

**CARTAGENA PROTOCOL ON BIOSAFETY:  
WTO-Consistency of Import Restrictions that Take into Account Socio-Economic Considerations**

**By Craig Thorn  
DTB Associates, LLP<sup>1</sup>**

**Summary**

The Cartagena Protocol on Biosafety (“CPB”) permits Parties to the CPB to take into account certain socio-economic considerations (“SECs”) in their regulatory decision-making regarding living modified organisms (“LMOs”). The CPB also encourages Parties to cooperate on research and information exchange regarding socio-economic impacts, and the Parties have initiated several activities designed to promote such cooperation. At this point there is little agreement regarding the definition of the term “socio-economic considerations,” the methodology for taking such considerations into account, or the types of measures that could be implemented to address them.

Regulations imposed for reasons related to SECs could act as significant barriers to trade in products of biotechnology. Such measures would therefore be subject to the rules of the World Trade Organization (“WTO”). Those rules establish a number of significant, well defined legal hurdles that any SEC-related import restriction would have to clear. They require that such restrictions be, *inter alia*, 1) based on an assessment of risk that takes into account available scientific information, and 2) no more trade restrictive than necessary to fulfill a legitimate objective.

**Socio-economic considerations and the CPB**

Article 26.1 of the CPB permits Parties to take certain socio-economic considerations into account in their regulatory decision-making regarding LMOs. It reads as follows:

*“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.”*

The provision contains a number of important caveats. First, Parties are permitted but not required to take SECs into account. Second, Parties that choose to take SECs into account are required to do so in a manner that is consistent with their other international obligations, presumably including obligations under the agreements of the WTO. Finally, Parties may take into account only those SECs that arise from the impact of LMOs on “the conservation and sustainable use of biological diversity.”

Article 26 also encourages Parties to “cooperate on research and information exchange on any socio-economic impacts” of LMOs, especially on indigenous and local communities. The Parties have initiated several activities designed to promote such cooperation. The United Nations Environment Program Division of Global Environment Facility Coordination (“UNEP GEF”) produced a report on the issue that was presented at the fifth meeting of the Conference of the Parties serving as the Meeting of the Parties

---

<sup>1</sup> <http://www.dtbassociates.com/dtbassociatesllp/id6.html>

to the Protocol (“COP-MOP 5”) in October 2010.<sup>2</sup> SEC-related capacity building is a standing agenda item at the Coordination Meetings for Governments and Organizations Implementing or Funding Biosafety Capacity-Building Activities. At COP-MOP 5 the Parties took note of the recommendations regarding SECs that came out of the sixth Coordination Meeting and established a work program related to SECs.<sup>3</sup> Since that time, the CPB Secretariat has hosted a series of online discussion groups and a workshop on SECs.<sup>4</sup>

The objectives for the SEC Workshop were to synthesize available information shared during online discussion groups and regional online real-time conferences, as well as from Parties responding to survey questions on capacity-building needs and priorities regarding SEC in the context of decision-making on LMOs. While the “official” description of objectives focuses on capacity building, the operational objective is “to, on the basis of research and information exchange, provide relevant guidance on socio-economic considerations that may be taken into account in reaching decisions on the import of LMOs.”

Despite all of this activity, there is little agreement regarding the definition of the term “socio-economic considerations.” The survey that provided the data for the UNEP GEF report presented at COP-MOP 5 contains a list of potential SECs that covers most of the considerations that have been mentioned by participants in the debate surrounding the issue:

- *“Impacts on market access and trade at national and international levels.*
- *Macroeconomic impacts, e.g. on sustainable development.*
- *Microeconomic impacts at the individual, household or community level.*
- *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.*
- *Compliance with biosafety measures, including institutional costs.*
- *Coexistence of LMOs, e.g. with conventional and organic agriculture.*
- *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, e.g. control of seeds.*
- *Indigenous and local communities, e.g. livelihoods, traditional knowledge associated with biodiversity.*
- *Cultural, spiritual and ethical aspects.*
- *Impact on the conservation and sustainable use of biodiversity, e.g. use value, cultural and spiritual value of biodiversity.*

<sup>2</sup> UNEP/CBD/BS/COP-MOP/5/INF/10

<sup>3</sup> MOP 5 Decision BS-V/3, <https://www.cbd.int/decision/mop/?id=12316>.

<sup>4</sup> See [http://bch.cbd.int/protocol/cpb\\_art26/discussiongroups\\_se.shtml](http://bch.cbd.int/protocol/cpb_art26/discussiongroups_se.shtml).

- *Intellectual property rights.*
- *Impact on public sector research and development.”*

It is worth noting that many of the items on this list (e.g., health-related impacts; labor and employment; impacts on consumer choice or consumption patterns; land tenure; farmers’ rights; intellectual property rights; etc.) have little to do with the impact of LMOs on the conservation and sustainable use of biological diversity and therefore appear to fall outside the scope of Article 26. Nevertheless, we use this list as the basis for our analysis of the WTO-consistency of potential SEC-related import measures.

## WTO rules

### Summary

Regulations imposed for reasons related to SECs could act as significant barriers to trade in products of biotechnology. Such measures would therefore be subject to the rules of the World Trade Organization, in particular the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement”)<sup>5</sup> and the *Agreement on Technical Barriers to Trade* (“TBT Agreement”).<sup>6</sup> Below is a brief summary of each agreement.

#### 1. Agreement on the Application of Sanitary and Phytosanitary Measures

The SPS Agreement applies to all sanitary and phytosanitary measures that may affect international trade. An SPS measure is defined as any measure applied:

- “(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;*
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;*
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or*
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.” (Annex A.1)*

SPS measures include

*“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 labelling requirements directly related to food safety.” (Annex A.1)*

The SPS Agreement explicitly recognizes the right of WTO Members to implement legitimate SPS measures. However, it obliges Members to ensure that any regulatory measure is a) applied only to the extent necessary to protect human, animal or plant life or health; b) based on scientific principles; and c) not maintained without sufficient scientific evidence (Article 2.2). All measures must be based on a scientific assessment of risk (Article 5.1). Members are also required to ensure that measures are not

<sup>5</sup> The text of the SPS Agreement can be found on the web at [http://www.wto.org/english/docs\\_e/legal\\_e/15-sps.pdf](http://www.wto.org/english/docs_e/legal_e/15-sps.pdf).

<sup>6</sup> The text of the TBT Agreement can be found on the web at [http://www.wto.org/english/docs\\_e/legal\\_e/17-tbt.pdf](http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf).

arbitrary or discriminatory and do not constitute a disguised restriction on trade (Article 2.3). Measures must be no more trade-restrictive than necessary to achieve a Member's appropriate level of protection (Article 5.6). Where scientific evidence is incomplete, the Agreement allows Members, subject to certain well-defined conditions, to adopt provisional measures (Article 5.7). The Agreement also sets out requirements for notification and transparency (Article 7 and Annex B).

## 2. Agreement on Technical Barriers to Trade

The TBT Agreement applies to all technical regulations and standards that are not covered by the SPS Agreement (Article 1.5). Because of its broad scope of application, it is less specific than the SPS Agreement. Nevertheless, it contains similar fundamental disciplines.

The Agreement requires regulations be non-discriminatory (Article 2.1). Members must ensure that regulations do not create unnecessary barriers to trade, that they are no more trade restrictive than necessary to fulfill a legitimate objective, and that they are based on an assessment of risk (Article 2.2). In assessing risks, Members are required to take into account available scientific and technical information (Article 2.2). Like the SPS Agreement, the TBT Agreement sets out certain requirements for notification and transparency (Article 10).

### WTO-consistency of SEC-related measures

#### 1. SPS Agreement

Although the SPS Agreement has relatively narrow scope of application, it would cover measures applied to address many of the considerations that have been mentioned most often in the SEC debate – i.e., economic considerations of all types, and those related to health and environmental impacts. A recent WTO dispute settlement case provides valuable guidance regarding the scope of application of the SPS Agreement and the nature of the disciplines. In that case (known as the “EC – Biotech” case in WTO) the European Union (“EU”) argued that import bans imposed by certain EU Member States on EU-approved products were not inconsistent with the SPS Agreement because some of the reasons for which the Member States adopted those measures fell outside the scope of that Agreement. Those reasons included several that are on the list in the UNEP GEF report – e.g., coexistence; contamination of conventional crops; long-term ecological effects in environmentally sensitive areas (impact on genetic diversity); effects on farm management practices; and health effects.

The dispute settlement Panel examined all of the reasons cited by the EU in turn and ruled that each fell within the scope of the SPS Agreement. The Panel found, *inter alia*, that

- “the term ‘other damage’ as it appears in Annex A(1)(d) [of the SPS Agreement] includes economic damage which arises from the entry, establishment or spread [of LMOs];”<sup>7</sup>
- a measure “applied to avoid potential long-term ecological effects of the release into the environment [of an LMO] falls within the scope of Annex A(1)(a) and (d);”<sup>8</sup>

---

<sup>7</sup> *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, Reports of the Panel, (WT/DS291/R), paragraph 7.2576.

- a measure applied to avoid “environmental impacts of specific cultivation, management and harvesting techniques” falls within the scope of Annex A(1)(d);<sup>9</sup> and
- a measure applied to avoid risks to consumer health falls within the scope of Annex A(1)(b).<sup>10</sup>

It is clear from the legal analysis in the ruling that the Panel would have considered most, if not all, LMO-related measures adopted to address economic, health or environmental considerations to fall within the scope of the SPS Agreement.

It is not illegal *per se* under WTO rules to take into account economic considerations when adopting SPS measures. On the contrary, it is common practice. For example, governments routinely apply SPS measures to protect crops against weeds, insects or diseases that might reduce yields or adversely affect the marketability of a crop. Indeed, the Agreement requires that Members, in assessing risks to plant or animal life or health,

*“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.”* (Article 5.3)

However, identification of a potential economic effect is not sufficient justification for the imposition of an SPS measure. In order to be consistent with the SPS Agreement, the measure must be based on a scientific assessment of risk. 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.”* (Annex A.4)

In a ruling in a case involving Australian restrictions on imports of salmon, the WTO Appellate Body found that a risk assessment must:

*“1) identify the diseases [or pests] whose entry, establishment or spread a Member wants to prevent on its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases [or pests];  
2) evaluate the likelihood of entry, establishment or spread of these diseases [or pests], as well as the associated potential biological and economic consequences; and  
3) evaluate the likelihood of entry, establishment or spread of these diseases [or pests] according to the SPS measures which might be applied.”<sup>11</sup>*

<sup>8</sup> Ibid, paragraph 7.2584.

<sup>9</sup> Ibid, paragraph 7.380.

<sup>10</sup> Ibid, paragraphs 7.2839, 7.343 and 7.344.

<sup>11</sup> *Australia – Measures Affecting the Importation of Salmon*, Report of the Appellate Body, WT/DS18/AB/R, paragraph 121.

The steps enumerated above apply to the assessment of economic or environmental risks. In assessing risks to human and animal health, it is only necessary to evaluate the potential for adverse effects (see Annex A.4, quoted above).

In EC – Biotech case, the Panel concluded that most of the papers and studies submitted by the Members States and the EU Commission in support of the Member State import bans were not risk assessments within the meaning of the SPS Agreement. For example, the EU Commission submitted to the Panel four documents in support of a French measure affecting Ms1/Rf1 oilseed rape. The Panel found that three of those documents simply identified a potential pest-related hazard but did properly not evaluate the risk of entry, establishment or spread of the pest or the potential biological or economic consequences of that entry, establishment or spread.<sup>12</sup>

The fourth document submitted in support of the French measure was the risk assessment carried out by the Member State competent authority (“CA”) at the time that Ms1/Rf1 oilseed rape was originally authorized in the EU. The Panel agreed that the CA study was a valid risk assessment within the meaning of the SPS Agreement. However, it noted that the study “found no evidence of that Ms1/Rf1 oilseed rape . . . is likely to cause any adverse effects on human health and the environment.” Consequently, the Panel therefore found that the French measure was not “based on” the CA risk assessment, as required by Article 5.1 of the SPS Agreement, and was therefore inconsistent with that provision.<sup>13</sup> The Panel made similar rulings in the case of every Member State import ban it reviewed.

The Panel report establishes legal precedents that WTO Members must take into account. EU Member State and EU Commission attempted to justify a number of LMO-related measures on the basis of considerations that have been frequently mentioned in the SEC discussions. They cited certain evidence in support of their position. In every case the Panel rejected EU arguments and ruled that the EU Member States had not met their obligation to base their measures on a scientific assessment of risk.

Producing a risk assessment is only the first of several important legal hurdles. If a Member does produce a valid risk assessment which identifies a risk that can be addressed by means of an SPS measure, that Member must, in choosing that measure, respect certain other rules, including the following:

- As indicated above, the measure must be based on the risk assessment; that is, there must be a “rational relationship” between the measure and the risk assessment (Article 5.1).<sup>14</sup>
- The measure must be no more trade restrictive than necessary to achieve the Member’s level of protection. If there is a significantly less trade-restrictive regulatory option reasonably available, taking into account technical and economic feasibility, that provides an equivalent level of protection, the Member is required to select that option (Article 5.6 and footnote 3). For example, the SPS Agreement does not permit the imposition of an import ban in cases where special handling requirements or limits on geographical distribution would provide a similar level of protection.
- The measure must not be arbitrary or discriminatory and constitute a disguised restriction on trade (Article 2.3). In the case of biotech regulations, this means that Members cannot favor domestic

---

<sup>12</sup> *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, Reports of the Panel, (WT/DS291/R), paragraph 7.3116, 7.3120 and 7.2121.

<sup>13</sup> *Ibid*, paragraphs 7.3126 – 7.3129.

<sup>14</sup> See *European Communities – EC Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, (WT/DS26/AB/R), paragraphs 193 and 194.

producers of LMOs over producers in another Member country, or producers in one Member country over those in another. It also means that a Member is not permitted to favor conventional products over products of biotechnology unless such discrimination is justified by sufficient scientific evidence.

The SPS Agreement permits countries to adopt provisional measures on a precautionary basis in cases where information is incomplete. However, this right is accompanied by clear obligations. A Member may provisionally adopt an SPS measure if that measure is 1) imposed in respect of a situation where ‘relevant scientific information is insufficient’; and 2) adopted ‘on the basis of available pertinent information’. However, such a measure may not be maintained unless the Member which adopted the measure 3) ‘seek[s] to obtain the additional information necessary for a more objective assessment of risk’; and 4) ‘review[s] the ... measure accordingly within a reasonable period of time’ (Article 5.7).

These four requirements are cumulative and are equally important for the purpose of determining the consistency of a provisional measure with this WTO SPS provision. Whenever one of these four requirements is not met, the measure is inconsistent with the Agreement. In the EC – Biotech case, the EU argued that the Member State bans mentioned above and the restrictions associated with the EU-level pre-marketing approval regime were justified under Article 5.7. The Panel ruled in every instance that the Member State and EU measures did not meet the requirements of Article 5.7 and were therefore subject to the other provisions of the Agreement, including the requirement in Article 5.1 that the measure be based on a scientific assessment of risk.

## 2. TBT Agreement

The TBT Agreement covers all technical regulations and standards that do not fall under the SPS Agreement. While the SPS Agreement is an explication of Article XX(b) of the General Agreement on Tariff and Trade (“GATT”), which permits Members to impose import restrictions that are “necessary to protect human, animal or plant life or health,” the TBT Agreement has a broader focus, as indicated by the general reference to GATT in its preamble. The Agreement explains Article III of GATT – that is, it enumerates the particulars of the national treatment (non-discrimination) obligations that Members are under when they impose technical regulations or standards – but it also establishes the rules that govern regulations that are imposed pursuant to other provisions of GATT, including Article XX.<sup>15</sup>

As indicated above, the fundamental disciplines of the TBT Agreement are similar to those of the SPS Agreement. It requires that technical regulations not be “more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create (Article 2.2).” That is, it requires a Member to assess risk before applying a regulation and, in cases where more than one policy option is available that would achieve the Member’s regulatory objective, to choose the least trade restrictive option. In assessing risks, Members are to consider, *inter alia*, “available scientific and technical information, related processing technology or intended end-uses of products.”

---

<sup>15</sup> Article XX provides an exception from other GATT disciplines, subject to certain conditions, for measures intended to address certain specific concerns. Some of the participants in the SEC debate have argued that Article XX of GATT provides legal cover for SEC-related regulations. They mentioned in particular the exceptions for measures necessary to protect public morals; measures necessary to protect human, animal or plant life or health; and measures relating to the conservation of exhaustible natural resources. It is important to note that even measures that legitimately fall under one of the exemptions in Article XX must conform to the disciplines of the SPS or TBT Agreements.

Since the work on SECs is in the early stages, it is difficult to say whether Parties will be able to identify potential risks associated with the non-SPS considerations on the UNEP GEF list or to evaluate their potential consequences. The literature contains no good examples of potential risks related to considerations such as gender equality, labor and employment, food security, land tenure or rural-urban migration. Assuming Parties are able to identify and evaluate such risks, they will also be obliged to avoid unnecessary trade restrictions by demonstrating that import restrictions are a more effective means of addressing those risks than other policy instruments.<sup>i</sup>

---

<sup>i</sup> List of acronyms: CA – competent authority (an EU Member State agency responsible for regulation of products of biotechnology); COP-MOP – Conference of the Parties serving as the Meeting of the Parties to the Protocol; CPB – Cartagena Protocol on Biosafety; EU – European Union; GATT – General Agreement on Tariff and Trade; LMO – living modified organism; SEC – socio-economic consideration; SPS – Sanitary and Phytosanitary; TBT – Technical Barrier to Trade; UNEP GEF – United Nations Environment Program Division of Global Environment Facility Coordination; WTO – World Trade Organization