Health and Environmental Regulation

Selected international developments regarding health and environmental regulation of relevance to the European Union

Denise Prévost, Research associate and Ph.D candidate at Maastricht University, Consultant for UNCTAD with regard to capacity building on dispute settlement under the SPS Agreement

Summary: This contribution provides an overview of a selection of significant recent developments on international level regarding the regulation of health and the environment, which are of relevance to the European Union. It focuses on developments with regard to the interaction between free trade and risk regulation in the area of health and the environment. Developments in this regard will be examined in the context of the World Trade Organisation, and other international organisations or initiatives establishing rules, setting harmonised standards or promoting international cooperation in this area. As the European Union plays an active role in the international arena, these developments will have an impact on its internal regulatory policies as well as on its external actions in international fora.

I. The World Trade Organization

National regulatory measures which address risks to human, animal or plant life or health or to the environment (such as maximum residue levels for pesticides, hygiene requirements for abattoirs, bans on the use of carcinogenic substances in beef production and quarantine measures to address plant pests) can constitute formidable trade barriers. The rules contained in the various agreements of the World Trade Organisation (WTO) aim to liberalise trade by reducing tariffs and other trade barriers and eliminating discrimination in international trade relations. As such, they place limits on the ability of WTO Members, including the European Communities (EC), to enact regulations for the protection of health and the environment against risks in ways that restrict trade. However, these rules do take into account the legitimate interest and sovereign right of governments to protect against risks in their territories. Whether they do so sufficiently has been disputed by some. The balance struck by WTO rules between free trade and the protection of health and the environment is fleshed out by the developing case law in this area.

The following section of this contribution will examine new developments with regard to the WTO rules that act on the interface between free trade and risk regulation in the area of human, animal or plant life or health and the environment. These rules are contained in the General Agreement on Tariffs and Trade 1994 (GATT), the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement).

As the disciplines in each of these agreements differ, including with respect to the role of science and risk assessment therein, it is necessary to determine which agreement applies to a given situation. This will depend on the nature and aim of the measure at issue. The GATT 1994 applies broadly to measures affecting trade in goods. The TBT Agreement applies to a narrower range of measures, namely technical regulations, standards and conformity assessment procedures. Technical regulations have been found by the Appellate Body in EC-Asbestos to include certain bans. The SPS Agreement applies only to those measures that fall within its definition of SPS measures and directly or indirectly affect international trade. SPS measures are defined according to their aim or purpose and, broadly speaking, cover measures aiming at food safety or at protecting against risks from pests or diseases. One can clearly envisage a possible overlap between the measures covered by these three agreements (for example, a technical regulation may aim at ensuring the safety of food products). It is thus necessary to determine what the relationship between these three agreements is. The TBT Agreement and the SPS Agreement are mutually exclusive – if a measure has been found to be an “SPS measure” under the definition in

1 This article discusses developments as of 21 October 2003, but has been partially updated to reflect the most important changes as of 29 January 2004.
2 See the Preamble to the Marrakesh Agreement Establishing the World Trade Organization, 3rd paragraph.
3 The term European Communities is used here, rather than European Community or European Union, since it is the European Communities that are a WTO Member.
4 Public concern regarding the impact of free trade on biodiversity was recently once again made apparent at the 18th session of the Global Biodiversity Forum (GBF-18), which brought together participants from over 40 countries to discuss the linkages between trade and biodiversity. One area discussed was that of risk, precaution and biosecurity. The GBF-18 sent a message to governments indicating their “growing concern about the urgent need to mitigate the negative impacts of the current trading system on the closely entwined fates of [the] local communities, to which we all belong, and the ecosystems upon which our livelihoods depend.” The GBF-18 was held in Cancun on 5-7 September 2003. See Bridges Trade BioRes, Special Issue, 8 September 2003.
5 Appellate Body Report, European Communities – Measures Affecting Asbestos and Asbestos-Containing Products (EC-Asbestos), WT/DS135/AB/R, adopted 5 April 2001, paras 74-75. In this case, the Appellate Body found that a ban based on product characteristics which provides for exceptions also based on product characteristics, is a technical regulation for purposes of the TBT Agreement.
6 Article 1.1 of the SPS Agreement.
7 The definition of SPS measures can be found in Annex A, para. 1 of the SPS Agreement.
the SPS Agreement, the TBT Agreement does not apply even if the measure is a technical regulation, standard or conformity assessment procedure. Although the GATT 1994 can apply concurrently with the SPS or TBT Agreements, a dispute where one of the latter agreements applies will first be examined under that more specific agreement. If a measure complies with the SPS Agreement, it is presumed to comply with the GATT 1994. However there is no such presumption of GATT-consistency for measures that comply with the TBT Agreement.

Significant new developments that deserve attention in this area are a recent WTO Panel and Appellate Body report on a dispute under the SPS Agreement regarding measures to protect against the risk of introduction of fire blight through the importation of apples, new panels that have been established to address disputes regarding the regulation of genetically modified organisms and the Australian quarantine regime, and the discussions on SPS and TBT concerns that have taken place at recent meetings of the SPS and TBT Committees. Particular attention will be given to the discussions at these Committees regarding the draft regulations under the US Bioterrorism Act and the EC’s proposed chemicals legislation. In addition, the ongoing negotiations at the WTO concerning the relationship between WTO rules and multilateral environmental agreements (MEAs) will be addressed.

The fire blight dispute

A new panel report on a dispute under the SPS Agreement was circulated on 15 July 2003. The panel report addressed a complaint by the US regarding Japan’s quarantine measures to protect its territory against the risk of introduction of fire blight through the importation of apples from the US. Fire blight is a bacterium native to North America, which infects various host plants (including apples), causing the infected parts to wither and darken. The disease has spread to northern and western Europe and the Mediterranean region. However, Latin America, and a large part of Africa and Asia, appear to remain fire blight-free.

In order to prevent the introduction of new plant pests into its territory, Japan maintains a general prohibition on the importation of host plants of 15 pests of quarantine significance, including fire blight, in terms of the Plant Protection Law and its Enforcement Regulations. However, a lifting of the prohibition is possible on a case-by-case basis, subject to certain criteria. Based on these rules, Japan allows the importation of apples from the US, provided that a range of cumulative conditions is met.

The US brought a challenge at the WTO against Japan’s quarantine measures. As consultations between the US and Japan failed to resolve the dispute, the US requested the establishment of a panel to examine Japan’s measures, individually and taken together, under inter alia, certain provisions in Arts 2, 5, 6, 7 and Annex B of the SPS Agreement. The Panel found that Japan’s measure was inconsistent with Arts 2.2, 5.1 and 5.7 of the SPS Agreement and these findings were appealed by Japan.

8 Article 1.5 of the TBT Agreement.
9 Under Art. 2.4 of the SPS Agreement, a measure found to comply with the provisions of this agreement is presumed to be GATT-consistent. Thus, in EC-Hormones, the Panel held that in a dispute where both the SPS Agreement and the GATT are raised, it would be most efficient to start by examining the matter under the SPS Agreement. If the measure is found to violate the SPS Agreement, it is unnecessary to proceed to an examination under the GATT. If a measure is found to be consistent with the SPS Agreement, the presumption of GATT-consistency also renders an examination under the GATT unnecessary. See Panel Report, EC Measures Concerning Meat and Meat Products (Hormones) (EC-Hormones), WT/DS26/R/CAN para. 8.45, WT/DS48/R/USA para. 8.42, adopted 13 February 1998 as modified by the Appellate Body Report.
10 The Panel in EC-Asbestos decided that where both the GATT and the TBT Agreement appear to apply, a panel should first examine the matter under the TBT Agreement as the latter deals with technical barriers to trade. However, if the measure were found to be consistent with the TBT Agreement, the panel would still have to examine the GATT-consistency of the measure, as there is no presumption that a measure in conformity with the TBT Agreement is also GATT-consistent. Panel Report, European Communities – Measures Affecting Asbestos and Asbestos-Containing Products (EC-Asbestos), WT/DS153/R and Add.1, adopted 5 April 2001 as modified by the Appellate Body Report WT/DS153/AB/R, para. 8.16.
11 There are no recent panel/Appellate Body reports on TBT or GATT issues relating to the interaction between free trade and risk regulation. The only case so far in which the substantive provisions of the TBT Agreement were interpreted was European Communities – Trade Description of Sardines, WT/DS231 (Panel and Appellate Body reports adopted on 23 October 2002). However, the measure at issue in this case was not a measure for the protection of health or the environment, but rather a rule regarding the name under which certain species of fish may be marketed in the EC, which was aimed at consumer information. The case will therefore not be discussed here.
13 These conditions are: that the apples are produced in designated fire blight-free orchards; that the orchard is free of fire blight-infected plants and other host plants of fire blight; that the orchard is surrounded by a 500-meter buffer zone; that the orchard and buffer zone are inspected at least three times per year; that the harvested apples, harvesting containers and interior of the packing facility be disinfected; that apples destined for Japan be kept separate from other apples after harvesting; that US officials certify that the apples are not infested or infected with fire blight and were disinfected; and that Japanese officials confirm the certification and carry out inspections themselves.
14 The panel request was made on 7 May 2002 and the Panel was established on 3 June 2002. Australia, Brazil, the EC, New Zealand and the separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu reserved the right to participate as third parties before the Panel.
15 The US also claimed a violation of Art. XI of the GATT and Art. 4.2 of the Agreement on Agriculture, but these claims were not addressed by the Panel due to considerations of judicial economy.
16 Specifically, the US claimed a violation of Arts 2.2, 2.3, 5.1, 5.7, 5.3, 5.5, 5.6, 6.1, 6.2, 7 and Annex B paras 5 and 7 of the SPS Agreement. In its submissions, the US did not argue its claims on Arts 2.3, 5.3, 5.5, 6.1 and 6.2 and thus the Panel did not make findings on these claims. In addition, the Panel exercised judicial economy with respect to the claims under Arts 5.2 and 5.6. With regard to the US claim under Art. 7 and Annex B, which contain notification obligations, the Panel found that the US did not provide sufficient evidence to make a prima facie case.
17 See Japan’s notification of appeal, document symbol WT/DS245/5. Japan claimed that the Panel erred in finding a violation of Arts 2.2, 5.1 and 5.7 and that the Panel erred in failing to make an objective assessment of the matter as required by Art. 11 of the Dispute Settlement Understanding.
Health and Environmental Regulation

In order to come to this conclusion, the Panel disassembled the sequence of events on the transmission pathway for fire blight to identify the risk, and compared the risk to the measure. 30 As a result, the Panel held that Japan’s measure was “clearly disproportionate” to the negligible risk identified, 31 thus introducing a proportionality test into the “rational relationship” requirement in Art. 2.2. 32 The Panel therefore came to a provisional conclusion that the measure

---

30 Panel Report, Japan-Apples, paras 6.1-6.4. After requesting suggestions of suitably qualified experts from the secretariat of the International Plant Protection Convention and the parties to the dispute, the Panel appointed four experts to advise it in this dispute. A summary of the written responses of the experts to the Panel’s questions can be found in Panel Report, Japan-Apples, paras 6.5-6.194.

31 Japan based its argument on the fact that the US had not made claims or submitted evidence in respect of the risk of transmission of fire blight by apples other than mature symptomless apples, yet the panel had made findings of fact with regard to these “other” apples.

32 The Appellate Body further held that the task of panel experts is not to make the case for one of the parties, but rather to assist the Panel in understanding and evaluating the evidence submitted and arguments made by the parties. Appellate Body Report, Japan-Measures Affecting Agricultural Products (Japan-Agricultural Products II), WT/DS76/AB/R, adopted 19 March 1999, para. 129.

33 Appellate Body Report, Japan-Apples, para. 158.

34 Appellate Body Report, Japan-Agricultural Products II, para. 73.


37 Panel Report, Japan-Apples, para. 8.92.


40 One of the experts consulted by the Panel, Dr Hayward, indicated that the standard scientific definition of “negligible” was a likelihood of between zero and one in a million.


42 The Panel based this finding on its conclusions on the basis of the evidence available to it with regard to mature symptomless apples and other apples. With regard to mature, symptomless apples, it found that infection with fire blight had not been established; that populations of endophytic bacteria have not been found and epiphytic bacteria are very rare; and that the risk of completion of the transmission pathway is negligible. With regard to apples other than mature, symptomless fruit, it held that infected apples are capable of harbouring populations of bacteria which could survive through the various stages of commercial handling, storage and transportation; that risks of errors of handling or illegal actions could legitimately be taken into account, although the experts considered these risks small or debatable; but that completion of the last stage of the transmission pathway (the transmission of the bacteria to the host plant) was not shown to be likely. This was because only a reduced number of bacteria would survive commercial storage, handling and transportation and the existence of a vector (such as rain splash or bees), which could transmit the bacteria from the imported apples to the host apple plant in Japan, had not been established. Panel Report, Japan-Apples, paras 8.136, 8.139, 8.153, 8.157, 8.161, 8.168.


44 The Panel proceeded to examine two elements of Japan’s measure, namely the buffer-zone requirement and the requirement of inspections three times yearly, as instances of elements most obviously maintained without sufficient scientific evidence either as such or when applied cumulatively with other elements. Panel Report, Japan-Apples, paras 8.182-8.197.
as a whole was maintained without sufficient scientific evidence contrary to Art. 2.2.33

On appeal, the Appellate Body accepted as appropriate the methodology of the Panel of disassembling the sequence of events and comparing the risk to the measure, in its Art. 2.2 analysis, but noted that this does not exhaust the range of possible methodologies and that the circumstances of each case will determine the appropriateness of a given methodology.34 It also did not take issue with the Panel’s view that “clear disproportion” between the risk and the measure implies that a “rational or objective” relationship does not exist.35 It rejected Japan’s contention that the Panel should have accorded it a “certain degree of discretion” in the way in which it chose, weighed and evaluated the scientific evidence, finding that deference by panels to the findings of national authorities would not be compatible with the standard of review36 applicable to panels.37

In order to come to a final conclusion on Art. 2.2, the Panel had to examine whether Japan’s measure could be justified under Art. 5.7, since Art. 2.2 states that a measure may not be maintained without sufficient scientific evidence except as provided for in Art. 5.7. Article 5.7 allows Members to take provisional measures in situations of insufficient scientific evidence, and has been held to reflect the controversial “precautionary principle” for purposes of the SPS Agreement.38 The precautionary principle refers to the principle that, in cases of scientific uncertainty, governments act with precaution and take measures to address possible risks to health or the environment without waiting for full scientific evidence confirming the risk.39 It is interesting to examine the Panel’s findings on this issue as they illustrate the extent to which this much-debated principle finds reflection in the SPS Agreement.

The Panel in this case was faced with the question whether Japan’s measure met the four cumulative requirements under Art. 5.7 namely:

- the measure is imposed in a situation where “relevant scientific evidence is insufficient”;
- the measure is adopted “on the basis of available pertinent information”;
- the Member “seek[s] to obtain the additional information necessary for a more objective assessment of risk”; and
- the Member “review[s] the ... measure accordingly within a reasonable period of time.”40

The first requirement is particularly significant, as it identifies the situation that triggers the application of the precautionary principle as embodied in Art. 5.7. This requirement had never been addressed in the case law before. Here, the Panel focused its analysis on this precise issue, making this a particularly interesting case for the understanding of the role of the precautionary principle in the SPS Agreement.

The Panel found that the fact that a measure has been found to be maintained “without sufficient scientific evidence” under Art. 2.2 does not automatically mean that “relevant scientific evidence is insufficient” under Art. 5.7, which is a separate question.41 The sufficiency requirement under Art. 2.2 requires that the evidence supporting the SPS measure applied be sufficient, whereas the evidence to be considered under Art. 5.7 “includes not only evidence supporting Japan’s position, but also evidence supporting other views.”42 In this case, the Panel found that a wealth of relevant, high quality, scientific evidence was available43 on the matter at issue and that this was thus “clearly not the type of situation Article 5.7 was intended to address.”44 According to the Panel, Art. 5.7 was instead “obviously designed to be invoked where little, or no, reliable evidence was available on the subject matter at issue.”45 It thus concluded that the first requirement of Art. 5.7 was not met and that Japan’s measure could therefore not be justified under this Article.46 As a result, the Panel came to the final conclusion that Japan violated its obligations under Art. 2.2.47

Japan challenged the Panel’s finding of non-compliance with the first requirement of Art. 5.7 on appeal, arguing that the insufficientness of the evidence should be interpreted to

---

33 Panel Report, Japan-Apples, para. 8.199.
34 Appellate Body Report, Japan-Apples, para. 164.
35 Appellate Body Report, Japan-Apples, para. 163.
36 This standard of review is found in Art. 11 of the Dispute Settlement Understanding, and requires that a panel undertake an “objective assessment of the matter before it, including an objective assessment of the facts of the case...” It is well-established case law that this standard applies neither total deference by panels to national authorities’ determinations, nor de novo review.
37 Appellate Body Report, Japan-Apples, para. 165.
38 Appellate Body Report, EC Measures Concerning Meat and Meat Products (Hormones) /EC-Hormones), WT/DS26/AB/R, WT/D/48/AB/R, adopted 13 February 1998, para. 124. In this case, the Appellate Body found it unnecessary to decide the question whether the precautionary principle has evolved into a general principle of customary international law. It held that the precautionary principle cannot override the specific scientific requirements of the SPS Agreement. It can only be applied to the extent that it finds reflection in the provisions of the Agreement itself, namely Arts 5.7 and 3.3 and the preamble.
39 It should be noted, however, that there is no generally accepted definition of the precautionary principle, which appears in various forms in international environmental treaties and national legislation. There is also some debate regarding whether it is in fact a “principle” or merely an “approach”. Broadly speaking, it can be said to embody the old adage “better safe than sorry” with regard to risk regulation.
40 Panel Report, Japan-Apples, para. 8.213. These cumulative requirements were first listed in Appellate Body Report, Japan Agricultural Products II, para. 89.
42 Panel Report, Japan-Apples, para. 8.216. The Panel later concluded that the term “insufficient scientific evidence” in Art. 5.7 refers to evidence in general on the SPS question at issue (in this case the risk of transmission of fire blight through apple fruit). Panel Report, Japan-Apples, para. 8.218.
43 The Panel noted that much relevant evidence had been submitted by the parties and panel experts, and scientific studies and practical experience on the matter had accumulated for the past 200 years. Panel Report, Japan-Apples, paras 8.216 and 8.219.
46 Panel Report, Japan-Apples, para. 8.222.
47 Panel Report, Japan-Apples, para. 8.224. The Panel, however, emphasised that its decision related to the application of the measure as a whole, without prejudging the question whether certain elements of the measure, individually or in combination with others, could be compatible with Art. 2.2. Panel Report, Japan-Apples, para. 8.225.
Health and Environmental Regulation

relate to a particular measure or a particular risk, but not to the subject matter in general. The Appellate Body, on the contrary, held that Japan’s reliance on this distinction was misplaced. Instead, it identified a contextual link between the first requirement of Art. 5.7 and the obligation to perform a risk assessment in Art. 5.1. Thus, relevant scientific evidence will be insufficient for purposes of Art. 5.7 if it “does not allow, in qualitative or quantitative terms, the performance of an adequate assessment of risks as required under Article 5.1.”

According to the Appellate Body, the factual findings of the Panel showed that the scientific evidence available did permit the performance of a risk assessment under Art. 5.1 and the relevant scientific evidence was thus not insufficient within the meaning of Art. 5.7.

Japan also appealed the Panel’s finding that Art. 5.7 is intended only to address situations where little, or no, reliable evidence was available on the subject matter at issue. Japan argued that this would not provide for situations of “unresolved uncertainty”. According to Japan, Art. 5.7 covers not only situations of “new uncertainty” (where a new risk is identified) but also “unresolved uncertainty” (where there is considerable scientific evidence but still uncertainty remains). The Appellate Body, however, upheld the Panel’s finding, pointing out that Art. 5.7 “is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence.” Moreover, it held that the Panel’s finding referred to the availability of reliable evidence, and thus did not exclude cases “where the available evidence is more than minimal in quantity, but has not led to reliable or conclusive results.”

This analysis of the first requirement of Art. 5.7 is groundbreaking. It clarifies the role of Art. 5.7, establishing that it is there to address situations where there is a true lack of sufficient scientific evidence regarding the risk at issue, either due to the small quantity of evidence on new risks, or due to the fact that accumulated evidence is inconclusive or unreliable. In either case, the insufficiency of the evidence must be such as to make the performance of an adequate risk assessment impossible. Thus Art. 5.7 cannot be used to justify measures that are adopted in disregard of existing scientific evidence. The Panel and Appellate Body’s findings establish the fact that the precautionary principle, as embodied in Art. 5.7, does not create a broad loophole in the scientific disciplines of the SPS Agreement through which protectionist measures can slip. Rather, it creates a limited exception for cases where there is a true lack of relevant and reliable scientific evidence on the risk at issue.

Finally, in this case the issue arose whether Japan’s measure was based on a “risk assessment, as appropriate to the circumstances, taking into account risk assessment techniques developed by the relevant international organisations” as required by Art. 5.1 of the SPS Agreement. The Panel noted that the obligation in Art. 5.1 contains two elements, namely:

- an assessment of risks; and
- that Members ensure that their SPS measures are based on such an assessment.

With regard to the first element, the Panel turned to the definition of a risk assessment in the SPS Agreement that is relevant to phytosanitary risks, as well as the terms of Art. 5.1, and found that such a risk assessment involves an 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”; 45
- whether this risk assessment is “as appropriate to the circumstances”; 46
- whether the risk assessment takes “into account risk assessment techniques developed by the relevant international organisations”. 47

The Panel found the latter two requirements to “pervade the entire assessment of the risk” and addressed them first. It found that Japan’s fire blight-free status and its climatic conditions, which are favourable to the spread of fire blight, were relevant circumstances. It also, rather obviously, noted that risks to plant life or health should be the focus of the risk assessment since the measure at issue is a phytosanitary measure. With regard to the obligation to take account of risk assessment techniques developed by international organisations, the Panel found that:

such techniques should be considered relevant, but that a failure to respect each and every aspect of them would not necessarily, per se, signal that the risk assessment on which the measure is based is not in conformity with the requirements of Article 5.1.

With regard to the first requirement, the Panel started by identifying the factual elements on which it would base its evaluation of Japan’s risk assessment. It noted that Japan had conducted two relevant risk assessments, one in 1996

---

48 Appellate Body Report, Japan-Apples, para. 179.
49 The Appellate Body found these contextual elements in the following: first, the concepts of relevance and insufficiency in Art. 5.7 imply a relationship between scientific evidence and something else; second, Art. 5.1, obliging Members to base their measures on a risk assessment, contains a key discipline under Art. 5 and informs the other provisions of Art. 5; and third, Art. 5.7 itself refers to “a more objective assessment of risks”. Appellate Body Report, Japan-Apples, para. 179.

50 Appellate Body Report, Japan-Apples, para. 179.
52 Appellate Body Report, Japan-Apples, para. 185.
54 It should be noted that Annex A para. 4 of the SPS Agreement contains two different definitions of a risk assessment. The first is applicable to risks from pests or diseases and the second to food safety risks. The definition of a risk assessment relevant here is the former, contained in the first sentence of Annex A para. 4.
55 This is a direct quote from the definition of a risk assessment in the first sentence of Annex A, para. 4 of the SPS Agreement.
56 Panel Report, Japan-Apples, para. 8.236.
57 Panel Report, Japan-Apples, para. 8.241. In this context, the Panel examined two relevant standards set by the International Plant Protection Convention, ISPM 2 on Guidelines for Pest Risk Analysis, and ISPM 11 on Pest Risk Analysis for Quarantine Pests. The parties agreed that both instruments build upon the same framework, thus the Panel focused on the key issue of whether Japan’s risk assessment sufficiently identified and assessed the possible pathways for the introduction and spread of fire blight through apple fruit and the likelihood for their being realised, as required by both instruments. Panel Report, Japan-Apples, para. 8.244.
concerning various pests including fire blight, and one in 1999 concerning, specifically, fire blight on apples imported from the US.58 The Panel agreed with the parties that the 1999 risk assessment was the most relevant and stated that it would therefore focus on the latter.59 However, it stated that, contrary to Japan’s arguments during the interim review of the report,50 it considered that information subsequent to the completion of the risk assessment could also be of relevance.51 In the interim review stage, it stated that “[s]ome assessment of the subsequent evolution of scientific evidence is not only acceptable, it is also necessary, if only to monitor the development of any new evidence which might require a revision of the risk assessment.”62 This finding puts countries in the rather onerous position of having to monitor continually the development of scientific evidence in order to revise the risk assessments on which their measures are based.63 The Panel then examined each of the three requirements for a risk assessment under the relevant definition in Annex A, para. 4, as set out by the Appellate Body in Australia-Salmon,64 namely that such a risk assessment must:

- identify the diseases whose entry, establishment or spread a Member wants to prevent in its territory, and the associated potential biological and economic consequences;
- evaluate the likelihood of entry, establishment or spread of the diseases and the associated potential biological and economic consequences;
- evaluate the likelihood of entry, establishment or spread of these diseases according to the SPS measures which might be applied.65

The first requirement was not in dispute as the US agreed that Japan’s risk assessment identified fire blight as the disease at issue.66 With regard to the second requirement, the Panel found that Japan’s risk assessment was not specific enough with respect to the product at issue as it referred to a variety of hosts of fire blight, including but not exclusively, apple fruit and did not come to a conclusion on the likelihood of entry, establishment or spread of fire blight specifically through apple fruit. It has been established in prior cases regarding this element of Art. 5.1 that a risk assessment must be sufficiently specific to the risk at issue.67 Japan challenged this finding on appeal, arguing that the specificity requirement relates to the risk and not the methodology of the risk assessment. It noted that the SPS Agreement does not prescribe a particular methodology for risk assessment and that the decision to assess a risk on the basis of the disease at issue or on the basis of the particular commodity is a “matter of methodology”. The Appellate Body agreed that Members are free to follow the risk assessment methodology of their choice, including considering multiple agents in relation to one disease, but noted that this is subject to the proviso that “the risk assessment attribute a likelihood of entry, establishment or spread of the disease to each agent specifically.”68

In addition, the Panel had found that the risk assessment did not “evaluate the likelihood” of the risk occurring as it identified the possibility of apple fruit acting as a pathway for the introduction of fire blight, but did not “indicate any quantitative or qualitative assessment of the probability of this occurring”.69 In making this finding, the Panel referred back to previous cases where it was established by the Appellate Body that the requirement in the definition of a risk assessment (with regard to phytosanitary measures),70 of an evaluation of the “likelihood” of the risk occurring involves more than a mere identification of possibilities. Instead, it requires an assessment of the probability of entry of the pest or disease. The Panel in this case referred to the EC-Hormones case, where the Appellate Body stated, “probability implies a higher degree or a ‘threshold of potentiality or possibility’”.71 However, the Panel noted that such probability

58 Panel Report, Japan-Apples, paras. 8.246.
60 Panel Report, Japan-Apples, para. 7.11.
63 Although Japan raised this issue on appeal, claiming that a risk assessment should be evaluated only against the evidence available at the time the risk assessment was conducted, the Appellate Body found it unnecessary to address this issue. This was due to the fact that Japan failed to show that the Panel had actually used subsequent scientific evidence to evaluate Japan’s risk assessment. Appellate Body Report, Japan-Apples, para. 215.
65 Panel Report, Japan-Apples, paras. 8.250.
66 Panel Report, Japan-Apples, paras. 8.252.
68 Appellate Body Report, Japan-Apples, para. 204 (emphasis added.) The Appellate Body found that the specificity requirement, as discussed in EC-Hormones, relates not only to the harm concerned but also to the precise agent that may cause the harm. It noted the Panel’s finding that the risk of entry, establishment or spread of fire blight varies significantly depending on the vector or host plant at issue. Thus it agreed with the Panel that an evaluation of the risks from all possible hosts taken together was not sufficiently specific. Appellate Body Report, Japan-Apples, paras. 202-204.
70 In Annex A, para. 4.
71 Appellate Body Report, EC-Hormones, para 184. This comment was made by the Appellate Body in this case in order to differentiate between the requirements for a risk assessment in the case of food safety risks (as defined in the second sentence of Annex A para. 4 of the SPS Agreement) and the requirements of a risk assessment for risks from pests and diseases (second sentence of Annex A para. 4). The former requires an evaluation of the “potential for adverse effects”, which the Appellate Body identified as the “possibility” of adverse effects, whereas the latter definition requires an evaluation of the “likelihood” of entry, establishment or spread of the pests or diseases, which the Appellate Body took to mean the “probability” of these risks. It should, nevertheless, be noted that even in the case of risk assessments with regard to pests or diseases, there is no requirement that a certain magnitude or threshold level of risk be shown, as was established by the Appellate Body in Australia-Salmon para. 125. The finding of the Appellate Body in EC-Hormones quoted by the Panel in Japan-Apples should thus not be understood to mean that a particular threshold level of risk must be established in cases of phytosanitary risks.
Health and Environmental Regulation

need not be expressed quantitatively, but could also be expressed in qualitative terms. As Japan’s risk assessment provided no more than an indication of the potential for entry of fire blight from the importation of apples and did not assess the probability that each of the steps necessary for the transmission pathway would be completed, it was held not to “evaluate the likelihood” of the risk occurring.

Finally, with regard to the third requirement, the Panel had found that it is not sufficient to conduct the evaluation with regard to the SPS measures actually being applied, as was done in Japan’s risk assessment, but that other possible alternatives must also be evaluated. This is indicated by the use of the words “measures which might be applied” in the definition of a risk assessment. The Panel thus concluded that Japan’s risk assessment did not meet the requirements for a risk assessment under Art. 5.1. On appeal, the Appellate Body agreed with the Panel that a risk assessment should not be limited to an examination of the measure already in place. It emphasised that a risk assessment “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.”

Aside from the substantive issues raised on appeal, it is of interest to note that Japan challenged the evaluation of the scientific evidence by the Panel, in terms of Art. 11 of the Dispute Settlement Understanding. This provision sets out the standard of review to be applied, requiring that a panel make “an objective assessment of the matter before it, including and objective assessment of the facts…” It is thus of importance to the question of how a panel must deal with the evidence before it, including scientific evidence. The most interesting of the three points raised by Japan in this regard was its argument that the Panel had failed to adequately take into account the precautionary principle in its evaluation of the evidence. According to Japan, the fact that the experts had recognised the need for caution with respect to the elimination of the phytosanitary measures protecting Japan from fire blight, should have been given greater weight by the Panel in considering the evidence regarding the completion of the transmission pathway for fire blight. The Appellate Body noted that Japan did not argue that the precautionary principle should have been applied as distinct from the provisions of the SPS Agreement, nor did it argue that the Panel should have used the precautionary principle as part of its interpretative analysis of the Agreement. Instead, it understood Japan to argue that the principle was embodied in the cautionary opinions of the experts and should have been given greater weight in the Panel’s conclusions on the completion of the pathway. The Appellate Body then noted that it is established case law that the credibility and weight to be properly ascribed to a particular piece of evidence is in the discretion of a panel as the trier of facts. This discretion is limited only by a panel’s duty to make an “objective assessment” of the facts. Since Japan made no argument challenging the objectivity of the Panel’s assessment, it failed to establish a violation of Art. 11.

The GMO dispute

The EC regime with respect to genetically modified organisms (GMOs) raises interesting questions with regard to risk regulation in the absence of sufficient scientific evidence regarding the existence and nature of a risk under the rules of the WTO. The EC has legislation in place, which requires that GMOs be authorised prior to being released into the environment or being marketed in the EC. However, despite applications for approval under this legislation, no new varieties of GMOs have been approved for use in the EC since October 1998. This was due to a suspension of the consideration of applications for approval of GMOs and a failure to consider new applications for approval of GMOs. This situation is commonly referred to as the de facto moratorium on the approval of GM products in the EC. In addition, six EC Member States are making use of the “safeguard mechanism” provided by the EC legislation in order to ban those 18 varieties of GMOs that received authorisation before October 1998.

The US, which is the world’s largest exporter of GM products, has long expressed its dissatisfaction with the de facto moratorium in the EC and Member States’ safeguard measures, which have resulted in trade restrictions on food

---

72 A fictitious example of a quantitative assessment of risk is the determination that there is a likelihood of one in one thousand that a particular additive used in a specific amount in tinned fruit will cause an allergic reaction.

73 A qualitative risk assessment is one where the conclusions of the magnitude of the risk are expressed in terms such as “high”, “medium”, “low” or “negligible” rather than in numerical terms.

74 Panel Report, Japan-Apples, para. 8.273. This fact has previously been established by the Appellate Body in Australia-Salmon, para. 124.

75 Panel Report, Japan-Apples, para. 8.278. This particular finding was not appealed by Japan.

76 Panel Report, Japan-Apples, para. 8.283.

77 Annex A para. 4 of the SPS Agreement.

78 It was therefore unnecessary to proceed in this case to an enquiry regarding whether Japan’s measure was “based on” such a risk assessment. Panel Report, Japan-Apples, para. 8.290-291.


80 The other two points raised related to the Panel’s erroneous characterisation of experimental evidence and the fact that it had made factual findings on the risk of transmission of fire blight by infected fruit on the basis of evidence which centred on mature, symptomless fruit. The Appellate Body found in both cases that a violation of Art. 11 had not been shown. Appellate Body Report, Japan-Apples, paras 224 and 231.

81 Appellate Body Report, Japan-Apples, para 283.


83 It should be noted, however, that on 28 January 2004, the Commission approved a proposal to authorise Syngenta’s GM corn (Bt-11) for use in food. If the Member States cannot reach agreement on authorisation within 90 days, it will be possible for the Commission to grant the authorisation on its own initiative. This would end the de facto moratorium. See Bridges Weekly Trade News Digest Vol. 8 no. 3, 28 January 2004.

84 The safeguard mechanism allows a Member State to temporarily ban an approved GM product when it has new information providing detailed grounds for considering that the product presents a risk to human health or the environment. It has to notify the European Commission, which has to review the ban within 60 days to determine if it is well founded.
and agricultural exports from the US.\(^{85}\) According to the US, the EC measure lacks a scientific basis. The US held back from initiating a dispute on this matter at the WTO until the end of the war in Iraq. On 13 May 2003, the US decided to request formal consultations on this issue with the EC.\(^{86}\) Argentina\(^{87}\) joined these consultations.\(^{88}\) Canada held separate consultations with the EC. Several other Members participated as third parties in the consultations.\(^{89}\) The EC expressed its surprise at the initiation of the dispute as it was in the process of revising its GMO legislation and expected the new legislation\(^{90}\) to be in place and authorisations to resume by the end of 2003.\(^{91}\) Consultations failed to settle the matter and the US,\(^{92}\) Canada\(^{93}\) and Argentina\(^{94}\) requested the establishment of a panel to hear the dispute on 7 August 2003.

In their panel requests, the US, Canada and Argentina do not challenge the EC legislation as written, but rather the de facto moratorium on approval of GMOs and the bans in place in six EC Member States with regard to approved GM products.\(^{95}\) The three complainants base their challenges on the following provisions of WTO law:\(^{96}\)

- Certain paragraphs of Arts 2, 5, 7 and 8 and Annexes B and C of the SPS Agreement;\(^{97}\)
- Certain paragraphs of Arts 2 and 5 of the TBT Agreement;\(^{98}\)
- Articles I:1, III:4, X:1 and XI:1 of the GATT 1994;\(^{99}\)
- Article 4.2 of the Agreement on Agriculture;

The EC blocked the consensus necessary to establish a panel to hear this dispute at the DSB meeting of 18 August 2003, indicating its disappointment that these three Members had chosen to resort to dispute settlement rather than engaging in international cooperative efforts to build an appropriate framework for GMOs which addresses potential risks and social concerns.\(^{100}\) The panel requests were again on the agenda of the DSB at its meeting of 29 August 2003, at which time a decision was taken by reverse consensus to establish a single panel to hear all three complaints.\(^{101}\) Several WTO Members reserved their rights to participate as third parties before this Panel.\(^{102}\)

---

85 According to the EC, the reason why the situation in the EC with regard to approvals of GMOs has a significant impact on US maize exports is that although only 35% of maize grown in the US is genetically modified, the fact that only 1-2% of production in the US is segregated means that 98% of maize from the US may contain GM varieties, some of which may not have been approved in other countries.

86 The US request for consultations can be found as document symbol WT/DS291/1.

87 Argentina is the world’s second largest producer and exporter of biotech products.

88 The US announced that Egypt would also request consultations with the EC on this issue. It seems that the US was counting on support from Egypt in order to back up its claim that the EC position regarding GMOs is harmful to the developing world. However, Egypt finally decided not to request consultations. A trade source noted that Egypt had no reason to join in the challenge as it did not have a significant export interest in GMOs and had itself banned Thai canned tuna due to concerns that the fish might be canned in GM soy oil. As a result of Egypt’s withdrawal from the case, the US cancelled talks towards a planned free trade agreement (FTA) with Egypt. In a letter to Egypt’s Minister of Foreign Affairs, US Senator Grassley stated that one of the criteria that ought to be used to determine with whom the United States negotiates future FTAs is whether a country shares the same vision of the global trading system as does the United States. See Bridges Trade BioRes, Vol. 3 no. 10, 2 June 2003.

89 Australia, Argentina, Brazil, Canada, Chile, Colombia, India, Mexico, New Zealand and Peru requested to join the US consultations as third parties. The EC accepted these requests but noted that it was not aware of any exports from Australia, Chile, Colombia, Mexico, New Zealand and Peru that were affected by the EC measures on GMOs. Further, it noted that some Australian states had moratoria in place with regard to the approval and use of GMOs, that New Zealand has implemented a full moratorium on the commercial release of GMOs, that Mexico had suspended authorisation for large-scale commercial growing of GM corn due to concerns over potential impacts on wild relatives and traditional crops, and that Peru strictly prohibited the importation, production, sale and marketing of GMOs for food, feed or sowing.

90 The new EC legislation on GM food and feed and on labelling and traceability of GMOs was adopted on 22 July 2003. It will come into force 20 days after publication in the Official Journal of the EC and companies will have to comply with its rules within 6 months of publication.

91 The EC has pointed out that its legislation does not provide for a moratorium on GM approvals. According to the EC, allegations of a de facto moratorium refer to the fact that the pace of GMO approvals has been affected by the review of risk assessment procedures in the light of scientific developments and experience gained in the management of GMOs. See the information on the website European Commission’s Directorate General on Trade, available at http://ec.europa.eu/intcomm/trade/issues/sectoral/agri_-fish/sp_s_bio/pr170603_en.htm.

92 The US panel request can be found as document symbol WT/DS291/23.

93 Canada’s panel request can be found as document symbol WT/DS292/17.

94 Argentina’s panel request can be found as document symbol WT/DS293/17. Egypt decided not to request a panel.

95 This fact was emphasised by the US representative to the WTO in her statement at the DSB meeting of 18 August 2003 where this panel request was discussed.

96 There are slight differences between the panel requests with regard to the paragraphs of these Articles that are claimed to be violated.

97 Argentina also claimed a violation of Art. 10 of the SPS Agreement, which provides for special and differential treatment of developing countries.

98 Argentina also claimed a violation of Art. 12 of the TBT Agreement, which provides for special and differential treatment of developing countries.

99 Argentina also claimed a violation of Art. X.3(a) of the GATT 1994, which requires uniform, impartial and reasonable administration of generally applicable measures pertaining inter alia to import restrictions or prohibitions.

100 The EC regards the Cartagena Protocol to the Convention on Biodiversity (discussed further below) as the most significant international cooperative effort to address the challenge of GMOs. According to Art. 6.1 of the Dispute Settlement Understanding, a panel will be established at the latest at the second DSB meeting at which a panel request is on the agenda, unless there is a consensus of the Members not to establish the panel. As a result, a complaining Member will always be entitled to a panel by the second DSB meeting, as they will prevent a reverse consensus not to establish the panel.

101 Australia, China, Chile, Colombia, El Salvador, Honduras, New Zealand, Norway, Peru, Thailand, Uruguay and Chinese Taipei.
Health and Environmental Regulation

An interesting issue raised by this dispute is the question of under which of the WTO agreements raised in the complaints the case will be decided.\(^{103}\) This is important as the disciplines under each agreement differ, especially with regard to the role of science as the touchstone by which measures are judged. If the de facto moratorium and the Member States’ bans are motivated by the aim of protecting human or animal life or health against risks from additives, contaminants, toxins or disease-carrying organisms in food, feed or beverages,\(^{104}\) (which raises the question whether GMOs can be seen as contaminants, toxins or disease-carrying organisms) they would be “SPS measures”. In addition, if these measures are aimed at protecting human, animal or plant life or health from pests, diseases, disease-carrying organisms or disease-causing organisms or at preventing any other damage from the entry, establishment or spread of pests,\(^{105}\) they would fall within the definition of “SPS measures”.\(^{106}\) In that case, the dispute is likely to be decided under the rules of the SPS Agreement only. If not, the question would arise whether these measures could be seen as technical regulations,\(^{107}\) or conformity assessment procedures for purposes of the TBT Agreement. Finally, if neither of the two more specific agreements applies, the dispute will be decided under GATT rules.\(^{108}\)

The challenge under the SPS Agreement addresses, inter alia, the scientific disciplines contained in this agreement. The following discussion will limit itself to the scientific disciplines raised in this dispute, in keeping with the risk focus of this contribution. The complainants have claimed that the EC measures are maintained without sufficient scientific evidence and are not based on a risk assessment, contrary to Arts 2.2 and 5.1 of the SPS Agreement. It may be difficult for the EC to rebut a case made under these provisions with regard to its de facto moratorium since it seems unlikely that this measure is a result of a definitive evaluation of the scientific evidence regarding risks from GMOs. For many of the GMOs at issue, a national or EC scientific body evaluated a risk assessment and concluded that the GMO was safe. However, these products nevertheless got stuck in the approval process as certain Member States have decided to block the process until new legislation is in place that addresses their concerns regarding labelling, traceability and GM food and feed. This decision does not seem to be scientifically based. The situation with regard to the bans imposed by certain Member States on those GMOs that were already approved before 1998, may be different if they can show that, as is required by the safeguard clause in EC legislation, they have new evidence providing detailed grounds for considering that the relevant GMOs endanger human health or the environment. If such new evidence exists, it would remain to be seen whether it fulfils the requirements of “sufficient scientific evidence” in Art. 2.2 and a “risk assessment” in Art. 5.1 of the SPS Agreement.\(^{109}\)

In response to the claims regarding the lack of scientific basis for its measures, it might be possible for the EC to rely on the provisions of Art. 5.7, which, as discussed above, provide an exception to the scientific requirements and reflect the precautionary principle for purposes of the SPS Agreement. This Article allows a Member to take provisional measures where scientific information is insufficient, provided that the measures are based on available pertinent information and that the Member seeks to obtain the additional information necessary for an objective risk assessment and reviews the measure accordingly within a reasonable period of time. The case of GMOs seems to be a typical example of a situation where sufficient scientific information regarding the possible risks is lacking. However, for those particular varieties of GMOs for which risk assessments were conducted as part of the approval process, where it was shown in all cases that the GMOs were safe, this criterion may be difficult to fulfill. It would be interesting to see whether the EC’s measures would be regarded as meeting the requirements of Art. 5.7.\(^{110}\) If so, this would be the first time that SPS measures are found to be justified by the provisions of this Article.

The complainants’ claims of violation under the TBT Agreement are very broad-ranging, covering obligations with regard to technical regulations and conformity assessment procedures such as non-discrimination;\(^{111}\) the prohibition on measures that are more trade restrictive than necessary to fulfill a legitimate objective, taking account of the risks that non-fulfillment would create;\(^{112}\) the prohibition on measures that create unnecessary obstacles to trade;\(^{113}\) the notification obligations for proposed measures;\(^{114}\) and the publication requirement for new measures.\(^{115}\) As there is very little case law on the TBT Agreement at present, if this

\(^{103}\) The scope of application of the three agreements is discussed in section 2 above.

\(^{104}\) See para. 1(b) of Annex A to the SPS Agreement.

\(^{105}\) See para. 1(a) and (c) of Annex A to the SPS Agreement.

\(^{106}\) Pests for purposes of this definition include weeds, so measures aimed at addressing the risk of the creation of “super weeds” by transference of GM traits to wild plant species would fall under this definition.

\(^{107}\) Technical regulations have been interpreted by the Appellate Body to include certain bans, namely those that are based on product characteristics and contain exceptions also based on product characteristics. Appellate Body Report, EC–Asbestos, paras 74-75.

\(^{108}\) Also, if the TBT Agreement applies and the measure is found to comply with this Agreement, it is possible that an examination of the measure under the GATT would be conducted.

\(^{109}\) Compliance with the provisos of the safeguard clause in EC legislation is irrelevant for purposes of the WTO challenge.

\(^{110}\) Even if this is the case, the EC’s measures may fall foul of the other, non-scientific, provisions of the SPS Agreement raised by the complainants, such as the prohibition on measures more trade restrictive than necessary to achieve a Member’s appropriate level of protection (Art. 5.6 ) and the obligation to avoid arbitrary or unjustifiable distinctions in the levels of protection a Member considers appropriate in different situations if such distinctions lead to discrimination or disguised trade restrictions (Art. 5.5). In addition, the complainants claim violations of the provisions requiring notification of SPS measures (Art. 7 and Annex B) and the rules disciplining control, inspection and approval procedures (Art. 8 and Annex C).

\(^{111}\) Article 2.1 with regard to technical regulations and Art. 5.1.1 with regard to conformity assessment procedures.

\(^{112}\) Article 2.2 with regard to technical regulations.

\(^{113}\) Article 2.2 with regard to technical regulations and Art. 5.1.2 with regard to conformity assessment procedures.

\(^{114}\) Article 2.9 with regard to technical regulations and Art. 5.6 with regard to conformity assessment procedures.

\(^{115}\) Article 2.11 with regard to technical regulations and Art. 5.8 with regard to conformity assessment procedures.
dispute is decided under the provisions of this agreement it will provide interesting additional insights into the content of these obligations. For purposes of this discussion, the most significant issue would be the question whether the EC’s moratorium on approval of GMOs and the ban by some Member States on approved GMOs could be regarded as more trade restrictive than necessary to fulfill a legitimate objective, taking account of the risks of non-fulfillment. The TBT Agreement provides that in assessing such risks, relevant considerations include available scientific and technical information, related processing technology or intended end-uses of products. The TBT Agreement does not contain an explicit requirement of a scientific risk assessment, nor any other scientific disciplines, but it is possible that this provision could be interpreted to require an assessment of the risks involved in case of non-fulfillment of the objectives of the legislation. However, it seems unlikely that the requirement that the resulting measure be based on such a risk assessment could be read into this provision. It seems sufficient that an assessment of the risks be taken into account. Possible legitimate objectives of the relevant measures could be the protection of health or the environment from risks that do not fall under the risks contained in definition of SPS measures under the SPS Agreement, or consumer information. The question would then arise whether there are less trade-restrictive measures to achieve these objectives, when the risks entailed by non-fulfillment are considered. Clearly, this is a far less exacting discipline than that contained in the SPS Agreement with regard to risk assessment as a basis for SPS measures.

The EC measures are further being challenged under the GATT disciplines that prohibit discriminatory measures and quantitative restrictions to trade, such as quotas, bans and other non-tariff trade restrictions. The EC de facto moratorium and Member States’ bans would very likely be caught by these provisions. It would then fall to the EC to justify its measures under Art. XX(b) or (g) of the GATT, which provide exceptions from GATT rules for measures that are necessary to protect human, animal or plant life or health, or that relate to the conservation of exhaustible natural resources, provided that these measures are not applied in a manner that constitutes arbitrary or unjustifiable discrimination or a disguised restriction on trade.

The disciplines of Art. XX(b) or (g) of the GATT contain no explicit reference to scientific requirements or risk assessments. However, the Panel in EC-Asbestos addressed the question of scientific evidence in its analysis under Art. XX(b) of the GATT and followed certain findings made with regard to the scientific disciplines of the SPS Agreement. It noted that to establish a justification of a measure under Art. XX(b), three elements must be considered: first, the existence of a risk to human health; second, the level of protection a Member wishes to achieve; and third, the existence of other measures that are consistent, or less-inconsistent, with the GATT 1994. It then held that an examination of scientific data should be concerned with the first and third elements only, as Members are free to set the level of protection they choose. The Panel stated that, as it was not composed of scientific experts, its role was not to settle a scientific dispute, but rather to determine whether there was sufficient scientific evidence of the existence of a health risk and that the measure at issue was necessary (least-GATT-inconsistent). It therefore noted that it had to make a “pragmatic assessment of the scientific situation” and that “the determination of the existent of other measures consistent or less inconsistent with the GATT largely depends on a scientific assessment of the risk.”

This Panel report was appealed and the Panel’s assessment of the scientific evidence before it was one of the issues challenged in this appeal. The Appellate Body declined to find that the Panel had erred in its assessment of the evidence by giving more weight to certain evidence than to other, and held that a Member imposing a measure for the protection of health under this Article does not have to follow mainstream scientific opinion but may, in good faith, rely on minority scientific views from qualified and respected sources. From this discussion of the EC-Asbestos case, it appears that certain scientific disciplines have been read into the requirements of Art. XX(b) of the GATT. However, the role of science here is limited to an instrument used by the Panel to establish if a health risk exists and if the measure imposed is necessary. Parties to the dispute should therefore bring scientific evidence to support their claims in this regard. However, this does not mean that an obligation can be read into the GATT requiring a Member imposing a health measure to base its measure on a risk assessment and not maintain it without sufficient scientific evidence, as is required under the SPS Agreement. Thus, the role of science under the GATT is clearly different

116 Otherwise, the SPS Agreement would apply to the measure and consequently the TBT Agreement would not apply. An example of a risk to the environment not covered by the SPS Agreement would be the possible threat to biodiversity due to the risk that GM genes might unintentionally spread to traditional crops.

117 This is a logical consequence of the fact that some of the risks entailed by non-fulfillment of the objectives of measures falling under the TBT Agreement are not capable of scientific analysis. For example, risks to national security or the risk of deceptive practices are not susceptible to scientific study.

118 Articles I and III of the GATT 1994.


120 In addition, the EC measures are being challenged under Art. XI.1 of the GATT, which requires prompt publication of import restrictions.

121 The de facto moratorium has a clear trade restrictive effect and would very likely fall under the prohibition on quantitative restriction in Art. XI.1 of the GATT. For a discussion of whether measures relating to GM food would fall under Art. XI.1, see Rex J. Zedalis, ‘GMO Food Measures as Restrictions’ under GATT Article XI(1)” [2002] EELR 16-28.

122 If the EC measures aim at protecting biodiversity, they could arguably fall within the category of measures provided for in Art. XX(g).

123 See the chapeau of Art. XX.


125 In this regard, the Panel followed the decision of the Appellate Body in EC-Hormones, para 8.171.


128 Appellate Body Report, EC-Asbestos, para. 178. In making this finding under the provisions of the GATT, the Appellate Body followed its decision under the SPS Agreement in EC-Hormones (para 161) on this point.
and creates less rigorous disciplines than is the case under the SPS Agreement.

Finally, the complainants allege a violation of Art. 4.2 of the Agreement on Agriculture.122 As this provision does not specifically address risk regulation, it will not be discussed here.

From the above discussion, it appears most likely that this dispute will be decided under the provisions of the SPS Agreement, and will probably turn on the controversial question of the position of measures taken in situations of scientific uncertainty under this Agreement. It is to be expected that the widely differing views of the EC and the US on this point will once again be evinced in their arguments with regard to the scientific disciplines of the SPS Agreement and the exception for provisional measures in Art. 5.7. It will be interesting to see the Panel’s findings on these matters.

In an interesting related development,130 the New Partnership for African Development (NEPAD) plans to establish an advisory panel on biotechnology and biosafety, composed of scientists, policy makers and representatives of industry and civil society, to assist it in developing an African strategy with regard to biotechnology. According to NEPAD’s science and technology advisor, Africa must make a decision regarding its GMO strategy, otherwise it will remain caught between the US and EC positions.

**The Australian quarantine measures dispute**

Despite being a leading proponent of trade liberalisation in the agricultural sector131 Australia maintains a strict quarantine regime to prevent the introduction and spread of pests and diseases through imported agricultural products. This results in trade barriers for food and agricultural products.132 It has been argued that Australia’s status as an island country that is relatively pest- and disease-free motivates this strict regime.133 In order to maintain this status, Australia takes a conservative approach to quarantine risks.

In October 2002, the Philippines requested consultations with Australia134 with regard to Australian quarantine measures affecting the importation of fresh fruit and vegetables, including bananas. After consultations failed to resolve this dispute, the Philippines requested a WTO panel to address its claims.135 In particular, the Philippines challenged the Quarantine Proclamation of 1998 (which contains an *a priori* prohibition on the importation into Australia of fresh fruit and vegetables, unless the Director of Quarantine grants an import permit) and the procedures and criteria applied for deciding whether to grant an import permit. The Philippines based its challenge, *inter alia*, on the following provisions of the SPS Agreement:136

- Article 5.1, which requires that an SPS measure be based on a risk assessment as appropriate to the circumstances (as defined in Annex A, para. 4);
- Articles 5.2 and 5.3 which set out the factors to be taken into account in a risk assessment;
- Article 2.2, which requires that SPS measures be based on scientific principles and not be maintained without sufficient scientific evidence;
- Article 5.6, which prohibits SPS measures that are more trade restrictive than required to achieve a Member’s appropriate level of protection;
- Article 6, which requires Members to adapt their SPS measures to take into account, *inter alia*, the prevalence of pests and diseases in the area of origin and the area of destination of the product;
- Article 3.1 that requires that SPS measures be based on international standards, guidelines or recommendations (except as provided for in Art. 3.3);
- Article 2.3 which obliges Members to ensure that their SPS measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail;
- Article 5.5, which prohibits arbitrary or unjustifiable distinctions in the levels of protection a Member considers appropriate in different situations if these distinctions lead to discrimination or disguised trade restrictions; and

122 This provision prohibits, subject to certain exceptions, resort to any measures of the kind that were required to be converted into customs duties under the Agreement on Agriculture. This includes quantitative import restrictions and similar border measures, but not measures maintained under the non-agriculture-specific provisions of the GATT or of the Multilateral Trade Agreements in Annex 1A (which include the SPS and TBT Agreements). Thus, it appears unlikely that the Panel would have to address this claim.

130 This development was reported in *Bridges Trade BiosRes.*, Vol. 3 no.14, 25 August 2003. This source also reports that, similarly, the South African Development Community (SADC) decided to set up an advisory committee on GMOs in October 2002 and the Common Market for Eastern and Southern Africa (COMESA) began efforts to develop a regional policy on GMOs in November 2002.

131 Australia is a member of the Cairns Group, a coalition of 17 leading agriculture-exporting countries, which advocate the liberalisation of the agriculture sector at WTO negotiations. The Cairns Group is chaired by the Australian Trade Minister.

132 In 1998, the Australian quarantine regime with regard to salmon was successfully challenged at the WTO by Canada and the US. Recently, there have also been consultations between Australia and the Philippines regarding Australia’s quarantine measures affecting the importation of fresh pineapple (WT/DS271) and between Australia and the European Communities regarding Australia’s quarantine regime, both in general and as it applies to specific products, pig meat and poultry meat (WT/DS287). In addition, concerns regarding Australian quarantine measures were raised at SPS committee meetings by several countries (see G/SPS/GEN/204/Rev.3 at 9-16).

133 Gavin Goh and Andreas R. Ziegler, “A Real World Where People Live and Work and Die: Australian SPS Measures after the WTO Appellate Body’s Decision in the Hormones Case,” *Journal of World Trade* 35, no. 5 (1998) 271-290 at 272. Goh and Ziegler point out that Australia would suffer considerable economic losses if it lost its pest- and disease-free status, not only with respect to expenditure on pesticides and loss of production but also with regard to the loss of the marketing advantage it has due to the “clean and green” image of its products.

134 The request for consultations by the Philippines can be found as document symbol WT/DS270/3.

135 The Philippines’s panel request can be found as document symbol WT/DS270/5/Rev.1.

136 In addition, the Philippines claimed a violation of the prohibition on import restrictions in Art. XI:1 of the GATT and a violation of Arts 3.5(f) and 3.2 of the Agreement on Import Licensing Procedures.
Health and Environmental Regulation

- Article 5.7, if Australia were to invoke it as a justification for its measures, which sets out the requirements for provisional measures in the absence of sufficient scientific evidence.

At the meeting of the Dispute Settlement Body on 29 August 2003, a panel was established to deal with the claims of the Philippines. The rights to participate as third parties in the dispute were reserved by China, the EC, Ecuador, India, Thailand and the US.

Also on 29 August 2003, the EC requested a panel regarding the Australian quarantine regime as applied to certain products of interest to EC Member States. A panel was established to hear this dispute on 7 November 2003. The outcome of these two disputes will have important implications for the Australian quarantine regime and, if this regime is found to be in violation of the rules of the SPS Agreement, it may result in a significant increase in market access into Australia for agricultural exports from other Members.

**SPS Committee**

Not all trade-related SPS conflicts end up forming the subject of a formal dispute at the WTO. The SPS Agreement obliges all Members to notify changes to their SPS measures to the WTO and to publish proposed SPS regulations that may have a significant effect on trade. Notifying Members must allow a reasonable period of time for other Members to comment on their draft regulations in writing, discuss these comments upon request, and take the comments and discussions into account. Many concerns regarding proposed SPS measures are resolved in this way. In addition, the SPS Agreement established the SPS Committee to provide a regular forum for consultations between Members. It is given the mandate to encourage and facilitate ad hoc consultations between Members on specific SPS issues. The SPS Committee provides a useful multilateral forum for Members to engage in discussions on their concerns regarding each other’s SPS regulations. Coupled with the transparency and notification obligations on Members, the provision of this forum for consultations goes a long way towards making it possible for disputes to be resolved in a low-cost manner, without recourse to formal dispute settlement procedures.

In this context, seven new trade concerns were raised at the SPS Committee meeting of 2-3 April 2003 by the EC, the US and South Africa. In addition, 16 previously raised trade concerns were discussed further and four notifications of proposed SPS measures were considered, including the EC notification of its proposed regulation on traceability and labelling of GMOs. In addition, the SPS Committee considered a report on the continuing discussions at informal meetings regarding the recognition of equivalence of different SPS measures that achieve the same level of protection. Finally, an interesting discussion took place at placed on the agenda of a DSB meeting as the decision is taken by reverse consensus. Thus, a panel was established.

The EC panel request can be found as document symbol WT/DS287/7/Rev.1. In this panel request, the EC challenged the provisions of the Australian Quarantine Proclamation of 1998 which prohibit importation of several animal and plant products unless the Director of Quarantine grants a permit to import them into Australia as well as the procedures and criteria applied by Directors of Quarantine for deciding whether or not to grant a permit for importation of those products. The EC claimed that these measures were not based on a risk assessment and were thus in violation of Arts 5.1 and 2.2 of the SPS Agreement. In addition, it challenged the specific conditions laid down for the import of pig meat from the EC into Australia under Arts 4.1 and 5.6 of the SPS Agreement. This panel request was on the agenda of the DSF for the first time at its meeting on 2 October 2003, where Australia blocked the establishment of a panel.

These products are tomatoes, fresh citrus fruit, apples, peaches, nectarines, cucumbers, lettuce, carrots, apricots, edible eggs and egg products, uncooked pig meat, pig semen, uncooked poultry meat, calf-milk replacer, and organic fertiliser based on chicken manure. For these products, an assessment of quarantine risk has not been carried out, and a Director of Quarantine thereof has not made a decision whether or not to grant a permit for their importation into Australia. Consequently, their importation into Australia is prohibited. In addition, Australia has laid down certain specific conditions for the importation of pig meat from the EC.

The following Members notified their intention to participate as third parties to this dispute: Canada, China, Chile, India, the Philippines, Thailand and the US.

The notification obligation does not apply if the proposed SPS regulation is substantially the same as an international standard, guideline or recommendation (Annex B, para. 5). Annex B, para. 5(d) of the SPS Agreement.

See Art. 12.1 of the SPS Agreement. Article 12.2 of the SPS Agreement.

The WTO Secretariat maintains a list of all specific trade concerns raised at SPS Committee meetings since 1995, and updates this list monthly. This list can be found under document symbol G/SPS/GEN/204.* According to the third revision of this document, which covers all SPS Committee meetings until that of 7-8 November 2002, 154 specific trade concerns were raised from 1995-2002.

By the end of 2002, for only 28 out of the 154 specific trade concerns raised had Members reported that they had fully resolved the dispute, and in 14 cases a partial resolution was reported. In over 70 cases, the trade concerns raised are over a year old and it seems likely that a solution was reached without informing the Secretariat of this. The Secretariat thus encouraged Members to report to the Committee when solutions had been found to trade concerns (see G/SPS/R/29, para. 46).

See the report of this meeting, document symbol G/SPS/R/29. At this meeting, new trade concerns raised were those of the EC regarding Australian import requirements for Netherlands truss tomatoes, Mexican restrictions on Austrian animal products due to foot-and-mouth disease, and Chinese quarantine measures on aquatic products; the concerns of the US regarding Mexican restrictions on the importation of dry beans; the EC’s proposed regulation regarding animal by-products and Japan’s new fumigation standards and the concerns of South Africa regarding the EC directive on foot-and-mouth disease. The South African concern was raised by means of a written document, as national experts were unable to attend the meeting. The report of the most recent meeting of the SPS Committee, held on 24-25 June 2003, has not yet been circulated.

Article 4 of the SPS Agreement obliges Members to accept different SPS measures as equivalent, if the exporting Member objectively demonstrates to the importing Member that it’s measures achieve the latter’s chosen level of protection. Due to

---

137 On 21 July 2003, at the first DSB meeting where the Philippines’ panel request was on the agenda, Australia blocked the establishment of a panel. The Philippines again placed its panel request on the agenda of the DSB meeting on 29 August 2003. According to Art. 6.1 of the WTO Dispute Settlement Understanding, it is impossible to block the establishment of a panel the second time a panel request is
Health and Environmental Regulation

this SPS Committee meeting regarding the draft regulations adopted by the US under its bioterrorism legislation, which deserves further attention here.

The US Bioterrorism Act
In order to protect US citizens against risks from food contaminated by bioterrorists, the United States enacted the Public Health, Security and Bioterrorism Preparedness Act (Bioterrorism Act) on 12 June 2002. Although this Act was not itself notified under the SPS Agreement, WTO Members were informed about the US activities under this Act at the November meeting of the SPS Committee. 149 The Bioterrorism Act contains several provisions that are significant for food and animal feed exports to the US. The four main requirements of the Bioterrorism Act are: (1) the registration of most food manufacturing and handling facilities; (2) prior notice to the US Food and Drug Administration (FDA) of all food consignments intended for import into the United States; (3) establishment and maintenance of certain records pertaining to the “immediate previous sources and immediate subsequent recipients” of foods; and (4) administrative detention of any food when there is credible evidence or information that it presents a threat of adverse health consequences to humans and animals.

The FDA is responsible for developing regulations to implement the Bioterrorism Act (except with regard to meat, poultry and processed eggs). The FDA published the draft regulations intended to implement the registration,150 prior notice,151 record-keeping152 and administrative detention153 provisions of the Bioterrorism Act. As required under the transparency provisions of the SPS Agreement, it notified the draft regulations on registration and prior notice to the WTO on 3 February 2003.154 The regulations on record keeping and administrative detention procedures were notified on 14 and 15 May 2003.155

The US provided a 60-day period for other Members to comment on this draft legislation, and indicated that these comments would be taken into account in developing the final regulations. In order to encourage Members to submit comments to the FDA, the US prepared an information package which it distributed to the SPS Committee at its meeting on 2-3 April 2003.

At the SPS Committee meeting of 2-3 April 2003, the proposed regulations were discussed.156 Several WTO Members, while recognizing the valid security interests of the US, raised concerns regarding the draft legislation. In particular, it was argued that the regulations are more trade restrictive than necessary, are not based on a risk assessment, discriminate against foreign food producers and involve high compliance costs for small and medium-sized enterprises. In addition, concerns were raised regarding the possible use of information obtained under the Bioterrorism Act for other purposes and the question of how the US planned to distinguish between inadvertent and deliberate acts of food contamination. The US delegate responded to these concerns and requested Members to submit their comments in writing to the FDA.

The comment periods for the two sets of regulations ended on 4 April and 8 July 2003 respectively and the final regulations are expected to be published no later than October 2003. They will come into force on 12 December 2003. To supplement its proposed regulation on the registration of food facilities, the US has notified a final guidance157 on the necessity of the use of food product categories in the registration of food facilities as the FDA has found that information on food product categories is necessary for a quick, accurate and focused response to a bioterrorist incident or other food-related emergency.158 If WTO Members are of the opinion that in the final version of the regulations under the Bioterrorism Act, the problems regarding the implementation of this provision, the SPS Committee adopted the Equivalence Decision (G/SPS/19), which sets out guidelines for the recognition of equivalence. There is currently ongoing work in respect of the clarification of certain provisions of the Equivalence Decision.

See the report of the meeting, document symbol G/SPS/R/28 at paras 10-17.

Available at http://www.fda.gov/ohrms/dockets/98fr/03-2443.pdf. This draft regulation will require all US and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the US to register with FDA by 12 December 2003. It aims to provide the FDA with information on all facilities that manufacture, process, pack, or hold food for consumption in the US in order to help the FDA and other authorities determine the source and cause of an outbreak of food-related illness and to quickly notify the facilities that might be impacted by the outbreak.

Available at http://www.fda.gov/ohrms/dockets/98fr/03-2444.pdf. This draft regulation requires US importers or purchasers of imported food or feed for consumption in the US to provide prior notice to the FDA of imported food shipments beginning on 12 December 2003. This aims to improve the FDA’s ability to detect accidental and deliberate contamination of food and deter deliberate contamination to help the FDA and other authorities to determine the source and cause of an outbreak of food-borne illness.

Available at http://www.fda.gov/ohrms/dockets/98fr/03-11459.pdf. This draft regulation aims to enable the FDA to act quickly in responding to a terrorist attack on the US food supply or other food-related emergency by providing it with information about all immediate previous sources and subsequent recipients of food in a tracing investigation. This will help the FDA to determine the source and cause of the event and to locate and notify the recipients of the implicated food who might be impacted by the outbreak. It is interesting that the requirement of record keeping on “all immediate previous sources and subsequent recipients of food” appears to be quite similar to the “one step forward, one step back” traceability provisions in the EC GMO regulation, which have been subject to strong criticism from the US.

Available at http://www.fda.gov/ohrms/dockets/98fr/03-11459.pdf. This draft regulation lays down “procedures for the detention of an article of food, if an officer or qualified employee of the FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.” In such cases, food may be detained for up to thirty days to enable the FDA to institute a judicial seizure action or injunction proceeding.

These notifications can be found as document symbols G/SPS/N/USA/690 and G/SPS/N/USA/691.

These notifications can be found as document symbols G/SPS/N/USA/703 and G/SPS/N/USA/704.

See the report of the meeting, document symbol G/SPS/R/29.

This guidance is available at www.fda.gov/ohrms/dockets/98fr/071703d.pdf.

See the US notification, document symbol G/SPS/N/USA/691/Add.1.
US did not address their concerns regarding possible violations of WTO law, this issue may become the subject of a dispute at the WTO. In that case, it would be interesting to see whether such dispute would be addressed under the disciplines of the SPS Agreement, the TBT Agreement or those of the GATT.\textsuperscript{159} In the latter case Art. XXI(b) GATT would be relevant, which provides an exception from GATT disciplines for any action which a Member “considers necessary for the protection of its essential security interests ... (iii) taken in time of war or other emergency in international relations”. Which agreement would apply would, to a large extent, depend on what the aim or purpose of the relevant measures is held to be. If the measures are found to be aimed at the protection of human life or health from risks arising from contaminants, toxins or disease-causing organisms in foods or beverages,\textsuperscript{160} the dispute would be decided under the rules of the SPS Agreement.\textsuperscript{161} If, on the other hand, the measures were found not to be aimed at health protection but rather at the protection of national security, and constitute technical regulations or conformity assessment procedures, the dispute would be decided under the rules of the TBT Agreement\textsuperscript{162} and possibly the GATT 1994.\textsuperscript{163} This will raise interesting questions regarding the determination of the policy objective of a measure, and the question of the position of measures with more than one objective.

The issue of the applicable agreement will have important implications in this case, as the disciplines of the SPS Agreement are more comprehensive and rigorous than those of the TBT Agreement and Art. XXI of the GATT 1994. As discussed above, the SPS Agreement contains requirements of sufficient scientific evidence and a basis on a risk assessment, which may be difficult to meet in the case of measures to address a hypothetical risk of a terrorist attack on the US food supply.\textsuperscript{164} The TBT Agreement does not contain explicit scientific requirements, although it does require a consideration of the risks of non-fulfilment of the legitimate objective aimed at by the measure. A scientific assessment of such risks would not be required in the case of a risk to national security. The disciplines of the exception contained in Art. XXI of the GATT contain no obligations regarding risk assessment at all.

The TBT Committee

As is the case with the SPS Agreement, the TBT Agreement establishes a committee to afford Members the opportunity to consult on issues relating to the operation of that Agreement. In this forum, Members raise and discuss their concerns regarding the technical regulations, standards or conformity assessment procedures of other Members. As these TBT measures may sometimes be aimed at the protection of health or the environment, some of the discussions at the TBT Committee are relevant for the purposes of this contribution.

Aside from the discussions on the US regulations adopted under the Bioterrorism Act of 2002, where similar concerns were raised as at the SPS Committee meeting discussed above, the meeting of the TBT Committee on 2 July 2003 is interesting with respect to the discussion on the EC’s proposed chemicals legislation.

The EC chemicals legislation

The EC has drafted new legislation on chemicals, to create a coherent regime for chemicals and replace the 40 pieces of legislation that currently regulate this matter. At the TBT Committee meeting of 20 March 2003, the EC White Paper on the Strategy for a New Chemicals Policy\textsuperscript{165} was discussed by Members. In May 2003, the EC informed the TBT Committee of its proposed chemicals legislation, on the

\textsuperscript{159} It is for the complainant to decide whether it will claim a violation of provisions of the SPS Agreement, the TBT Agreement, the GATT or any combination of these. The jurisdiction of the panel will be limited by the claims made by the complainant in its panel request. However, the panel may decide that certain of these agreements are not applicable to the case, so it is usually wise for a complainant to make its claims in the panel request as broad as possible, including all possible violations of WTO Agreements.

\textsuperscript{160} Such a measure would fall under the definition of an “SPS measure” under Annex A, para. 1(b), and would thus be subject to the disciplines of the SPS Agreement according to Art. 1.1 thereof, which provides that the SPS Agreement applies to all SPS measures which may directly or indirectly affect international trade. The regulations under the Bioterrorism Act have a clear impact on international trade.

\textsuperscript{161} As set out above, the SPS Agreement and the GATT 1994 are not mutually exclusive. However, as a measure that fulfils the requirements of the SPS Agreement is presumed to comply with the disciplines of the GATT that relate to SPS measures (in terms of Art. 2.4 of the SPS Agreement), a panel faced with an “SPS measure” will always start its analysis by examining the measure against the disciplines of the SPS Agreement. If the measure violates the SPS Agreement, there is no need to examine the measure under the GATT 1994. If the measure complies with the SPS Agreement, it is presumed to comply with the GATT rules relating to SPS measures. As a result, if the SPS Agreement is applicable, the relevant measure will most likely be examined only under the disciplines of the SPS Agreement.

\textsuperscript{162} One of the “legitimate objectives” of technical regulations mentioned in Art. 2.2 of the TBT Agreement is “national security requirements”.

\textsuperscript{163} As mentioned above, the SPS Agreement and the TBT Agreement are mutually exclusive in application (Art. 1.5 of the TBT Agreement). However, the TBT Agreement and the GATT may apply concurrently, and there is no presumption of GATT-conformity of a measure that meets the requirements of the TBT Agreement. However, it is likely that a TBT measure will first be examined under the TBT Agreement, as it is more specific.

\textsuperscript{164} However, it should be noted that a risk assessment, for purposes of the SPS Agreement, does not exclude “all matters not susceptible to quantitative analysis by empirical or experimental laboratory methods commonly associated with the physical sciences,” but does require “a process characterized by systemic, disciplined and objective enquiry and analysis, that is a mode of studying and sorting out facts and opinions”. See Appellate Body Report, EC-Hormones, para 187. Thus, provided that a real risk of a bioterrorist attack on the US food supply can be objectively established through systematic analysis, the lack of scientific assessment of the risk would not lead to a violation of Art. 5.1. On the other hand, Art. 2.2 specifically requires that a measure not be maintained without sufficient scientific evidence, which has been interpreted to mean evidence gathered through scientific methods, as discussed above (See Panel Report, Japan-Apples, para 8.92).

basis of this White Paper, and of the eight-week public internet consultation process underway, which would end on 7 July 2003. The new regime is termed REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals) and aims to balance the need to protect health and the environment with the need to ensure that the European chemicals industry remains competitive and is encouraged to innovate. It shifts the burden of proof regarding the safety of chemicals from the public authorities to the companies that manufacture, use or supply chemicals, which must conduct chemical safety assessments. An 11-year period is provided during which chemical substances produced or imported in volumes of one tonne or more must be registered. In the case of high-risk substances, authorisation is required. Authorisation will be granted if a company can prove that it can adequately control the risks posed by a particular use of a chemical. The legislation establishes a new European Chemicals Agency to administer its operation.

At the TBT Committee meeting of 2 July 2003, WTO Members raised several concerns regarding the proposed chemicals legislation, including questions regarding its scientific basis, its complexity and the costs of compliance, and the fact that the draft legislation had not been notified as required by the TBT Agreement. The EC assured the TBT Committee that it would submit a proper notification of its draft legislation under the TBT Agreement after the conclusion of the internet consultation process. Some Members referred to the fact that the OECD is currently conducting work towards a harmonised system of principles for chemicals and questioned why the EC was taking a unilateral approach to the issue. The EC Commission has been revising its legislative proposal for the new EC chemicals regime on the basis of comments received in the consultation process. The final legislative proposal is expected on 29 October 2003. Once again, if Members' concerns regarding this legislation are not resolved through discussions at the TBT Committee or bilateral consultations, the legislation may form the subject of a dispute at the WTO. The US has indicated that it takes a serious view of this proposed legislation, which it believes will “dwarf the GMO dispute.”

The MEA-WTO relationship
Multilateral environmental agreements (MEAs) contain internationally agreed rules regarding measures to address risks to the environment. They sometimes have provisions creating trade obligations on parties to those agreements. These obligations may create trade barriers and thus be susceptible to challenge under the rules of the WTO. The question has therefore arisen what the relationship between MEAs and WTO rules is. The Doha Ministerial Declaration on the new round of WTO negotiations, adopted in November 2001, contains an express mandate for negotiations on the relationship between WTO rules and specific trade obligations in MEAs, in para. 31(i), and on the procedures for information exchange between MEA secretariats and WTO committees as well as criteria for granting observer status to MEAs, in para. 31(ii). These negotiations are taking place in special sessions of the Committee for Trade and Environment (CTE).

As these special sessions of the CTE will negotiate rules regarding the relationship between MEAs and WTO disciplines, it is important for MEA secretariats to be

---

166 This information is available under document symbol G/TBT/W/208.
169 The information requirements for registration will largely depend on the volume manufactured or imported, but may be tailored, based on intrinsic properties of the chemical and its conditions of use.
170 This covers CMRs (carcinogens, mutagens, and reproductive toxins), PBTs (persistent and bioaccumulative and toxic), vPvBs (very persistent and very bioaccumulative).
171 Decisions are taken by the European Commission.
172 Bridges Weekly Trade News Digest, Vol. 7 no. 25, 10 July 2003.
173 Bridges Weekly Trade News Digest, Vol. 7 no. 25, 10 July 2003.
174 Under the revised proposal, the legislation would no longer apply to polymers (thus excluding around 30 000 substances from the new regime), the requirements for chemical safety assessments have been reduced and certain vague provisions for chemicals in imports have been clarified and softened. See Bridges Trade News Digest, Vol. 7 no. 32, 1 October 2003.
175 It would then have to be presented to the European Parliament for its first reading.
177 MEAs may contain rules regulating trade in the product that is the subject of the MEA. Three clear examples are the Vienna Convention for the Protection of the Ozone Layer (26 ILM 1516 (1987)) and the Montreal Protocol thereto (26 ILM 1541 (1987)), which require parties to introduce import quotas on ozone-depleting substances; the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (28 ILM 649 (1989)), which limits trade in dangerous waste products to parties to that Convention; and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (12 ILM 1085 (1973)), which, contains, as its title suggests, rules restricting trade in species which are endangered.
178 It should, however, be noted that no WTO Member has yet challenged trade restrictions provided for in an MEA under WTO rules.
179 Paragraph 31(i) of the Doha Ministerial Declaration, adopted on 14 November 2001. This subparagraph further states that the negotiations shall be limited in scope to the applicability of WTO rules among parties to the relevant MEA, and not prejudice the rights of any Member that is not party to that MEA. This was inserted due to concerns by the US, which is not a party to several MEAs, such as the Convention on Biological Diversity and the Cartagena Protocol thereto, and the Kyoto Protocol to the UN Framework Convention on Climate Change (Bridges Weekly Trade News Digest, Vol. 6 no. 35, 17 October 2002).
180 Para. 31(ii) of the Doha Ministerial Declaration, adopted on 14 November 2001. Para. 31(iii) provides a mandate for negotiations on the liberalisation of trade in environmental goods and services.
present in order to be able to answer questions that Members may have on the MEAs at issue. The attendance of MEAs at the special sessions of the CTE has, however, been blocked by political conflicts at the General Council level regarding the issue of observer status.\(^{181}\) In order to overcome this deadlock for purposes of the environment negotiations, the Chair of the CTE special session proposed, at the February 2003 meeting, that MEA secretariats be allowed to attend the next meeting of the CTE special session as *ad hoc* observers. Members agreed to this proposal,\(^{182}\) and the secretariats of six MEAs attended the special session on 1-2 May 2003. The authorisation of participation of MEAs is purely *ad hoc* and is reviewed for each meeting. At the meeting on 8 July 2003, the EC proposed formalizing the participation of MEAs by sending text for inclusion in the draft Ministerial Declaration for adoption in Cancún, giving certain MEA secretariats a standing invitation to attend all meetings of the special session of the CTE (thus for purposes of the negotiations under the Doha mandate only), de-linking this from the broader issue of observer status under discussion at the General Council and the negotiations under para. 31(ii) regarding criteria for granting observer status to MEAs in general.\(^{183}\) However, this proposal was strongly opposed by several Members at the CTE special session meeting on 23 August and thus MEA participation remained on the basis of *ad hoc* invitation.\(^{184}\) Discussions under the mandate in para. 31(ii) of the Doha Declaration have so far focused on procedures for regular information exchange with MEA secretariats, rather than the more sensitive issue of criteria for observer status.\(^{185}\)

Discussions on the relationship between WTO rules and specific trade obligations in MEAs under para. 31(i) of the Doha Declaration have also been contentious. Members strongly disagreed on how to examine this relationship.\(^{186}\) The EC and Japan advocated a “top-down” approach of first addressing conceptual issues (principles and parameters) before applying them to specific trade obligations under MEAs. Australia, supported by many other Members, proposed a “bottom-up” approach of first identifying the specific trade obligations in MEAs to be addressed and then examining them under WTO rules. On 12 November 2002, the CTE special session\(^{187}\) reached a compromise agreement, according to which negotiations would focus on specific trade obligations contained in certain MEAs identified in a Secretariat document (bottom-up approach),\(^{188}\) but the Chair would raise conceptual issues as these arose in the course of the negotiations. Members began substantive discussions at the meeting of 12-13 February 2003 and the discussions were still at an early stage during the meeting of 1-2 May 2003,\(^{189}\) where Members attempted to define what constitutes a specific trade obligation, which MEAs should be considered and how the WTO-MEA relationship should be clarified.\(^{190}\)

The report of the special session of the CTE was finalized at the meeting of 8 July 2003 and submitted to the Trade Negotiations Committee.\(^{191}\) The paragraph on environment in the draft text of the Cancún Ministerial Declaration forwarded for agreement at Cancún, merely took note of the progress made in the CTE special session regarding its mandate under para. 31 of the Doha Declaration and reaffirmed Members’ commitment to the negotiations. Immediately before the Cancún Ministerial Conference, a High-Level Round Table on Trade and Environment was convened by the Mexican government, bringing together trade and environment ministers, representatives of civil society and intergovernmental organisations and academics to discuss the link between trade and environmental policies.\(^{192}\) At the Cancún Ministerial itself, negotiations on trade and environment were conducted in the Working Group on Miscellaneous Issues.\(^{193}\) Although most issues remained unresolved, there was some movement towards consensus on the invited status of MEA secretariats at the special sessions of the CTE for the duration of the negotiations.\(^{194}\) However, by the close of last day of the Ministerial Conference, negotiations had collapsed due to deep divisions between Members.\(^{195}\) As a result, the only

---

181. These conflicts relate to the approval of the League of Arab States as a WTO observer.
182. Members agreed to include those secretariats that are observers at the regular sessions of the CTE and those with pending requests for observer status at the special sessions. Thus the secretariats of UNEP, the Basel Convention, CITES, the CBD, the Montreal Protocol, the ITTO, and the UNFCCC were included.
183. The EC proposal was supported by the US, Japan, Chile, Australia, Canada, Switzerland and Norway. See *Bridges Weekly Trade News Digest*, Vol. 7 no. 29, 28 August 2003.
184. Egypt, China, Indonesia, Malaysia and the Philippines are concerned that such a decision would prejudice the outcome of the discussions at the General Council. See *Bridges Weekly Trade News Digest*, Vol. 7 no. 29, 28 August 2003.
186. This issue was debated at the CTE special session meeting of 10-11 October 2002. See *Bridges Weekly Trade News Digest*, Vol. 6 no. 35, 17 October 2002.
187. The special session was preceded by an informal meeting between Members’ trade and environment officials and MEA secretariats, organised by UNEP, in order to lay the groundwork for the CTE special session.
189. The WTO Secretariat has compiled the submissions so far in document symbol TN/TE/S/3/Rev.1 and updated the list of specific trade obligations under selected MEAs in document symbol WT/CTE/W/160/Rev.2.
192. The Round Table was held in Cozumel, Mexico on 8-9 September 2003. For a summary of the discussions at the Round Table, see *Bridges Trade BioRes*, Special Issue: High Level Round Table on Trade and Environment, 10 September 2003.
193. At the Cancún Ministerial, five Working Groups were set up, open to all Members, to conduct negotiations on various issues (agriculture, non-agricultural market access, development, Singapore issues and miscellaneous issue). Trade and environment was discussed in the Working Group on “miscellaneous issues”, which has been referred to by a trade delegate as the “cemetery group” as the expectations for negotiations in this body were very low. See *Bridges Daily Update* on the Fifth Ministerial Conference, Issue 2, 11 September 2003.
194. See *Bridges Daily Update* on the Fifth Ministerial Conference. Issue 4, 13 September 2003. The revised draft Ministerial Declaration provided that the secretariats of MEAs, UNEP and UNCTAD would be invited to the special sessions of the CTE for the duration of the negotiations.
195. The main cause of the breakdown of negotiations was the fact that no agreement could be reached on the launching of
text to emerge from the Ministerial Conference was a Ministerial Statement calling for the convening of a General Council meeting no later than 15 December 2003 to take the action necessary to enable Members to move towards a timely and successful conclusion of the negotiations. Despite this lack of agreement on a Ministerial Declaration, it is to be hoped that discussions on the trade-MEA relationship will continue in Geneva and that Members’ representatives to the CTE will agree to invite MEA secretariats to all special sessions in order to ensure that the negotiations regarding the relationship between WTO rules and MEAs reach a balanced outcome.

II. Other Developments at International Level

Aside from the developments at the WTO, there have been other significant international developments relevant to the interaction between trade and risk regulation. In the following section of this contribution, a brief overview will be given of those developments, focusing on initiatives that are likely to be of particular interest to the EU.

The Standards and Trade Development Facility

A crucial aspect of the interaction between free trade and risk regulation is the fact that developing country trade is adversely affected by the serious difficulties these countries face in meeting the health regulations and standards that apply on their export markets. This is particularly important in the light of the fact that many developing countries mainly export agricultural products and thus depend on market access in this sector for their export earnings. The EU is often criticised for setting strictly SPS standards with which developing countries cannot comply, thus effectively denying them market access.

With a view to addressing this problem, and in the light of the fact that an important aim of the Doha round of trade negotiations is the integration of developing countries into the international trading system, the WTO, World Bank, World Health Organization, Food and Agriculture Organization, and International Office of Epizootics established the Standards and Trade Development Facility (STDF) in September 2002. The STDF aims to strengthen the capacity of developing countries to meet international standards applicable to food and agricultural products and facilitates cooperation between the five partner institutions in the area of capacity building. Current developments with regard to the STDF will be set out here, as it is important to examine the extent to which the needs and difficulties of developing countries in the area of risk regulation and implementation of standards are being addressed at international level.

In the first year of the existence of the STDF, its partner institutions agreed to exchange information, on a regular basis, on the nature, aim and available funding of the capacity building projects they currently implement or plan to establish. They also decided to create an information-exchange mechanism to promote coordination and information sharing. Finally, they agreed to identify, select and plan pilot projects that will receive funding from the STDF in the private and public sectors. Exploratory work has begun in these areas, and the WTO Secretariat has appointed an adviser to assist it by collecting information, coordinating capacity-building activities, creating an STDF website and identifying pilot projects for consideration by the partner institutions. This adviser works closely with a project manager in the Agriculture and Commodities Division of the WTO Secretariat.

It is still too early to tell what impact the STDF will have on increasing the ability of developing countries to comply with health regulations in their export markets. Much will depend on the amount of funding available and effective administration of these funds, channelling them into projects that have long-term, sustainable benefits for developing countries. However, it is indisputable that the promotion of smooth coordination between the capacity-building activities of the participating institutions, in order to make the best use of the synergies between them and their combined expertise for the benefit of developing countries, represents an important step in the right direction.

The Cartagena Protocol on Biosafety

Multilaterally agreed solutions to address the potential conflicts between trade and the regulation of certain risks are preferable to unilateral action, as they create international rules reflecting agreement between countries on how best to balance their trade interests with their environment and health concerns. Among these is the Cartagena Protocol on Biosafety, which entered into force on 11 September 2003, 90 days after its ratification by its 50th signatory. The Cartagena Protocol is a protocol adopted under the negotiations on the so-called Singapore issues (investment, competition, trade facilitation and transparency in government procurement). As the Chair decided to address the Singapore issues first in the final stretch of the negotiations, the failure to reach agreement on this matter led to the failure of the negotiations as a whole. See Bridges Daily Update on the Fifth Ministerial Conference, Issue 6, 15 September 2003.

Available as document symbol WT/MIN(03)/W/24.

This fact has led to the Doha negotiating mandate often being referred to as the Doha Development Agenda.

The STDF is administered by the WTO. It is funded by contributions from donors. Current the WTO and World Bank have made financial contributions to the STDF, and funding from other donors will be sought. The governance structure consists of a Policy Committee comprised of high-level representatives of the five partner organisations and a Working Group of technical-level representatives of the partner organisations. See G/SPS/GEN/371.

This information is provided in a note by the WTO Secretariat, document symbol G/SPS/GEN/371.

This division of the Secretariat also services the SPS Committee.

The Cartagena Protocol was adopted in Montreal on 29 January 2000 and signed by 130 countries. The US is not a party to the Convention on Biodiversity (CBD) and as such can also not be a party to the Cartagena Protocol in terms of Art. 32.1 of the CBD. However, it had observer status in the negotiations for the Cartagena Protocol.

The 50th country to ratify the Cartagena Protocol was the island state of Palau, which ratified the Protocol on 13 June.
The Cartagena Protocol\textsuperscript{203} sets out rules to ensure an adequate level of protection with regard to the transfer, handling and use of LMOs that may have adverse environmental or health risks.\textsuperscript{206} Its rules apply to the transboundary movements of LMOs that are intended to be released into the environment or to form part of the food chain. However, the Advanced Informed Agreement\textsuperscript{207} procedure\textsuperscript{208} that it establishes applies only to LMOs intended for release into the environment in the importing country,\textsuperscript{209} not to LMOs in transit or destined for contained use\textsuperscript{210} or for direct use in food, feed or for processing.\textsuperscript{211} For trade in LMOs intended for food, feed or processing, which make up most of trade in GM products, the Cartagena Protocol creates a Biosafety Clearinghouse for the exchange of information, including risk assessments, regarding LMOs approved for domestic use.\textsuperscript{212} As no consensus could be reached about the nature or extent of risks from LMOs, the Cartagena Protocol expressly incorporates the precautionary principle, allowing parties to take measures affecting imports of LMOs in the absence of scientific certainty on these potential risks.\textsuperscript{213}

A contentious point in the negotiations for the Cartagena Protocol was the question of identification of shipments containing LMOs for food, feed or processing. Proper identification and documentation is essential for the implementation of national labelling regimes. The compromise reached in the Protocol provides that only LMO shipments intended for release into the environment must be accompanied by documents identifying the LMOs, their traits and certain other information.\textsuperscript{214} For LMOs intended for food, feed or processing, it is sufficient if the documentation provides that the shipment “may contain LMOs” and is not intended for intentional release into the environment.\textsuperscript{215} Detailed rules on identity specification of LMOs for food, feed or processing are to be agreed upon within two years of the entry into force of the Cartagena Protocol. At the third meeting of the Intergovernmental Committee on the Cartagena Protocol on 22-26 April 2002, little progress was made in establishing these rules as parties reiterated the positions they had taken in the original negotiations. The EC, China, Japan and Mexico advocated the use of unique identification codes, whereas the US, Australia and Argentina (the world’s largest exporters of LMOs) did not want information requirements that go beyond the existing text of the Protocol.\textsuperscript{216} It is hoped that now that the Cartagena Protocol has come into force, the agreement necessary to establish clear rules in this area will be achieved by the first Meeting of the Parties, scheduled for 23-27 February 2004.

The Cartagena Protocol provides rules relating to trade in LMOs and, as such, its provisions raise issues of international trade law. In the first place, trade and environmental agreements should be interpreted in a mutually supportive way. However, it is possible that unavoidable conflicts may arise between the Cartagena Protocol and WTO rules. The relationship between the Protocol and other international agreements, and in particular the WTO agreements,\textsuperscript{217} was addressed during the negotiations. The resulting text in the preamble of the Protocol is very ambiguous, providing in the tenth recital that the Cartagena Protocol “shall not be interpreted as implying a change in the rights and obligations of a Party under existing international agreements” and in the eleventh recital that the foregoing “is not intended to subdivide this Protocol to other international agreements”. It is therefore not clear which of the two international agreements would have priority in case of conflict. WTO Members are, as discussed above, currently discussing the issue of the relationship between WTO rules and trade obligations in MEAs. It is likely that the Cartagena Protocol will form part of these discussions.

**International standard-setting organisations**

An important factor that contributes to the trade-restrictive effect of national measures that address health risks, is the fact that these measures often differ widely between countries. Thus, an exporter is faced with a plethora of regulatory standards and is unable to exploit economies of scale on the export market. For this reason, international

---

\textsuperscript{203} The CBD was concluded in June 1992, after 10 years of negotiations under the auspices of the United Nations Conference on Environment and Development (31 I.L.M. 818). It was signed by 168 countries and entered into force on 29 December 1993. The United States refused to ratify this Convention.

\textsuperscript{204} The Cartagena Protocol defines LMOs as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology” (Art. 3(g) of the Cartagena Protocol).


\textsuperscript{206} Article 1 of the Cartagena Protocol.

\textsuperscript{207} This is based on the Prior Informed Consent procedures that apply to trade in hazardous waste, but a different term was used due to concerns that otherwise the implication would be made that LMOs are per se “hazardous”.

\textsuperscript{208} According to this procedure, the exporting party must notify the importing country before the first intentional import of a specific type of LMO. The importing country must decide whether to allow the importation or not, according to its own domestic procedures or according to the procedure set out in the Protocol. A risk assessment must be conducted as a basis for the decision.

\textsuperscript{209} Article 7(1) of the Cartagena Protocol.

\textsuperscript{210} Article 6 of the Cartagena Protocol.

\textsuperscript{211} Article 7(2) of the Cartagena Protocol.

\textsuperscript{212} Article 11 of the Cartagena Protocol.

\textsuperscript{213} Articles 10(6) and 11(8) of the Cartagena Protocol.

\textsuperscript{214} Article 18(2)(c) of the Cartagena Protocol.

\textsuperscript{215} Article 18(2)(a) of the Cartagena Protocol.

\textsuperscript{216} *Bridges Weekly Trade News Digest*, Vol. 6 no. 17, 7 May 2002.

Health and Environmental Regulation

Harmonisation of standards is seen as an important tool to facilitate free trade. On international level, there are organisations engaged in establishing voluntary international standards, guidelines or recommendations in the areas of food-safety and plant and animal life and health. The most important of these are the Codex Alimentarius Commission in the area of food safety, the International Plant Protection Convention in the area of plant health, and the International Office of Epizootics in the area of animal health. The WTO’s SPS and TBT Agreements encourage, without obliging, Members to adopt the standards, guidelines or recommendations set by these three organisations.218 The EU participates actively in international standard-setting organisations. Recent developments in these three organisations will now be examined.

**Codex Alimentarius Commission**

The Codex Alimentarius Commission is a joint body of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), established in 1963 to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. It aims to protect consumer health and ensure fair practices in food trade. It meets biannually in Rome or Geneva to adopt standards, guidelines or related texts that have been developed by its committees. Scientific advice is provided to these committees by expert committees or meetings and expert consultations jointly convened by the WHO and FAO.219

In 2002, the FAO and WHO initiated a process of evaluation of their Joint Food Standards Programme, concentrating on the Codex Alimentarius Commission, which was completed in December 2002. The evaluation was conducted by an independent team advised by an independent expert panel. The report of the evaluation was considered by the 25th (Extraordinary) Session of the Codex Alimentarius Commission in February 2003, which supported the overall thrust of the Evaluation report and expressed its commitment to implement the strategies that would meet the objectives of the recommendations in the report. In particular, it agreed that Codex and the FAO and WHO should work towards: greater efficiency in the development of Codex standards, but ensuring that transparency and inclusiveness are maintained; increased participation of developing countries and countries in economic transition in the work of the Codex; greater usefulness of Codex standards to members in terms of relevance to their needs and timeliness; strengthening the scientific base for risk analysis, including food safety risk assessment to improve the efficiency and effectiveness in providing expert scientific advice to the Commission and members and to improve risk communication; and more effective capacity building for the development of national food control systems.220 At this same meeting, the FAO/WHO Trust Fund for Participation of Developing Countries in Codex Standard Setting Procedures was launched. This Trust Fund is a significant initiative in that it aims to address the constraints that developing countries face in effectively participating in the standard-setting process at Codex.

At the 26th Session of the Codex Alimentarius Commission, held in Rome on 30 June to 7 July 2003,221 it approved most of the proposals submitted by the Secretariat for the implementation of the recommendations of the Joint FAO/WHO Evaluation of Codex. *Inter alia*, it agreed: to meet annually for the next two years, but that in future each session of the Commission would decide the interval between meetings; to review the structures and mandates of all Codex committees by 2004; and to develop improved processes for standards management and monitoring. It also welcomed progress made regarding the Trust Fund for developing countries and expressed the hope that it would soon become operational.222 All these reforms and initiatives are crucial to ensure that internationally harmonised standards in the area of food safety are adopted in a speedy, efficient and inclusive way.

A landmark decision was taken at this meeting with regard to the assessment and management of risks to consumers from foods derived from modern biotechnology.223 The Codex Alimentarius Commission adopted four instruments in this regard.224 These instruments were adopted to take into account the fact that the normal principles for risk analysis, including risk assessment, are intended to apply to discrete hazards that may be present in food (for example from pesticide residues or microbial contaminants), not to a *whole* food as such, which is the case with risk analysis for GMOs. Thus, some modification of

218 The SPS Agreement expressly refers to these three organisations, whereas the TBT Agreement does not identify the relevant international standardising bodies. Article 3 of the SPS Agreement obliges Members to base their SPS measures on these international standards, guidelines or recommendations except if they can show scientific justification for deviation or if they adopt a different level of protection. In either case, a risk assessment must support the measure. In addition, if Members actually conform their SPS measure to the international standard, guideline or recommendation, their measure will be presumed to be consistent with the SPS Agreement and the GATT. Under Art. 2.4 of the TBT Agreement, members are obliged to base their technical regulations on international standards where they exist or are imminent, except where they would be an ineffective or inappropriate means to achieve the legitimate objective pursued by the measure.

219 For example the Joint FAO/WHO Meeting on Pesticide Residues and the Joint FAO/WHO Expert Committee on Food Additives.


222 A second progress report on the Trust Fund was considered at the 26th Session of the Codex. In the report, basic criteria for eligibility of countries for support from the Trust Fund were set out for discussion. See ALINORM 03/26/12.

223 The term modern biotechnology refers to genetic modification in this context. Although several Codex members expressed their preference for the term “genetically modified”, the Task Force finally agreed to use the words “modern biotechnology” in order to ensure consistency in terminology between Codex texts and the Cartagena Protocol.

224 These standards were developed by the Codex Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology and forwarded to the Codex Alimentarius Commission in March 2003. These instruments can be found as ALINORM 03/34 Appendix II, III, and IV and ALINORM 03/34A Appendix II.
the risk analysis principles is necessary. First, the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology were adopted. This document identifies as possible risk management tools, food labelling, conditions for marketing approvals and post-market monitoring. In addition, it specifically mentions among the tools that may be needed to facilitate the implementation and enforcement of risk management measures, the tracing of products for the purpose of facilitating withdrawal from the market in case of identified human health risks or to support post-market monitoring in certain circumstances. The reference to the “tracing of products” and to labelling as a risk management tool, is interesting and might vindicate the EC position with regard to labelling and traceability of GMOs in its new legislation.225 With regard to risk assessment, these Principles refer to two other texts also adopted at the 26th Session of the Codex, namely the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and the Guideline for the Conduct of Food Safety Assessment in Recombinant-DNA Microorganisms. These risk assessment guidelines are based on the principle that the safety of foods derived from recombinant-DNA plants or produced using recombinant-DNA microorganisms should be assessed relative to the conventional counterpart that has a history of safe use, taking into account both intended and unintended effects.226 Lastly, an Annex on the Assessment of Possible Allergenicity was adopted to supplement the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. It addresses the problem that no definitive test exists to predict allergic response in humans to a newly expressed protein. It therefore recommends an integrated, case-by-case approach to assess the possible allergenicity of these proteins.

The Codex further adopted a new standard for irradiated products, accepting higher levels of radiation in food in order to eliminate bacterial spores without the need to resort to toxic chemicals to combat bacteria. In addition, the Working Principles for Risk Analysis for Application in the Codex Framework227 were adopted, which provide guidance to the Codex and the joint FAO/WHO expert bodies and consultations to ensure that Codex standards are based on proper risk analysis.

Finally, at this session, the Codex Alimentarius Commission agreed to changes to its Rules of Procedure, which would allow Regional Economic Integration Organizations to become members.228 This means that the EC will now be able to join the Codex as a member in its own right.

In a related development, the FAO and WHO are examining ways to improve the manner in which scientific advice is provided to the Codex. Scientific advice is crucial to the standard-setting process, a fact that was acknowledged in the recent FAO/WHO Evaluation of their Joint Food Standards Programme. The FAO and WHO have thus recently initiated a consultative process to examine ways to improve the provision of expert advice to the Codex, focusing specifically on issues related to the quality, independence, integrity, transparency, timeliness, efficiency and sustainability of this scientific advice.229

International Plant Protection Convention

The International Plant Protection Convention (IPPC) is a multilateral treaty,230 which is deposited with the Director General of the FAO. It aims to facilitate international cooperation to ensure common and effective action to prevent the spread and introduction of pests of plants and plant products and promote measures for their control.231 The IPPC came into force on 3 April 1952 and was revised in 1979,232 and again in 1997.233 The more recent revision was in response to the new role of the IPPC with regard to setting international harmonised standards of relevance to the disciplines of the WTO’s SPS Agreement. Also to address this new role, the FAO established a Secretariat for the IPPC in 1992 and adopted standard-setting procedures in 1993, together with the creation of a Committee of Experts on Phytosanitary Measures.234 The new revised text of the IPPC emphasises the adoption of international standards for phytosanitary measures, which are developed through a defined process including country consultation. The resulting standards are adopted by an Interim Commission on Phytosanitary Measures (ICPM), pending the coming into force of the new revised text and the establishment of the Commission on Phytosanitary Measures thereunder. The standard-setting process is currently managed by the Interim Standards Committee.

The use of phytosanitary measures to address the risk of pests in the wood material used to package imports has been the subject of some controversy, as they can have the effect of restricting a large proportion of imports. This issue has been raised on several occasions at SPS Committee meet-

225 However, the US is of the opinion that traceability is not the same as tracing of products as the former relates to the entire food chain whereas the latter is limited to “one step forward and one step back”. See Bridges Trade BioRes, Vol. 3 no. 13. A new working group has been established to deal with the definition of traceability/product tracing and will report to the Codex Commitee on General Principles.
226 In other words, rather than trying to identify every hazard associated with a certain food, the intention is to identify new or altered hazards relative to the conventional food product.
227 These principles are contained in ALINORM 03/41 Appendix IV.
228 These amendments are contained in ALINORM 03/41 Appendix II.
229 The consultative process will consist of an electronic forum, a workshop and an expert consultation. See World Health Organization, Food Safety News no. 7, 10 September 2003.
230 It currently has 120 Contracting Parties.
231 Preamble to the IPPC.
232 The revised text of the IPPC was approved by the 26th Session of the FAO. It incorporated amendments, proposed at a Government Consultation held in Rome in November 1976, with modifications subsequently recommended by the FAO Committee on Agriculture in 1979, on the proposal of an Ad Hoc Consultative Group. In accordance with Art. XIII of the IPPC, the revised text came into force with respect to all Contracting Parties on 4 April 1991, the thirtieth day after acceptance by two-thirds of the contracting parties.
233 The FAO Conference approved these amendments at its 29th Session (November 1997). In accordance with Art. XIII of the IPPC, the new text will come into force with respect to all Contracting Parties as from the thirtieth day after acceptance by two-thirds of the contracting parties. In January 2003, 43 countries had notified the Secretariat of their acceptance.
234 Before 1992, the IPPC had not adopted any standards. Since then, 19 standards have been adopted.
Health and Environmental Regulation

ings. In an effort to harmonise measures in this area, the ICPM adopted the Guidelines for Regulating Wood Packaging in International Trade at its Fourth Session in March 2002. This standard sets out measures to reduce the risk of introduction and spread of pests associated with wood packaging material, made of coniferous and non-coniferous raw wood, which is used in international trade. National plant protection organisations are encouraged to accept wood packaging material that has been subjected to an approved measure without imposing further requirements. Further, the Guidelines provide that procedures should be in place in both exporting and importing countries to verify that an approved measure, including the use of a globally recognized mark, has been applied.

At the meeting of the Fifth Session of the ICPM, on 7-11 April 2003, the ICPM adopted two new standards, namely the Guidelines for the Use of Irradiation as a Phytosanitary Measure and the Guidelines for Regulated Pests Lists. In addition, two standards have been amended by supplements, namely the supplement on Analysis of Environmental Risks approved by the ICPM has been integrated into the existing Pest Risk Analysis for Quarantine Pests including Analysis of Environmental Risks, and the Guidelines on the Understanding of Potential Economic Importance and Related Terms have been supplemented. Finally, the Glossary of Phytosanitary Terms has been amended.

In the report of the Chairman to this Session of the ICPM, he pointed out that on average, less than two new standards are adopted by the IPPC per year and noted that this “is considered absolutely insufficient to solve the current needs in relation to the increase in international trade of plant and plant products”. He also referred to the fact that the standards established to date by the IPPC lay down general principles and concepts rather than precise standards for specific pests and commodities, thus making it impossible for WTO Members to justify their measures on the basis of IPPC standards under the SPS Agreement. Instead, they have to base all their phytosanitary measures on pest risk assessments, something particularly difficult for developing countries. As a result, IPPC members and regional plant protection organisations were requested to submit their priorities for specific IPPC standards to the ICPM.

The issue of developing country participation in standard setting is also receiving increased attention at the IPPC. In response to an expression of interest by IPPC Members in the level of participation by developing countries in IPPC standard setting, the IPPC Secretariat prepared a document on this issue, circulated at the Fifth Session of the ICPM. In this document, the Secretariat addressed the issue of participation costs for developing country nationals, both in the expert groups that provide the scientific input for IPPC standard setting and in the meetings of the ICPM where final standards are actually adopted. It explained that the costs of participation in IPPC expert working groups of persons nominated by countries or regional plant protection organisations on the basis of their expertise, are covered by the Secretariat from the regular programme budget of the FAO. However, in 1999 the ICPM adopted a recommendation that developed countries voluntarily fund their own experts. This has resulted in savings that have increased the possibilities for funding additional experts from developing countries. In this way, it is possible to promote the inclusion of data from developing countries in the scientific discussions that form the basis for IPPC standards. In addition, although funding for participants in ICPM meetings, which are government representatives, is normally the responsibility of governments, it has been the practice of the IPPC Secretariat to ensure that funding is available for developing country participants before organising such meetings. This funding may come from the regular programme budget of the Secretariat or from donors. In this way, developing countries can make their voices heard at meetings where harmonised standards are adopted by the ICPM, ensuring that their interests are included in the standards finally adopted.

International Office of Epizootics

The International Office of Epizootics (OIE) is an international organisation, established by the International Agreement of 1924. It aims to guarantee the transparency of animal disease status world-wide; collect, analyse and disseminate veterinary scientific information; provide expertise and promote international solidarity for the control of animal diseases; and provide rules for international trade in animals and animal products in order to secure the sanitary safety of world trade. The latter objective is achieved by establishing voluntary harmonised norms that can be applied by countries to prevent the spread of animal or fish diseases (for example with regard to animal health conditions on import permits and export certificates). These

235 For example, in November 2000 Canada raised its concerns before the SPS Committee regarding an emergency measure of the EC with regard to wood packaging material, arguing that as wood packaging was used for a large volume of traded products, the EC cont.

236 This standard can be found as ISPM 15.

237 ISPM 18.

238 ISPM 19.

244 An exception to this situation is when meetings are donor-funded. In such cases, the Secretariat requires that the same policies and procedures be followed as are applied to working group meetings funded by the Secretariat.

245 In addition, in this document the Secretariat provided a statistical summary of developing country participation in IPPC meetings in 2002. It indicated that 39 meetings were held in that year, attended by a total of 100 countries of which 79 were developing countries. Of the total number of participants, 53% were from developing countries.

246 The abbreviation is based on the French name of the organisation, namely Office International des Epizooties.
norms are found in the OIE Terrestrial Animal Health Code\textsuperscript{247} and the OIE Aquatic Animal Health Code.\textsuperscript{248} In addition, the Manual for Standards for Diagnostic Tests and Vaccines and the Diagnostic Manual for Aquatic Animal Diseases describe the standards for laboratory diagnosis of all diseases covered by the OIE.

The highest organ of the OIE is the International Committee, composed of government representatives with the technical expertise to participate in the discussions and decisions of the Committee. The International Committee of the OIE meets annually in its General Session to adopt revisions of the Codes or Manuals, on the basis of updates which are prepared by the OIE Terrestrial Animal Health Standards Commission and the OIE Aquatic Animal Health Standards Commission. They are assisted by experts and specialists in the fields covered by the Codes. Any OIE member can request the International Committee to consider the review of any standard in the Codes.

At the 71st Session of the International Committee of the OIE on 18-23 May 2003,\textsuperscript{249} members discussed the use of economic analysis to define animal health policies and regionalisation as an instrument to prevent the propagation of animal diseases. The Chairman of the OIE Working Group on Animal Production Food Safety reported on the outcomes of its first meeting, which identified as a priority issue the joint review by the OIE and the Codex of their standards to identify gaps and areas of duplication. The International Committee approved amendments and additions to the Terrestrial Code on animal disease notification; evaluation of veterinary services; and several diseases. Of particular interest are the guidelines on the judgement of equivalence of sanitary measures,\textsuperscript{250} which were adopted and incorporated in the Terrestrial Code.\textsuperscript{251} Additions and amendments to the Aquatic Code were adopted regarding guidelines forallowing in aquaculture; surveillance and sampling guidelines; consistency in nomenclature between Aquatic Code chapters and the Aquatic Manual; and various fish diseases. Criteria for listing an aquatic animal disease and for urgent notification of an aquatic animal disease were also approved. Finally, the OIE Scientific Commission revised the lists of countries it considers to be free or contain regions that are free of rinderpest and foot-and-mouth disease.\textsuperscript{252}

**III. Summary**

The discussion in section I above draws attention to relevant aspects of the WTO rules that act on the interface between free trade and risk regulation. In particular, the description of the Panel decision in the fire blight dispute provides a good illustration of the way in which panels, composed of trade experts, deal with scientific disciplines in trade agreements. Their findings flesh out the meaning of terms such as “sufficient scientific evidence”, “risk assessment” and “likelihood” in these disciplines. The way in which they apply these requirements to the scientific evidence before them is interesting for an understanding of the role of science in the adjudication of trade disputes involving measures to address risk. The fact that the Appellate Body upheld all the findings of the Panel appealed in this case means that these findings will provide guidance to the interpretation of these terms in future disputes. Members, including the EC, would do well to take note of the content given to these provisions of the SPS Agreement hereby, as this establishes the parameters for their own SPS regulations.

Section I then addresses some of the issues faced by the new panel that has been established to hear the dispute regarding the EC’s GMO regime. It aims to highlight the importance of establishing the policy objective and nature of a regulatory measure, and consequently the WTO agreement that will apply to it, in light of the fact that the different agreements follow different approaches to the use of science and risk assessment to discipline measures for the protection of health or the environment.

Following that, the disputes regarding the Australian quarantine regime are set out, focusing on the various provisions of the SPS Agreement that form the basis for the challenge to this regime. These disputes are interesting as they deal with a particularly conservative approach to risks from pests and diseases adopted by a country that enjoys a relatively pest- and disease free status and the extent to which such an approach is compatible with WTO rules.

Later the section addresses discussions at the SPS and TBT Committees of the WTO with regard to specific far-reaching examples of risk regulation and their position under WTO rules, drawing attention to the fact that concerns regarding regulatory measures’ compliance with trade rules can be raised at the consultation fora provided by these Committees, or bilaterally, at the time that draft regulations are notified to the WTO and in this way can influence the final regulation adopted. This promotes the use of scientific risk analysis methods during the drafting of regulatory measures, in order to avoid future challenges on the basis of the concerns raised before the relevant Committees.

Lastly, section I describes the ongoing negotiations on the issue of the relationship between WTO rules and MEAs. These negotiations are noteworthy as they tackle the controversial issue of the position of internationally agreed rules to address environmental risks with regard to another set of internationally agreed rules, namely those to promote trade liberalisation. They thus reflect the tension between trade and risk regulation at international level. The contentious nature of these negotiations is illustrated by

\textsuperscript{247} Previously called the International Animal Health Code.

\textsuperscript{248} Previously called the International Aquatic Animal Health Code.

\textsuperscript{249} Of the 164 countries that are members of the OIE, 140 were represented at this meeting.

\textsuperscript{250} The SPS Committee expressly requested the OIE and IPPC to undertake work on guidelines for the recognition of equivalence of SPS measures in their fields, to contribute to its own work towards operationalising the rules on the recognition of equivalence in Art. 4 of the SPS Agreement.

\textsuperscript{251} These guidelines can be found in Chapter 1.3.7 of the 2003 OIE Terrestrial Animal Health Code and were notified to the WTO’s SPS Committee as document symbol G/SPS/GEN/406.

\textsuperscript{252} See Resolution XXIII on the recognition of members as free of rinderpest and Resolution XX on the foot-and-mouth disease status of members.
the lack of progress made thus far. The discussion in this section includes the issue of the participation of MEA secretariats as observers to these negotiations, due to the importance of this issue in securing a balanced outcome of the negotiations, reflecting environmental interests as well as trade interests.

Section II turns to recent developments on international level with regard to the interaction between trade and risk. It starts by examining the STDF, an important initiative to address the impact of regulatory measures to address risks on the trade of developing countries. Since developing countries are most vulnerable to trade restrictive regulatory measures, due account must be taken of their position in any discussion of the relationship between risk and trade.

The entry into force of the Cartagena Protocol on Biosafety is considered thereafter. This Protocol embodies a hard-won agreement between countries regarding how to regulate transboundary movement of LMOs. It is the product of compromise and represents a significant achievement in creating internationally accepted rules regarding risk regulation in this controversial area.

The recent developments discussed last with regard to new harmonised measures adopted by the three international standard-setting bodies, the improvements to their procedures and initiatives to promote the participation of developing countries are interesting for various reasons. First, the procedural changes indicate that the standard-setting organisations are aware of the increased responsibility they bear due to the new status their standards have as benchmarks under the WTO’s SPS and TBT Agreements. They are thus concerned with ensuring that the standard-setting process is efficient and results in standards of high quality. Second, the new standards adopted promote harmonisation of risk regulation in new areas, thus facilitating trade between countries. Third, the new standards make it easier for WTO Members to comply with the requirements of the SPS and TBT Agreements, as measures conforming to or in accordance with international standards benefit from a presumption of compliance with some or all of Members’ obligations under these agreements.253 This is particularly useful for developing countries that want to enact SPS regulations as these countries often lack the resources to undertake the scientific risk assessments required by the SPS Agreement as a basis for SPS measures. Fourth, the new drive to address the constraints that developing countries face with regard to participation in the standard-setting process is crucial in ensuring that the standards set by these bodies will reflect developing country data, interests and capabilities and cover areas of importance to these countries.

List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Code</td>
<td>OIE Aquatic Animal Health Code</td>
</tr>
<tr>
<td>Aquatic Manual</td>
<td>Diagnostic Manual for Aquatic Animal Diseases</td>
</tr>
<tr>
<td>Bioterrorism Act</td>
<td>US Public Health, Security and Bioterrorism Preparedness Act</td>
</tr>
<tr>
<td>CBD</td>
<td>Convention on Biological Diversity</td>
</tr>
<tr>
<td>Codex</td>
<td>Codex Alimentarius Commission</td>
</tr>
<tr>
<td>CTE</td>
<td>Committee on Trade and Environment</td>
</tr>
<tr>
<td>DSB</td>
<td>Dispute Settlement Body</td>
</tr>
<tr>
<td>EC</td>
<td>European Community/Communities</td>
</tr>
<tr>
<td>FAO</td>
<td>Food and Agriculture Organization</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>GATT</td>
<td>General Agreement on Tariffs and Trade</td>
</tr>
<tr>
<td>GBF-18</td>
<td>18th Session of the Global Biodiversity Forum</td>
</tr>
<tr>
<td>GMOs</td>
<td>Genetically Modified Organisms</td>
</tr>
<tr>
<td>GM</td>
<td>genetically modified</td>
</tr>
<tr>
<td>ICPM</td>
<td>Interim Commission on Phytosanitary Measures</td>
</tr>
<tr>
<td>ISPM</td>
<td>International Standard on Phytosanitary Measures</td>
</tr>
<tr>
<td>IPPC</td>
<td>International Plant Protection Convention</td>
</tr>
<tr>
<td>LMOs</td>
<td>Living Modified Organisms</td>
</tr>
<tr>
<td>MEA</td>
<td>Multilateral Environmental Agreements</td>
</tr>
<tr>
<td>OIE</td>
<td>International Office of Epizootics</td>
</tr>
<tr>
<td>SPS</td>
<td>Sanitary and Phytosanitary</td>
</tr>
<tr>
<td>SPS Agreement</td>
<td>Agreement on the Application of Sanitary and Phytosanitary Measures</td>
</tr>
<tr>
<td>SPS Committee</td>
<td>Committee on Sanitary and Phytosanitary Measures</td>
</tr>
<tr>
<td>STDF</td>
<td>Standards and Trade Development Facility</td>
</tr>
<tr>
<td>TBT</td>
<td>Technical Barriers to Trade</td>
</tr>
<tr>
<td>TBT Agreement</td>
<td>Agreement on Technical Barriers to Trade</td>
</tr>
<tr>
<td>TBT Committee</td>
<td>Committee on Technical Barriers to Trade</td>
</tr>
<tr>
<td>Terrestrial Code</td>
<td>OIE Terrestrial Animal Health Code</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WTO</td>
<td>World Trade Organization</td>
</tr>
</tbody>
</table>

253 Under Art. 3.2 of the SPS Agreement, an SPS measure that conforms to an international standard is presumed to comply with the entire SPS Agreement and the GATT. Under Art. 2.5 of the TBT Agreement, a technical regulation that is in accordance with relevant international standards and aims at one of the legitimate objectives enumerated in Art. 2.2, it is presumed not to create an unnecessary obstacle to trade.