Paper presented at the Fourth World Congress of Environmental and Resource Economists (WCERE 2010) in Montreal, Canada, June 28- July 2, 2010.

The Current Status of the Debate on Socio-Economic Assessments and Biosafety Highlighting Different Positions and Policies in Canada and the US, the EU and Developing Countries

Jose Falck Zepeda[a], Justus Wesseler[b] and Stuart Smyth[c]

Abstract

Article 26.1 of the Cartagena Protocol on Biosafety has the option of considering socio-economic issues in biosafety regulatory approval processes related to genetically engineered (GE) organisms. National laws and regulations in some countries have already defined positions and may have enacted policies dealing with socio-economic assessments. Many more countries, especially developing countries, are building their biosafety regulatory systems. This paper considers issues related to socio-economic assessments inclusion in biosafety processes by describing the current status and issues in Canada, U.S., E.U. and selected developing countries. Socio-economic assessment inclusion introduces benefits, costs and risks, and tradeoffs. There is a broad variation amongst examined countries in terms of inclusion modalities and guidance for assessment implementation. Countries need to consider whether such inclusion is mandatory or voluntary, and whether implemented during the pre-approval and/or post-approval stages. The need exists to define scope and if assessments are strictly socio-economic or expanded to include broader considerations such as ethical, religious, or cultural issues. The scope chosen will have an impact on methods used and even the feasibility of the assessment itself. Countries need to define clearly decision making rules and standards by which to render decisions as unclear procedures can lead to negative outcomes.

Keywords: biosafety, socio-economic assessment, regulation, E.U., U.S., developing countries

JEL: Q16

[a] International Food Policy Research Institute (IFPRI),Washington, DC, USA Corresponding author
[b] Wageningen University Wageningen, Netherlands
[c] University of Saskatchewan, Saskatoon, Canada

Paper presented at the Fourth World Congress of Environmental and Resource Economists (WCERE 2010) in Montreal, Canada, June 28- July 2, 2010.

The Current Status of the Debate on Socio-Economic Assessments and Biosafety Highlighting Different Positions and Policies in Canada and the US, the EU and Developing Countries

1. Introduction

Socio-economic assessments of genetically modified organisms (GMOs) have become a controversial issue under the Cartagena Protocol on Biosafety to the Convention on Biological Conservation (Falck-Zepeda, 2009). The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of 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, also taking into account risks to human health and specifically focusing on transboundary movements (Article 1 of the Protocol, Secretariat of the Convention on Biological Diversity, 2000).

Under the protocol, parties may also include socio-economic considerations in reaching decisions on imports, including the planting of GMOs, as stated in Article 26 of the convention (see Box 1). Some authors as Jaffe (2005) argue that the Cartagena Protocol limits the scope of socio-economic assessments to those factors affecting biodiversity with an emphasis on those affecting local and indigenous communities. Nevertheless, even if the scope of the Protocol is limited, many countries are or have considered inclusion of socio-economic aspects in their national legislation. While Article 26

provides the opportunity for including a socio-economic assessment in national biosafety regulations, international concern have been raised that socio-economic assessments will become a mandatory part of the approval process. Mandatory inclusion of socio-economic considerations for the approval of a GM crop may have negative effects on the efficiency or even the viability of biosafety, if inclusion in a biosafety process is done without clear standards and rules for decision making or if issues to be explored are not clearly defined. (Falck-Zepeda 2008)

Article 26 of the Cartagena Protocol on Biosafety

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: Secretariat of the Convention on Biological Diversity (2000).

In this contribution we provide an overview of the different positions and policies in Canada, the US, the European Union (EU) and selected developing countries. In doing so, we compare the positions based on a number of criteria discussed in the following section. The results highlight the contrast between the political desires to ensure socio-economic assessments are part of the state's regulatory framework against the potential economic losses.

2. Criteria comparing different positions with respect to socio-economic assessments

In general, a socio-economic assessment can provide useful information about the impacts of a new technology. In the case of a GM crop, this information may include socio-economic impacts at the farmer, household, industry and trade levels. Furthermore, socio-economic assessments may include non-pecuniary and indirect impact considerations including the effect on lower health risks through reductions in pesticide use or shifts to less toxic active ingredients, market size of the new crop, possibilities for tracking and tracing, implications for biodiversity, the need for specific regulations in areas close to important ecological zones, changes in farm labor organization and more (Fransen et al., 2005). Nevertheless, the results of a socio-economic assessment can almost always be expected to be controversial and may vary depending on the choice of methods, baseline data used, spatial and time focus and even the researching team conducting the analysis.

Even when a common method is used, there may be variations between regions, countries or disaggregation level chosen for the analysis (i.e. small vs. large households). Take for example the case of herbicide-tolerant corn (HT-corn) in the EU. Wesseler *et al*. (2007) calculated the maximum incremental social tolerable irreversible costs (MISTICs) associated with an introduction of HT-corn. The MISTICs per capita and year in the EU are below 0.50€, while the MISTICs per farm household are more than 200€ per year. In the case of France, the MISTICs are 90€ per hectare per year, or in total more than 25 million Euro annually. It is reasonable to expect that interest groups will choose the indicator they prefer the most. For example, a group of persons objecting to the technology might declare their willingness-to-pay limit for not having HT-corn introduced to be more than 0.50€ and thus serve as support to maintain their hypothesis of not needing the technology in their context.

The debate about the farm-scale evaluation trial in the United Kingdom can serve as an illustrative example about the scientific and public controversy a socio-economic assessment may trigger due to conflicting or inconclusive results or selective use of research outputs for supporting a position, especially when data used is weak or even worse, based on a faulty research design (e.g. information provided by AgBioWorld, 2005). This situation can also arise due to the use of (raw) baseline production and input use data (i.e. yields, output damage or pesticide use changes) without carefully

considering potential biases and confounding factors and attempting to correct for these issues[4].

A fundamental public policy issue is that if a GM crop has been approved for deliberate release into the environment by the regulatory authority,[5] delaying the introduction of such technology due to a socio-economic assessment can reduce society welfare. First, it is questionable if a regulator should decide whether a safe product should be made available to producers in the country. The technology developer's role in an innovative process is to introduce the technology, face the risk of a market or product failure and reap some of the benefits in case of a success. Intervention by the regulator reduces or in some cases denies farmers and consumers the freedom of choice, while also denying farmers and technology developers the freedom to operate. Second, a delay caused by a socio-economic assessment results in opportunity costs in the form of foregone benefits provided by the new crop. Third, a socio-economic assessment will require additional financial resources and time required for the overall assessment, increasing the direct costs for the approval of the technology. These three concerns are of special interest to public sector developers and farmers in developing countries, where additional hurdles to innovation may reduce even further the availability of appropriate biotechnologies centered on crops and traits of interest to their special conditions.

[4] For example, Crost *et al.* (2008) showed that disregarding bias can influence yield differences between Bt and conventional cotton upwards. Any economic impact estimate based on raw data will itself be biased upward. This problem is amply described in Smale *et al*. (2008).

[5] The safety assessment can be based on the widely used and accepted substantial equivalence (Kuiper *et al*., 2001), or even by a regulatory system guided by the weak or median interpretation of the precautionary principle concept. A strong interpretation of the precautionary principle is likely to not approve any technology as there may always be a small and hypothetical risk of damage.

While the additional financial resources for the assessment may be considered reasonable or addressable by some multilateral donors and technology developers – much less so by the public sector in developing countries – the delay in the approval process can be substantial. Demont *et al.* (2004) calculated foregone benefits of about 141€ million per year for HT sugar beet, and Wesseler *et al.* (2007) 100€ million for Bt-corn (Bt = *Bacillus thuringiensis*) and 111€ million for HT-corn, respectively, per year for the EU-15. For delay of approval in Uganda, Kikulwe *et al.* (2008) calculated an amount of about 200 million US$ per year of foregone benefits for a banana resistant to a common fungal disease. In this particular case, the cost of the delay particularly would harm relatively poor households, the primary users of the technology (Kikulwe *et al*., 2009).

Nevertheless, a socio-economic assessment can provide additional information about the benefits and costs of introducing the new crop and be part of the monitoring process. Because the assessment of the benefits and costs has to be done *ex-ante* and has to consider uncertainty as well as irreversibility (e.g. Wesseler *et al*., 2007, 2004; Hennessy and Moschini, 2006; Gollier and Treich, 2003; Gollier *et al*., 2000; Batie, 2003; Morel *et al*., 2003; Mooney and Klein, 1999), calculating the MISTICs (Wesseler *et al*., 2007; Scatasta *et al*., 2006) is one approach and the general principles of a cost-benefit analysis assessing regulations in the field of environment, health and safety, as suggested by Arrow *et al*. (1996) apply. Such an approach considers the uncertainties about future benefits and costs of the new crop explicitly, includes proper treatment of risk aversion of

the decision maker, and considers the positive and negative irreversibilities of possible environmental and health effects. The approach further considers that over time, new information will emerge, includes the costs of foregone benefits caused by a delay and may help to guide future policy decisions (Kikulwe, 2010). For example, results can provide information about the contribution of GM crops for habitat conservation, income generated for different societal groups and in general contribute to the exchange of information as mentioned in Article 26 of the Cartagena Protocol.

The explicit problems introduced by the introduction of socio-economic considerations is further compounded by the fact that national legislations in many countries have considered or are considering, expanding the scope of socio-economic considerations to include ethical, religious, philosophical and ancestral considerations for the approval of these technologies. Besides the obvious enormous (if not impossible) hurdle of trying to estimate the potential impact of broader considerations (i.e. ethical, religious, philosophical) from the adoption of a specific technology in a country, is compounded by the lack of decision making rules that would balance competing outcomes from socio-economic analysis and other considerations.[6] Furthermore, socio-economic considerations can be used (or abused) as a blanket justification for rejecting the

[6] An obvious example is balancing potential economic gains by farmers and the ethical opposition by another segment of the population against any genetic modification. Although the possibility exists of ensuring co-existence, identity preserved systems, labeling, etc. the "decision maker" has to choose between pecuniary gains and an expressed ethical concern by a segment of the population. How does the regulator decide between these two (or other) competing societal values?

technology without the need to support claims or debating the strength of the evidence presented to support such claim.

For countries that carefully debated the costs and benefits derived from the inclusion of socio-economics in their biosafety approval processes – especially when debating the strong arguments presented in this paper and elsewhere – and whom still decide for inclusion, they need to minimize the impact of regulations on the flow of societal benefits. This can be accomplished by establishing clear and predictable decision-making standards and rules, ensuring that the assessment procedures are concurrent with other biosafety assessment procedures and thus ensure minimization of delays and cost to developers.

3. Overview about positions in different countries

Determining the status of socio-economic considerations in biosafety processes is not an easy task to complete. The need exists to review binding and non-binding law and policy instruments at the national and international levels, the National Biosafety Framework, as well as informal and formal documents released by the national competent authority(ies) on biosafety issues. An analysis of inclusion of socio-economic considerations is further complicated by the fact that biosafety and biotechnology issues may be included in biosafety or biotechnology laws, policies and regulations considering handling, transport, packaging and identification and human and/or animal health. Furthermore, there may be specific laws or policy instruments that guide GMO assessments for direct use as feed,

food, for processing and for transboundary movement (import/export). In this section we will discuss a select group of countries mostly based on whether they have had approvals for commercialization (or at least confined field trials) and/or which represent interesting cases where a lesson can be drawn from its discussion. Addressing each and every country in Asia, Africa or Latin America would be an overwhelming task to complete and is not necessary to draw conclusions in this paper.

3.1. The position held by Canada and the United States

Canada is a signatory country to the Cartagena Protocol on Biosafety, but has not taken any action towards ratification, while the Unites States has not signed the CPB. Socio-economic assessment is not part of either the formal or informal regulatory process in either Canada or the Unites States. When the regulatory framework discussions were occurring in the late 1980s and early 1990s, it was determined that the correct approach would be to adapt the existing regulatory frameworks, allowing for GM crop varieties to be treated as substantially equivalent to non-GM crop varieties. The regulatory frameworks are science-based, meaning that any regulatory requirements applied solely to GM crops have to be based upon empirical data that justifies the enhanced regulatory requirements. When a new crop variety is submitted for regulatory approval, once all the scientific and agronomic conditions have been satisfactory addressed by the developer, the regulators approve the variety for commercial production. At no time in Canada or the US, do aspects of socio-economic consideration enter into the regulatory decision-making process.

Socio-economic aspects can affect GM crop commercialization, but only once the products have entered the marketplace. Canola, corn, cotton and soybeans successfully entered the market in the mid 1990s, when producers accepted the technology and consumers accepted the end products. This is not to say that there were no negative aspects to the commercialization of GM crops, but by-in-large, these concerns have been addressed through the growth of the organics market in the past decade. While the four staples of the GM crop industry entered the market in a relatively smooth fashion, the same can not be said of the commercialization of GM flax and potatoes.

Flax was modified to be herbicide tolerant and potatoes were modified to be insect resistant to the Colorado potato beetle. In a Canadian split-run decision, GM flax received feed approval in 1996 and entered a seed multiplication program. Full variety approval came in 1998 and the 1999 flax crop was to be the final year of seed multiplication. This point in time coincided with the European backlash against GM crops and their products and European flax importers made it very clear to the Canadian flax industry that if any GM flax entered commercial production, Europe would halt all flax imports from Canada. Given that Europe is the major export market for Canadian flax, the Canadian flax industry was forced to withdraw GM flax from the market and ultimately, deregistered the variety. GM potatoes on the other hand, entered the market and were being commercially produced, when the leading fast-food company announced that they would not buy french fries made from GM potatoes. McDonald's announcement

that they would not serve GM french fries to their customers, ended potato producers ability to grow and market GM potatoes and demand for the seed ended.

Most socio-economic considerations are addressed in the marketplace in both the U. S. and Canada by the use of the court system. One of the widely acknowledge negative economic impacts from GM technology occurred when a variety of GM corn that was approved solely for animal feed use entered the supply chain for human food products, creating multiple food product recalls (the "StarLink case"). In this case, the developer, Aventis CropScience (now Bayer CropScience) was sued by the American corn industry for contributing to the decline in the price of commodity corn. The case was settled out of court for US$110 million. As the Starlink case shows, the separation of GMOs approved for feed and GMOs approved for food is difficult to maintain, and in cases of co-mingling, results in severe costs for the companies and countries involved (Carter and Smith, 2007).

Socio-economic concerns were the backbone of a court case in Canada against the developers of GM canola. Both Monsanto and Aventis were listed in a lawsuit filed by the Saskatchewan Organic Directorate (SOD), who claimed that the international export market for organic canola had been destroyed by the commercialization and adoption of GM canola. In the trial, organic farmers testified that they had not had an organic shipment of canola rejected by any export market and in reality; organic farmers were

still producing and exporting organic canola. The judge denied the SOD claims and subsequent appeals to higher courts did not change the original findings.

The ability of stakeholders and/or organizations opposed to GM crops seeking redress for socio-economic issues continues as is witnessed in some recent court cases. In the fall of 2009, Bayer CropScience was held liable in a jury trial for not properly managing a variety of GM rice, which entered the market without variety approval and ordered to pay two Missouri farmers US$2M. This was the first decision regarding the unintended release of LL601 rice and is likely to be the first of many lawsuits against Bayer. The commercialization of GM alfalfa was overturned by the courts in the US, when the judge deemed that a proper environmental impact assessment had not been undertaken by the USDA. Similarly, GM sugar beets are presently before the court regarding the conditions of commercialization. It is expected that an environmental impact assessment will have to be completed and it is even possible that GM sugar beets may have to be withdrawn from the market.

In North America, the courts are able to satisfactorily address socio-economic concerns. However, if the courts were unable to manage this aspect of innovation and the socio-economic concerns had to be managed by the regulators, some research suggests that the cost of this would be substantial. Early estimates of the cost of regulatory delay regarding the commercialization of GM crops identified a decrease in return on investment (ROI) of 2.8% for a one-year delay, while a two-year delay created a 5.2% decrease (Heller,

1995). More recent estimates for the cost of regulatory approval come from Kalaitzandonakes *et al*. (2007) where the authors estimate the total regulatory compliance cost for insect resistant corn ranged from US$7-15M and the cost for herbicide tolerant corn ranged from US$6-14M. Smyth and Phillips (2008) have estimated that a two-year regulatory delay in Canada would reduce the seed development industry's ROI by C$65M. Clearly, time is considerably more expensive as doubling the cost of regulatory approval reduces ROI by C$36M.

The innovation of GM crops is similar to past innovations, in that the full extent of benefits is not known until some time after the point of commercialization. One important benefit from GM crops that has developed over the first decade of use, it the environmental benefit from GMHT canola when the producer uses minimum or zero tillage practices (Smyth *et al*. forthcoming (a)). The reduction in intensive tillage of land and the move to zero and minimum tillage with GMHT canola allows producers to seed GMHT canola with a minimum of soil disturbance, thereby reducing the soil's exposure to wind and improving soil structure. Eighty-three percent of respondents to a survey on GMHT canola production practices indicated that they have greater soil moisture and 86% of producers identified that they have reduced soil erosion. Continuous planting of crops sequesters carbon at a calculable rate (McConkey *et al*. 2007). When the practices of minimum and zero tillage practices are combined, the volume of carbon being sequestered is 470,000 tones. It is also possible to measure the carbon no longer released through tillage, which is estimated to be 520,000 tones. When these measures are

combined, nearly one million tones of carbon is sequestered or no longer released annually in Western Canada.

The adoption of GMHT canola has resulted in a decrease of agro-herbicide toxicity. Herbicide use has changed dramatically and there has been a decrease in terms of active ingredient applied of 3.6 million kg when contrasting 1995 and 2006 (Smyth *et al*. forthcoming(b)). The adoption of GMHT canola has resulted in a drop in the environmental impact of herbicides application to canola production by 59%. Farmer exposure to herbicides has dropped by 61%.

The lack of inclusion of socio-economic criteria in the regulatory decision making process in Canada and the US has resulted in successful commercialization of numerous crop types. The private market has been able to address the socio-economic concerns once the products enter the marketplace, as is evidenced by the use of the courts. If the use of the courts to examine socio-economic impacts were not allowed, and if this aspect was incorporated into the regulatory framework, then the cost of variety approval would rise. A major concern of incorporating socio-economic issues into the regulatory framework is that the risks or externalities of a GM crop will tend to be over-stated, while the potential for benefits will tend to be under-stated and hence, the technology will not be commercialized.

3.2 The position held by the EU, Norway and Switzerland

Experience with ‘mad cow’ disease and similar food scandals has resulted in the EU separating risk assessment and risk management for food and feed products. Risk assessment is done by the European Food Safety Authority (EFSA) while risk management includes standing committees, the Commission and the Council of Ministers. In June 1999, Denmark, Greece, France, Italy and Luxembourg declared that they would block new approvals of GMOs until the European Commission proposed additional legislation governing their introduction including labelling, traceability and risk assessment. This has given rise to the ‘quasi-moratorium’ on GMOs.

GMOs can be approved at three different levels: as food or feed, for import and processing and for cultivation. In the EU, approval for import and processing and as food or feed is mainly managed by the Directorate General for Health and Consumer Affairs, while approval for cultivation is managed by the Directorate General Environment. In order to provide EU consumers with a choice, food products derived from or containing GMOs need to be labeled (with a threshold of 0.9%) and traceable, but products derived from animals fed with GMOs need not be labeled. Minute traces of yet unauthorized GM material may be present in conventional food and feed, as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing. Such presence is tolerated up to a maximum of 0.5% for a limited number of events (DNA recombinations) which have benefited from a favourable risk evaluation. For technical reasons (uncertainties in testing), this threshold also applies to other non-authorized GMOs.

Currently, the EU maintains a zero tolerance level for GMOs not approved for import and processing. In combination with the asynchronous approval process (i.e. approval at different times by different countries), this causes frictions in international trade and results in a temporal increase of feed imports in particular, harming EU farmers (Backus *et al*., 2009). A similar problem to asynchronous approvals is the split approval of GMOs, that is, approval for feed but not for food.

Until now, a number of transgenic events of cotton, maize, oilseed rape and soybeans are allowed for EU import, while only one crop, Bt maize MON810, has approval for planting. The EU approval process for GMOs resulted in 2003 in separate WTO complaints by Argentina, Canada and the USA. In 2006, the WTO ruled that the EU's GMO policies from 1984 to 2004 were effectively a ban on GMO products and illegal under the trade agreement. In 2009, Canada and the EU signed an agreement ending the dispute, and, while the discussion with Argentina continues, a settlement was expected by the end of 2009. The EU and the US discussed the dispute in October 2008 and have allowed time for further talks although the US has retained the right to retaliate. All three countries maintain that the dispute is not yet solved and that discussions need to continue (Austen and Kanter, 2009). While the three are afraid of restricted market access, many GMOs have actually been approved for import since 2004, while the approval process takes longer than in many other non-EU countries (CEC, 2009).

EU market access for seed companies is still restricted. No new GMO has been approved for cultivation since 1998, but the import market for GMO seeds is much smaller than the market for other agricultural products (less than 1%). Still, some EU member states have banned the cultivation of the only currently GMO approved for planting. The ban is in violation of the EU regulations and the Maastricht Treaty, but is supported by the Council of Ministers of the Environment and remains an issue in international trade.

The European Union as well as Norway and Switzerland have signed and ratified the Cartagena Protocol and in particular EU member states were instrumental in establishing and implementing the Protocol (Paarlberg, 2001). The role of socio-economic assessment as part of the approval process has become an issue within the EU regulations on GM crops lately (Ministry of Agriculture, Nature and Food Quality, 2009).Within the EU, The Netherlands have taken the initiative and The Netherlands Commission on Genetic Modification (COGEM) (2009) published a report on the potential role of socio-economic assessments as part of approval process for GMOs. The Dutch Ministry of Agriculture (LNV) did organize an international conference in November 2009 to discuss those issues. As expected the role of a socio-economic assessment is controversial (LNV, 2009). The proposal for a socio-economic assessment by The Netherlands includes the following nine items (COGEM, 2009, p. 7-8):

- Benefits to society – e.g. yield increase or food quality improvement;
- Economics and prosperity – such as increased employment and productivity;
- Health and welfare – for workers, the local population and consumers;

- Local and general food supply – these should remain at the same level or improve;
- Cultural heritage – if desired, specific elements of cultural heritage or local customs should be preserved;
- Freedom of choice – both consumers and producers should be able to choose between GMO and GMO-free products;
- Safety – in terms of bother personal and the environment;
- Biodiversity; and
- Environmental quality.

The debate on the role of socio-economic assessment illustrated that a socio-economic assessment in one way or the other will become part of the approval process, while the on-going debate is whether or not and what parts this should be *ex-ante* (mandatory for approval) or *ex-post* (monitoring and assessment).

Norway has been one of the few countries that did include socio-economic aspects in the approval process for GMOs from the beginning. The Gene Technology Act of 1993, Section 10 explicitly mentions:

> The deliberate release of genetically modified organisms may only be approved when there is no risk of adverse effects on health or the environment. In deciding whether or not to grant an application, considerable weight shall also be given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development.

The Norwegian Biotechnology Advisory Board has prepared a document "describing the implementation of the concepts in the Gene Technology Act" (Norwegian Biotechnology Advisory Board, 2009, Preface), which among others includes information for the assessment of benefits to the community. The assessment criteria are not strict, but should include problems being solved, availability of alternatives and possible problems as applied similarly to approval of antibiotics in Norway. Those elements are seen "as a source of inspiration for how the Biotechnology Advisory Board will implement the requirements of 'benefit to the community.'" (Norwegian Biotechnology Advisory Board, 2009, p. 15). Interestingly, the socio-economic considerations not necessarily only apply to GMOs imported – Norway currently does not produce any GMOs – but also to the conditions of producers in the exporting country.

3.3 The position held by Latin American countries

In Latin America, the countries that have approved commercially GM crops include Argentina, Bolivia, Brazil, Colombia, Mexico, Honduras, Paraguay and Uruguay (Falck-Zepeda *et al*. 2008). Chile authorizes GM crop propagation for external seed markets but does not allow internal use. Peru, Ecuador, Bolivia and Venezuela have formal or informal moratoriums on GM crops, in some cases pending formal policy, law, and/or regulatory development.

Argentina formally includes socio-economic considerations in its biosafety approval process but limits its scope to impact on Argentinean exports (SAGPyA Argentina 2003,

2006, 2007). In Colombia, Article 16 of Presidential Decree 4525 of 2005 (MoADR, 2005) requires a complete risk assessment but leaves the door open to the examination of socio-economic considerations if required by the competent regulatory authority.

In Mexico, the Biosafety Law and other related law instruments, make specific references to the need of considering socio-economic issues. For example, Article 64 of the National Biosafety Law of 2005 (GEUM, 2005) and Chapter III, Article 16, Section V (d) of the regulations for the implementation of the National Biosafety Law of 2005 (GEUM, 2008) strongly encourages consideration of socio-economic issues.

Chapter II Article 5.XIV of 2006 decree (CONACYT, 2007) defining the roles of the competent authority (Comite Intersecretarial de Bioseguridad de los Organismos Geneticamente Mejorados – CIBIOGEM), defines one of its roles to be, deciding on the socio-economic studies needed to analyze the impact of GMOs. Proponents must perform the socio-economic assessments, while CIBIOGEM conducts a detailed review and can ask for additional information; however, there are no defined methodologies or decision making standards in the law or policy instruments. As an example of the process of including socio-economic considerations in biosafety decision making in Mexico, the application dossier of the confined trials of GM corn approved in 2008 included a socio-economic study on the potential impacts on traditional agriculture, on the environment, on biodiversity, on seed supply, on the freedom to use landraces by farmers and potential monopoly power.

.

Brazil's Biosafety Law No. 11.105 approved in 2005 considers two distinct bodies for the regulation of GMOs (GoB, 2005). A technical body which is the competent regulatory body, the national biosafety committee (CTNBio) and an independent body called National Biosafety Council (CNBS) that is formed by Ministers and designated experts. CTNBio approves new GMOs by performing an assessment on human health, animal health and environmental impacts, whereas the CNBS decides on the commercial deployment if any social or economic issue is raised during the evaluation process. In Brazil's case, there are several advantages derived from separating the functions done by the technical body from those made by the body that examines non-biosafety related issues.

The main advantage is that such arrangement in essence separates the risk assessment from political issues that may obscure the technical assessment. Important to note that the Brazilian system is similar to the one used by the European Union. The main difference would be that the political process has to deal only with one country rather than many. However, there is still no clarity on methodologies or decision making standards.

In both Brazil and Mexico, there have been instances of technologies that may have cleared the technical risk assessments but where there have been pressures from interest groups to stop the release of technologies already deemed as safe. This is the case of

insect resistant cotton and herbicide resistant soybeans in Brazil, and the case of insect resistant maize in Mexico. Certainly in both countries, socio-economic and broader issues have been used by pressure groups to argue against the commercial release of GM crops in their respective countries. This fact has two distinct impacts including regulatory delays but also the inclusion of regulatory uncertainty for decision making.

The Andean Community is a sub-regional organization with international legal status composed of five countries, namely Bolivia, Colombia, Ecuador, Peru and Venezuela and by the Andean Integration System (AIS). The Andean Community adopted in 2002 a Regional Biosafety Strategy which does not displace or substitute existing laws. However, the Regional Strategy may develop and propose resolutions to the Andean Council of Foreign Ministers and Andean Community Commission for approval. The importance of the AC Regional Biosafety Strategy is that it does consider socio-economic considerations that may be adopted by member countries that are developing their own laws and regulations. Similar to other regional model laws, approaches and strategies the AC Regional Biosafety Strategy does not provide guidance in terms of implementation of such assessments. Note that four Andean Community members, Bolivia, Ecuador, Peru and Venezuela have explicit or *de facto* moratoriums or bans on the approval of GMOs in their countries.

3.4 The position held by South and Southeast Asian countries

In China, the 2002 Decrees 8, 9 and 10 of the Ministry of Agriculture (MoA PRC, 2002a, 2002b, 2002c) and the 2002 Decree 304 of the State Council of the People's Republic of China (SC-PRC 2002) and other regulations, governs the application of biosafety in the country. The Chinese government is currently revising laws, guidelines and regulations to address new GMO applications although details are not readily available (USDA FAS, 2009). The explicit text of available regulations only consider the technical aspects of biosafety assessment made by the competent regulatory authority, yet the final decision for commercial approval lies in the Chinese central government where other considerations including socio-economic such as impacts on foreign trade may play a role in the decision making process. The process of assessing socio-economic considerations is not explicitly defined at this point in time.

In the Philippines Executive Order No. 514 of 2006 (GoP, 2006) includes as one of its principles taking into account social, economic, cultural and ethical considerations. This Executive Order mandates the competent authority, the National Committee on Biosafety of the Philippines (NCPB) to draft detailed guidelines on the conduct of socio-economic impact evaluation of biosafety decisions. These guidelines are still under development and have not been finalized, thus there is no clarity how socio-economic considerations will be included in biosafety decision making processes.

In India, current rules from 1989 (GoI, 1989) guide the manufacture, use/import/export and storage of hazardous microorganisms/genetically engineered organisms. The 1989

rules do not explicitly require inclusion of socio-economic considerations, although the competent regulatory authority, the Genetic Engineering Advisory Committee (GEAC) has commissioned in past biosafety evaluations, economic studies assessing the potential impact from the introduction of GM crops in India. The extent and how these evaluations have been considered for decision making are not clear.

Thailand is an interesting case as even though during the period of 1994-2000 confined field trials were conducted in Thailand with cotton, corn, papaya, tomatoes and other crops, a ban on additional biotech field trials was implemented in 2001. The main reason to implement a ban was fear for losses of Thai exports in trade sensitive markets. The Thailand Cabinet revoked the 2001 biotech field trials ban in December 2007, yet no more trials have been conducted in Thailand. Biosafety laws still in development and based on the trade related considerations the possibility that any resulting law will include socio-economic considerations is indeed high.

3.5 The position held by African countries

The only countries in Africa who have commercial approvals for GM crops are Burkina Faso, Egypt and South Africa. However, only Burkina Faso and South Africa have actually transferred GM crop technologies to farmers. Confined field trials have been conducted in Egypt, Kenya, Uganda, Tanzania and Zimbabwe.

In South Africa, the 1997 Biosafety Act No. 15 in its Article 5-9 (GoRSA, 2007) indicates that the competent authority may consider socio-economic considerations resulting from the introduction of a GMO especially for those communities located in the vicinity area. The text of the Kenya's Biosafety Act of 2009 approved February 2009 (GoK, 2009) does not include socio-economic considerations in its text. This is the same situation for the current biosafety guidelines currently in use in Uganda and Burkina Faso, although this may change as both countries are rapidly developing and/or renewing their own laws and regulations, although at this point in time it is premature to venture a projection of the outcome from two countries' legislative processes.

GMOs are regulated in Egypt based on Ministerial decrees as there is no specific biosafety law approved. Egypt is an interesting case where final commercialization was stopped for some time due to perceived impact on exports to sensitive markets. However, an analysis of Egyptian commodities export flows to GM trade sensitive markets such as Europe and Japan indicate that losses due to GMO use are minimal (Paarlberg *et al*., 2007). The commercialization of Bt cotton may generate trade related concerns as there may be an impact on organic cotton exports. Socio-economic considerations entered the decision making process, although it is not clear whether formal socio-economic impact assessment studies have been done to support the biosafety regulatory process. Egypt approved the commercialization of insect resistant maize in 2008, representing a potential change in the regulatory and policy context.

The African Union Model Law (Africa Union, 2008) although coming from Africa's most important regional political body, it is not clear if and how the Model Law has been incorporated in its member countries legislation. Examining this law is important as it may have an impact on current laws and regulation development in Africa. The current version of the African Union Model Law defines socio-economic conditions as "the economic, social or cultural conditions, livelihoods, knowledge, innovations, practices and technologies of indigenous and local communities including the national economy." The AU Model Law in Annex II.F., thus expands socio-economic considerations to include religious and cultural impacts, impact on and/or substitution of tradition varieties and agricultural practices, and impacts on sustainable agriculture, amongst other issues.

The AU Model Law requires a socio-economic assessment before approval, while indicating that those GM technologies that have a deleterious impact on socio-economic conditions should not be researched, developed or released in countries. The AU Model law does not define methods nor approaches to socio-economic considerations assessments and thus it is not clear how (and if it can be done) this expanded assessment can be included in biosafety decision making processes.

4. Comparing and discussing the different positions

As described in Section 3 of this paper, many countries and some regional model laws recommend or even mandate inclusion of socio-economic considerations for biosafety regulatory purposes and/or the approval of genetically modified crops. Very few,

however, provide guidance in terms of methodologies, implementation approaches and decision making rules. This vagueness is compounded by the fact that the inclusion of socio-economic considerations is itself quite controversial. It is interesting to note that very few countries mandating regulatory impact assessments that would measure the benefits, costs and risks derived from the inclusion of socio-economic considerations, have perceived that this process could become an additional regulatory burden.

In terms of implementation approaches, we observe a wide range of potential approaches in dealing with socio-economic issues. In this broad range of countries we have those who do not have a mandate for the inclusion of socio-economic issues with the regulatory dossier as done in the USA and Canada. Certainly the proponent can submit a socio-economic impact assessment study as part of the regulatory dossier, and in some cases may have an impact on the final decision after the product has been deemed safe. Other countries, such as Argentina mandate the inclusion of socio-economic issues but narrow the scope to a very specific impact area. In other countries with mandatory requirements for socio-economic considerations inclusion, as in the case of Norway and proposed approach in The Netherlands, their legislation indicates what issues to address in a socio-economic assessment, but not how the outcome of the risk or socio-economic assessment will be judged. In other words, these countries' legislation does not provide indication of methods or decision making rules for balancing risk assessment outputs and the socio-economic assessments.

An important observation is that countries that do not have a mandatory consideration of socio-economic considerations (such as the US or Canada) tend to rely on the court system to balance needs and claims by tech developers, producers and consumers. If the court option were not available the issue to address risk and liability, regulatory and information asymmetries may arise and thus compromise participation and impacts on stakeholder interests. .

In those countries that may impose a mandate on the inclusion of socio-economic requirements without sufficient guidance in terms of methods and decision making rules, may introduce unnecessary regulatory delays and uncertainty to biosafety and GM crop approval processes. Although, in some situations, leaving the inclusion mandate broad and generic, leaves the door open for developers to submit socio-economic impact assessment studies they may deem sufficient for enabling a biosafety regulatory process. However, unclear procedures for socio-economic assessments may discourage investments in new technologies by private sector as it introduces regulatory uncertainty and unpredictability. In fact, lack of clarity may even be more discriminatory to the public sector in developing countries as they may not be capable of financing additional costs or addressing uncertainty, especially when dealing with international public goods where the rates of private returns are low, although the social returns may be high. In essence, increasing regulatory burdens will make R&D processes in crops and traits of interest to developing countries harder to invest in the long run.

5. Conclusions

The inclusion of socio-economic considerations in biosafety approval and/or technology decision making processes is quite controversial. Such inclusion introduces a set of benefits, costs and risks to developed and developing countries, as well as, many tradeoffs and biosafety management issues that such countries need to consider when developing their own legislation and policies.

Certainly one of the main regulatory decision points will be whether the inclusion of socio-economic considerations is mandatory or voluntary. In those countries that opt to pursue voluntary inclusion of such assessments, they may need to consider how the market deals with stakeholders' issues and responsibilities, especially examining liability and legal approaches in courts. Another issue to consider is whether socio-economic assessments will be implemented during the pre-approval, post-approval stages or both. Very few countries, one notable exception is the European Union requires the implementation of post-release monitoring of socio-economic impacts.

A final issue is the scope of socio-economic assessments. Whether the scope is strictly on socio-economic issues, or whether it is expanded to include broader considerations including ethical, religious, cultural or individual/group expressions of opposition; will have an impact on the methods and approaches needed for the analysis, as well as the decision making rules governing such approaches. Socio-economic assessments pursuing a narrow scope have a robust history in terms of methods and approaches for conducting

such assessments. If the scope is expanded to broader considerations, there are several uncertainties as to the feasibility, robustness and reliability of such estimations, especially in an *ex ante* (pre-approval) regulatory process. Socio-economic assessments in these situations may not be even feasible. In terms of methods, the need exists to greatly expand the scope of approaches followed by practitioners to include those that deal with risk and uncertainty, irreversibility, and flexibility.

The inclusion of socio economic considerations assessments, especially in those systems where there is very little clarity in terms of methods and decision making rules, can introduce the potential of increasing regulatory lags due to delays, and certainly will increase the cost of conducting such assessments. In both cases, there are social costs attached that may even impact negatively the deployment of technologies that address crops and traits of interest to developing countries. Irrespective how countries deal with having more guidance in terms of methods, they need to have clarity in terms of decision making rules that will guide inclusion of socio-economic considerations.

Finally, countries need to come to the realization that socio-economic considerations are just one aspect of biosafety management. There are other considerations where policy and decision makers can make biosafety systems more efficient and protective, including regional approaches to biosafety regulations, building up flexible regulatory systems, matching regulatory intensity to the technology's objective risk and others. The latter are important issues in terms of biosafety regulatory design and management to which

economics and other disciplines can contribute for ensuring the deployment of safe and effective technologies to resource poor farmers and farmers in a more industrialized setting.

References:

AgBioWorld (2005), 'Analysis and Comments on The Farm Scale Evaluations of GM Crops in UK' Compiled from postings to AgBioView Newsletter of http://www.agbioworld.org. Available at <http://www.agbioworld.org/biotech-info/articles/biotech-art/farmscaleevaluations.html> (accessed March 24, 2009).

Arrow, K. J., M. L. Cropper, G. C. Eads, R. W. Hahn, L. B. Lave, R. G. Noll, P. R. Protney, M. Russell, R. Schmalensee, V. K. Smith, and R. N. Stavins (1996), ' Is There a Role for Benefit-Cost Analysis in Environmental, Health, and Safety Regulation?' *Science* 272, No. 5259: 221-222.

Austen, Ian and James Kanter (2009) Canada Settles a Crop Trade Complaint Against Europe. New York Times. http://www.nytimes.com/2009/07/16/business/global/16gene.html?_r=1&ref=business

Backus, Ge, Petra Berkhout, Derek Eaton, Ton de Kleijn, Eveline van Mil, Pim Roza, Wilhelm Uffelmann, Linus Franke, Bert Lotz (2009) EU policy on GMOs: a quick scan of the economic consequences. The Hague: LEI Wageningen UR.

Batie, Sandra S. (2003) The Environmental impacts of genetically Modified Plants: Challenges to Decision Making. *American Journal of Agricultural Economics* 85(5): 1107-1111.

Carter, Colin A. and Aaron Smith (2007) Estimating the Market Effect of a Food Scare: the Case of Genetically Modified Starlink Corn. *Review of Economics and Statistics* 89(3):522-533.

CEC (Commission of the European Communities) (2009) EU and Canada settle WTO case on Genetically Modified Organisms. IP/09/1142, Brussels. http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1142&type=

COGEM (2009) Socio-Economic Aspects of GMOs. Building Blocks for an EU Sustainability Assessment of Genetically Modified Crops. COGM Report CGM/090929-01. Available at http://www.cogem.net/main-adviesdetail-signaleringEN.aspx?pageid=54&loc=2&version=&mode=&id=517. Accessed January 26, 2010.

CONCACYT (2007) 'Acuerdo por el que se expiden las Reglas de Operación de la Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados'. Consejo Nacional de Ciencia y Tecnología, Estados Unidos Mexicanos, December 5 2007. http://www.cibiogem.gob.mx/Docum_interes/Reglas_Op_05dic07.pdf

Demont, M., J. Wesseler, and E. Tollens (2004), 'Biodiversity versus transgenic sugar beets – the one Euro question', *European Review of Agricultural Economics* 31:1-18.

Falck-Zepeda, J. (2009), 'Socio-Economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake?' *AgBioForum*.

Fransen, L., A. La Vina, F. Dayrit, L. Gatlabayan, D. A. Santosa, S. Adiwibowo (2005), *Integrating Socio-Economic Considerations into Biosafety Decisions: The Role of Public Participation*, Washington DC: World Resources Institute.

Gollier, Christian, Nicolas Treich (2000): Decision-Making Under Scientific Uncertainty: The Economics of the Precautionary Principle. *Journal of Risk and Uncertainty* 27(1):77-103.

Gollier, Christian, Bruno Jullien, Nicolas Treich (2000): Scientific progress and irreversibility: an economic interpretation of the 'Precautionary Principle'. *Journal of Public Economics* 75:229-253.

Government Administration Services. Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organisms, etc. (Gene Technology Act). Including amendments of June 17, 2005. Available at: http://www.regjeringen.no/en/doc/Laws/Acts/gene-technology-act. html?id=173031. Assessed January19, 2010.

GoB (2005). 'Decree 5.591/2005, which regulates Law 11.105/2005.' Government of Brazil. November 2005. http://bch.biodiv.org/database/attachedfile.aspx?id=600

GEUM (2005). 'Ley de Bioseguridad de los Organismos Genéticamente Mejorados'. Gobierno de los Estados Unidos Mexicanos, March 18 2005. http://www.diputados.gob.mx/LeyesBiblio/pdf/Ley_BOGM.pdf

GEUM (2008). 'Reglamento de la Ley de Bioseguridad de los Organismos Genéticamente Mejorados.' Gobierno de los Estados Unidos Mexicanos, March 19 2008. http://www.cibiogem.gob.mx/Norm_Leyes/Reglamento_LBOGM.pdf

GoP (2006). 'Executive Order No. 514'. Government of the Philippines, May 22 2006. http://bch.dost.gov.ph/system/files?form_id=105.096.098.86.67.073.042.097.63.2

5.111.09.51.76.87.082.&file=Executive%20Order%20514%20-Establishing%20the%20NBF.pdf&loc=related_docs

GoRSA (2007). 'Genetically Modified Organisms Act, 1997'. Government of the Republic of South Africa. http://www.nda.agric.za/docs/geneticresources/AnnexureGMO.htm and http://www.info.gov.za/acts/1997/act15.htm

Heller, J. (1995) Quoted in Goudey, J. & D. Nath. 1997. *Canadian Biotech '97: Coming of Age.* Toronto: Ernst & Young.

Hennesy, David and GianCarlo Moschini (2006) Regulatory Actions under Adjustment Costs and the Resolution of Scientific Uncertainty. *American Journal of Agricultural Economics* 88(2): 308-323.

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

Kalaitzandonakes, N., J. M. Alston and K. J. Bradford (2007) Compliance costs for regulatory approval of new biotech crops, *Nature Biotechnology* 25: 5: 509-511.

Kikulwe, Enoch (2010): On the introduction of genetically modified bananas in Uganda: Social benefits, costs, and consumer preferences. PhD-Thesis. Wageningen University.

Kikulwe, E., E. Birol, J. Falck Zepeda, and J. Wesseler (2009), 'Rural consumers' preferences for banana attributes in Uganda: Is there a market for GM staples?', in J.W. Bennett and E. Birol (eds.), *Choice experiments in developing countries:*

Implementation, challenges and Implications, Cheltenham: Edward-Elgar Publishing, pp. ????.

Kikulwe, E., J. Wesseler, and J. Falck Zepeda (2008), 'GM Banana in Uganda: Social Benefits, Costs, and Consumer Perceptions', *EPTD Discussion Paper 00767*, IFPRI, Washington DC.

Kuiper, H. A., G. A. Kleter, H. P. J. M. Noteborn, and E. J. Kok (2001), 'Assessment of the food safety issues related to genetically modified foods', *The Plant Journal* 27:503-528.

LNV (2009): GMOs in European Agriculture and Food Production. Conference Report. Available at http://www.minlnv.nl/gmoconference2009. Accessed January 26, 2010.

McConkey, B., Angers, D., Bentham, M., Boehm, M., Brierley, T., Cerkowniak, D., Liang, C., Collas, P., de Gooijer, H., Desjardins, R., Gameda, S., Grant, B., Huffman, T., Hutchinson, J., Hill, L., Krug, P., Martin, T., Patterson, G., Rochette, P., Smith, W., VandenBygaart, B., Vergé, X., and Worth, D. 2007. Canadian Agricultural Greenhouse Gas Monitoring Accounting and Reporting System: Methodology and greenhouse gas estimates for agricultural land in the LULUCF sector for NIR 2006. Agriculture and Agri-Food Canada, Ottawa, ON.

MoA- PRC (2002a). 'Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms Decree 8'. Ministry of Agriculture, PR China January 5 2002. http://bch.biodiv.org/database/attachedfile.aspx?id=559

MoA- PRC (2002b). 'Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms Decree 9'. Ministry of Agriculture, PR China, January 5 2002. http://bch.biodiv.org/database/attachedfile.aspx?id=561

MoA- PRC (2002c). 'Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms Decree 10'. Ministry of Agriculture, PR China, January 5 2002. http://bch.biodiv.org/database/attachedfile.aspx?id=563

MoADR (2005). Decreto 4525 por la cual se reglamenta Ley 740 del 2002. Republica de Colombia, December 6 2005. http://bch.biodiv.org/database/attachedfile.aspx?id=626

Mooney, Siân, K.K. Klein (1999): Environmental Concerns and Risks of Genetically Modified Crops: Economic Contributions to the Debate. *Canadian Journal of Agricultural Economics* 47:437-444.

Morel, Benoît, R. Scott Farrow, Felicia Wu, Elizabeth A. Casman (2003): Pesticide Resistance, the Precautionary Principle, and the Regulation of *Bt* Corn: Real Option and rational Option Approaches to Decision Making. In Ramanan Laxminarayan (ed.) Battling Resistance to Antibiotics and Pesticides, pp. 184-213. Washington, DC: Resources for the Future.

Norwegian Biotechnology Advisory Board. 2009. Sustainability, Benefit to the Community and Ethics in the Assessment of Genetically Modified Organisms: Implementation of the Concepts set out in Sections 1 and 10 of the Norwegian Gene Technology Act. 2nd Revised Edition. Oslo, Norway: The Norwegian Biotechnology Advisory Group.

Paarlberg, Robert (2001) The Politics of Precaution. Genetically Modified Crops in Developing Countries. Washington, DC: The International Food Policy Research Institute.

Paarlberg, R. D. Wafula, I. Minde, J. Wakhungu (2006). 'Projected Farm Income Gains in the COMESA-ASARECA Region from Commercialization of Bt Maize.' RABESA Report No.1-4. ACTS Press, Nairobi, Kenya pp 35.

Secretariat of the Convention on Biological Diversity (2000), 'Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes.' Secretariat of the Convention on Biological Diversity, Montreal.

SAGPyA (2003). 'Resolución 39 Liberación al Medio de Organismos Vegetales Genéticamente Modificados (OVGM)'. Secretaria Agricultura, Ganadería, Pesca y Alimentos, Republica de Argentina, July 11, 2003. http://www.sagpya.mecon.gov.ar/new/0-0/programas/conabia/resolucion39.PDF

SAGPyA (2007). 'Resolución 60: Régimen para la Comercialización de Organismos Genéticamente Mejorados que Contengan Eventos Acumulados'. Secretaria Agricultura, Ganadería, Pesca y Alimentos, Republica de Argentina, February 5 2007. http://www.sagpya.mecon.gov.ar/new/0-0/programas/conabia/Resolucion_60_2007.pdf

SAGPyA Argentina (2006). Resolución 212: Producción de Semilla de Maíz Genéticamente Modificada en Etapa de Evaluación en Republica Argentina Secretaria Agricultura, Ganadería, Pesca y Alimentos, Republica de Argentina,

May 15 2006. http://www.sagpya.mecon.gov.ar/new/0-0/programas/conabia/res212.pdf

SC-PRC (2002). 'Regulations on Safety of Agricultural Genetically Modified Organisms'. State Council of the People's Republic of China. May 9, 2001.

Smyth, S. J. and P. W. B. Phillips (2008) Thresholds for profitable genomic innovations, presentation at the 12th International Consortium for Agricultural Biotechnology Research (ICABR) conference. Ravello, Italy, June 12-14.

Smyth, S. J., M. Gusta, K. Belcher, P. W. B. Phillips and D. Castle (forthcoming(a)) Environmental Benefits from GMHT Canola Production.

Smyth, S. J., M. Gusta, K. Belcher, P. W. B. Phillips and D. Castle (forthcoming(b)) Changes in Herbicide Use Following the Adoption of Herbicide Tolerant Canola in Western Canada.

Wesseler, J., S. Scatasta, and E. Nillesen (2007), 'The Maximum Incremental Social Tolerable Irreversible Costs (MISTICs) and other Benefits and Costs of Introducing Transgenic Maize in the EU-15', *Pedobiologia* 51:261-269.