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Socio-economic Considerations and International Trade Agreements

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Abstract
The provision for the inclusion of socio-economic considerations in domestic regulatory frameworks pertaining to living modified organisms has been established by Article 26 of the Cartagena Protocol on Biosafety to the Convention on Biological Conservation. Many countries are, or have, considered inclusion of socio-economic aspects in their domestic legislation, raising international concern that socio-economic risk assessments will become a mandatory part of approval processes and further complicate the approval, and international trade, of new genetically modified crops. Barriers to international trade, unfortunately, enjoy a long and robust history. The objective of this article is to review the various international agreements that have a governance capacity pertaining to international trade and assess how these agreements might interpret the domestic implementation of socio-economic risk assessments. The result of this will be a clearer understanding of what cost and benefit tradeoffs will be required by countries that have, and are planning to, include socio-economic considerations as part of their domestic regulatory framework.

1. Introduction

The Cartagena Protocol on Biosafety (CPB), under the Convention of Biological Diversity (CBD) of the United Nations, was ratified and adopted as an international agreement providing one set of rules for the international trade of genetically modified organisms (GMOs) for those nations that chose to ratify the CPB. Under the CPB any country wanting to export a GMO for deliberate introduction into the environment must seek an advanced informed agreement with the importing country before trade occurs. The advanced informed agreement is not required for those GMOs that are to be used for food, feed or processing. All decisions under the CPB are based on risk assessment procedures in addition to provisions for GMO identification.

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In many cases, the CPB has been expanded to domestic laws and regulations regarding the approval of GMOs for experimental trials, controlled trials and deliberate release into the environment. The objective of the CPB is to ensure an adequate level of protection in the safe transfer and handling during transboundary movements of living modified organisms,[2] resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity while taking into account risks to human health (Article 1 of the Protocol, Secretariat of the Convention on Biological Diversity, 2000).

One of the substantive issues included in the CPB – and in some countries' domestic laws and regulations – that has become quite controversial is the potential inclusion of socio-economic considerations (SECs) in decision-making as contemplated in Article 26 of the CPB (Falck-Zepeda, 2009; Falck-Zepeda, 2012). In the CPB, countries may decide to include SECs in decision-making for the approval or import and use of GMOs. Some authors have argued that a strict interpretation of Article 26 of the CPB means that, SECs are only allowed if they impact the value of biological diversity to indigenous and local communities (i.e. Jaffe, 2005). Yet, many countries have expanded the narrow scope of Article 26 of the CPB to include broader SECs, especially in developing countries (Falck-Zepeda, 2012). Whether a narrow or broad interpretation of the scope of SECs, the inclusion of socio-economic assessments in decision-making processes may enter into conflict with international obligations, especially those contemplated under the World Trade Organization (WTO) agreements.

[2] In the Cartagena Protocol on Biosafety the term 'living modified organism' is defined in the text as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology." A living organism in turn is defined as "any biological entity capable of transmitting or replicating genetic material, including sterile organisms, virus or viroids." While the Protocol provides a definition of LMOs, there is not at present a multilaterally agreed definition of genetically modified organisms which is the term used in most of the literature. The European Community has defined GMOs in its Directive 2001/18/EC, but this definition cannot be regarded as universally accepted. For the purposes of this article we will the term GMOs as it is widely used in practice.

This article is structured as follows. Section 2 provides the details of Article 26 of the CPB. Section 3 describes potential issues between the CPB and other international treaties, particularly the WTO. Section 4 examines the WTO report from the case brought against the European Union by a group of countries for its risk assessment policies and the aftermath of such WTO processes. Section 5 discusses potential policy issues for developed and developing countries as they impact trade and other considerations. Finally, in Section 6, we provide some concluding comments.

2. Article 26 of the CPB

Article 26 of the CPB provides countries with the opportunity to include SECs in their domestic regulatory decision-making process. Several aspects of Article 26 are important to highlight. Article 26 allows, but does not mandate, countries the potential inclusion of SECs in decision-making for import or use under domestic measures of GMOs. In this sense, Article 26 is a re-affirmation of nation's sovereign right to implement policy in their own jurisdiction, although this Article also indicates that such inclusion is dependent on the countries' international obligations. Article 26 limits socio-economic inclusion in decision-making to those issues where transboundary movements will have an adverse impact on the value of biodiversity to indigenous and local communities. A literal interpretation would make this article narrow in scope and limited in its application. Interestingly, by not explicitly defining socio-economic considerations in its text (Box 1) Article 26 gives countries the freedom to choose what they want to include in such assessments.[3]

[3] Australia for example has taken the position that impacts on human health and socio-economic considerations are those that arise from those adverse impacts on the environment (see The Biosafety Protocol - Biosafety and Trade in Living GMOs. Speech by Ralph Hillman, Australian Ambassador for the Environment, to the ABARE Outlook 2000 Conference, Canberra, 2 March 2000. http://www.dfat.gov.au/environment/bsp/hillman0300.html).

Box 1: Article 26 of the Cartagena Protocol on Biosafety

SOCIO-ECONOMIC CONSIDERATIONS

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

There have been some attempts to define potential SECs that may be included in biosafety decision-making (Fransen *et al*., 2005). Table 1 lists the SECs identified in a CBD Secretariat expert meeting report, providing examples that parties to the CPB may take into consideration during their decision-making processes. The list in Table 1 is quite similar to the Fransen, *et al*. compilation.

A strict interpretation of Article 26 would only include the last two items from Table 1, as they may reflect an impact on biodiversity. This implies that other impacts in this list may not be considered in socio-economic assessments prior to a science-based biosafety assessment unless they have an impact on biodiversity or it is specifically included in domestic measures to conduct such procedures. Several countries have already included SECs as part of their domestic measures. Inclusion of SECs have been done through policies, laws and other regulatory instruments under domestic biosafety frameworks. See Falck-Zepeda and Zambrano (2011) for a thorough discussion of the issues associated with such inclusions.

Table 1: List of potential socio-economic considerations

- Impacts on market access and trade at national and international levels
- Macroeconomic impacts, including those on sustainable development
- Microeconomic impacts at the individual, household or community level
- Compliance with biosafety measures, including institutional costs

- Coexistence of LMOs
- Health-related impacts, including those resulting from changes in the use of pesticides and herbicides
- Gender impacts
- Labor and employment
- Impacts on consumer choice or consumption patterns
- Food security
- Land tenure
- Rural-urban migration
- Farmers' rights
- Cultural, spiritual and ethical aspects
- Economic impacts of changes in pest prevalence due to changes in farm management practices
- Economic impacts of changes in application rates and effectiveness of pesticides and herbicides
- Indigenous and local communities impacts on livelihoods, knowledge and biodiversity
- Impact on the conservation and sustainable use of biodiversity

Source: CBD Secretariat.

3. Relationship between CPB and the WTO

According to Article 31 of the Vienna Convention on the Law of Treaties, the terms of a treaty shall be interpreted not only in good faith and in their context, but also in light of its object and purpose by considering the ordinary meaning that has been given to its terms, which most likely will reflect the intention of the parties. Article 30 states that there is no hierarchy between treaties, although it does provide for two exceptions to this rule. The first is the peremptory norms (*jus cogens*). These are norms that have been, according to Article 53, accepted and recognized by the international community of States as a whole, from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character. Second, according to Article 30 (3), a more recent treaty that deals with the same subject matter as an earlier treaty prevails in the case of conflict but only as between parties to the more recent treaty. For example, according to this, some could argue that

the CPB would prevail over the Sanitary and Phytosanitary Measures Agreement within the WTO.

This can be further expanded by considering two additional aspects. First, although international treaty law norms allow the possibility that a supplementary agreement linked to an earlier treaty to stand alone, the same norms also allows the original treaty to limit supplementary protocol membership to those parties to the original treaty. In this case, Article 32.1 of the CBD has specific provisions limiting access to its protocols including the CPB. A country cannot be a party to the CPB unless it is a party to the CBD, but the opposite is not limited, thus there are 191 parties to the CBD whereas the CPB has 153.

Second, the fact that the 'savings clauses' are in the CPB Preamble and not in the body of the text may lead to several interpretations with regard to the relationship between the CPB, the WTO and other international agreements. There are specific 'savings clauses' throughout the CPB by which the agreement addresses overlap problems with other international agreements. For instance, Article 5 explicitly excludes from its scope "the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations". Another example is Article 18(3) that refers to the development of standards with regard to identification, handling, packing and transport practices "in consultation with other relevant bodies". Nevertheless, the third clause (Box 2) in the CPB Preamble renders it somewhat inconclusive with regard to its relationship with other agreements in the case of a conflict between states' obligations under the Protocol and under WTO

agreements.

Box 2: Relevant clauses in the Cartagena Protocol on Biosafety

- Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development.
- Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements.
- Understanding that the above recital is not intended to subordinate this Protocol to other international agreements.

According to Alfonso (2002) the EU accepted the inclusion of the 'savings clause' in the preamble because of its reduced impact as opposed to inclusion in the body of the text. In contrast, Safrin (2002) argues that the fact that the text delimiting the relationship between the CPB and other international agreements appears in the preamble does not diminish its effect of stating the parties' intention to preserve rights and obligations deriving from earlier agreements. Aust (2000) indicates that statements included in any treaty preamble may serve as indicators of the background and purpose of the treaty, as political statements, negotiation matters not resolved but included in a watered down version or as a repository of causes lost during the negotiation process. Ricci and Cullet (2002) argue that inclusion of the third clause was aimed to be a counterweight to the scope of the savings clause, which would raise questions on the coherence of the CPB. This would imply that preambles are an integral part of treaties and thus binding.

Alfonso (2002) argues that the intention of the parties to the CPB negotiations was to set forth four concepts describing relationships between the CPB and other international agreements. The four concepts include: 1) the main purpose of the CPB is biosafety; 2) a recognition that other international agreements are relevant to sustainable development which carry their own

rights and obligations; 3) the CPB and other international agreements are of equal status; and 4) trade and environmental agreements and policies should be mutually supportive.

The relationship between the CPB and other multilateral agreements is primarily set forth in the CPB's Preamble. The last three clauses of the Preamble are specific to the relationship with other international agreements (Box 2). Alfonso (2002) argues that the second last clause, known as the 'savings clause', proposed by some of the parties focuses on restraining the scope of the CPB to trade issues (i.e. The Miami Group, which are mostly GMO exporting countries) was formulated in general terms, while its real aim was to discourage any CPB party to use it as a measure against meeting obligations under the WTO Agreements. It is interesting that in the CPB negotiations, most developing countries (i.e. the Like-Minded Group) and the European Union's perspective was that the application of comprehensive rules within the CPB should not be jeopardized by having text that allows previous treaties to prevail in case of dispute. For this reason, the Like-Minded Group and the European Union (EU) firmly opposed the introduction of a 'saving clause' in the body of the protocol.

According to Alfonso (2002), from the CPB negotiations, it is clear that the parties had expressly intended to set up a specific trade regime for GMO products falling within its scope. In this line of argument the CPB can claim the status of special law (*lex specialis*), which could derogate all general laws (*legi generali*) such as those from WTO agreements. This interpretation is further strengthened by the fact that the CPB is a new agreement and thus given precedence when contradicting with WTO agreements (*lex posterior*).

World Trade Organization Agreements

The inclusion of SECs may constitute a significant barrier to trade and thus be subject to WTO obligations. The importance of this is stressed in Article 26.1 of the CPB where it states that the

implementation of SECs must be done with respect to a country's international obligations. Zarrilli (2005) indicates that four issues related to the CPB could overlap with WTO agreements, including: (i) the scope for legitimate government action short of conclusive scientific evidence; (ii) risk assessment and risk management; (iii) the socio-economic factors that may be taken into account in the decision-making process; and (iv) documentation obligations. Potentially, there are a number of WTO agreements that could apply to the case of including SECs in decision-making such as, the Sanitary and Phytosanitary Measures (SPS), the Technical Barriers to Trade (TBT) Agreement, Trade-Related Aspects of Intellectual Property Rights (TRIPs) and the General Agreement on Tariffs and Trade (GATT).

Sanitary and Phytosanitary Measures

In the SPS Agreement, a SPS measure is one taken to protect an entity from a recognized risk. Table 2 includes protected entities and the causal agent protected by the measure. The SPS Agreement in Annex A.1 defines SPS measures as all sanitary and phytosanitary measures that may affect international trade. SPS measures include all:

> … laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants . . . ; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.

Table 2: Measures included in the SPS Agreement under the WTO in Annex A.1	
Protected entity	*From*
Animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread	Pests, diseases or disease-causing organisms
Human or animal life or health within the territory of the Member	Risks arising from additives, contaminants, toxins or disease-causing organisms in their food, beverages or feedstuffs
Human life or health within the territory of the	Diseases carried by animals, plants or products

member from risks arising from	thereof, or from the entry, establishment or spread of pests
Territory of the member	Damage caused by the entry, establishment or spread of pests

Source: Annex A.1, SPS Agreement.

SPS member countries have the right to implement SPS measures to protect human, animal and plant life within their territory. This is not an unlimited right as the SPS Agreement requires that any measures used to protect human, animal or plant life or health be necessary for protection. SPS measures have to be based on scientific principles and maintained over time based upon scientific evidence such as those in a well-defined and accepted risk assessment procedure. Annex A.4 of the SPS Agreement defines risk assessment as:

> The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease causing organisms in food, beverages or feedstuffs.

SPS measures cannot be arbitrary or discriminatory[4] and cannot be a disguised trade restriction, nor can they be more than necessary to allow protection while minimizing trade restrictions. In those cases, where there is insufficient scientific evidence, the SPS Agreement allows temporary measures for protection based on available and pertinent information, but members are mandated to review temporary measures in a reasonable period of time by seeking additional information necessary to conduct an objective risk assessment. The conditions under

[4] As described by Isaacs (2003) the principle of non-discrimination is quite complex including three definitional aspects. First is whether a product is like another product. Second, national treatment should be the same. Third, most favored nation treatment for a like product cannot be selective. This implies that those products derived from production enhancing GM technologies which are like those produced by organic means, cannot be in principle differentiated under WTO agreement rules.

which temporary measures are allowed are considered to be cumulative and equally important in defining whether temporary measures are compliant with a SPS measure.

Technical Barriers to Trade Agreement

The TBT Agreement covers all technical regulations and standards not covered by the SPS Agreement. The TBT Agreement is less specific than the SPS Agreement as it covers a broader scope of applications. Nevertheless, those regulations and standards covered under the TBT Agreement have to comply with a similar set of implementation requirements such as those in the SPS Agreement. A member country cannot implement measures that are discriminatory with like products, must have a specific and legitimate objective based on a well-defined risk assessment and not be more trade restrictive than necessary. Member countries have to account for available technical and scientific information in the implementation of such measures.

GATT and TRIPS Agreements

Article XX of the GATT Agreement introduces an exception from GATT rules to protect health or the environment by allowing balancing of trade and non-trade issues. A country would need to show the need for non-compliance with GATT in order to achieve health or environment protection. GATT may be relevant for the discussions on the import and export of products obtained on the basis of genetic modification (food, seeds and plants, animals and medicines) and in the identification of genetically obtained products through labeling. Labeling usually applies where no risk has been identified (Cottie, 2008).

In turn, the TRIPs Agreement requires a minimum level of protection for intellectual property rights as related to GMOs. In some situations, countries may exclude from patent protection, plants and animals and biological processes for the development of such organisms.

The TRIPs agreement also allows temporary measures to exclude patenting when there may be a risk to human, animal or plant life or health, or damage to the environment.

The Precautionary Principle

The precautionary principle has been widely debated in many policy forums as well as in the literature (Szajkowska, 2010). The precautionary principle was adopted by the Rio Conference in 1992, but its origins can be traced back to German environmental legislation from the 1970s. Sandin (1999) and others have pointed out that there is very little consensus about the exact meaning of the precautionary principle. In most formulations those actions that may incur significant risk should be avoided even when there is no full scientific evidence that the risk may actually be realized in practice. In short, the precautionary principle is a notion which supports taking protective action before there is complete scientific proof of a risk; that is, action should not be delayed simply because full scientific information is lacking. The precautionary principle has been incorporated into several international environmental agreements and some authors have suggested that it is now being recognized as a general principle of international environmental law (Falkner and Gupta, 2009).

In the fields of food safety, plant and animal health protection, the need for taking precautionary actions in the face of scientific uncertainty has long been widely accepted. For example, there may be instances when a sudden outbreak of animal disease is suspected of being linked to imports and trade restrictions must be immediately imposed while further information about the source of the outbreak and its extent are gathered. The discipline of risk assessment, one of the basic obligations of the SPS Agreement, was developed to guide action in the face of incomplete knowledge about risks to health. It focuses on probabilities of hazards occurring and

the probable consequences, because it is impossible to scientifically prove '100% safety' of a food or product.

The CPB Preamble embraces precaution as one of its operating principles. In fact, Paragraph 6 of the Preamble encourages harmonization of national SPS measures with international standards without requiring Members to change their sovereignly-determined appropriate levels of health protection. Article 3.3 of the SPS Agreement allows members to adopt SPS measures which may be more stringent than relevant international standards when so desired. Other articles in the SPS Agreement allow measures that can be considered under the precautionary principle operating mode. For example, Article 5.7 of the SPS Agreement allows members to take temporary measures if there is no sufficient evidence of safety. As indicated in the text, members must seek additional pertinent information to render a safety assessment in a reasonable amount of time. These additional requirements within the SPS Agreement, in addition to the more general requirements for the application of SPS measures, limit the implementation of the precautionary principle under the WTO agreements, thus providing a measure of discipline for regulatory design.

4. The WTO Agreements and Socio-Economic Considerations

As established above, Article 26 of the CPB requires that inclusion of SECs has to be consistent with the obligations and requirements posed by a parties' international agreements including the WTO agreements. The WTO agreements emphasize measures based on scientific risk assessments and evidence which tend to limit decision-making based on non-scientific issues. Article 5.3 of the SPS Agreement states:

> In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from

> such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

In essence, Article 5.3 provides a set of narrow conditions under which SECs are considered when taking protective measures.

There has not been a WTO ruling specifically discussing the potential inclusion of SECs in decision-making. Based on the discussion on the requirements for SPS or TBT measures, we speculate that inclusion of SECs would need to strictly follow a narrow interpretation of Article 26.1 of the CPB based on a well-defined assessment that follows a broadly accepted socio-economic protocol or those identified as 'best practice' by relevant experts in the field since an internationally accepted protocol does not exist. Any attempt to include considerations broader than the narrow scope of the strict interpretation of Article 26.1 would have to be included under domestic measures, which in turn would have to be compliant with WTO agreements. We further explore the relationship between the WTO and SECs under the CPB by discussing a specific WTO case against the EU for their moratorium on products of biotechnology.

WTO Case Against the European Communities

The 2006 ruling on the European Communities, *Measures Affecting the Approval and Marketing of Biotech Products Case*, addresses the complex and contentious international trade situation for GMOs between the United States, Canada and Argentina (later joined by other interested parties) against the European Union (EU), provides some preliminary ideas on the potential relationship between the WTO and the CPB with regard to the inclusion of SECs in decision-making. The dispute focused on the application of the EU's approval regime for GM foods and GMOs, which

also included specific measures developed and maintained by EU member states prohibiting or restricting marketing for GM foods and GMOs. The Panel did not discuss whether GMOs were safe or are like their conventional counterparts or whether the EU has the right to require pre-market approval of GMOs or if the EU requirements for a product-by-product scientific risk assessment violated their obligations under the WTO Agreements.

The primary objective of the EU regime was described as a safeguard for human health and the environment. The contesting parties argued that both the EU and the EU member state measures violated Articles 2, 5, 7, 8 and Annexes B and C of the SPS Agreement, Articles 2 and 5 of the TBT Agreement, and Articles I, III, X, XI of the GATT. The Panel issued its decision in 2006 and found that the EU between June 1999 and August 2003 applied a *de facto* moratorium on the approval of GM foods and GMOs and therefore violated their obligations under Annex C(1)(a) and Article 8 of the SPS Agreement due to the undue delay caused by the moratorium.

The EU argued that the reasons why some of its member countries imposed bans on biotech products were not inconsistent with the SPS Agreement as some of the reasons guiding those decisions fell outside of the scope of the SPS Agreement. Reasons include those such as loss of biodiversity, protection of native crops, impacts on farms and farming systems and long-term ecological impacts, which they associated with socio-economic considerations. In fact, the Dispute Settlement Panel (DSP) ruled that reasons given by the EU for allowing a ban by member states on EU approved biotechnology products fell within the scope of the SPS agreement.

Countries can use economic, health or environmental considerations to justify an SPS measure as it is not illegal under WTO rules, in fact countries use this type of assessments customarily to define and implement measures. The Panel also ruled that identification of a

potential economic impact is necessary but not sufficient for imposing a SPS measure. Measures have to be based on well-defined scientific risk assessments in order to be consistent with Article 5.1 of the SPS agreement. Documents supporting measures must be consistent with identified risk assessment procedures themselves.

The DSP report indicated that in every case the EU arguments had been rejected, as the EU member states had not met their obligation of basing their measures on a scientific risk assessment. The EU argued that Article 5.7 of the SPS Agreement justified that some of its member state bans and pre-marketing approval restrictions. The Panel rejected this argument indicating that EU member state measures did not meet requirements under Article 5.7, thus measures were subject to the other provisions of the SPS Agreement, including the requirement in Article 5.1, that the trade restricting measure be based on a scientific risk assessment.

The Panel indicated that the EU could not rely on either non-expert civil society (non-governmental organization – NGO) reports or general scientific studies, even those appearing in peer-reviewed journals, which did not otherwise provide an assessment of specific context-based health or environmental risks pursuant to specifically defined scientific protocols. Indeed, in the Panel's view, these sources did not constitute 'adequate' risk assessment because, prima facie, they did not look to or take "into account risk assessment techniques [protocols] developed by the relevant international organizations". The Panel, by raising this issue, once again reaffirmed that a science-based risk assessments and politics-based risk management decisions are indeed two distinct but related disciplines involving different experts and considerations.

In the Panel ruling, only science-based risk assessments are relevant for purposes of determining whether a WTO member has satisfied SPS Article 5.1 and Annex (A)(4). This may have an impact on those SEC procedures that may be included under the auspices of the CPB.

The Panel report sets a legal precedent that WTO members have to account for their future decision-making with regard to protective measures. In the future, any inclusion of SECs in decision-making will require identification and assessment of risk considerations associated with the SEC in order to be compliant with SPS measures. This may be a significant hurdle as there is very little experience associated with some of the broader SECs, such as those listed in Table 1. This also implies that the conditions under which inclusion of SECs is implemented in decision-making would also need to comply with the procedural requirements for SPS measures including non-discrimination and minimal impact as trade barriers.

Although the DSP report sets a precedent by finding fault in the ban on GMO approved events and other measures taken by the EU (Kogan, 2007; Cho, 2006), bans set in place by individual EU country members remain in place. The EU seems to be re-affirming the right of individual member countries to ban any EU approved GMO event, in some cases based on SECs. These bans may runs counter to the WTO SPS Agreement rules and thus may need a formal ruling by the Dispute Settlement Body mechanism to determine the appropriateness of such inclusion into decision-making. However, a ruling by the WTO Dispute Settlement Body against a party regarding actions allowed by the WTO rules has not been a deterrent for parties in the past. This is evident by how the EU has chosen to accept retaliation after losing the hormone beef case brought by the US, Canada and Argentina, rather than allow these products to enter into the EU (Kerr and Hobbs, 2002; Young, 2012). Although Canada and Argentina have recently reached a mutually agreed upon resolution with the EU, the US seems to continue debating whether to try and reach negotiations to reach a similar settlement or make use of the retaliatory practices allowed under the WTO for the non-compliance of the EU on the recommendations by the DSP report (Hanrahan, 2010).

5. Policy Issues for Socio-economic Inclusion in Decision-making

Although Article 26.1 allows countries to include SECs in their decision-making, the scope of such inclusion in the CPB is quite narrow to the value of biological diversity to indigenous and local communities. Although there are several questions about definitions (e.g. Which biodiversity is important, agricultural biodiversity or overall biodiversity?; Where to measure such impact, in the local community or where adoption occurs?) included in the Article which are likely to require more negotiations by the CPB parties, any potential course of action will need to consider compliance with the SPS Agreement.

As we discuss in this article, especially with regard to the EU biotech case, the inclusion of SECs in biosafety decision-making will have to be non-discriminatory, will have to minimize trade barrier impacts and will have to be based on scientific principles recognized in accepted international protocols, probably based on a risk assessment. Since there is no international protocol on socio-economic assessments, such as those for food/feed safety assessments included in *Codex Alimentarius*, we speculate that to minimize the possibility of non-compliance with the SPS measure rules, any SEC inclusion will need to comply with those elements of best practice that experts in the field have set forward in guidelines and other documents. This may require further negotiations under the CPB and a ruling by the WTO Dispute Settlement mechanism to fully determine whether this is sufficient to comply with the technical requirements such as those in the risk assessment procedures.

Another issue for the potential inclusion of SECs is that any issues included in the assessment may be judged under the standard of scientific evidence and thus would require a scientifically-based assessment for inclusion. The WTO Panel report indicated that the procedures needed to conduct a risk assessment would have to be specific and compliant with the

specific protocol steps to ensure a robust risk assessment. Indirect evidence such as peer reviewed publications, although contributing to a robust risk assessment, would not be sufficient scientific evidence unless they meet the requirements of assessment procedures considered best practice.

Finally, although this may be a legal language point, the question remains whether the SEC assessment would focus only on risk issues (i.e. the safety aspects) arising from socio-economic impacts or whether the assessment would be able to consider the socio-economic impacts themselves. This may be a moot point, as in many risk assessment procedures these may be one and the same. Yet, when countries decide to include broader SECs, the likelihood exists where the only assessment possibility for many issues is through a qualitative measurement. This may be a limitation as there is very little experience in measuring risk under these conditions, especially in developing countries. In fact, there is relatively little experience with socio-economic assessments in developing countries, although the literature is growing (Smale *et al*., 2009) most of it focused on quantitative methods and economics impacts (Smale *et al*., 2008). Whether the assessment of broader social issues would be considered scientifically-based is open for interpretation.

6. Concluding Comments

This article has discussed the potential inclusion of SECs in biosafety decision-making allowed by Article 26 of the Cartagena Protocol on Biosafety. Inclusion of SECs by Article 26 of the CPB is voluntary (not mandatory), limited to the value of biodiversity to local and indigenous communities and for import decisions unless included in domestic measures. Inclusion in domestic measures may allow for broadening the scope of SECs, but would still need to comply with international obligations such as the WTO's SPS and TBT Agreements.

Rules and general principles for delimiting the potential applicability of SECs in decision-making have been delineated in the SPS Agreement. These rules and principles are similar for TBT and other WTO agreements such as GATT. As such, potential inclusion of SECs, whether under the CPB or domestic measures, will have to demonstrate that they are non-discriminatory to like products, based on scientific evidence and thus be based on a set of defined and internationally recognized protocols for risk assessment and if a temporary measure, then they would have to undergo an assessment procedure in a reasonable amount of time determined on a case-by-case basis.

Based on these requirements, inclusion of broader SECs in domestic measures may be limited to those not involved with international trade (i.e. commercial cultivation) and still subject to the rules and principles set forth by the WTO agreements. Although the final outcome may require a specific ruling by the WTO dispute settlement mechanism. From this standpoint, if developing countries have made the decision to include SECs in their decision-making under the CPB and/or through domestic measures, they should be vigilant that these procedures are indeed compliant with the WTO and other international agreements.

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