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## Consistency of Assessment of Socio-Economic Considerations under the Cartagena Protocol on Biosafety with Other International Obligations

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Compliance with international obligations is the lynch-pin to the sustainability and success of international agreements, treaties and organizations. Without this compliance these bodies will fail to function, or at the very least experience a reduction in their functionality. As part of the process to develop biosafety legislation, the Cartagena Protocol on Biosafety, through Article 26, provides for the voluntary inclusion of socio-economic considerations. Crucial to this provision is that socio-economic consideration incorporation must be "consistent with [the parties] international obligations". Numerous international agreements and protocol obligations are applicable to the various SEC factors that can be considered for inclusion. This article provides concise overviews of the most significant of the various international agreements relevant to the potential SEC factors and then offers a thorough discussion of the terms and commitments from parties to the CPB that are considering the inclusion of SEC factors into their domestic regulatory biosafety frameworks. This article clarifies the legal complexities of these commitments to

international obligations and encapsulates the numerous obligations into a single source.

Keywords: biosafety, decision-making regulations, socio-economic considerations, treaty obligations

#### 1. Introduction

The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) specifically concerns transboundary movements of genetically modified organisms (GMOs). A country wanting to export a GMO to another country for deliberate release into the environment must apply to the prospective importing country for prior approval (art 8.1). CPB Article 26.1 permits nations to include socio-economic considerations (SECs) in decision-making regarding such applications. Inclusion is not mandatory, and whether SECs are included as part of decision-making by a particular nation is a matter for its lawmakers, but Article 26.1 goes on to provide that if SECs are included in decision-making, that inclusion must be "consistent with their international obligations".

The significance of Article 26.1's limitation to "[SECs] arising from the impact of LMOs [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" has been extensively considered by academics (e.g. Jaffe, 2005) and the CPB parties. So too, the likely conflict between obligations imposed by the World Trade Organization agreements (which generally exclude SECs) and those rights given by the CBD and its protocols. Experts in some SECs, such as traditional knowledge (Phillips, 2014), biodiversity (Falck-Zepeda, Zambrano and Smale, 2014) and labour (Gouse, 2014), have also begun considering the international laws relevant to particular SECs. However, little work has been done in bringing rights and obligations under these international laws together.

Many international agreements can be relevant to the same SEC and vice versa, with many SECs addressed by the one agreement. Bringing international law regimes together is difficult because of the lack of any real hierarchy amongst international laws and lack of a centralized court system for review or enforcement of such laws (Hestermeyer, 2014). Adding to that confusion is the CPB's lack of any binding dispute resolution mechanism, including regarding the appropriateness of a purported SEC assessment or its consistency with obligations under other international agreements. Indeed, outside of the WTO agreements there is generally a lack of or only weak enforcement and dispute resolution arrangements in international

multiparty agreements. As Kerr et al. (2014) note, CPB Article 34 addresses non-compliance by parties. It envisages cooperation in such cases but also states that compliance processes in the CBD apply. The CBD in turn (in art 27) provides for resolution through negotiation and, if that is unsuccessful, third party mediation. If mediation also fails, then disputes are settled by arbitration or submission to the International Court of Justice (ICJ), as the parties have previously agreed. The involvement of the ICJ is not without its own problems given its past deferral to the WTO in disputes concerning agriculture and trade and that many GMO adopting countries are not party to the CBD and/or CPB (Kerr et al., 2014).

This article provides an overview of the international agreements and institutions most relevant to the potential factors that may be considered in a CPB SEC assessment and discusses their implications for the domestic biosafety regulatory frameworks of CPB parties and key areas where international obligations may complement or conflict. The article begins in section 2 with a primer on the general principles of international law. Section 3 is a discussion of the current proposed approach to classifying SECs under the CPB. That approach, a five-dimensional framework, is then used to organize section 4, which groups the most significant international agreements into the five dimensions and considers possible complements and conflicts between the terms and commitments under those agreements and a CPB SEC assessment. The final section, section 5, provides a discussion and conclusions.

#### 2. Inconsistent Treaty Obligations

There are many international regulatory regimes, including those around trade, environment and labour. However, not all countries are party to all regimes, and, further, the regimes do not address discrete areas, meaning each regime has the potential to overlap with the concerns of other regimes. Problems arise where one regulatory regime imposes obligations contrary to those of another regime: Which regime has primacy? Academics have analyzed how international law is likely to apply in such cases. In the context of GMOs in particular, readers are referred to Kerr et al. (2014) and Smyth and Falck-Zepeda (2013). A summary of that work is provided here.

A useful starting point is the Vienna Convention on the Law of Treaties 1969. It provides that where treaties concern the same subject matter, one treaty may specify that it is subject to or not incompatible with another treaty. In that case, the other treaty prevails if the treaties concern the same subject matter (art 30.2). Where there is no such provision, the earlier treaty applies but only in so far as it is compatible with the terms of the later treaty; if the two treaties do conflict though, the later treaty

prevails (art 30.3). Adding to the complexity, these provisions only apply where the two treaties concerned have the same parties. Where the parties are different (such as where not all countries that are party to the earlier treaty are parties to the later treaty), the treaty to which they are both party governs their mutual rights and obligations (art 30.4).

The CPB preamble provides that "this Protocol shall not be interpreted as implying a change in the rights and obligations of a party under any existing international agreement" but adds "understanding that the above recital is not intended to subordinate this Protocol to other international agreements" (Secretariat of the Convention on Biological Diversity [CBD], 2000, 2). The result of these preambular statements is, as concluded by Kerr et al., that it is virtually impossible to predict the outcome of a potential clash between the terms of the CPB with other international agreements.<sup>6</sup> Kerr et al. also point out ambiguity if not contradiction within the CPB's main text. Article 2 allows parties to take action on biosafety that is more protective than that envisaged by the protocol, subject to the proviso that such measures will be "consistent with the Parties' other obligations under international law" (Secretariat of the Convention on Biological Diversity [CBD], 2000, 3), but Article 26.1 authorizes parties to "take into account socio-economic considerations arising from the impact of LMOs [living modified organisms] on ... biological diversity" (Secretariat of the Convention on Biological Diversity [CBD], 2000, 19) when such inclusion is not allowed under the WTO agreements (Kerr et al., 2014).

The Vienna Convention (art 31) also provides for principles regarding interpretation of a treaty's actual terms. A treaty can provide for its own interpretation, definitions and so on. However, it cannot derogate from a peremptory norm, such a norm being one that is accepted and recognized by the international community of states as a whole, as a norm from which no derogation is permitted and which can only be modified by a subsequent norm of the same character (art 53). Further, interpretation of a treaty is to be done in good faith, in context and in light of its object and purpose. In addition, any relevant rule of international law is to be taken into account.

"Rule" in the Vienna Convention has been considered by a WTO dispute settlement panel in a decision on a complaint brought by the United States, Canada and Argentina against the European Communities over the EC's de facto moratorium on approval of biotech products between June 1999 and August 2003 and also certain measures adopted and maintained by some EC member states prohibiting or restricting the marketing of biotech products. "Rule", at least for the purposes of WTO dispute settlement, was interpreted by the panel to include treaties, customary

international law and general principles of law. The generality of this interpretation itself creates room for dispute. For example, although the WTO agreement concerned (discussed below) does not use the word "precaution", the EC argued that the precautionary principle which is used in environmental agreements was a general principle and so a "rule" applicable to the dispute (Wirth, 2014). The panel found the precautionary principle's status in international law was unsettled and therefore there was no need to address that issue.

#### 3. CPB Framework for Classification of SECS

The governing body of the CPB, the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Protocol (COP-MOP), has considered the issue of SECs. At its most recent meeting, COP-MOP7 in October 2014, SECs were discussed extensively.<sup>9</sup>

The COP-MOP adopted working group recommendations based on a report by the Ad Hoc Technical Expert Group on SECs (AHTEG). Amongst other things, the AHTEG report suggests a system for classifying SECs. It created a framework to assist CPB parties in taking into account SECs in decision-making regarding GMOs. The framework states that it is to be adapted "as appropriate to national and regional specificities and consistent with international obligations, for addressing [SECs]". The framework also notes, as a general principle, that such account of SECs must be consistent with "relevant international obligations, which include trade agreements, environmental agreements and human rights agreements" and that "human health related issues arising from impacts of [GMOs] on the conservation and sustainable use of biological diversity should also form part of [SECs], provided they were not already addressed in the risk assessment". Public participation and consultation are also noted as part of the process.

Following the COP-MOP7 adoption of the framework, and funding permitting, the AHTEG has been instructed to develop "conceptual clarity on [SECs] arising from the impact of [LMOs] on the conservation and sustainable use of biological diversity, taking into account and improving upon the [framework]" and the results of other investigations by the AHTEG.<sup>17</sup>

The current framework does not define or list SECs, noting that any list would be indicative only and non-exhaustive. Instead it lists five dimensions for classification of elements of SECs and notes that elements can fall into more than one such dimension. The listed dimensions, together with the example elements given in the framework, are as follows:

(a) economic: e.g. impact on income;

- (b) social: e.g. impact on food security;
- (c) ecological: e.g. impact on ecosystem functions;
- (d) cultural/traditional/religious/ethical: e.g. impact on seed saving and exchange practices; and
- (e) human health-related: e.g. impact on nutritional status. 18

This article adopts that list for its analysis, recognising as the AHTEG itself did that any particular element, or SEC, can fall into more than one dimension. It should also be remembered that the same GMO may raise different SECs in different countries.

#### 4. International Agreements Raised by SECs

#### a) Economic Dimension

Conflict between an SEC assessment for the purposes of decision-making under the CPB and a nation's obligations under other international agreements is most likely in the economic dimension. In particular, the WTO agreements<sup>19</sup> – the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), the Technical Barriers to Trade (TBT) Agreement, the General Agreement on Tariffs and Trade (GATT) and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) are central to any discussion about SEC decision-making regarding trade in agricultural biotechnology.

The WTO rules codify international trade law and are most logically placed within the economic dimension of the AHTEG list because of the WTO's objective of ensuring non-discriminatory trade and in turn enhancing the global interest. The TRIPS Agreement though, because of its relationship with intellectual property (IP), seed saving and exchange practices, which are expressly given by the AHTEG as an example of the cultural/ traditional/ religious/ ethical dimension, is considered under that heading below. Consumer choice, which could also be treated as part of the cultural/ traditional/ religious/ ethical dimension, is also an important part of market economies and so is considered here, under ii) Consumer choice. The AHTEG's example for the economic dimension of "impact on income" means labour impacts are also included here, under iii) Labour impacts.

#### i) International trade

The WTO has not established regulations specifically governing international trade in GMOs. Nevertheless, in terms of compliance of a nation's biosafety regulations with

that nation's other international obligations, the WTO is likely to be the predominant benchmark. This is because most countries are party to the WTO, the WTO has specific requirements regarding trade barriers and it also has an effective and binding dispute settlement mechanism. If SEC assessment under a nation's standards or regulations cannot document compatibility with WTO obligations, the implementing country can be subject to any other WTO member nation filing a claim with the WTO's Dispute Settlement Body that the assessment is an unjustified trade barrier and therefore compensation is payable for lost trade opportunities. The growing importance of conflict between the rules of the CPB and the WTO has been well recognised, as are the reasons for the increase in direct conflict between the two regimes (see Kerr et al., 2014). The most significant areas of possible conflict are summarized below.

#### SPS AGREEMENT

The SPS Agreement governs food safety measures and quarantine. While trade barriers are generally prohibited, the SPS Agreement allows countries to adopt or enforce measures, even if trade limiting, if the measure is necessary to protect human, animal or plant life or health within the WTO member's territory or to protect the member's territory from a risk within a specified list of risks. <sup>20</sup> SPS measures, for the purposes of the SPS Agreement, include all

relevant 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, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.<sup>21</sup>

SEC decision-making regarding GMOs under the CPB would clearly be such a measure. The decision of the WTO dispute settlement panel referred to above is useful here.22 The panel found that the EC's regulatory framework for GMOs requiring premarketing approval were SPS measures pursuant to the SPS Agreement because their purpose was to protect the life or health of humans, animals or plants from risks in the specified list (Gonzalez, 2007). As Gonzalez (2007, 616-617) observes, the panel concluded that "the SPS Agreement is likely to be triggered even if the primary purpose of the GMO legislation is to protect farmers from economic damage resulting from the 'pest-like' quality of GMOs, including economic losses arising from the

contamination of non-GM crops by GM crops, from the transfer of undesired traits ... to conventional crops or wild flora, and from the acceleration of insect resistance."

To prevent protectionist measures being disguised as SPS measures, the SPS Agreement imposes criteria regarding their application, including that the SPS measure be *necessary* for protection while minimizing trade restrictions. Whether decision-making or a measure is necessary to protect the relevant entity from a required risk and is therefore permitted depends upon the particular measure. SPS measures which conform to international standards, guidelines or recommendations are deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with WTO obligations.

The SPS Agreement refers to three international standards-setting organizations the standards of which will be deemed necessary: the Codex Alimentarius Commission (Codex) for food safety; the World Organization for Animal Health (OIE) for animal health and zoonoses; and the International Plant Protection Convention (IPPC) for plant health. There has been significant effort by Codex to develop a standard for the labeling of food products derived from biotechnology. This is discussed under ii) Consumer Choice below. The OIE has very few standards relevant to GMOs, most of which concern GM vaccines. However, the IPPC, a multilateral treaty seeking to protect natural flora, cultivated plants and plant products from the spread of pathogens through international trade, has addressed the regulation of biotechnology and GM crops through several of its International Standards for Phytosanitary Measures (ISPMs). The International Commission on Phytosanitary Measures considers that plant pest risks raised by GMOs fall within the ambit of the IPPC.<sup>23</sup> ISPM No 11, Annex 3 deals expressly with GMOs, in particular with pest status assessment, and ISPM No 5, Supplement No 2 provides guidelines relevant to understanding the potential economic importance and the related terms of reference for environmental considerations. Based on the definition of economic damage in ISPM No 5 and therefore as part of the SPS Agreement, SEC decision-making on GMOs that does not address risk reduction for the environment or human, plant or animal health is at risk of having the measure fail to be "necessary" and therefore deemed a trade barrier. The country concerned could have a dispute case brought to the WTO against it to have the barrier removed.

Standards different from established international standards or where no international agreement exists can be considered necessary and therefore not trade barriers if based on scientific principles (art 2.2; see also arts 3.3 and 5.2) and if a risk assessment is completed (art 5.1) that satisfies SPS Agreement requirements. Risk assessment is defined in the SPS Agreement Annex A.4 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.

This context gives rise to four areas of disparity between CPB provisions and WTO obligations (Zarrilli, 2005). The WTO considers that

- 1. legitimate government action requires conclusive scientific evidence;
- 2. risk assessment and risk management must follow accepted practices;
- 3. a very limited group of SECs are relevant to decision-making; and
- 4. documentation obligations must be met.

In regards to point 1, the SPS Agreement allows for scenarios where there is insufficient scientific evidence by allowing for temporary measures based on the information that is available (art 5.7). However, the country concerned must review the temporary measures within a reasonable period by seeking additional information necessary to conduct an objective risk assessment (Smyth and Falck-Zepeda, 2013). Article 5.7 only applies while the member "seek[s] to obtain the additional information necessary for a more objective assessment of risk". Further, as Gonzalez (2007) notes, Article 5.7 is triggered by insufficiency of scientific evidence and not by scientific uncertainty.

The SPS Agreement (Annex C 82 ¶1(a)) also prohibits "undue delay". Wirth (2014,1181) notes that the WTO dispute settlement panel found that this did not preclude the application of a prudent and precautionary approach, but it also considered that "It is quite possible that ... where science evolves and there is limited available scientific evidence, a deferral of substantive decisions might allow for better decisions at a later point in time, provided that appropriate analyses and research are undertaken. However, we do not consider that [the SPS discipline prohibiting undue delay] can or should be interpreted to allow Members to go into a sort of holding pattern while they or other entities undertake research with a view to obtaining additional scientific information and data." Therefore "evolving science, scientific complexity and uncertainty, and limited available scientific information or data are not, in and of themselves, grounds for delaying substantive approval decisions" (Wirth, 2014, 1181).

Further to this, Gonzalez (2007, 617-620) explains that countries must "grant or reject applications based on the legislation currently on the books, but may grant conditional approvals subject to compliance with additional requirements. Second, ...

countries may not use lack of scientific knowledge as a justification for delaying substantive approval decisions. Instead ... countries should request additional scientific information from the applicant, adopt provisional measures under Article 5.7 ..., grant conditional approvals, or reject applications pending the availability of additional scientific information." She notes (617-620) that this comes with a caveat: whether a delay is undue depends on the reasons for it rather than the length of the delay and must be determined case by case, taking into account relevant facts and circumstances. This may include the limited capacity of developing countries to process GMO pre-marketing approval applications. The panel decision was ultimately based on a proven failure by the EC to meet procedural requirements of the SPS Agreement. It was found that the EC and nation states' moratorium and failure to approve resulted in "undue delay in the completion of product approval procedures" in violation of the SPS Agreement (Gonzalez, 2007, 619).

In regards to the second area of disparity between the CPB and SPS obligations, to be acceptable under the SPS Agreement a risk assessment must meet certain criteria, and the country into which the GMO is intended to be imported must justify its import measure based on a risk assessment. Under the CPB, the exporting country is responsible for ensuring the exporter has a legal obligation to provide accurate information (art 8.2), and in certain circumstances the importing country can ask the exporter to carry out the risk assessment.

The third point of disparity, the limited set of SECs that can be considered in decision-making, arises because the SPS Agreement (art 5.3) provides for only a narrow set of conditions under which SECs can be considered when a member is deciding whether to take protective measures. Article 5.3 provides as follows:

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.

As Kerr et al. (2014) explain, risk assessments under the CPB of many potential SECs, such as labour impacts, IP rights, religious/ cultural aspects, market access and trade and consumer choice, are unlikely to satisfy these requirements. Therefore a regulation restricting trade in a GMO on the basis of them is likely to be found to be a trade barrier in violation of the country's WTO obligations. To avoid this, "inclusion of SECs would need to 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 procedures identified as 'best practices' by relevant experts in the field, since an internationally accepted protocol does not exist" (Smyth and Falck-Zepeda, 2013, 29). Finally, as observed by Ludlow, Smyth and Falck-Zepeda (2014, 7), "The lack of success of countries seeking to justify social trade regulations in the WTO dispute resolution process illustrates the preference of that forum to prevent interference with the global interest in international trade by the disparate values held by different societies even where they are linked to plant and animal health concerns."

#### TBT AGREEMENT

All technical regulations and standards not covered by the SPS Agreement come under the auspices of the TBT Agreement. As with the SPS Agreement though, the TBT Agreement is intended to ensure that labeling and other technical requirements do not create unnecessary obstacles to trade. However, unlike the SPS Agreement discussed previously, the TBT Agreement does not identify relevant standard-setting bodies for international standards.

The TBT allows governments to choose measures based on their national requirements to meet a wider range of legitimate objectives than those of SPS measures, such as to standardize products, ensure quality or avoid consumer deception. But as with the SPS Agreement these must not be discriminatory with regard to like products, must have a specific and legitimate objective based on a well-defined risk assessment and not use measures that are more trade restrictive than necessary (Smyth and Falck-Zepeda, 2013, 27). Rules, regulations and laws pertaining to an SEC are likely to be viewed as trade barriers unless there is demonstrable, product-related evidence that the use of such standards is necessary. That evidence can be scientific information, but other elements can also be considered. Further, it is uncertain whether labeling of imports according to production methods is possible within the framework of the TBT.

#### **GATT**

GATT (arts I and III) requires identical treatment for "like" products, regardless of the country of origin. Products produced by means of production measures that do not alter the final product in any material or differentiable way must be treated as "like" products. Any decision to prevent a product's import must be based on the characteristics of the product itself and not on the process or production method (PPM) by which the product was manufactured. To paraphrase Butler (2014),

production measures that might ensure satisfaction of an SEC must demonstrate that the product is materially different from similar products that do not use the same (SEC enhancing) production measures.

Article XX, entitled "General Exceptions", provides exceptions from the GATT rules on the basis of a limited group of social regulation objectives. Article XX(a) allows trade to be restricted "to protect public morals". Butler has observed that it would probably be necessary to argue that the product itself was offensive and against "public morals" and not the production process, which, as pointed out above, would probably contravene GATT. In addition, in the case of a product produced outside of the importing country's jurisdiction, the question arises as to whether this exception could apply.<sup>25</sup>

Article XX(b) allows trade restrictions to protect human, plant and animal health, but reliance on this exception requires a scientifically established link between the organism's health and the relevant measure. However, again, in the case of a product produced outside of the importing country's jurisdiction, the question arises as to whether this exception could apply, particularly if articles I and III of GATT are invoked.

Article XX(g) allows measures that are "related to the conservation of exhaustible natural resources". It is possible that an argument could be made under GATT Article XX(g) that if a GMO was released into the wild and its release impacted the conservation of an exhaustible natural resource, then it could be listed as an exclusion under GATT Article XX (Butler, 2014).

#### ii) Consumer choice

Consumer choice could be considered an SEC of its own or at least relevant to the economic dimension. Food labeling is one approach to providing for consumer choice. At the international level, Codex develops "international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in the food trade". The Codex Committee on Food Labelling was tasked in 1993 to initiate work on the development of a standard for the labeling of GM-derived foods. Nevertheless, there is still no internationally agreed standard on such labeling, and governments apply their own rules to this. However, Codex has adopted principles for risk analysis for food safety of foods derived from genetic modification which establish that if a risk is identified, labeling is an appropriate management strategy. Codex stresses that any risk analysis of biotechnology-derived foods has to be science-based and that these principles do not address "environmental, ethical, moral and socio-economic aspects ..." (Codex, 2003, 1).

As noted above, countries may impose different standards to Codex if the requirements discussed above are met. In particular, the standards must be based on scientific principles and a risk assessment that satisfies the requirements of the WTO agreements. The methods used to determine consumer preference for labeling or not of GM food and what type of labeling should be adopted must be transparent, repeatable and unbiased (Kerr et al., 2014, 116). As Kerr et al. discuss, this has so far proved difficult to satisfy and so labeling standards may not comply with WTO obligations.

#### iii) Labour impacts

If liberal interpretations of "conservation" and "use" in the CPB to include farming, farming practices and labour are used, then labour-impact issues may be considered in an SEC assessment for Article 26.1 purposes to justify the prohibition of importation or general release of a proposed GMO (Gouse, 2014, 196). As Gouse notes, the WTO trade agreements do not make any mention of labour impacts of trade besides reference to products of prison labour (2014, 196). He concludes that the lack of provisions for potential negative impacts of technology adoption on labour in the WTO agreements means a decision not to allow importation of a GMO, even with proof of potential negative impacts on labour, will still be in breach of WTO requirements (2014, 196).

In regards to international labour law itself, there are several hundred documents of legal significance (Thomas, 2004, 375). The International Labor Organization (ILO), a specialized UN agency concerned with social justice, particularly labour standards, has over 180 binding conventions concerning subjects such as labour law, industrial relations and occupational safety. Not all countries have ratified all ILO conventions, although most member countries are bound by eight fundamental conventions not relevant to GMOs. Of the other conventions, the most relevant to GMOs concern occupational health and safety. Occupational health and safety concerns would already be addressed under the scientific assessments done with respect to GMOs, rather than as part of an SEC assessment, and so are unlikely to cause any inconsistencies between obligations under the CPB and ILO conventions.

The one exception to this is ILO Convention No. 169, the Indigenous and Tribal Peoples Convention 1989, which deals specifically with the rights of indigenous and tribal peoples. Such rights include nondiscrimination, government responsibility for ensuring that, inter alia, the labour, cultures and environment of indigenous and tribal peoples are safeguarded (art 4) and such peoples are consulted in a meaningful way wherever administrative or legislative measures are considered that may directly affect

them (art 6). As Gouse (2014, 197) has observed, "it might be possible to argue that a specific labor saving technology might infringe the protection and rights of indigenous tribes and people, but the validity of this argument has not been tested." The requirement of the ILO convention that such peoples be consulted in a meaningful way may have implications for decision-making on GMOs under the CPB. It should also be noted, as Gouse has observed, that the convention has been ratified by only a small number of countries, mainly in South America.

Other important points regarding possible inconsistency between obligations under ILO conventions and assessments under the CPB concern focal points and enforcement. The preamble to the ILO constitution provides that to attain the ILO's objective of universal and lasting peace, conditions of labour must be improved, including "protection of the interests of workers when employed in countries other than their own". Further, the preamble goes on to say that "the failure of any nation to adopt humane conditions of labour is an obstacle in the way of other nations which desire to improve the conditions in their own countries." According to the COP-MOP7 however, CPB decision-making has a much narrower focus, it being focused on SECs that are "specific to local, national and regional circumstances". 28 The economic impact of a GMO release on the adopting country's workforce may be positive, for example, from the farmers' perspective by decreasing the labour needed for agriculture or by improving their living standards by freeing up time for education or child rearing, or it could be negative from the workers' perspective by decreasing the need for labour. In either case, the decision by that country regarding adoption or rejection of the GMO may have implications for a second country. Under the ILO conventions, this could be considered an obstacle in the way of improving conditions in the adopting country. However, it would seem irrelevant under the CPB.

In regards to enforcement, although complaints of nonobservance of ILO conventions can ultimately be taken to the ICJ by members, <sup>29</sup> the ILO's enforcement record has been described as "woeful" (Thomas, 2004, 350) because of inconsistent legal obligations and because ILO's enforcement favours fact-finding and reporting over sanctions (Thomas, 2004, 351); however, there are also only weak dispute-settling mechanisms and enforcement provisions in the CPB. Therefore, the venue for settlement of a dispute regarding inconsistency between CPB and ILO convention obligations is unclear.

#### b) Social Dimension

The Ad Hoc Technical Expert Group on SECs (AHTEG) gives food security as an example element of the social dimension of SECs relating to GMOs. There is,

however, no clear definition of that term. The UN Food and Agriculture Organization (FAO) at its 1996 World Food Summit defined food security as existing "when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life" (FAO, 1996). Some consider that GMOs have much to offer in addressing both domestic and international food security problems. Others argue that GM technology undermines food security (Dibden, Gibbs and Cocklin, 2011). For example, for some the socio-economic implications of industrial agriculture, of which GM technology is a part, exacerbate poverty and therefore hunger (Gonzalez, 2007).

The reference to food preferences in the FAO definition is also controversial. Some scholars do not consider it part of the food security issue (see, e.g., Brookes, 2009) but others assert that food security includes consumer choice. This article has dealt with consumer choice under discussion of the economic dimension, above. Some scholars go further regarding consumer choice and include conservation of biological diversity, requiring that choices be made so sufficient food can be ensured. Others (such as Dibden, Gibbs and Cocklin, 2011) expand the term food security to include the nature of agriculture itself, insisting that, at the least, the form of agriculture used must be sustainable. Biodiversity conservation and sustainability are considered in this article under *c*) *Ecological Dimension* below. It should also be noted that the WHO and WTO have observed that food insecurity is affected by market access, taking us back to the economic dimension.<sup>30</sup>

The International Covenant on Economic, Social and Cultural Rights, 1966 (ICESCR), a UN treaty imposing binding legal obligations, is the international agreement most relevant to food security. The ICESCR guarantees certain fundamental human rights regarded as essential by the international community, and these rights overlap with some elements of SECs regarding GMOs, including food security. Decisions for or against the importation or general release of GMOs based on food security considerations under CPB Article 26.1 may therefore have implications for a state party's compliance with obligations under the ICESCR. However, although inconsistencies between obligations under it and SEC assessments under the CPB are possible, its aspirational nature and unenforceability means the CPB process could be followed without a legally sanctionable breach of ICESCR legal obligations.

Article 11.1 of the ICESCR states that it is "the right of everyone to ... adequate food", and Article 11.2 recognizes "the fundamental right of everyone to be free from hunger ...". Article 11.2 goes on to require the state parties to

take individually and through international co-operation, the measures, including specific programmes, which are needed:

(a) To improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge ....

The covenant's use of the term "adequate food" would not seem to include consideration of consumer preferences. Further, whilst the ICESCR recognizes the right to take part in cultural life (art 15.1(a)), there is equal recognition of the right to "enjoy the benefits of scientific progress and its applications" (art 15.1(b)). As Donat (2003, 450) has noted, "there is essentially a need to balance the rights of the hungry to food, and the rights of [those opposed to GMOs] to culinary sovereignty." Donat goes on to assert that, particularly where opposition to GMOs is based on scientifically unsupported objections but even where based on non-measurable objections such as religious or ethical objections, a right to food would seem stronger (2003, 451). She concludes that those states opposed to GMOs have a duty under the ICESCR "to avoid depriving other states from the right to food, including a duty to avoid international policies and practices that deprive other states of their means of subsistence ... this duty could extend to avoiding international policies that inhibit delivery of food" (450).

As was the case with the ILO conventions, the narrower focus of the CPB decision-making to consideration only of potential impact on local, national and regional circumstances as recognised at COP-MOP7 may encourage the creation of conflict with ICESCR obligations, given the ICESCR's global, rather than local, national or regional, concern with the right to adequate food. However, it is important to note again that the ICESCR is aspirational and its provisions are essentially unenforceable. The right to adequate food has been specifically singled out as not being enforceable in international law, although it is regarded as an important aspirational target (Donat, 2003). The ICESCR also does not provide for any methods of quantification of adherence to its aspirations.

#### c) Ecological Dimension

Assessment of, and regulation responding to, the risk of environmental harm from a GMO release are clearly permitted under the WTO agreements. However, as with human health, discussed below, the CPB allows assessment of SEC elements in the ecological dimension beyond those assessed in a typical environmental risk assessment. What these are is not entirely clear, the AHTEG giving the example of "impact on ecosystem functions". Ecosystem functions are defined in the CBD (art 2) as "all the ecosystem components and processes capable of generating ecosystem services benefiting human welfare"; ecosystem services include both tangible and

intangible contributions. These terms therefore include matters broader than are typically assessed in an environmental risk assessment.

The most significant international treaty relevant to the ecological dimension is the CBD and its subsidiary agreements, namely the CPB and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity 2010 (Nagoya Protocol). The other international regime that may have implications for the ecological dimension of CPB SEC assessment is the International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty). These are considered below.

#### i) CBD and subsidiary agreements

The CBD's objectives (art 1) of "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources" limit the scope of the CBD and its protocols. The CBD provisions, which provide members with wide-ranging discretion as to implementation, are legally binding, but as noted by Thomas (2004, 354), many of its obligations are hortatory, being qualified with the phrase "as far as possible and as appropriate". Further, many provisions make parties' obligations subject to their national legislation. In any case, given that the CPB is a protocol of the CBD, together with the Nagoya Protocol, inconsistency between obligations under those agreements and the CPB is unlikely.

Points of note are that the CPB process allows consideration of both negative and positive impacts, that all forms of agriculture impact the environment, and the impact of GMOs may in fact be smaller than that of the non-GMOs they replace (Wesseler and Smart, 2014). Further, assessments done under the CPB may be influential or be influenced by practices and policies adopted under other protocols and agreements in the CBD regime. For example, the Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress, a supplementary protocol to the CPB, requires parties to evaluate a biodiversity baseline and define important terms such as "adverse effect" (damage) and "significant effect", amongst other things. As Falck-Zepeda, Zambrano and Smale (2014) note, SEC assessments under the CPB may have a role in valuations under the Supplementary Protocol. Further, like the CBD and CPB, the Nagoya Protocol expressly accepts that other international agreements continue to have force (Lawson, 2013).

#### ii) International Treaty on Plant Genetic Resources for Food and Agriculture

The Plant Treaty may influence policy formulation and decision-making at the national and international levels regarding SEC assessments (Falck-Zepeda, Zambrano and Smale, 2014). In contrast to international IP regimes such as TRIPS, where private rights are preferenced, the Plant Treaty regime aims to allow access to the genetic material of 64 plants and recognize farmers' rights – that is, "rights to save, use, exchange and sell farm-saved seed, and other propagating material, and to participate in decision-making, and in the fair and equitable sharing of the benefits arising from, the use of plant genetic resources for food and agriculture" (preamble). However, restrictions on private IP rights over material covered by the Plant Treaty are limited to plant genetic resources when they are in the form received from the multilateral system (art 12.3(d)). Most GMOs assessed under a CPB SEC assessment would be different from that form, if material within the scope of the Plant Treaty were used at all.

Under the Plant Treaty, each party agrees to ensure conformity of its laws, regulations and procedures with the obligations imposed by the treaty (art 4). However, the treaty's preamble also states that

Affirming that nothing in this Treaty shall be interpreted as implying in any way a change in the rights and obligations of the Contracting Parties under other international agreements;

Understanding that the above recital is not intended to create a hierarchy between this Treaty and other international agreements....

Obligations under the treaty include taking steps to minimize or, if possible, eliminate threats to plant genetic resources for food and agriculture (art 5.2), developing and maintaining appropriate policy and legal measures that promote the sustainable use of plant genetic resources for food and agriculture (art 6.1) and protecting and promoting farmers' rights (art 9.2). As with the Declaration on the Rights of Indigenous Peoples discussed below, the treaty also obliges parties to protect and promote farmers' right "to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture" (art 9.2c). It should also be noted that treaty obligations are imposed only "where appropriate" and "subject to [a member's] national legislation" (arts 5.1, 6.1, 9.2).

The treaty expressly provides that its objectives are "the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the [CBD],

for sustainable agriculture and food security" (art 1.1) and that these will be attained by closely linking the treaty to the CBD (art 1.2). Therefore, inconsistency between the CBD regime, including the CPB, and the Plant Treaty can be expected to be kept to the minimum. Nevertheless, there are some differences in focus between the regimes. The Plant Treaty has a narrower focus, focusing on agriculture and plant genetic resources for food and agriculture (see art 1.1 and art 3) whereas Article 26.1 of the CPB has a broader focus on the "sustainable use of biological diversity". As noted above in the discussion concerning the CBD, there is a tension between the environment and its broader biological diversity on the one hand and agriculture and the plant genetic resources for food and agriculture on the other. Agriculture can be considered as part of the environment or as an activity that can impact the environment. A further difference in focus or context is the Plant Treaty's clear recognition of the part of "modern biotechnologies" in crop genetic improvement, the preamble stating that that improvement is relevant to adapting to environmental changes and future human needs. The preamble goes on to call on other international agreements relevant to the treaty to "be mutually supportive with a view to sustainable agriculture and food security".

Dispute settlement processes (art 22) follow the same steps as the CPB described above, and there is no provision for sanctions. Instead, compliance is encouraged through monitoring, advice and assistance (art 21).

#### d) Cultural / Traditional / Religious / Ethical Dimension

The fourth dimension of the AHTEG framework reflects concerns about adverse impacts on any or all of culture, tradition, religion or ethics (grouped together here and called cultural) by GMOs and the legal developments accompanying them, particularly the growing role of intellectual property (IP) in agriculture. Multiparty international agreements most relevant to cultural concerns generally are discussed in *i) Culture* below, except for the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), part of the WTO regime and the most significant international agreement on IP, which is discussed in *ii) Intellectual Property*. The introduction of agricultural GMOs has driven and continues to drive developments in a number of these regimes. Consistency in behaviour under these agreements and decision-making under the CPB will be needed as well the participation of indigenous peoples in decision-making.

#### i) Culture

The relationship between GMOs and culture is controversial. New technologies and the possibilities they offer are commonly challenged as raising conflict with existing cultural values (Moses, 2007), and the balancing of innovation adoption with a society's demand for a "continuing and unchanging culture" (Kirsch, 2001, 177) is a task for policy makers. A difficulty for policymakers, though, is that "it is unclear whether all aspects of a people's culture are equally valuable or by what criteria – to say nothing of by what agency – that shall be determined" (Rosen, 2001, 189). As noted by Ludlow (2015),

The answer to this will be impacted by the purpose of the decision-making. For example, different criteria may be relevant where the objective is biodiversity protection than where the objective is to create a more equitable regime for traditional societies or, again, where it is to enhance trade. In light of these different objectives, it may be that approaches to traditional innovation in one regulatory arena are inappropriate in others.

A starting point in the consideration of international agreements relevant to the cultural dimension is the UN Declaration on the Rights of Indigenous Peoples 2007. The declaration's objective is to provide for the individual and collective rights of indigenous peoples. Article 31 of the declaration provides as follows:

- 1. Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.
- 2. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights.

These provisions allow for both conservation and development of culture. Whether, and the extent to which, GMOs are relevant to either or both is a matter for assessment, but the declaration makes clear the intention that indigenous peoples be entitled to do either. Articles 18 and 19 provide for the right of indigenous peoples to be involved in decision-making in matters affecting their rights and to give prior

consent to legislative or administrative measures that may affect them. Decision-making under the CPB may not be consistent with a decision to exercise the right to protect or develop culture under the declaration. This is particularly the case because the exercise of rights under the declaration is not limited to a consideration of the impact of GMOs on conservation and sustainable use of biodiversity as decision-making under the CPB is. Nor are decisions under the declaration necessarily to be made by the same group as decisions under the CPB, so countries would need to address that potential for conflict. However, the declaration is not legally binding, instead being an aspirational statement. Further, whilst aspirational rights are granted by the declaration, those granted such rights do not have to exercise them.

Two other important international fora are also currently addressing the protection of culture and are relevant to GMOs: the World Intellectual Property Organization (WIPO) and the Convention on Biological Diversity (CBD). WIPO is currently negotiating IP rules to protect culture (or, more accurately, traditional knowledge, traditional cultural expressions and genetic resources) and so is considered in *ii*) *Intellectual property* below. The CBD is relevant because it obliges members to protect, amongst other things, culture as part of its objectives to conserve and protect biodiversity. It is contested how far, if at all, beyond association with genetic resources the protection of culture is to go. CBD Article 8(j) provides as follows:

The Strategic Plan For Biodiversity For The Period 2011-2020, "Living in Harmony With Nature", sets the strategy for meeting the CBD's objectives.<sup>31</sup> Twenty headline targets (the Aichi Biodiversity Targets), organized under five strategic goals, are included within the plan. Target 18 is particularly relevant to the cultural dimension, providing

*Target 18:* By 2020, the traditional knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biodiversity, and their customary use of biological resources, are respected, subject to national legislation and relevant international obligations, and fully integrated and reflected in the implementation of the Convention with the full and effective participation of indigenous and local communities, at all relevant levels.<sup>32</sup>

Target 18: By 2020, the traditional knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biodiversity, and their customary use of biological resources, are respected, subject to national legislation and relevant international obligations, and fully integrated and reflected in the implementation of the Convention with the full and effective participation of indigenous and local communities, at all relevant levels.<sup>33</sup>

The most recent WG meeting (WG8) on 7-11 October 2013 considered the remaining programme tasks.<sup>34</sup> In the Secretariat's view tasks still to be done include the development of guidelines for the development of legislation or other mechanisms, as appropriate, to implement Article 8(j) and its related provisions (which could include sui generis systems) and the definition of relevant key terms and concepts in Article 8(j) and related provisions at international, regional and national levels that recognize, safeguard and fully guarantee the rights of indigenous and local communities over their traditional knowledge, innovations and practices, within the context of the CBD. The twelfth meeting of the COP to the CBD in 2014 instructed the WG to undertake these tasks<sup>35</sup> and also noted (reflecting WG8's recommendation) that these tasks should be advanced "in a manner that avoids any inconsistencies with the Nagoya Protocol, avoids duplication and overlap of work undertaken in other international fora, and takes into account relevant developments, including under the Nagoya Protocol, the United Nations Permanent Forum on Indigenous Issues and the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization (WIPO), and the United Nations Declaration on the Rights of Indigenous Peoples".<sup>36</sup> The Nagoya Protocol addresses access to genetic resources and benefit sharing from commercialization of such resources.<sup>37</sup> Culture in the context of the Nagova Protocol is limited to traditional knowledge associated with genetic resources, and this means the priority of other cultural issues in future work on Article 8(j) is contested.<sup>38</sup>

The COP-MOP also instructed the executive secretary to continue to consult with the WIPO Intergovernmental Committee to ensure complementarity and avoid overlaps.<sup>39</sup> As Ludlow (2015) has observed, "The restriction on the WG's work to avoid duplication with work in other fora means that decisions regarding assessments of ... ramifications of the introduction of modern biotechnology may be left to the AHTEG on Article 26 of the [CPB] rather than the WG on CBD Article 8(j)." If that is not the case, inconsistency between the CBD and the CPB would be difficult to reconcile.

#### ii) Intellectual property

Amongst the international agreements and for relevant to IP are the World Intellectual Property Organization (WIPO), the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and The International Union for the Protection of New Varieties of Plants (UPOV).

WIPO, a specialized UN agency, is tasked with the "development of a balanced and effective international intellectual property (IP) system that enables innovation

and creativity for the benefit of all". <sup>40</sup> WIPO administers 25 IP treaties, <sup>41</sup> although the lack of a dispute settlement mechanism to address noncompliance and its relatively weak enforcement mechanism make this regime less significant than the TRIPS Agreement in the IP arena. In relation to the cultural dimension, in 2013 the WIPO General Assembly renewed the mandate of its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) for the 2014/2015 biennium. That mandate requires the IGC to continue negotiations with the objective of reaching agreement on a text (or texts) of an international legal instrument(s) to ensure the effective protection of traditional knowledge, genetic resources and traditional cultural expressions. Draft texts were provided to the 54<sup>th</sup> session of the 2014 WIPO General Assembly <sup>42</sup> but the General Assembly did not take a decision on them or set a work program for the IGC for 2015. <sup>43</sup>

As noted above, development on the protection of culture in the CBD arena is occurring together with the work of WIPO, and so developments by WIPO may be influential on CPB assessments. The draft WIPO texts so far though remain unsettled, and important basic points, such as the definition of protected subject matter, have still to be agreed. Nevertheless, what is intended is that state members will protect certain parts of culture. Under the current draft, the protected cultural subject matter includes some innovations, and the protection to be given to that subject matter includes the right to develop it. It is also of importance that the policy objectives of the current draft texts clearly allow and intend innovation to occur (Ludlow, 2015).

The most important international obligations regarding IP arise under TRIPS, which obliges WTO member states to comply with a range of international IP agreements. 44 TRIPS also imposes minimum standards for various IP rights. Although the objectives of TRIPS include protection of IP rights "in a manner conducive to social and economic welfare" (art 7), and Article 8 recognizes that members may adopt measures to "promote the public interest in sectors of vital importance to their socio-economic and technological development", these measures must be consistent with the obligations under TRIPS (art 8). Of particular importance here is that acquisition of IP rights does not and should not require additional measures such as an SEC assessment as set out in the CPB (see Lawson, 2013).

TRIPS obligations are enforced through WTO mechanisms, but because TRIPS imposes an obligation to provide a minimum standard of IP protection through national laws, countries are able to provide varying standards above that minimum. These differing standards mean there is not uniformity in international IP protection. As Lawson (2014) has observed, this complexity is added to by "further entrenched".

obligations under bilateral and regional trade agreements. These bilateral agreements ... often impose significantly higher IP obligations than the existing multiparty agreements. The effect in the international arena is that the particular IP landscape of each nation-state needs to be determined according to their particular commitments."

Adding to the difficulty of an assessment of IP as an element of an SEC assessment is that, as analyzed by Lawson (2013), although there are internationally binding standards of protection under agreements such as TRIPS, the norms for the circumstances in which IP will or won't be adopted and asserted may be different in each case and are certainly subject to different influences, including private contracts and material transfer agreements entered into by private entities and national and international institutions such as the Consultative Group on International Agricultural Research (CGIAR). Further, genetic resource access and benefit sharing laws are being used by some countries to control the exercise of IP rights in order to harmonize them with objectives under the CBD (Dutfield, 2004).

Also of significance with regard to agricultural GMOs is The International Union for the Protection of New Varieties of Plants (UPOV). This intergovernmental organization<sup>45</sup> has the objective of providing and promoting "an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society". <sup>46</sup> There are four versions of UPOV (1961, 1972, 1978 and 1991), but under the most recent version, plant breeders can obtain both plant breeders' rights (PBR) under UPOV and patents on the same cultivar. Even those countries that are not party to UPOV may be committed to the UPOV as the standard of IP protection for cultivars under fair trade agreements between countries (Oguamanam, 2014). As with TRIPS obligations, countries will have to determine their particular commitments in this arena.

#### (e) Human Health-related Dimension

The AHTEG example element for the human health–related dimension is impact on nutritional status. GMOs have been and are being developed with value added traits such as improved nutrition and food functionality (Newell-McGloughlin, 2014). As Newell-McGloughlin has observed, there will be clear differences in what is needed by different regions and different socioeconomic groups, so any SEC assessment considering this element would need to be uniquely assessed for each group and region.

The World Health Organization (WHO), the United Nations authority for global health, defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". <sup>47</sup> Whilst the WHO has a

comprehensive membership, the only international health agreement binding on its member states concerns matters not relevant to GMOs. 48 Instead, WHO's relevance here is because it, together with the food and agriculture division of the United Nations, the Food and Agriculture Organization (FAO), created Codex. Codex has created a risk analysis model for evaluating food safety of GMOs. This was based on Organization for Economic Co-operation and Development (OECD) international consensus documents on the particular components that can be analyzed for specific GM crops to provide a common base to be used in the regulatory assessment of an agricultural or food product derived from biotechnology, which includes the weighing of risks against other issues, such as the benefits, with the aim of ensuring the highest appropriate level of public health (Newell-McGloughlin, 2014). Codex's place as an international standard-setting body for WTO purposes means assessments outside of Codex's model would need to be sure of compliance with WTO obligations described in the economic dimension discussion above.

#### 5. Conclusions

Table 1 summarizes the key attributes of the international agreements and organizations discussed in this article, as being the most significant of those relevant to SEC assessments under the CPB. Although the majority of these agreements are not specifically concerned with biotechnology, the obligations imposed by them must be considered when SEC assessment processes are included as part of a nation's biosafety regulatory framework. Whilst free to pursue their own particular socioeconomic priorities, nations must be sure that they are not acting contrary to obligations imposed by other international regimes they have agreed to be part of.

There is no definitive or agreed list of SECs that could be included in an SEC assessment. Nor are international agreements and regimes bounded within distinct boundaries in so far as their subject matter is concerned. This makes the listing of relevant international agreements and mapping of those agreements onto particular SECs difficult. Attempts to map international agreements onto SECs are further hampered because SECs can be interpreted in numerous ways, with shifting priorities and concerns. The five-dimensional framework suggested by AHTEG – economic, social, ecological, cultural and human health–related – has been adopted by this article as a tool to map international regimes onto SECs. Table 2 summarizes the dimensions that each identified international regime is most relevant to. However, this categorization is largely subjective and, as with the SECs that make up the dimensions, the dimensions are not fixed and their boundaries shift when the focal point changes.

Using the key attributes in table 1 and the mapping onto the AHTEG dimensions in table 2, this article identifies opportunities for coherence whilst pointing out inconsistencies for compliance with international agreements relevant to the five dimensions. The most significant inconsistencies arise in the economic, cultural and human health–related dimensions. In those three dimensions, WTO regimes, including TRIPS and Codex, are in place. Such agreements impose binding obligations and are reinforced by strong enforcement mechanisms.

In the social dimension the most relevant obligations are imposed under the ICESCR. These obligations may conflict with decisions made under a CPB assessment. However, although binding, the obligations are not enforceable. Nevertheless, membership in the ICESCR obliges nations to consider global impacts on human rights such as the right to adequate food. ICESCR also provides equal recognition to cultural life as to enjoyment of the benefits of scientific progress, although there is no express reference to biotechnology, which in turn impacts on the cultural dimension.

In the ecological dimension, the agreements considered expressly reference biotechnology and impose legally binding obligations. The CPB itself can be treated as within this dimension. The difficulty for nations that are party to agreements in the ecological dimension though is that many of the obligations are hortatory and qualified by phrases such as "as appropriate" or "as far as possible". Further, all make (perhaps contradictory) statements recognising the continuation of obligations under other international agreements. There are also inconsistencies in the focus of agreements in this dimension that may cause concerns regarding compliance with obligations. For example, the Plant Treaty focuses on agriculture and plant genetic resources for food and agriculture whereas the CPB has a broader focus on biological diversity. The Plant Treaty also expressly recognizes the part of modern biotechnology in crop genetic improvement, which in turn links back to the rights protected by the ICESCR in the social dimension.

Looking across all five dimensions, common problems arise for nations seeking consistency between SEC assessments and obligations under other international agreements. These problems occur at both the international (i.e., between nations) and national (i.e., within a nation) levels. They must be addressed if the CPB regime is to successfully progress.

The most important problem at the international level is the urgent need for clear definitions of SECs. The "food security" SEC discussed in the social dimension above illustrates definitional difficulties. Identification of conflicting obligations under other international agreements cannot occur without settled definitions. A second problem at

this level is inconsistency in the focus / context of CPB obligations with that of other international agreements. This can make compliance with obligations under other agreements difficult. The ecological dimension provides an example of this: the CBD and CPB have a broad focus on biological diversity without reference to agriculture, whereas the Plant Treaty has a narrow focus on agriculture and plant genetic resources for food and agriculture. A decision under one of these may therefore be inconsistent with the priorities of the other. Thirdly, international regimes impact each other. Indeed, some nations intentionally use particular international regimes to do just that, to drive international law developments in their preferred direction. In the ecological dimension, for example, it is likely that the CPB will be influenced by developments in other CBD regimes such as the Nagoya Protocol. Outside the CBD regime, the developments under the Plant Treaty may influence those under the CBD. This is significant because the Plant Treaty recognizes the relevance of modern biotechnology in crop genetic improvement for securing food. Food security considerations in turn return assessment back to the issues of compliance with the ICESCR, discussed in the social dimension, the ICESCR also requiring the full use of scientific knowledge.

The fourth and fifth problems at the international level are process issues: prioritization and dispute resolution. If the same international agreement obligation is relevant to multiple dimensions (like ICESCR obligations to both the social and cultural dimensions) where will its priority be? How will that be decided? Further, who will decide if agreement on prioritisation cannot be reached? As raised above, for example, are the rights of the hungry to food stronger than rights to culinary sovereignty in any balancing of these two considerations? Should the decision be made on the basis of possible sanctions or the "intrinsic value" of the SEC concerned and if so, how and who will decide that? Will the fact that a particular obligation is aspirational only or has no enforcement mechanism determine the priority?

At the national level, three important problems must be addressed. First, nations may need their own SEC definitions to reflect their own policies and priorities. Secondly, each nation will need to determine its own compliance landscape – both in terms of deciding what its relevant international obligations are and, as discussed above in the cultural dimension, its IP landscape. Finally, some international obligations require particular decision-makers to be involved in decision-making. Different groups of decision-makers under different international regimes in the one nation may reach inconsistent decisions on similar issues, causing legitimacy and priority problems for the nation concerned.

Addressing these problems is going to take work. But they must be addressed if SEC assessment is to be a legitimate and useful part of biotechnology regulation rather than a deliberately vague obstacle to GMO adoption.

**Table 1** Key Attributes of International Agreements and Organisations Relevant to SEC Assessment in Agri-bio Regulation

Agreement	Objective	Parties	Express Reference to Biotech/GMOs	Legally Binding	Enforcement Mechanism
Cartagena Protocol on Biosafety (CPB)	Regulates international transboundary movements of GMOs	168 members	Yes	Yes	No
ECONOMIC DIMENSION					
WTO Agreements  O SPS Agreement  TBT Agreement  GATT	Creation of non-discriminatory free trade	160 members	No (although is specific reference in standards of Codex, OIE and IPPC)	Yes	Yes, including trade sanctions
Codex Alimentarius Commission (Codex)	International food standards, guidelines and codes of practice	186 members	Yes	No (although often adopted by national legislation/ through WTO agreements)	No (although may be relevant through national legislation/ WTO agreements)
ILO Conventions, including ILO Convention 169	Social justice, particularly labour standards	185 members but not of all conventions	No	Yes	Yes
SOCIAL DIMENSION					
International Covenant on Economic, Social and Cultural Rights 1966 (ICESCR)	Guarantees certain fundamental human rights	163 members	No	Yes	No
ECOLOGICAL DIMENSION					
CBD, protocols and supplementary protocols	Conservation of biological diversity, sustainable use of its components and fair and equitable sharing of benefits from genetic resources	194 parties to CBD	Yes	Yes	Yes
International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty)	Conservation and sustainable use of plant genetic resources for food and agriculture and fair and equitable sharing of benefits arising out of use for sustainable agriculture and food security	134 contracting parties	Yes (preamble - 'modern biotechnologies' as a form of crop genetic improvement)	Yes	No
CULTURAL DIMENSION					
UN Declaration on the Rights of Indigenous Peoples 2007	Provide for individual and collective rights of indigenous peoples	182	No (although is reference to development of genetic resources)	No	No
CBD	As above	As above	As above	As above	As above

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World Intellectual Property Organization (WIPO)	Development of international IP system enabling innovation and creating benefit for all	188 members	Yes	Yes	Weak	
TRIPS	Provide minimum standards of IP protection	WTO members	No (although is reference to plants and biological processes)	Yes	Yes	
International Union for the Protection of New Varieties of Plants (UPOV)	Provide and promote effective system of plant variety protection	72 members	No	Yes	No	
HUMAN HEALTH-RELATED DIMENSION						
Codex Alimentarius Commission (Codex)	As above	As above	As above	As above	As above	

Table 2 Mapping of International Agreements & Organisations in Agri-bio Regulation SEC Assessment onto AHTEG Dimensions	ECONOMIC DIMENSION	SOCIAL DIMENSION	ECOLOGICAL DIMENSION	CULTURAL DIMENSION	HUMAN HEALTH- RELATED DIMENSION
WTO agreements (SPS, TBT & GATT)	V			V	V
TRIPS	$\sqrt{}$			V	
ILO Convention No 169	~		V	$\sqrt{}$	
ICESCR		V		V	
CBD & Subsidiary agreements	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	
Plant Treaty		$\sqrt{}$	V	$\sqrt{}$	
UN Declaration on the Rights of Indigenous Peoples	V			V	
WIPO	V			V	
UPOV	V	V		V	
CODEX	$\sqrt{}$			V	$\sqrt{}$

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#### **Endnotes**

<sup>&</sup>lt;sup>1</sup> The CPB actually uses the term "living modified organisms" (LMOs), but this article uses the more commonly used term, "GMO".

<sup>&</sup>lt;sup>2</sup> This is not required where the import is for food, feed or processing. See also arts 5 and 6.

<sup>&</sup>lt;sup>3</sup> Final Report of the Meeting, UNEP/CBD/BS/COP-MOP/7/16 4 October 2014, Annex 1 BS-VII/13. See discussion below regarding COP-MOP 7.

<sup>&</sup>lt;sup>4</sup> Secretariat of the Convention on Biological Diversity [CBD], 2000, p. 2.

<sup>&</sup>lt;sup>5</sup> For the background to and reasons for this apparent contradiction, see Kerr et al., 2014, p. 107.

<sup>&</sup>lt;sup>6</sup> See also Hagen and Barlow Weiner, 2000, p. 707.

<sup>&</sup>lt;sup>7</sup> Panel Report, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept 29, 2006).

<sup>&</sup>lt;sup>8</sup> As Gonzalez (2007) explains, pursuant to Article 3.2 of the WTO Dispute Settlement Understanding, interpretation of WTO agreements is to be done "in accordance with customary rules of interpretation of public international law." This includes those in the Vienna Convention.

<sup>&</sup>lt;sup>9</sup> As decision BS-VII/13. Final Report of the Meeting, UNEP/CBD/BS/COP-MOP/7/16 4 October 2014 [152], that decision now annex I to the Final Report of the Meeting.
<sup>10</sup> UNEP/CBD/BS/COP-MOP/7/11/Rev.1 28 July 2014. The AHTEG meeting was in February 2014.

<sup>&</sup>lt;sup>11</sup> Final Report of the Meeting, UNEP/CBD/BS/COP-MOP/7/16 4 October 2014 [138].

<sup>&</sup>lt;sup>12</sup> Final Report of the Meeting, UNEP/CBD/BS/COP-MOP/7/16 4 October 2014 [139].

<sup>&</sup>lt;sup>13</sup> Elements of a framework for conceptual clarity on socio-economic considerations, annex, UNEP/CBD/BS/COP-MOP/7/11/Rev.1 28 July 2014.

<sup>&</sup>lt;sup>14</sup> Elements of a framework for conceptual clarity on socio-economic considerations general principle 2, annex, UNEP/CBD/BS/COP-MOP/7/11/Rev.1 28 July 2014.

<sup>&</sup>lt;sup>15</sup> Elements of a framework for conceptual clarity on socio-economic considerations general principle 6, annex, UNEP/CBD/BS/COP-MOP/7/11/Rev.1 28 July 2014.

<sup>&</sup>lt;sup>16</sup> Elements of a framework for conceptual clarity on socio-economic considerations general principle 10, annex, UNEP/CBD/BS/COP-MOP/7/11/Rev.1 28 July 2014.

<sup>&</sup>lt;sup>17</sup> Final Report of the Meeting, UNEP/CBD/BS/COP-MOP/7/16 4 October 2014, Annex 1 BS-VII/13 [2].

<sup>&</sup>lt;sup>18</sup> Elements of a framework for conceptual clarity on socio-economic considerations, annex, UNEP/CBD/BS/COP-MOP/7/11/Rev.1 28 July 2014.

<sup>&</sup>lt;sup>19</sup> Which are annexed to the agreement that establishes the WTO 33 ILM 1144 (1994).

<sup>&</sup>lt;sup>20</sup> Listed in Annex A.1 SPS Agreement.

<sup>&</sup>lt;sup>21</sup> Annex A.1 SPS Agreement.

- <sup>22</sup> Panel report, European Communities Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept 29, 2006).
- <sup>23</sup> CPM RECOMMENDATION ICPM-3/2001 ICPM RECOMMENDATIONS CONCERNING LIVING MODIFIED ORGANISMS, BIOSECURITY AND ALIEN INVASIVE SPECIES AT <a href="https://www.ippc.int/core-">https://www.ippc.int/core-</a>
- <u>ACTIVITIES/GOVERNANCE/CPM-RECOMMENDATIONS/RECOMMENDATIONS-CONCERNING-LMOS-BIOSECURITY-AND-ALIEN-INVASIVE-SPECIES</u> (ACCESSED 2 FEB 2015).
- <sup>24</sup> WTO and WHO, 2002, WTO Agreements and Public Health. A Joint Study by the WHO and the WTO Secretariat [269].
- <sup>25</sup> See Tuna–Dolphin panel decision *Dispute Panel Report on United States Restrictions on Imports of Tuna*, Sept 3 1991, GATT B.I.S.D. (39<sup>th</sup> Supp) at 155, P2.3 (1993).
- <sup>26</sup> While the Shrimp-Turtle case was considered legitimate by the WTO Appellate Body, the U.S. lost the case because it discriminated between WTO members
- http://www.wto.org/english/tratop\_e/envir\_e/edis08\_e.htm. The Tuna–Dolphin report was never adopted and therefore is not a legal interpretation of GATT law. Nevertheless, it is of interest because of its implications for environmental disputes.
- <sup>27</sup> http://www.codexalimentarius.org/ (accessed 9 Feb 2015).
- <sup>28</sup> Final Report of the Meeting, UNEP/CBD/BS/COP-MOP/7/16 4 October 2014, annex I, BS-VII/13, preamble.
- <sup>29</sup> Constitution of the International Labour Organization, arts 26 and 29.
- <sup>30</sup> WTO and WHO, 2002, WTO Agreements and Public Health. A Joint Study by the WHO and the WTO Secretariat [255].
- <sup>31</sup> UNEP/CBD/COP/10/27, [14] and Decision X/2 Annex (p. 116).
- <sup>32</sup> Ibid., Decision X/2 Annex (p. 120).
- <sup>33</sup> Ibid., Decision X/2 Annex (p. 120).
- <sup>34</sup> Focusing on tasks 1, 2, 4, 7, 10 and 12.
- <sup>35</sup> Decision XII/12, in Conference of the Parties to the Convention on Biological Diversity, 2014. Report of the twelfth meeting of the Conference of the Parties to the Convention on Biological Diversity. Korea, UNEP/CBD/COP/12/29 17 October 2014 p. 89.
- <sup>36</sup> Preamble to section D of Decision XII/12, in Conference of the Parties to the Convention on Biological Diversity, 2014. Report of the twelfth meeting of the Conference of the Parties to the Convention on Biological Diversity. Korea, UNEP/CBD/COP/12/29 17 October 2014 p. 88.
- <sup>37</sup> Conference of the Parties to the Convention on Biological Diversity. 2011. *Report of the Tenth Meeting of the Conference of the Parties to the Convention on Biological Diversity*, UNEP/CBD/COP/10/27. Montreal: CBD Secretariat, [103] and Decision X/1 (pp. 89-109).
- <sup>38</sup> IISD Reporting Services, Summary of the 8<sup>th</sup> Meeting of the Working Group on Article 8(j) and 17<sup>th</sup> meeting of the Subsidiary Body on Scientific, Technical and Technological Advice of the Convention on Biological Diversity 7-18 October 2013. [Online]. Available at http://www.iisd.ca/vol09/enb09611e.html [accessed 22 October 2013].
- <sup>39</sup> Decision XII/12, in Conference of the Parties to the Convention on Biological Diversity, 2014. Report of the twelfth meeting of the Conference of the Parties to the Convention on Biological Diversity. Korea, UNEP/CBD/COP/12/29 17 October 2014 p. 91.
- 40 http://www.wipo.int/about-wipo/en/ accessed 22 Jan 2015.
- <sup>41</sup> Listed at <a href="http://www.wipo.int/treaties/en/">http://www.wipo.int/treaties/en/</a>
- <sup>42</sup> In Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), WO/GA/46/6. 22 July 2014. <sup>43</sup> Item 16, Assemblies of the Member States of WIPO. Synthesis of Decisions. 54th Series of
- <sup>43</sup> Item 16, Assemblies of the Member States of WIPO. Synthesis of Decisions. 54th Series of Meetings, Sept 22-30, 2014.
- <sup>44</sup> These are the Paris Convention for the Protection of Industrial Property, the Stockholm Act of the Paris Convention for the Protection of Industrial Property (1967), the Berne Convention for the Protection of Literary

and Artistic Works, the Paris Act of the Berne Convention for the Protection of Literary and Artistic Works (1971), the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, the Treaty on Intellectual Property in Respect of Integrated Circuits (1989): TRIPS Art 2.

45 By the International Convention for the Protection of New Varieties of Plants (UPOV Convention).

<sup>46</sup> http://www.upov.int/overview/en/upov.html.

<sup>&</sup>lt;sup>47</sup> Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19 June - 22 July 1946; signed on 22 July 1946 by the representatives of 61 states (Official Records of the World Health Organization, no. 2, p. 100) as cited on WHO webpage at <a href="http://www.who.int/suggestions/faq/en/">http://www.who.int/suggestions/faq/en/</a> (accessed 30 January 2015).

<sup>&</sup>lt;sup>48</sup> It concerns pandemic influenza virus.