AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

Preamble SPS

Members,

Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

Desiring to improve the human health, animal health and phytosanitary situation in all Members;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

Recognizing the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

Desiring therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b);[1]

Hereby agree as follows:

Footnote *1*: In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.

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A. General

1 Like most WTO agreements, the SPS Agreement begins with a Preamble. A treaty's preamble has recognized status under the Vienna Convention on the Law of Treaties which states that the preamble and annexes of a treaty are part of its context for the purpose of treaty interpretation.[1] In

[1] Art. 31.2 VCLT.

US—Shrimp, the Appellate Body drew insights from the Preamble of the WTO Agreement to determine that Art. XX lit. g GATT 1994 is "by definition, evolutionary," rather than merely "static" in its content and reference.[2] This holding demonstrates that preambles of WTO agreements can exert significant influence on the interpretation of provisions in those agreements. In *EC—Hormones (US)*, the Appellate Body twice drew upon the text of the SPS Preamble in interpreting SPS provisions.[3] This jurisprudence demonstrates the relevance of the SPS Preamble.

B. Relationship to Art. XX GATT 1994 (Recs 1 and 8)

Rec. 1 reaffirms "that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health", and this affirmation is subject to the requirement that such measures "are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade". This recital should be read in conjunction with Rec. 8, which states the intention of the drafters as "*[d]esiring* therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)", including its Chapeau. In *Australia—Salmon*, the Appellate Body noted that Rec. 1 of the SPS Preamble reflects the Chapeau of Art. XX GATT 1994.[4] 2

Although Rec. 8 seemingly suggests that the SPS Agreement is merely an elaboration of rules for the application of Art. XX GATT 1994,[5] that limited view has not animated the application of SPS, especially after the first SPS decision *EC—Hormones*. In that dispute, the Panel rejected the EC's claim that the SPS Agreement does not impose substantive requirements **additional** to those already contained in GATT Art. XX lit. b GATT 1994.[6] In addition, the panel held that recourse to the SPS Agreement does not require a prior showing of a GATT violation.[7] In the Panel's view, many SPS provisions impose substantive obligations that "go significantly beyond 3

[2] Appellate Body Report, *US—Shrimp*, WT/DS58/AB/R, paras 129–130. See also para. 155 (stating that the Preamble to the WTO Agreement gives colour, texture, and shading to the rights and obligations of WTO Members).
[3] Appellate Body Report, *EC—Hormones*, WT/DS26/AB/R, WT/DS48/AB/R.
[4] Appellate Body Report, *Australia—Salmon*, WT/DS18/AB/R, para. 251.
[5] One former member of the WTO Appellate Body has written that the provisions of the SPS Agreement are an elaboration of Art. XX lit. b GATT 1994. *Matsushita*, in: *Cottier & Mavroidis* (eds), 193–212.
[6] Panel Report, *EC—Hormones (US)*, WT/DS26/R/USA, para. 8.38.
[7] *Ibid.*, para. 8.41.

and are additional to the requirements for invocation of Article XX(b)".[8] Thus, the panel held that the SPS Agreement imposes obligations that are different from those in the GATT.[9]

4 The relationship between GATT and SPS is that they are separate agreements relating to trade in goods. Of course, like all of the other Annex 1A agreements, the SPS Agreement would prevail over the GATT if there were a conflict between the GATT and the SPS Agreement.[10] A review of the negotiating history suggests Rec. 8 of the SPS Preamble is simply an inelegantly drafted artifact of convoluted SPS negotiation.[11] If one were trying to impart meaning to Rec. 8, it would be that the SPS has substantially **narrowed the benefit of the Art. XX lit. b GATT 1994 exception** for challenges to sanitary or phytosanitary measures, while leaving Art. XX lit. b GATT 1994 unaffected for challenges to measures that do not have a sanitary or phytosanitary purpose. The negotiations that drafted the SPS Agreement began as part of the agriculture talks and were imagined as a way of minimizing the impact that unnecessary SPS measures have on trade in agriculture.[12] Attempts to discipline such measures had from the 1920s been pursued by the international community with only limited success.[13] Thus, the SPS Agreement establishes new rules that can be violated in many ways that do not transgress any GATT rule (for which a justification may be sought under Art. XX GATT 1994).

5 Commentators have occasionally posited that conformity with the GATT might be a defence against an SPS violation. Such an interpretation would seem to contradict the purpose of the SPS Agreement, which was to establish disciplines **for trade-restrictive measures that were not in violation of the GATT.**

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[8] *Ibid.*, para. 8.38.
[9] *Ibid.*, para. 8.40.
[10] See WTO Agreement, General Interpretative Note to Annex 1A: "In the event of conflict between a provision of the General Agreement on Tariffs and Trade 1994 and a provision of another agreement in Annex 1A to the Agreement Establishing the World Trade Organization (referred to in the agreements in Annex 1A as the 'WTO Agreement'), the provision of the other agreement shall prevail to the extent of the conflict." In addition, the use of an international SPS standard may support a defence to an alleged violation of the GATT. See Art. 3.2 SPS and *Landwehr*, Article 3 SPS, paras 27–29.
[11] One commentary suggests that because of the recital, a panel might interpret ambiguous provisions in the SPS Agreement to accord with the GATT. *Marceau & Trachtman*, in: *Ortino & Petersmann* (eds), 275, 335.
[12] *Croome*, 111, 117, 237–38, 241, 387. See Agreement on Agriculture, Preamble, Rec. 4, UNTS 1867 (1995), 410. See <www.wto.org/english/tratop_e/agric_e/agric_e.htm>.
[13] One success was the League of Nations Convention concerning the Export and Import of Animal Products (other than Meat, Meat Preparations, Fresh Animal Products, Milk and Milk Products), 20 Feb. 1935, LNTS 193, 59.

The WTO jurisprudence on the SPS Agreement has influenced the jurisprudence on Art. XX.[14] Rec. 1 is seemingly a restatement of Art. XX lit. b GATT 1994 in the context of Art. XX's Chapeau. The one major difference is that Art. XX GATT 1994 appears to be more obligatory (by using the word "shall") than the SPS Preamble which uses the word "should." Yet in *Canada—Aircraft*, the Appellate Body interpreted the term **"should"** in Art. 13.1 DSU as **"normative"** rather than "exhortative," and therefore conferring a duty.[15] The question thus arises whether a reaffirmation that "no Member" should be prevented from adopting or enforcing measures necessary to protect life or health (subject to listed requirements) could be directly invocable as a defence by a WTO Member. In my view, it is one thing to use a preamble to interpret a particular obligation; it is quite another to treat a preamble as an obligation or an exception. Thus, **the Appellate Body would not elevate Rec. 1 to a freestanding defence.** 6

This analysis leads to a conclusion that despite Rec. 1, the SPS Agreement can render nugatory measures by Member governments that are objectively necessary to protect human, animal or plant life or health, even when those measures are not applied through arbitrary or unjustifiable discrimination and are not a disguised restriction on international trade.[16] A hypothetical example might be an otherwise valid SPS measure for which the regulating government cannot point to a risk assessment fulfilling the extensive requirements of the SPS Agreement.[17] 7

In *Australia—Salmon*, the Appellate Body noted that the fundamental importance of Art. 2.3 is reflected in Rec. 1.[18] One can also see Rec. 1 reflected in Arts 2.1 and 2.2. 8

Rec. 1 refers to the requirement that SPS measures not be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination. This provision highlights the fact that the SPS Agreement aims to prevent discrimination (see arts. 2.3, 5.5). But it is important to recognize that the SPS Agreement goes well beyond the goal of preventing discrimination. To quote Prof. *Hudec*, the SPS Agreement embodies "post-discriminatory" WTO law.[19] 9

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[14] *Goh*, JWT 40 (2006), 655, 668.

[15] Appellate Body Report, *Canada—Aircraft*, WT/DS70/AB/R, para. 187. See *Behboodi*, JIEL 3 (2000), 563–592.

[16] In *EC—Sardines*, the panel examined Rec. 6 of the TBT Preamble, which has a similar syntax and substance to Rec. 2. The Panel found that this provision, as well as Art. 2 TBT, imposes some limits on the regulatory autonomy of WTO Members. Panel Report, *EC—Sardines*, WT/DS231/R, adopted as modified by Appellate Body Report, *EC—Sardines*, WT/DS231/AB/R, paras 7.119–7.120. The Panel did not appear to consider the recital as a possible defence.

[17] *See Australia—Salmon*, WT/DS18/AB/R, paras. 127–135.

[18] *Ibid.*, para. 251.

[19] *Hudec*, B. C. Int'l & Comp. L. Rev. 26 (2003), 185–195.

C. Improving Health (Rec. 2)

10 The SPS Agreement clearly has a trade purpose, but whether it also has a health purpose is not as clear. Rec. 2 of the Preamble to the SPS Agreement memorializes the desire of Members "to improve the human health, animal health and phytosanitary situation in all Members." Rec. 2 therefore suggests that improving human, animal and plant health is one of the aims of the WTO Agreement. In *EC—Hormones*, the Appellate Body took note of the "right *and duty* of Members to protect the life and health of their people".[20] Indeed, the WTO Secretariat echoes that position in contending: "Consumers in all countries benefit. The SPS Agreement helps ensure, and in many cases enhances, the safety of their food as it encourages the systematic use of scientific information in this regard, thus reducing the scope for arbitrary and unjustified decisions."[21] It is interesting to note, however, that a leading health law scholar argues that the WTO is merely "reactive to health policies" and can only "say no to such policies," and that "the WTO can neither formulate its own health policies nor instruct members to do so."[22]

11 Rec. 2 has relevance for all of the SPS Agreement and particularly for the scope of Art. 9 regarding technical assistance. WTO efforts to promote food safety were slow in starting, but the Standards and Trade Development Facility (a joint venture of international organizations) shows the potential for cooperation. Recently, several international organizations, including the WTO, established the International Portal on Food Safety, Animal & Plant Health, which has a wealth of information on health issues. The portal says that its purpose is to facilitate trade in food and agriculture products and to support the implementation of the SPS Agreement.

12 The term "phytosanitary situation" in Rec. 2 is not defined, and one might infer the meaning of plant health.

D. Bilateral Agreements (Rec. 3)

13 Rec. 3 notes that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols.[23] This recital should be read in conjunction with Art. 4.2, which states that Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral

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[20] *EC—Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para. 177 (emphasis added).
[21] *WTO*, Understanding the SPS Agreement, para 17, See <www.wto.org/english/tratop_e/sps_e/spsund_e.htm>.
[22] *Bloche*, JIEL 4 (2002), 825, 845.
[23] See, *e.g.*, *Aritake*, BNA Int'l Trade Rep. 21 (2004), 1758.

agreements on recognition of the equivalence of specified SPS measures. Also relevant is Art. 12.2 on the role of the SPS Committee in encouraging negotiations. The question whether a bilateral agreement could serve as a defence to an SPS challenge at the WTO has not arisen.

E. Minimizing Negative Trade Effects (Recs. 4 and 5)

Rec. 4 states the desire to establish a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of SPS measures in order to minimize their negative effects on trade. This recital should be read with Art. 5.6 which implements the goal of minimizing the negative effects of SPS measures on trade. The multilateral framework of rules in the SPS Agreement is strengthened considerably by the continuous incorporation of international standards. Rec. 5 recognizes the important contribution that international standards, guidelines and recommendations can make in this regard, that is, in helping to achieve the goal of minimizing the negative trade effects of SPS measures. Art. 12.4 directs the SPS Committee to establish a list of international standards relating to national measures that have a "major trade impact." Annex B:5 calls for notification when SPS regulations may have a significant effect on trade. *14*

In *EC—Approval and Marketing of Biotech Products*, the Panel suggested that its interpretation of Annex C:1 lit. a was supported by the object and purpose of the SPS Agreement as evidenced by Rec. 4 which refers to minimizing negative trade effects.[24] *15*

F. Harmonization and the Precautionary Principle (Rec. 6)

Rec. 6 states the desire to further the use of harmonized SPS measures on the basis of international standards, guidelines and recommendations developed by the relevant international and regional organizations "without requiring Members to change their appropriate level of protection of human, animal or plant life or health." This phrase was added to the draft SPS Agreement toward the end of the negotiation.[25] *16*

A Member's **appropriate level of protection** is a concept referred to in Art. 3.3 (and many other provisions) and defined in Annex A:5. Although Rec. 6 might be taken to mean that the harmonization requirements of SPS could not require a Member to change its appropriate level of *17*

protection, the actual discipline in Art. 3.3 makes it clear that a Member has to determine its own level of protection in accordance with Art. 5. Furthermore, regardless of a Member's appropriate level of risk, if an SPS measure would result in a level of protection different from that dictated by an international standard, that measure must not be inconsistent with any provision of the SPS Agreement.[26]

18 **The goal of furthering use of harmonized measures** is promoted through the disciplines in Art. 3 (Harmonization). In *EC—Hormones*, the Appellate Body referred to Rec. 6 in reversing the Panel's interpretation of Art. 3.1.[27] At issue was whether the Panel was correct that the requirement in Art. 3.1 that measures be based on international standards meant that measures had to "conform to" international standards. The Appellate Body held that the harmonization of SPS measures on the basis of international standards was a goal of the SPS **Agreement to be realized in the future** rather than obliged "in the here and now".[28] The Appellate Body marshalled several arguments to reach this conclusion, including that Rec. 6 records the desire by Members "to further the use" of harmonized measures rather than to mandate conformity.[29]

19 The **precautionary principle** counsels preemptive action or inaction in the absence of scientific information about potentially irreversible risks.[30] The principle has proved difficult to put into practice for many reasons, including the fact that it has become imbued with transcendental and cultural values. In *EC—Hormones*, the Appellate Body held that the "precautionary principle" is "reflected" in Arts 3.3 and 5.7, and in Rec. 6, which recognize the right of Members to establish their own level of sanitary protection that "may be higher (*i.e.*, more cautious) than that implied" in existing international standards.[31] Although comprehensible with regard to Art. 5.7, this holding is puzzling with regard to Art. 3.3 and the Preamble. A choice to be more risk averse than implied in an international standard has little to do with the precautionary principle, which is about decision-making in the absence of scientific information. When sufficient scientific data is available to make rational decisions in the presence of uncertainty, then the precautionary principle has little relevance. The principle becomes relevant, however,

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[26] See Art. 3.3.

[27] *EC—Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para. 165. In *EC—Sardines*, the Appellate Body referred to Rec. 3 of the TBT Preamble as recognizing the contribution of international standards. *EC—Sardines*, WT/DS231/AB/R, para. 215.

[28] *EC—Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para. 165.

[29] *Ibid.* See *Landwehr*, Article 3 SPS, para. 18.

[30] For the precautionary principle see: *Boutillon*, Mich. J. Int'l L. 23 (2002), 429–469; *Wiener*, Duke J. Comp. & Int'l L. 13 (2003), 207–262; *Gehring*, in: *Koufa* (ed.), 583–599; *Salmon*, 138–155; *Victor*, Transnat'l Law. 14 (2001), 295–321; *Bohanes*, Colum. J. Transnat'l L. 40 (2002), 323–389.

[31] *EC—Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para. 124.

when there is not enough scientific information to make such decisions. Normally when an international standard exists, it was written because there was scientific information available. Thus, a decision by a government to seek a higher level of protection than provided in an international standard would typically not need to stand on the precautionary principle. Rather, it would be a normal exercise by a government of its regulatory autonomy, to be more protective of individuals than the level agreed upon in the international process.

In *EC—Hormones*, the Appellate body explained that the precautionary principle "has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement".[32] 20

The WTO Secretariat has opined that Members "can to some extent apply the 'precautionary principle', a kind of 'safety first' approach to deal with scientific uncertainty".[33] 21

Many **international SPS standards** have been adopted by the Codex Alimentarius Commission, the International Office of Epizootics and the Secretariat of the International Plant Protection Convention.[34] 22

G. Developing Countries (Rec. 7)

Rec. 7 refers to the challenges faced by developing countries. In particular, this recital recognizes that developing country Members may encounter **special difficulties** in complying with the SPS measures of importing countries, and also in the formulation and application of SPS measures in their own territories. The recital expresses a desire to assist, and that goal is pursued in Arts 9, 10, and 14.[35] 23

H. Outlook

The SPS Preamble is a roadmap to the future dualistic course of the SPS Agreement. Certainly, the expectations of the drafters will play out of using the Agreement to rigorously supervise national SPS measures. Yet on 24

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[32] *Ibid.*

[33] *WTO*, Standards and Safety, availabale at <www.wto.org/english/thewto_e/whatis_e/tif_e/agrm4_e.htm.

[34] G/SPS/W/18 and Corr.1 (Codex); G/SPS/W/21 and G/SPS/W/23. For updated information, see *e.g.* G/SPS/W/107/Rev.1, G/SPS/GEN/177, G/SPS/GEN/185, G/SPS/GEN/266, G/SPS/GEN/271, and G/SPS/GEN/282.

[35] See *Seibert-Fohr*, Article 9 SPS, paras 1 *et seq.*; *Seibert-Fohr*, Article 10 SPS, paras 1 *et seq.*; *Röben*, Article 14 SPS, paras 1 *et seq.*

the other hand, public opinion will continue to drive WTO Members to broaden the work of the WTO Secretariat and the SPS Committee so as to embrace normative and technical assistance activities in favour of promoting public health.[36] Improvements in public health could also occur if a government tightens regulation against particular risks in order to achieve the "consistency" mandated in Art. 5.5 SPS.

[36] See *Charnovitz*, in: *Sampson & Chambers* (eds), 207, 225–227

Rüdiger Wolfrum, Peter-Tobias Stoll and Anja Seibert-Fohr (eds), *WTO-Technical Barriers and SPS Measures*.
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Article 1 SPS
General Provisions

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.
3. The annexes are an integral part of this Agreement.
4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

Annex A
Definitions[4]

1. *Sanitary or phytosanitary measure*—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.

   Sanitary or phytosanitary measures 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.
2. *Harmonization*—The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.
3. *International standards, guidelines and recommendations*
   a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
   b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
   c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
   d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.
4. *Risk assessment*—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.
5. *Appropriate level of sanitary or phytosanitary protection*—The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

6. *Pest- or disease-free area*—An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.
NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area—whether within part of a country or in a geographic region which includes parts of or all of several countries—in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.
7. *Area of low pest or disease prevalence*—An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.

Footnote 4: For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

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Cross References

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A. Application of the SPS Agreement (Art. 1.1)

I. Direct or Indirect Effect on Trade

Art. 1.1 states that the SPS Agreement applies to sanitary and phytosanitary measures that "may, directly or indirectly, affect international trade". In *EC—Hormones (US)*, the panel parsed this provision and explained that it set the two requirements for the Agreement to apply—namely, that there is an SPS measure and that it affects trade.[1] SPS measures are defined in Annex A as elaborated below. With regard to affecting trade, the panel pointed to Art. 1.1 and noted that it cannot be contested that the import ban at issue affects international trade.[2] The phrase "directly or indirectly" is contained in 11 WTO covered agreements. The phrase "affecting trade in services" appears in Art. I:1 GATS (Scope and Definition). 1

The term of "**affecting**" in Art. 1.1. is not defined, but past GATT and WTO practice suggests that this term would be given a broad play. Thus, the term "affecting" does not seem to require showing a quantifiable impact on trade. In *EC—Bananas III*, the Appellate Body stated that the term "affecting" in Art. I:1 GATS reflects the intent of the drafters to give a broad reach to the GATS, and is reinforced by conclusions of previous panels that the term "affecting" in the context of Art. III GATT 1994 is wider in scope than such terms as "regulating" or "governing".[3] In an influential early GATT case, *Italy—Agricultural Machinery*, the panel found that the word "affecting" implies that the drafters intended to cover not only the laws and regulations that directly govern the conditions of sale or purchase, but also any laws or regulations that might adversely modify the conditions of competition between domestic and imported products on the internal market.[4] 2

In *EC—Approval and Marketing of Biotech Products*, the panel explained that for an SPS measure to affect international trade, it is not necessary that there be a demonstration that the measure "has an actual effect on trade".[5] The panel also emphasized that trade could be affected in a direct or indirect way. 3

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[1] Panel Report, *EC—Hormones (US)*, WT/DS26/R/USA, para. 8.36.
[2] *Ibid.*, para. 8.23.
[3] Appellate Body Report, *EC—Bananas III*, WT/DS27/AB/R, para. 220.
[4] Panel Report, *Italy—Agricultural Machinery*, BISD 7S/60, para. 12.
[5] Panel Report, *EC—Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 7.435.

II. Trade in Goods

4 SPS measures often apply equally to imported and internally made products. Thus, SPS measures will regularly be manifestations of domestic policy, not trade policy. Sometimes, SPS measures are applied exclusively to imported products or to products whose importation is being attempted.

5 Art. 1.1 does not specify trade in goods, but because SPS is an Annex 1A covered agreement, its scope is limited to **trade in goods**. Thus, a measure affecting a sanitary or phytosanitary service presumably is not covered by the SPS Agreement.

III. Obligation to Develop SPS Measures

6 Art. 1.1 states that SPS measures "**shall be developed** and applied in accordance with the provisions of this Agreement". The concept of development is reflected in Rec. 4 of the SPS Preamble which states that SPS rules guide the *development*, adoption, and enforcement of SPS measures. The issue whether the phrase "shall be developed" is itself an obligation has not been litigated in WTO dispute settlement. In *EC—Hormones*, the question ensued as to whether there were "procedural requirements" in SPS Art. 5.1 for the regulator to actually take the risk assessment into account in developing an SPS regulation. The Appellate Body characterized as an "error in law" the panel's holding that there was a "minimum procedural requirement" in Art. 5.1 for some "subjectivity" to be present in particular individuals.[6] The Appellate Body's ruling seems to suggest that regulators do not have to develop an SPS measure by using a risk assessment so long as a defendant government can show that a measure is substantively based on a risk assessment by the time that the matter goes before a WTO panel. Perhaps that issue will be reconsidered by the Appellate Body in a future case. There may also be consideration in the future as to whether Art. 1.1 requires Members to proactively develop SPS measures.

IV. Obligations Regarding Subnational Measures

7 As with WTO covered agreements generally, a Member's obligations extend not only to measures of the central government, but also to measures of **subnational governments**. In the compliance phase of the *Australia—Salmon* case, the panel, noting Art. 13 SPS and Art. 22.9 DSU, held that

[6] Appellate Body Report, *EC—Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para. 189. Rather than a subjective requirement, the Appellate Body declared that Art. 5.1 referred to an objective relationship between the challenged SPS measure and a risk assessment.

a measure taken by the state of Tasmania fell under the responsibility of Australia even if Australia objected to the measure.[7]

V. Temporal Application

The question of the temporal application of the SPS Agreement arose in *EC—Hormones*. The Appellate Body held that the Agreement applies to **measures enacted before 1995** that continue to be in force.[8] Furthermore, the Appellate Body stated that Arts 2.2, 2.3, 3.3 and 5.6 expressly contemplate their applicability to SPS measures existing before 1 January 1995. *8*

VI. Relationship to Accession Protocols

The relationship of SPS rules to the additional disciplines in individual Protocols of Accession has yet to be determined. Many accession protocols contain applicant WTO-plus SPS obligations. *9*

B. Definition of Treaty Terms (Art. 1.2 and Annex A)

Art. 1.2 states that the definitions in Annex A shall apply. Art. 1.3 states that all of the SPS Annexes are an integral part of the SPS Agreement. *10*

I. Scope of SPS Measures (Annex A, Para. 1)

SPS measures are defined in Annex A:1. In *EC—Approval and Marketing of Biotech Products*, the Panel opined that in determining whether the measure in dispute is an SPS measure (rather than a non-SPS measure), "regard must be had to such elements as the **purpose of the measure**, its **legal form** and its **nature**".[9] *11*

1. Purpose

Annex A:1 provides definitions of the **purposes of measures that come within the scope of the SPS Agreement**. If a measure does not have a purpose listed in para. 1, then that measure is not covered by the SPS Agreement. Para. 1 begins by listing four purposes, lit. a–d, broadly related *12*

[7] Panel Report, *Australia—Salmon (Article 21.5—Canada)*, WT/DS18/RW, paras 7.12–7.13, 7.162.
[8] *EC—Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, paras 128, 130.
[9] *EC—Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 7.149.

to human, animal or plant life or health or to the prevention of other damage from pests. Nevertheless, in an SPS dispute, no shorthand description can substitute for a careful examination of the contested measure to see if it matches one or more of the enumerated risks that come under the terms of the Agreement.[10] In all of the SPS cases decided up to November 2006, the panel or Appellate Body noted that the measure was aimed at least one of the lit. a—d purposes.[11]

13 In *Japan—Apples*, the Panel noted that the Annex A:1 definitions do not consider the **trade effect** of a given measure as a factor to determine whether such a measure is or is not a phytosanitary measure.[12] The Panel further stated that the definition does not require SPS measures to be mandatory or legally enforceable.[13]

14 A particular SPS measure—for example, one aimed at pests—can come within the scope of three of the subparagraphs. In *Australia—Salmon*, the Panel seemed to select the subparagraph by which the measure was more "appropriately covered".[14]

15 Each of the lit. a—c refers to a distinct range of beneficiaries. Thus, lit. a is aimed at the protection of "animal or plant life or health". Lit. b is aimed at the protection of "human or animal life or health". Lit. c is aimed at the protection of "human life or health". Lit. d does not specify a beneficiary. In *EC—Approval and Marketing of Biotech Products*, the Panel held that the purpose for which a measure was adopted is not conclusive on whether the measure is an SPS measure; rather, a panel has to look at whether the measure is being "applied" for one of the enumerated purposes.[15] In doing so, the purpose is to ascertained "on the basis of objective considerations", not just the purposes articulating by the defendant government.[16]

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[10] See *Echols*, 97; *Wolff*, in: *Meléndez-Ortiz & Sánchez* (eds), 223.

[11] In three of the cases, the purpose was found in lit. a. Those were: Panel Report, *Australia—Salmon*, WT/DS18/R, para. 8.37; Appellate Body Report, *Australia—Salmon*, WT/DS18/AB/R, para. 172; Panel Report, *Japan—Agricultural Products II*, WT/DS76/R, para. 8.12; Panel Report, *Japan—Apples*, WT/DS245/R, para. 8.13. In the fourth case, the purpose was found in lit. b. *EC—Hormones (US)*, WT/DS26/R/USA, para. 8.22. In the fifth case, *EC—Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, the purpose was found in all four subparagraphs.

[12] *Japan—Apples*, WT/DS245/R, para. 8.24.

[13] *Ibid.*, para. 8.111. The Appellate Body did not review this holding. In an earlier case, the Appellate Body found that a non-legally-enforceable instrument that was applicable generally is within the scope of Annex B. Appellate Body Report, *Japan—Agricultural Products II*, WT/DS76/AB/R, paras 104–105.

[14] *Australia—Salmon*, WT/DS18/R, para. 8.34; *Pauwelyn* (1999), JIEL 2 (1999), 641, 644.

[15] *EC—Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 7.167.

[16] *Ibid.*, para. 7.2558.

16 Not all regulatory measures relating to food fall into one of these categories.[17] For example, measures that would restrict the entry of junk food, non-Kosher food, non-organic food, food that violates cultural taboos, or food from animals treated inhumanely appear to be **outside the terms of the SPS Agreement**. Risks from bioterrorism in food appear to be covered by lit. b. This is the author's analysis; no such issues have come through WTO dispute settlement as of November 2006.

17 All four subparagraphs of para. 1 describe measures as being aimed at the protection or prevention of damage **"within the territory"** of the Member imposing the measure. Thus, the geographic domain of the SPS Agreement does not extend to measures to protect humans, animals or plants outside the territory of the regulating government. For example, a measure preventing the export of animals with certain diseases would presumably not be covered by the SPS Agreement. When a measure is not covered by the SPS Agreement, such a measure cannot violate the SPS Agreement.

18 With regard to the **proper interpretative approach to ascertaining the existence of an SPS measure**, the Panel in *EC—Approval and Marketing of Biotech Products* held that the "general definition" in Annex A:1 "must not be applied in mechanistic fashion" and that "account should also be taken of the specific context" within the SPS Agreement.[18] As with everything in this Panel Report, this holding (or dicta) was not reviewed by the WTO Appellate Body.

19 The degree to which the **environment** comes within the scope of the SPS Agreement has been the subject of considerable scholarly commentary.[19] Certainly, some environmental measures are SPS measures. This can be seen in several ways in the text of the SPS Agreement: The named beneficiaries in Annex A—namely, animals, plants, and humans—are part of the environment. The listed risk agents, such as pests, diseases, organisms, additives, toxins, etc., come within the terms of environmental policymaking. The Annex A:1 definitions define "animal" to include fish and wild fauna, "plant" to include forests and wild flora, and "contaminants" to include pesticide and veterinary drug residues. Art. 5.2 states that in the assessment of risks, a Member shall take into account a number of factors, including "relevant ecological and environmental conditions." Art. 6.2 states that

[17] The Uruguay Round Draft Final Act of December 1991 states that most participants in the negotiation were of the view that only some aspects of consumer concerns related to health were within the scope of the draft Decision by Contracting Parties on the Application of Sanitary and Phytosanitary Measures. Draft Final Act Embodying the Results of the Multilateral Trade Negotiations, GATT Doc. MTN.TNC/W/FA,20 December 1991, Section L, Part C.

[18] *EC—Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 7.1337.

[19] See, e.g, *Roberts*, JIEL 1 (1998), 377, 382.

determination of areas that are pest-free, low-pest, or disease-free "shall be based on factors such as geography, ecosystems, epidemiological surveillance", and the effectiveness of SPS controls.

20 In *EC—Approval and Marketing of Biotech Products*, the Panel explained that measures to protect the environment are "not *a priori* excluded from the scope of application of the *SPS Agreement*" if the measure is covered by one of the purposes in Annex A:1.[20] Although some measures to protect the health of humans, animals, and plants are, *ipso facto*, environmental measures, not all environmental measures are aimed at protecting humans, animals, and plants. In particular, the Panel ruled that Annex A:1 lit. d encompasses "certain damage to the environment other than damage to the life or health of animals or plants".[21] The Panel also offered a converse hypothetical example of an environmental measure that is excluded from the SPS scope. The example is a measure to reduce air pollution in order to protect the life or health of animals and plants.[22] In reaching these conclusions, the Panel addressed some aspects of the preparatory work on SPS.[23]

21 A horizontal issue for the interpretation of Annex A:1 is the **meaning of "pests"** In *EC—Approval and Marketing of Biotech Products*, the Panel endowed this term with a broad meaning, perhaps broader than was intended or anticipated by the drafters of the SPS Agreement in the early 1990s. Using as an informative aid the International Standard for Phytosanitary Measure No. 11 adopted in 2004 by the IPPC,[24] the Panel held that pests include any animal or plant that is "destructive" or that is a "troublesome or annoying" animal or plant.[25] Thus, genetically modified plants that "grow where they are undesired" are "pests" within the scope of Annex A:1, as are "cross-breeds" exhibiting "undesired introduced traits".[26] For this reason, governmental measures to avoid to invasiveness of genetically modified plants are SPS measures.[27]

22 The meaning of the **Annex A:1 lit. a purpose** was explicated in *EC—Approval and Marketing of Biotech Products.* With respect to the term "animal or plant life or health", the Panel held that it was "meant to be comprehensive in coverage", and encompasses macro and micro fauna and flora as well as

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[20] *EC—Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 7.207.
[21] *Ibid.*, para. 7.209. The Panel further stated that a measure to "avoid adverse effects of GMOs on the environment other than adverse effects on animal or plant life or health" is covered by Annex A:1 lit. d. *Ibid.*, para. 7.2583.
[22] *Ibid.*, para. 7.210.
[23] See *ibid.*, paras 7.208, 7.211.
[24] *Ibid.*, paras 7.233, footnote 390, 7.253, footnote 406.
[25] *Ibid.*, para. 7.240.
[26] *Ibid.*, paras 7.247, 7.255, 7.2581.
[27] *Ibid.*, paras 7.2579, 7.2580.

soil and aquatic micro-organisms. [28] With respect to the term "risks arising from the entry, establishment or spread of pests" the Panel held that the term includes risks "which might arise" from pests.[29] In addition, the Panel said that measures taken to protect against risks "that arise indirectly or in the longer term" lie within the scope of Annex A:1 lit. a.[30] Thus, for example, risks from a change in pesticide or herbicide use could arise indirectly from the entry of a pest.[31] With respect to the terms "disease-carrying organisms" and "disease-causing organisms," the Panel referenced World Health Organization definitions that define the former as a "vector" and the latter as a "pathogen."[32] Thus, a pathogen that develops resistance to an antibiotic qualifies as a disease-causing organism under Annex A:1 lit. a.[33]

The meaning of the **Annex A:1 lit. b purpose** was explicated in *EC— Approval and Marketing of Biotech Products.* With respect to the term "human [...] life or health", the Panel held that a requirement that food "not be nutritionally disadvantageous for the consumer" lies outside the meaning of human health.[34] With respect to the term "additives", the panel held that genes can be additives when they are intentionally added to plants that will be used as an input into processed foods.[35] This includes antibiotic resistance marker genes. With respect to the term "contaminants," the Panel held that "proteins produced through the *unintended* expression of modified genes in agricultural crops" are additives if they "infect or pollute" the food product.[36] With respect to the term "toxins", the Panel held that a "poisonous substance which is produced during the metabolism or growth" of a genetically modified crop could be a toxin.[37] Having noted that the Annex text is silent on the question of whether an allergen is a toxin, the Panel held that the SPS term "toxins" encompasses "food allergens which might be produced by GMOs".[38] With respect to the term "food, beverages or feedstuffs", the Panel held that genetically modified seeds for sowing purposes are "food" for animals, and a genetically modified crop that is eaten by an animal also constitutes animal "food" even when the crop is not intended for that purpose.[39] In addition, the term "food" encompasses genetically modified plants that are processed into products that are eaten.[40]

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[28] *Ibid.*, para. 7.219.
[29] *Ibid.*, para. 7.225.
[30] *Ibid.*, para. 7.226.
[31] *Ibid.*, paras 7.266, 7.2582.
[32] *Ibid.*, para. 7.277, citing a 1997 document.
[33] *Ibid.*, para. 7.282.
[34] *Ibid.*, para. 7.414.
[35] *Ibid.*, para. 7.301.
[36] *Ibid.*, para. 7.313.
[37] *Ibid.*, para. 7.323.
[38] *Ibid.*, paras 7.333, 7.337.
[39] *Ibid.*, para. 7.292.
[40] *Ibid.*, para. 7.299.

24 The meaning of the **Annex A:1 lit. c purpose** was explicated in *EC—Approval and Marketing of Biotech Products*. With respect to the term "pests", the Panel found no legal requirement for "pests" to be living.[41] In other words, dead pests can still be "pests".

25 The meaning of the **Annex A:1 lit. d purpose** was explicated in *EC—Approval and Marketing of Biotech Products*. With respect to the term "other damage", the Panel held that this term means damage "other than damage to the life or health of plants, animals or humans" and that lit. d is a "residual category".[42] The Panel noted that this residual category is "potentially very broad," and could include damage to "property" and "infrastructure".[43]

2. Legal Form

26 In *EC—Approval and Marketing of Biotech Products*, the Panel explained that the second paragraph of Annex A:1 ("laws, decrees, regulations") addresses both the **"legal form"** and the **"nature of measures"**.[44] This interpretation was not reviewed by the WTO Appellate Body and has been criticized by some commentators. The Panel also explained that Annex A:1 "should not be taken to prescribe a particular legal form".[45]

3. Nature of Measures

27 The final sentence of Annex A:1 states that SPS measures 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". The use of the term "*inter alia*" suggests that the list is an open one. In *EC—Approval and Marketing of Biotech Products*, the Panel explained that the listing is "by way of example".[46]

28 The meaning of **"requirements and procedures including"** was explicated in *EC—Approval and Marketing of Biotech Products*. The Panel held that the term "requirements" is "broad in scope" and can include an "authorization to market a particular product" and "a ban on the marketing of a

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[41] *Ibid.*, para. 7.351.
[42] *Ibid.*, paras 7.369, 7.370.
[43] *Ibid.*, para. 7.370. Such damage can be physical harm or economic harm. *Ibid.* (noting Art. 5.3).
[44] *Ibid.*, para. 7.149.
[45] *Ibid.*, para. 7.422.
[46] *Ibid.*, para. 7.1334.

particular product."[47] The Panel also opined that the omission of the term "application" of a requirement suggests that although the requirement as such is an SPS measure, the application of such a requirement is not an SPS measure.[48] Furthermore, the Panel held that the term "requirements" includes requirements that are either "generally applicable" or are specifically applicable.[49]

The meaning of the **"packaging"** has not yet been addressed by a panel.[50] 29
The meaning of **"labelling requirements directly related to food safety"** in Annex A:1 was to some extent explicated in *EC—Approval and Marketing of Biotech Products*. The Panel held that such a label would have to "clearly and unambiguously" serve one of the four purposes in Annex A:1.[51] The Panel also opined that labels "to provide quality assurance, volume of contents, or to reflect consumer preferences or moral considerations" would not be subject to the SPS Agreement.[52] With respect to labelling requirements on "novel foods" aimed at avoiding labels that "mislead the consumer," the Panel held that such concerns, such an "nutritional value," are "unrelated to food safety".[53]

With regard to the interpretation of **"certification and approval pro-** 30
cedures", see the discussion in this volume regarding Art. 8 (Control, Inspection and Approval Procedures) and Annex C.[54] Footnote 7 in Annex C states that "[c]ontrol, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification." In *Japan—Apples*, the Panel noted that the contested measure "falls within the definition" of SPS measures in Annex A:1 "which includes certification and approval procedures".[55] In *EC—Approval and Marketing of Biotech Products*, the Panel held that "approval procedures" can be understood as "encompassing procedures applied to check and ensure the fulfillment of one or more substantive SPS requirements the satisfaction of which is a prerequisite for the approval to place a product on the market".[56]

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[47] *Ibid.*, para. 7.1334.
[48] *Ibid.*, para. 7.1335.
[49] *Ibid.*, para. 7.1336. This holding further addresses the requirements for a risk assessment.
[50] The WTO Secretariat has opined that "quality and packing regulations are generally not considered to be sanitary or phytosanitary measures and hence are normally subject to the TBT Agreement." *WTO*, Understanding the SPS Agreement, at 8.
[51] *EC—Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 7.390, footnote 527.
[52] *Ibid.* Some of this holding, especially the Panel's irrelevant reference to "moral" considerations, is dicta.
[53] *Ibid.*, paras 7.411, 7.412.
[54] *Böckenförde*, Article 8 SPS.
[55] *Japan—Apples*, WT/DS245/R, para. 8.24.
[56] *EC—Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, para. 7.424.

31 The reference to **"processes and production methods"**,[57] known as PPMs, needs to be read in conjunction with the geographic limitation in lit. a–d. Thus, a PPM designed to protect foreign country health would not come within the terms of the SPS Agreement. The term **"relevant"** as a modifier to "transport of animals and plants" is thought by analysts to generally exclude government measures regarding the mishandling and mistreatment of animals.[58]

32 The SPS Committee has noted that the SPS Agreement uses the terms "measures" and "regulations" interchangeably in connection to Annex A:1.[59]

II. Definition of Harmonization (Para. 2)

33 Harmonization among WTO Members is the establishment, recognition and application of common SPS measures.[60]

III. Definition of International Standards (Para. 3)

34 The term "International standards, guidelines, and recommendations" is defined according to the type of measure.[61] Three international standard-setting mechanisms are specifically listed.[62] For food safety, the UN Codex Alimentarius Commission (**CAC**) is identified. For animal health and zoonoses, the International Office of Epizootics is identified. This body is now called the World Organisation for Animal Health (**OIE**). For plant health, the bodies operating within the framework of the International Plant Protection Convention (**IPPC**) are identified. For matters not covered by these organizations, Paragraph 3 points to appropriate standards promulgated by "*other* relevant international organizations open for membership to all Members, as identified by the [SPS] Committee". None has been identified as of November 2006.

35 Only one of the multilateral organizations listed in para. 3 permit full participation by all WTO Members. That is the OIE. The others refuse to admit Taiwan.

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[57] This term also appears in Art. 5.2 SPS and Annex 1 TBT.

[58] The WTO Secretariat has opined that measures "[…] for the welfare of animals are not coverd by the SPS Agreement." *WTO*, Understanding the SPS Agreement, at 6.

[59] Committee on Sanitary and Phytosanitary Measures, Review of the Operation and Implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures, Report of the Committee, G/SPS/36, 11 July 2005, para. 92.

[60] See *Landwehr*, Article 3 SPS, para. 5.

[61] Relevant SPS documents can be found at <www.wto.org/english/tratop_e/sps_e/sps_e.htm>.

[62] See *Victor*, N.Y.U. J. Int'l L. & Pol'y 32 (2000), 865, 884–894 for an overview of these three mechanisms.

In *EC—Hormones (US)*, the Panel stated that it was not required to consider whether an international standard had been adopted by **consensus**, or by a wide or narrow **majority**.[63] Indeed, Annex A contains no minimum prerequisites for when the outputs of listed international standard-setting entities can attain lawmaking force within the WTO. Such standards so far have been deemed legitimate under SPS law.[64] 36

IV. Definition of Risk Assessment (Para. 4)

Para. 4 defines a "risk assessment" and this term has been interpreted in WTO dispute settlement in conjunction with Art. 5.1.[65] The Appellate Body has explained that a risk assessment must: "(1) **identify** the diseases whose entry, establishment or spread a Member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases; (2) **evaluate the likelihood** of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences; and (3) evaluate the likelihood of entry, establishment or spread of these diseases **according to the SPS measures which might be applied.**"[66] 37

The concept of risk has been clarified to some extent by the Appellate Body. In *EC—Hormones*, the Appellate Body explained that a risk assessment need not establish "a minimum quantifiable magnitude of risk" and need not *exclude* "factors which are not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences".[67] Furthermore, it explained that the risk to be evaluated includes "risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die".[68] In *Australia—Salmon*, the Appellate Body explained that the risk "must be an **ascertainable risk**" and cannot be merely "theoretical uncertainty".[69] Furthermore, the Appellate Body held that a WTO Member may determine its own appropriate level of risk to be "zero risk".[70] 38

In *Australia—Salmon*, in ruling that Australia's risk assessment was inadequate, the Appellate Body held that a risk assessment must evaluate "the" **likelihood** 39

[63] *EC—Hormones (US)*, WT/DS26/R/USA, para. 8.69.
[64] *Pauwelyn*, in: *Joerges & Petersmann* (eds), 199, 212.
[65] See *Stoll & Strack*, Article 5 SPS, paras 12 *et seq.*
[66] *Australia—Salmon*, WT/DS18/AB/R; para. 121 (emphasis in the original).
[67] *EC—Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para. 253(j).
[68] Ibid., para. 187.
[69] *Australia—Salmon*, WT/DS18/AB/R, para. 125. See *Trebilcock & Soloway*, in: *Kennedy & Southwick* (eds), 537, 564 *et seq.*
[70] *Australia—Salmon*, WT/DS18/AB/R, para. 125.

of entry and spread of diseases, and that, in an assessment, merely "some" evaluation is not enough.[71] Relatedly, the Appellate Body explained that the likelihood may be expressed either quantitatively or qualitatively.[72]

40 The Appellate Body has held that Members have a "right" to adopt "any appropriate 'methodology' consistent with the definition of 'risk assessment'" in SPS Annex 4.[73] Nevertheless, the Appellate Body has also held that a risk assessment should not be limited to an examination of the measure already in place or favoured by the importing government. In other words, the evaluation contemplated in para. 4, according to the Appellate Body, "should **not be distorted by preconceived views** on the nature and the content of the measure to be taken; nor should it develop into an exercise tailored to and carried out for the purpose of justifying decisions *ex post facto*".[74] Furthermore, in *Japan—Apples*, the Appellate Body has made clear that under Art. 2.2, a panel is not obliged "to give precedence to the importing Member's approach to scientific evidence and risk when analyzing and assessing scientific evidence".[75]

41 In *EC—Hormones*, the Appellate Body held that a risk assessment need not come to a "monolithic conclusion".[76] Rather it could set out both the mainstream scientific opinion as well as the opinion of scientists taking a diverging view.

42 In *Japan—Apples (Article 21.5—US)*, the Panel held that the issue of whether there is a valid risk assessment is not separable from the issue of whether there is a rational relationship between the disputed measure and the risk assessment.[77]

V. Definition of Appropriate Level of Protection (Para. 5)

43 The appropriate level of protection (ALOP) is the level "deemed appropriate by the Member" applying the SPS measure. The ALOP concept is referred to in Arts 3.3, 4.1, 5.3, 5.4, 5.5, 5.6, 9.1, 10.2, 12.4, and Annex B:3(c) of the SPS Agreement. An ALOP is a government's choice regarding its values and its tolerance of specific risks. The ALOP can differ from one government to another. Thus, it seems that an SPS measure could be WTO-consistent in one country, while the same measure is WTO-inconsistent in another country.

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[71] *Ibid.*, paras 124, 134.
[72] *Ibid.*, para. 124.
[73] *Japan—Apples*, WT/DS245/AB/R, para. 205.
[74] *Ibid.*, para. 208.
[75] *Japan—Apples*, WT/DS245/AB/R, para. 167.
[76] *EC—Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para. 194.
[77] *Japan—Apples (Article 21.5—US)*, WT/DS245/RW, para. 8.129. This decision was not reviewed by the appellators.

A WTO Member's ability to determine its own ALOP is **not unlimited.** 44
In *EC—Hormones*, the Appellate Body stated that the "right of a Member to establish its own level of protection "is an important right".[78] But then the Appellate Body hastened to add that this right "is not, however, an absolute or unqualified right".[79] This leads to the obvious question of what exactly a "right" of a Member means in the context of the SPS Agreement. Does it have any meaning independent from being a beneficiary of a WTO discipline? The Appellate Body has taken note of what it calls the "carefully negotiated balance in the *SPS Agreement* between the shared, but sometimes competing, interests of promoting international trade and protecting the life and health of human beings".[80] This statement too suggests that the Appellate Body sees limits to the so-called "right" of a Member to establish its own level of health protection.

Arts 5.4 and 5.5 of the SPS Agreement impose disciplines on a Member's 45
choice of ALOP, and therefore those disciplines may conceivably infringe a Member's choice.

Noting that Japan had described its ALOP as equivalent to what would 46
result from an import ban on commercial apples, the Panel in *Japan—Apples (Article 21.5—US)* stated that it was for Japan to determine its ALOP and "we should not question it".[81] Then the Panel went on to hold that since there was no evidence that mature, symptomless apples would spread fire blight to Japan, a less restrictive measure permitting the importation of such apples "theoretically meets" Japan's ALOP.[82]

The SPS Agreement seems to contain an **implicit obligation** for a Mem- 47
ber to determine its own ALOP.[83] This determination logically precedes a Member's decision to adopt an SPS measure.[84] If a Member does not choose its own ALOP with sufficient precision, then the ALOP may be established by panels on the basis of the level of protection reflected in the SPS measure actually applied.[85] In 2004, the WTO's SPS Committee adopted a decision on Art. 4 stating that "[t]he importing Member should indicate the appropriate level of protection which its sanitary or phytosanitary measure

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[78] *EC—Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, para. 172. In addition, the Appellate Body held "that the right of a Member to establish its own level of sanitary protection under Article 3.3 of the SPS Agreement is an autonomous right"; *Ibid.* Presumably this means that the "right" inures from state sovereignty.
[79] *Ibid.*, para. 173 (referring to Art. 3.3).
[80] *Ibid.*, para. 177.
[81] *Japan—Apples (Article 21.5—US)*, para. 8.193.
[82] *Ibid.*
[83] Appellate Body Report, *Australia—Salmon*, WT/DS18/AB/R, paras 205–206. See also *ibid.*, para. 200 (stating that the ALOP is the government's objective).
[84] *Ibid.*, para. 201.
[85] *Ibid.*, para. 207.

is designed to achieve".[86] According to WTO Director-General Pascal Lamy, this decision "has positively added to the WTO in adopting more detailed and specific rules to implement broad treaty provisions."[87]

VI. Pest-/Disease-Free and Low-Pest or Disease Prevalence Area (Paras 6–7)

48 Pest or disease-free areas are referred to in Arts 5.2, 6.2, and 6.3.[88] Areas of low pest or disease prevalence are referred to in Arts 6.2 and 6.3.

C. Relationship to the TBT Agreement (Art. 1.4)

49 Art. 1.4 states: "Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement." This provision should be read in conjunction with Art. 1.5 TBT which states that the provisions of the TBT Agreement do not apply to SPS measures as defined in Annex A of the SPS Agreement. Thus, a government's **SPS measures are governed by the SPS Agreement, not by the TBT Agreement**, even though all SPS measures will be technical barriers, as that term is normally used. (A government's SPS measures will also be governed by the GATT.) Commentators have suggested that a particular law or regulation could have distinctive aspects, some of which could be governed by the SPS Agreement and some by the TBT Agreement.[89] In *EC—Approval and Marketing of Biotech Products*, the Panel took this view.[90]

50 **Food labelling** is an issue that could come within the terms of either the SPS or the TBT agreements, depending on the purpose of the label. Measures regarding consumer or nutritional labelling not aimed at providing information about one of the listed Annex A:1 lit. a–d risks would come under the supervision of the TBT Agreement.[91] Measures regarding consumer or nutritional labelling aimed at providing information about one of the listed risks would come under the supervision of the SPS Agreement.

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[86] Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures, G/SSP/19/Rev.1 (2 Apr. 2004), para. 2 (footnote omitted).

[87] *Lamy*, The WTO in the Archipelago of Global Governance, 14 March 2006, available on WTO website.

[88] See the definition in the explanatory note to Annex A:6.

[89] For example, see *Marceau & Trachtman*, in: *Ortino & Petersmann* (eds), 275, 328.

[90] *EC—Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, paras 7.167, 7.2524.

[91] See *Josling et al.*, 158 (detailing discussions in TBT Committee on process attribute labels).

D. Outlook

51 The **SPS Agreement** will remain one of the **most controversial of the WTO covered agreements** because it supervises the application of governmental measures to protect public health. All of the risk of WTO panel error is allocated to the regulating country. For example, in a case like *Japan—Apples* or *Australia—Salmon*, the WTO offers no indemnity to those countries if they change their regulations in order to comply with recommendations of the Dispute Settlement Body and then suffer damaging consequences from the introduction of a new disease into an island environment.

52 The issue of the **definition of SPS measures** is likely to remain contested in the years ahead as the WTO dispute system clarifies these terms. Because the most rigorous supervision of domestic policy in the WTO occurs in the SPS Agreement, there is much at stake in whether a disputed measure comes under the supervision of the SPS Agreement. The decision of the Panel in *EC—Approval and Marketing of Biotech Products* stakes out a greater scope for the SPS Agreement than what might have been anticipated.

53 Further developments can be expected with respect to the **policies of the international standard-setting organizations** responsible for food safety and animal health. Some commentators have seen these developments as demonstrating a "hegemonic" attitude by the WTO in seeming to dictate to other international organizations and entities what policies are acceptable or unacceptable in the global economy. The term "hegemonic" may be too pejorative, but there can be no doubt that SPS rules are having an ongoing normative effect on the work of standard-setting organizations.

WTO – Technical Barriers and SPS Measures

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