutional frameworks in which GM crops are released (National Academies of Sciences, Engineering, and Medicine, 2016).

Implementation Challenges

Biosafety assessment and decision-making processes must be functional. Functionality requires a clear and feasible regulatory process pathway, as well as decision-making processes that are robust and responsive to all stakeholders but not unduly influenced by pressure groups in order to avoid rent-seeking behaviour. To achieve these objectives, it is critical to focus not only on regulatory design as discussed above but also on regulatory implementation issues. Implementation issues include having clear regulatory end points, triggers and decision-making rules and standards.

Best practice implementation will require establishing periodic regulatory impact assessment activities with a focus on ensuring broad public participation, especially to discuss results from risk assessments, cost and time efficiency, transparency and promotion of innovative approaches to regulation. In addition, the need exists for establishing quality standards for research, evidence, causality lines and burden of proof in the assessment and in the decision-making processes.

To define a functional decision-making process, it is important to describe the burden of proof, rules for accepting evidence, and decision-making standards. As the experience in Brazil and Argentina has shown, it is prudent to consider the inclusion of socio-economics only for commercialization or post-commercialization and after the risk assessment procedures have been completed. This will help ensure a focus on technologies that may reach the end user and not waste valuable resources on those which have been identified as ineffective or not complying with biosafety. As decision-making processes mature by gaining experience and familiarity with crops and traits, an option may be to focus on broad impacts of biotechnology and

technology in society rather than on an event basis. Another alternative may be the consideration of doing socio-economic assessments by class of events (i.e., insect resistance or herbicide tolerance) while focusing on specific differences an event may have with respect to other events of the same class.

5. Potential Roadmap for Inclusion of Socio-Economic Considerations

To develop a pragmatic approach to an idealized process such as the one we have described so far, we propose of the following steps, which may help countries navigate the regulatory assessment process considering inclusion of socio-economic considerations as an option.

1) Evaluate tradeoffs from inclusion of SECs in decision-making. This is a worthwhile exercise even in those countries which have already taken the decision to include SECs in their decision-making. It provides intellectual justification for the policy decision of including socio-economics in decision-making and thus strengthens the credibility of the decision-making process.
2) Ensure that the technical risk assessment process is science-based, able to identify relevant risks and able to address all aspects of risk analysis (assessment, management and communication). This implies striving towards meeting the characteristics for a functional biosafety system (Jaffe, 2008). For some countries it may be useful to review examples from Brazil, Argentina and South Africa to gain lessons in terms of decision-making processes.
3) Ensure that the SEC process follows all the elements of best practice as described by Smale, 2012 and Smale et al., 2009.
4) Ensure proper and clear assignment of roles and responsibilities within the decision-making and assessment continuum. The experience from Brazil and Argentina is important here, particularly the need to avoid duplications and to reduce inefficiencies, and to maximize synergies between regulatory agencies.
5) If a country has made the decision to include SECs in decision-making, it will need to proceed to focus on the inclusion and implementation process. The following directions can be given on this step:
    a) As learned from the experience in Brazil and Argentina, it is critical to first allow completion of biosafety risk assessment/analysis processes. Thus, a sequential approach is preferred. In this option, the risk assessment and public consultations are held first, and if any SEC is identified as relevant, the designated decision-making body can pursue the proper course of action.

   b) Explore potential graduated information requirements approaches such as those in the U.S. NEPA process. This option can help by activating the principle of proportionality between the level of potential or likely socio-economic impact and the level of assessment and data compilation efforts.
6) Conduct stakeholder and expert consultations to identify and prioritize SECs of interest to society. It is prudent to consider formal approaches to such ranking and priority setting. These may vary depending on the crop and trait, so these exercises need to consider such specificity. Some countries may already have identified priority crops and traits as part of their national development goals and plans, setting a course to pursue.
7) Conduct an inventory of human and financial resources to accomplish socio-economic assessment and/or review tasks. The level of assessment and/or review will likely have implications for capacity building/strengthening efforts.
8) If the process of inclusion is defined as mandatory, consider having a basic requirement of a standard economic review/assessment with defined evaluation criteria, similar to Argentina. For example, a typical review may consider impacts on producers' net incomes, smallholders' net incomes, production/financial risk, or trade and competitiveness. These are quantifiable parameters of interest to many stakeholders.
9) Define internal and external compliance and consistency.
   a) Ensure there are no authority conflicts between regulatory agencies, in order to maximize collaboration synergies.
   b) Ensure there are no conflicts with international obligations, especially with the WTO.
   c) Ensure there are decision-making standards/rules, processes to evaluate evidence quality, and validation and review processes that may be included in guidelines and standard operating procedure documents.
10) Conduct periodical regulatory impact assessments that include monitoring and impact evaluation procedures to ensure that the process is and remains transparent, feasible, fair, time/cost efficient and protective.

6. Concluding Comments

Regardless of the outcome of a country's decision to include SECs in its decision-making, there is a clear and critical need to use robust, science-based assessment approaches in support of decision-making. To this effect it is essential to achieve a systematic understanding of the possible implications of the issues that may affect the

adoption and diffusion of GMOs. A number of studies in the literature report beneficial social and economic impacts of GMO adoption which may help elucidate and in some cases maximize the benefits and minimize the risks from their adoption and use. However, it is also necessary to evaluate whether to introduce socio-economic assessment in decision-making processes and to consider the net benefit to society from such inclusion.

Use of socio-economic assessments can be critical in the evaluation of new technologies. Such evaluations are typically a prudent approach, especially if they focus on crops and attributes of interest for those developing countries which have made significant advances in public and private sector biotechnology R&D and innovation. Countries such as Brazil, Argentina, Mexico, Philippines, South Africa, Burkina Faso, Indonesia and China will continue to take an important role in the development of GM technologies. Producers in these – and other – countries will have access to crops and traits of interest and of public or private economic value if they are able to solve regulatory and institutional issues constraining innovation.

The issue of SEC inclusion in decision-making is delicate for a number of countries. In many cases, such inclusion has already been done in the legal frameworks that have been developed and implemented, but inclusion is usually ill defined. Based on the experiences described in this article, defining socio-economic issues at the local and national levels is preferred in contrast to attempting to make such a definition at a global level, where the level of generality will be too broad to help a particular country in its decision-making. This approach allows the framing of socio-economics within the context of the particular country and the issues at hand, while addressing other issues that are likely to impinge on national decision-making. It has the drawback, however, of resulting in a patchwork of decision-making processes with different approaches to SECs, thus making regulatory compliance more difficult. This may be mitigated by achieving some agreement on pursuing elements of best practice for evaluations and addressing specific issues and SEC assessments at the national level.

A major conceptual challenge which is likely to be a wicked problem is the reality that, in practice, implementation of decision-making processes that consider SECs will be done in environments with unclear or ill-defined rules and standards, poorly defined sets of best methodological practices, highly discretionary decisions, uncertainty about relevancy to some or all stakeholders, and capture and influence by industry and/or pressure groups. These issues may be compounded by the inherent situation of data and methodological gaps, limitations and uncertainties associated with any technology assessment process. In essence the issues related to SEC

assessments may be quite similar to those currently related to environmental assessments.

Nevertheless, the experiences of other countries can teach us all important lessons for implementation. As of now, some countries will have to implement a law or policy already approved and which may be part of a larger decision-making process. Whether countries may want to revisit and examine how prudent inclusion of SECs in decision-making has been and whether it leads to better decisions is an open question. Better understanding of a technology's impact on the society where it is released is clearly a pressing need but one that may not necessarily be earmarked for regulatory decision-making; rather, a country may follow a more basic priority-setting process while leaving decisions to end users, who will indeed demand information about such technologies. Maintaining a prudent balance between all needs and efforts will be critical.

References

Ansink, E., and J. Wesseler. 2009. Quantifying type I and type II errors in decision-making under uncertainty: The case of GM crops. *Letters in Spatial and Resource Sciences* 2: 61-66.

Bayer, J.C., G.W. Norton, and J.B. Falck-Zepeda. 2010. Cost of compliance with biotechnology regulation in the Philippines: Implications for developing countries. *AgBioForum* 13(1): 53-62. Available at http://www.agbioforum.org/v13n1/v13n1a04-norton.htm

Bryson, N. Forthcoming. Legal lessons from GM alfalfa and beets. In *The Coexistence of Genetically Modified, Organic and Conventional Foods: Government Policies and Market Practices*, eds. N. Kalaitzandonakes, P.W.B. Phillips, S.J. Smyth and J. Wesseler. New York: Springer.

El-kawy, O.A.G. Catacora-Vargas. TWN Briefings for COP-MOP7 #3, Third World Network. In *Socioeconomic Considerations in Biosafety Decision Making – International Agreements in Context*. Penang, Malaysia: Third World Network. Downloaded from http://www.twn.my/title2/books/Socio-economic%20Considerations%20in%20GMO%20Decision-Making.htm

Falck-Zepeda, J., J. Yorobe, Jr., B. Amir Husin, A. Manalo, E. Lokollo, G. Ramon, P. Zambrano, and Sutrisno. 2012. Estimates and implications of the costs of compliance with biosafety regulations in developing countries: The case of the Philippines and Indonesia. *GM Crops and Food: Biotechnology and Agriculture in the Food Chain* 3(1).

Fransen, L., A. La Vina, F. Dayrit, L. Gatlabayan, D.A. Santosa, and S. Adiwibowo. 2005. Integrating Socio-economic Considerations into Biosafety Decisions – The role of public participation. WRI White Paper. Washington, DC: World Resources

Institute. Downloaded from http://www.wri.org/sites/default/files/pdf/fransen_lavina_biosafetywhitepaper.pdf

Gouse, M. 2012. GM maize as subsistence crop: The South African smallholder experience. *AgBioForum* 15(2): 163-174. Available at http://agbioforum.org/v15n2/v15n2a05-gouse.htm

Hodgson, G.M. 2006. What are institutions? *Journal of Economic Issues* XL(1).

Huang, J., J. Mi, R. Chen, H. Su, K. Wu, F. Qiao, and R. Hu. 2014. Effect of farm management practices in the Bt toxin production by Bt cotton: Evidence from farm fields in China. *Transgenic Research* doi:10.1007/s11248-013-9775-7.

Jaffe, G. 2005. Implementing the Biosafety Protocol through national biosafety regulatory systems: An analysis of key unresolved issues. *Journal of Public Affairs* 5(3-4): 299-311.

Ludlow, K., S.J. Smyth, and J. Falck-Zepeda. 2014. Assessing the SEC landscape and moving forward. In *Socio-Economic Considerations in Biotechnology Regulation*, eds. Karinne Ludlow, Stuart J. Smyth, and José Falck-Zepeda. Springer. Available at http://link.springer.com/book/10.1007%2F978-1-4614-9440-9

National Academies of Sciences, Engineering, and Medicine. 2016. *Genetically Engineered Crops: Experiences and Prospects.* Washington, DC: The National Academies Press. doi: 10.17226/23395.

Qiao, F. 2015. Fifteen years of Bt Cotton in China: The economic impact and its dynamics. *World Development* 70: 177–185. doi:10.1016/j.worlddev.2015.01.011.

Smale, M. 2012. Rough terrain for research: Studying early adopters of biotech crops. In *Farmers and Researchers Discovering Biotech Crops: Experiences Measuring Economic Impacts among New Adopters*. A Special Issue of *AgBioForum*, Melinda Smale and José Falck-Zepeda, Guest Editors, 15(2). Available at http://agbioforum.org/v15n2/index.htm

Smale, M., P. Zambrano, G. Gruère, J.B. Falck-Zepeda, I. Matuschke, D. Horna, L. Nagarajan, I. Yerramareddy, and 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.

Smyth, S.J., J. McDonald, and J.B. Falck-Zepeda. 2014. Investment, regulation, and uncertainty: Managing new plant breeding techniques. *GM Crops and Food: Biotechnology in Agriculture and the Food Chain* 5: 4 – 3. Available at http://dx.doi.org/10.4161/gmcr.27465

Wesseler, J., and D. Zilberman. 2014. The economic power of the Golden Rice opposition. *Environment and Development Economics* 19: 724-742. doi:10.1017/S1355770X1300065X. Accessed Aug 21, 2015.

Yoke Ling, C. 2008. Some issues for the implementation of Article 26 on socio-economic considerations. Third World Network Briefings for MOP 4 #3, Third World Network, Penang, Malaysia: The Third World Network.

Endnotes

[1] The CPB utilizes the term 'Living Modified Organisms' (LMOs). The CPB defines LMOs as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology." The term LMOs can be used interchangeably with GMOs, although wide variation exists on how GMOs are defined. We use the term GMOs, as it has been used widely in the economics and other disciplines' literature.