A step backwards for international environmental law, but not the end of GE restrictions

Genetic Engineering and the WTO: an Analysis of the Report in the 'EC-Biotech' Case

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1. Introduction

On 29 September 2006, a Dispute Settlement Panel at the World Trade Organization (WTO) issued its report in the **European Communities - Measures affecting the Approval and Marketing of Biotech Products** case[1]. The contents of the report had been presaged by a leaked interim report.[2] The report, at 760 pages, plus some 2,500 pages of appendices, being possibly the longest in WTO history[3], was the outcome of a 2003 complaint by the United States (US), Canada and Argentina. A number of analyses of the earlier interim report have been published.[4]

The EU had not issued any authorisation for the commercial release of a genetically engineered (GE) organism since October 1998, while some European countries called for the suspension of new authorisations pending the adoption of new rules on labelling and traceability, which entered into force in April 2004.[5]

The complaints involved the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS),[6] Agreement on Technical Barriers to Trade (TBT)[7] and the General Agreement on Tariffs and Trade

1 European Communities – Measures Affecting the Approval and Marketing of Biotech Products: Reports of the Panel WT/DS291/R, WT/DS292/R, WT/DS293/R, 29 September 2006, ('Final Panel Report'). The report is available at http://www.wto.org/english/news_e/news06_e/291r_e.htm . All web references were as of October 21, 2006.

2 On February 7, 2006, a Dispute Settlement Panel at the World Trade Organization (WTO) had issued its interim report to the Parties only, a leaked copy was published on the internet by Friends of the Earth Europe. The interim report was subject to amendments suggested by Parties: *Understanding on rules and procedures governing the settlement of disputes* Article 15. See discussion at para. 6.2 of Final Panel Report, and see report at Friends of the Earth Europe, *World Trade Organisation GM dispute* - secret report leaked, at http://www.foeeurope.org/biteback/WTO_decision.htm.

3 See "WTO Publishes Final GMO Ruling; U.S., EU Decline to Say if They Will Appeal", *WTO Reporter*, October 2, 2006.

4 Including, Nathalie Bernasconi-Osterwalder and Maria Julia Oliva, Center for International Environmental Law (CIEL), *Overview and Analysis of the Panel's Interim Report* (March 2006), at http://www.ciel.org/Tae/ECBiotech_InterimReport_31Mar06.html, Heike Baumüller, Knirie Sogaard and Yvonne Apea, ICTSD, *Overview of the WTO Biotech Dispute and the Interim Ruling*, (March 2006), at http://www.trade-environment.org/output/theme/tewto/biotechcasebackground.pdf, Steve Suppan, Institute for Agriculture and Trade Policy, *The "EC Biotech Products" Ruling at the World Trade Organization and the Cartagena Protocol on Biosafety*, March 2006, at http://www.tradeobservatory.org/library.cfm?refid=78778, Charles Hanrahan, US Congressional Research Service, *Agricultural Biotechnology: The US - EU Dispute*, March 2006, http://italy.usembassy.gov/pdf/other/RS21556.pdf.

5 Regulation (EC) No. 1830/2003 on the Traceability and Labelling of Genetically Modified Organisms, 22 September 2003, at http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32003R1830:EN:HTML and Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed, 22 September 2003, at http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf#search=%22regulation%201829%2F2003%20%22. All products with more than 0.9% must be labelled as containing GE products under Article 21(3) of Directive 2001/18/EC as amended by Regulation 1830/2003.

6 Agreement on the Application of Sanitary and Phytosanitary Measures, 15 April 1994, GATT. Doc. MTN/FA II-AIA-4, 1867 U.N.T.S. 493, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instruments—Results of the Uruguay Round, at http://www.wto.org/english/docs_e/legal_e/final_e.htm, ("SPS Agreement").

7 Agreement on Technical Barriers to Trade, 15 April 1994, 33 ILM 1125, 1153, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, Legal Instruments—Results of the Uruguay Round, at http://www.wto.org/english/docs_e/legal_e/final_e.htm, ("TBT Agreement").

(GATT) 1994.[8] The European Communities (EC) relied on the precautionary language in the SPS, Article 5.7 of which allows for provisional measures to be implemented in cases of insufficient scientific evidence, as well as the Biosafety Protocol, which reflected international rules on the precautionary principle and risk assessment.

The Panel found that

- The EC applied a general de facto moratorium from June 1999 until August 2003, and in doing so acted inconsistently with Art. 8 and Annex C(1)(a) of the SPS Agreement.

- The Panel recommended that the Dispute Settlement Body request the European Communities to bring the general de facto moratorium on approvals into conformity with its obligations under the SPS Agreement, if, and to the extent that, that measure has not already ceased to exist. In so doing, the Panel reversed its interim report findings that the general moratorium had ended and therefore made no recommendation on it.

- The approval process for 24 of 27 so-called[9] 'biotech products' had been unduly delayed.

- The nine safeguard measures imposed by certain EU member States were not based on a risk assessment, and sufficient scientific evidence had been available for the member states to perform a risk assessment as required under Art. 5.1 of the SPS Agreement since the relevant EC level scientific committee had evaluated the potential risks to human health and the environment. The safeguards were therefore not consistent with the requirements of Art. 5.7 of the SPS agreement, which allows for WTO Members to provisionally adopt SPS measures in cases where relevant scientific evidence is insufficient.

The Panel recommended that the Dispute Settlement Body (DSB) request the EC to bring the relevant product-specific measures into conformity with its obligations under the SPS Agreement,[10] or in other words to complete the approval process for the outstanding applications, and that the DSB request the EC to bring the relevant member State safeguard measures into conformity with its obligations under the SPS Agreement,[11] or in other words revoke them or provide an SPS -compliant risk assessment to justify the safeguard measures.

This analysis discusses the implications of the ruling, if it stands after any appeal, for old and new restrictive measures on GE organisms as well as the relationship between the Biosafety Protocol and the WTO regime.

This analysis concludes that

- Restrictions on GE organisms remain possible if implemented according to the parameters of the ruling.

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8 General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, The Legal Texts: the Results of the Uruguay Round of Multilateral Trade Negotiations 17 (1999), 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) at http://www.wto.org/English/docs_e/legal_e/legal_e.htm ("Gatt 1994").

9 The Report used the term 'biotech products' to refer to plant cultivars that have been developed through recombinant deoxyribonucleic acid ("recombinant DNA") technology. Final Panel Report para. 2.2. However, the term 'biotechnology' is more frequently used to refer to the application of science and engineering in the direct or indirect use of living organisms includes the use of traditional or conventional breeding, as well as genetic engineering. The Biosafety Protocol uses the term 'living modified organism' or LMO.

10 Final Panel Report para. 8.40.

11 Final Panel Report para. 8.48, 8.64.

• The narrow interpretation of the relevance of other international agreements such as the Biosafety Protocol taken by the Panel is unwarranted and counterproductive to both the WTO and Multilateral Environmental Agreement systems and undermines environmental governance. It ignores and is contrary to specific goals agreed to by Heads of States and Governments at the Johannesburg World Summit on Sustainable Development in 2002 as well as calls for more coherence at the UN World Summit in 2005. The ruling, if it stands, would lead to further fragmentation of international law, to the detriment of international law as a whole. In taking an unduly narrow approach, the Panel discarded consideration of a whole other body of pertinent law and practice, and in doing so, has create more difficulties. States face the simultaneous difficulty of complying with the law and practice under the applicable MEA (in this case the Biosafety Protocol), with WTO laws while addressing the need to protect the environment and population.

• The decision, if upheld on any appeal, highlights the need for a comprehensive review and reform of the relationship between the WTO and multilateral environmental agreements (MEAs). The decision would at best ignore and at worse undermine or run contrary to specific internationally agreed policies and rules specifically relevant to the dispute, in this case the Biosafety Protocol, which is highly relevant to the issues before the Panel, which could and should have informed the Panel's deliberations. The decision is likely to encourage calls for solutions such as a joint compliance and dispute settlement mechanism for MEAs, arbitration or referral to international adjudication such as before the International Court of Justice which can by their terms of reference take into account both WTO and MEA rules.

• The excessively broad interpretation of the scope of the SPS Agreement increases uncertainty as to compliance with the SPS and TBT agreements and increases the burden of compliance by importing States. In any appeal, it can be hoped that the Appellate Body would more accurately describe and define the applicability of the SPS Agreement to the benefit of both agreements.

• The decision, if upheld, highlights a failure of the SPS to give clear guidance on risk management, as opposed to risk assessment. This has been the case since the Appellate Body has in a previous case denied that a distinction exists under the SPS between risk assessment and risk management. The Panel in this case, however, did acknowledge that a risk assessment may support a range of measures, and a Member may choose one, which provides the best protection of human health and/or the environment, as long as the measure is reasonably supported by the risk assessment, and is not inconsistent with other provisions of the SPS Agreement. So great emphasis is therefore placed on the risk assessment and on Article 5.1 of the SPS. In particular, much would turn on whether there are sufficient divergent views to justify the measure.

• There still exist some situations where, at least in theory, a risk assessment need not be carried out. As long as the four requirements of Article 5.7 exist, SPS measures may be provisionally adopted and maintained even if not based on a risk assessment. That is, relevant scientific evidence must be insufficient, the measure must be adopted on the basis of available pertinent information, the Member must seek to obtain the additional information necessary for a more objective assessment of risk and the Member must review the measure within a reasonable period of time.

• However, this approach effectively robs Article 5.7 of its reflection of the precautionary principle, and indeed of much of its meaning. Its very nature is that it is provisional, and therefore it is appropriate that in case of scientific uncertainty, that the precautionary principle can be invoked in the sense that provisional measures can be implemented under Article 5.7 until a risk assessment can be carried out. But the approach taken by the Panel means that if a risk assessment can be carried out according to the criteria in the Panel report, then Article 5.7 has no application, and risk managers cannot act in the common-sense situation where scientific information is insufficiently reliable to permit an adequate assessment of risks and so base provisional measures based on Article 5.7. Instead, measures must be based on a risk assessment and must be permanent. Much would turn on whether an assessment renders sufficient information to carry out a risk assessment.

• The Panel took a very broad view of the scope of the SPS Agreement, both with respect to measures with respect to genetically engineered crops and with respect to labelling. Since much labelling is intended to inform the consumer or allow the consumer to make a choice, it is not desirable that it falls to be analysed under the SPS Agreement. However, the Panel interpreted labelling requirements intended to inform the consumer as requirements related to food safety as they are aimed at protecting health from additives, contaminants and so on. In doing so, it failed properly to analyse whether the requirements were 'directly related' to food safety, as is required by the SPS Agreement. The Technical Barriers to Trade (TBT) Agreement does not apply to SPS measures, so a broad scope of applicability of the SPS would tend to exclude application of the more appropriate TBT Agreement. With respect to measures to protect health or the environment, if the broad scope of the SPS Agreement is upheld – such as the finding that harvested plants are, and could continue to be 'pests', even after they were no longer living, and that labelling measures fall under the SPS Agreement rather than the TBT Agreement if only one purpose is related to human health it could fall under the SPS Agreement, - then the SPS may be far more applicable than was previously thought. This is likely to lead to uncertainty as to the applicability of the TBT and SPS Agreements, and has already lead to at least one GE organisms' exporting State arguing that imports are subject to SPS requirements, which are more burdensome for importing States than TBT requirements - particularly in the light of this Panel report.

The report took umbrage at the release of the conclusions and recommendations and of the full Interim Report by Friends of the Earth Europe (FoE),[12] stating that it was "surprising and disturbing that the same NGOs which claimed to act as amici, or friends, of the Panel when seeking to convince the Panel to accept their unsolicited briefs subsequently found it appropriate to disclose, on their own websites, interim findings and conclusions of the Panel which were clearly designated as confidential."[13] The Panel did note[14] that FoE had said it had refrained from publishing confidential information, but said that the leak "could damage the integrity of the WTO dispute settlement system as a whole." However, as early as 1998 the then Director-General Renato Ruggiero observed that "almost all interim reports have been leaked, sometimes within hours, usually within a matter of a few days"[15] and it has been observed in 2000 that

12 Final Panel Report, paras. 6.183-6.196.

13 Final Panel Report, para. 6.196.

14 Final Panel Report para. 6.185.

15 Statement by the Director-General, General Council, 24 April 1998, at http://www.wto.org/english/news_e/sprr_e/stat17_e.htm.

interim reports are frequently leaked to the press.[16] Thus the leak in the EC-Biotech case can hardly have been surprising, and in this case some of the participants commented on early reports. It is also notable that there is no specific provision in the Dispute Settlement Understanding (DSU) for confidentiality in the interim report, including in the specific Article, which sets out the process for the interim report,[17] whereas the DSU does specifically provide that Panel deliberations shall be confidential.[18] The insistence on confidentiality of the interim report also tends to undermine public confidence in justice, which under the principle of open justice should be seen to be done. The importance of access to information, participation in decision-making and access to justice in environmental matters is emphasised in the Aarhus Convention.[19] Greenpeace co-published the conclusions and recommendations[20] in the public interest and would not hesitate to do so again.

16 John Howard Jackson, "The Role and Effectiveness of the WTO Dispute Settlement Mechanism," *Brookings Trade Forum 2000* (2000), 179-219,187, at http://muse.jhu.edu/demo/brookings_trade_forum/v2000/2000.1jackson.pdf 0

17 See Dispute Settlement Understanding, Article 15. Appendix 3 of the DSU provides that the deliberations of the panel and the documents submitted to it shall be kept confidential.

18 DSU Article 14. The Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes WT/DSB/RC/1 (Rules of Conduct) Article VII:1 provides that each 'covered person' shall at all times maintain the confidentiality of the dispute settlement deliberations and proceedings together with any information identified by a party as confidential. At http://www.wto.org/English/tratop_e/dispu_e/rc_e.htm. Covered persons include persons serving on the panel and experts.

19 Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, done at Aarhus, Denmark, 25 June 1998, entered into force on 30 October, 2001, 38 ILM (1999) 517. Text at http://www.unece.org/env/pp/treatytext.htm. Article 1 provides that each Party shall guarantee the rights of access to information, public participation in decision-making, and access to justice in environmental matters in accordance with the provisions of the Convention. See also the Almaty Guidelines on Promoting the Application of the Principles of the Aarhus Convention in International Forums, applicable to multilateral international environmental decision-making processes. Decision 11/4 Promoting the application of the principles of the Aarhus Convention in international forums, ECOSOC ECE/MP.PP/2005/2/Add. 5 (20 June 2005), at http://unece.org/env/documents/2005/pp/ece/ece.mp.pp.2005.2.add.5.e.pdf. Paragraph 11 notes that access to information, public participation and access to justice in environmental matters are fundamental elements of good governance at all levels and essential for sustainability.

20 See: http://eu.greenpeace.org/downloads/gmo/WTOpublish060208.pdf

2. The relationship between the Biosafety Protocol and the WTO Rules

The Panel gave an unduly narrow answer to the question of the relationship between the Biosafety Protocol and global trade rules. It focused entirely on interpretation, and even on that basis, concluded without explanation that it did not have to take the Biosafety Protocol into account – not that it *could* not do so. It completely failed to take account of the Biosafety Protocol and State practice developed within the Protocol and actions taken pursuant to it as relevant to the question of the application rather than interpretation of the SPS, particularly in the crucial areas of risk assessment and import approvals, including timeframes and appropriate delays. In doing so the Panel acted in contradiction to the Johannesburg Plan of Implementation (JPOI) injunction towards mutual supportiveness between trade and environmental law regimes and calls in the World Summit 2005 Outcome calling for a more coherent institutional framework.

The Panel focused its analysis on narrow issues of treaty interpretation instead of the task of the application of the SPS to the measures in question and the relevance of other treaties and State practice to that analysis. In doing so, the Panel failed to grasp the connection between MEAs and the SPS and discarded consideration of pertinent law outside the SPS. The Panel instead of throwing light on the MEA/WTO relationship obscured the relationship and created more difficulties. States face the simultaneous difficulty of complying with the law and practice under the applicable MEA (in this case the Biosafety Protocol), and with WTO law, while addressing the need to protect the environment and the population.

The question here is not so much whether the Panel's narrow interpretation of the Vienna Convention on the Law of Treaties[21] was correct,[22] but whether it took the appropriate approach. The writer considers that it did not. The Panel approached the question as a narrow one of statutory interpretation. It was not only one of statutory interpretation. It was one of the application as well as the interpretation of

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21 Vienna Convention on the Law of Treaties, concluded at Vienna 23 May 1969, entered into force 27 January 1980, UN Doc A/Conf 39/28, UKTS 58 (1980), 8 ILM 679.

22 Alice Palmer, in "The WTO GE Organisms Dispute: Implications for developing countries and the need for an appeal," (November 2006), at http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/WTO_Biotech_case_dcsummaryfinal_1.pdf, also argues that the Panel's interpretation of the relevance of international law violates customary international rules of treaty interpretation. See pages 6 and 11-12.

23 See Joost Pauwelyn, "The Role of Public International Law in the WTO: How Far Can We Go?," in 95 American Journal of International Law (2001), 535-578, at http://www.asil.org/ajil/pauwelyn.pdf#search=%22technical%20barriers%2033%20ILM%201125%2C%201154%22, noting that it is crucial to distinguish between panel jurisdiction, applicable law, and the process of interpreting the WTO treaty, and that potentially all international law may be applicable law before a panel: These rules are also essential to ensuring the coherence and integrity of public international law as the legal system encompassing the WTO. "Hence, if the WTO neglected other rules of international law, it would not only impoverish the WTO legal system and risk reducing it to a uniform one-rule-fits-all framework implemented as a trade-only "safe haven." In addition, it would threaten the unity of international law."

the applicable law, and in particular the SPS Agreement.[23] Secondly, the Panel's approach flies in the face of consistent and developing concern at fragmentation of international law and at the need to avoid conflict between multilateral environmental agreements and the WTO agreements. The JPOI called for States to promote mutual supportiveness between the multilateral trading system and the multilateral environmental agreements, consistent with sustainable development goals, in support of the work programme agreed at the WTO, while recognizing the importance of maintaining the integrity of both sets of instruments, and to enhance synergy and mutual supportiveness between the Biodiversity Convention and WTO agreements.[24]

The CBD Parties similarly endorsed an approach of mutual supportiveness.[25] Such an approach has the attraction of avoiding the fragmentation of international law, something that the International Law Commission (ILC) has been examining.[26] The Panel ignored all this, despite the concept of mutual supportiveness having been brought to its attention.[27] This is despite inherent imbalances in the concept, in that WTO dispute resolution mechanisms are likely in practice to outweigh MEAs since disputes will be submitted there and there is no countervailing dispute mechanism for MEAs.[28] The Panel decision also conflicts with last year's World Summit Outcomes document, which aims at a more coherent institutional framework in the context of environmental agreements.[29]

The Panel said that "[p]ursuant to Article 3.2 of the DSU, we are to interpret the WTO agreements "in accordance with customary rules of interpretation of public international law."[30] However, the DSU (Dispute Settlement Understanding)[31] Article 3.2 actually provides that "[t]he Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public

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24 World Summit on Sustainable Development Plan of Implementation, at http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/WSSD_PlanImpl.pdf, Para. 98, Para. 44(r). See also para. 97, which called upon States to continue to enhance the mutual supportiveness of trade, environment and development with a view to achieving sustainable development through actions at all levels.

25 See Decision VI/20 on Cooperation with other organizations, initiatives and conventions, para 27, at http://www.biodiv.org/decisions/default.aspx?m=COP-06&id=7194. Paragraph 27 reads that "Recognizes the importance of cooperation with the World Trade Organization with regard to matters that are relevant to the Cartagena Protocol on Biosafety and in preparing for the implementation of the Protocol, emphasizes the need to ensure mutual supportiveness with the relevant agreements under the World Trade Organization, in particular with the Agreement on Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade, with a view to achieving sustainable development."

26 See International Law Commission, *Fragmentation of international law: difficulties arising from the diversification and expansion of international law*, at http://untreaty.un.org/ilc/summaries/1_9.htm.

27 The EC did bring it to the attention of the Panel: see para. 7.54.

28 For a general discussion on the WTO-MEA relationship, see Adelphi, Friends of the Earth Europe and Greenpeace, I*s the WTO the only way? Safeguarding Multilateral Environmental Agreements from international trade rules and settling trade and environmental disputes outside the WTO*, http://www.greenpeace.org/raw/content/international/press/reports/is-the-wto-the-only-way.pdf.

29 UN Resolution 60/1 2005 World Summit Outcome, 24 October 2005. The outcome called for more system-wide coherence, including a call for coherence and co-ordination in paragraph 38 and a call in 169 "Recognizing the need for more efficient environmental activities in the United Nations system, with enhanced coordination, improved policy advice and guidance, strengthened scientific knowledge, assessment and cooperation, better treaty compliance, while respecting the legal autonomy of the treaties, and better integration of environmental activities in the broader sustainable development framework at the operational level, including through capacity-building, we agree to explore the possibility of a more coherent institutional framework to address this need, including a more integrated structure, building on existing institutions and internationally agreed instruments, as well as the treaty bodies and the specialized agencies."

30 Final Panel Report para. 7.65.

31 Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 354 (1999), 1869 U.N.T.S. 401, 33 I.L.M. 1226 (1994), (DSU), at http://www.wto.org/English/docs_e/legal_e/28-dsu.doc.

international law." The first function is the preservation of the rights and obligations of Members under the covered Agreements. That does not exclude reference to other agreements such as the Cartagena Protocol. The second function is the clarification of the existing provisions of those agreements.

The EU argued that various provisions of the Biosafety Protocol must be taken into account by the Panel.[32] The Panel dismissed this, stating that the EC "has not explained how these provisions are relevant to the interpretation of the WTO agreements at issue in this dispute."[33] The Panel seemed not to consider that the provisions may be of assistance other than in interpreting the SPS Agreement. Curiously, the Panel did state that materials provided by international organizations such as Codex, FAO, and the CBD Secretariat "have been taken into account by us, as appropriate."[34] One is left wondering which materials and how they were taken into account without any further explanation, which is surprising in a report of such length.[35]

Rather than approaching the issue as one of interpretation, the questions resolve in large part to the application of applicable law to the facts. For example, with respect to the safeguards, a question is whether they were provisional measures adopted on the basis of available pertinent information, which would fall to be assessed under Article 5.7. To assess this, the Panel could have taken into account international standards developed outside the WTO framework, even if one or more WTO parties did not participate in setting the standard. The SPS Preamble itself recognizes the important contribution that international standards, guidelines and recommendations can make in establishing a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures, and promotes the use of harmonized sanitary and phytosanitary measures between Members on the basis of international standards, guidelines and recommendations developed by the relevant international organizations. The SPS lists the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention. Article 3 implements this, in providing that Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in the Agreement, and in particular in paragraph 3. That paragraph provides that all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of the SPS Agreement. Members are directed to play a full part in the development of standards.[36] While Codex Alimentarius, the International Office of Epizootics and International Plant Protection Convention are listed, the list is not exhaustive.

The United States is participating in the Protocol's Clearing House Mechanisms under Articles 11 and 20 of the Biosafety Protocol, and the EU argued that they must be taken to have no objection taken to the Protocol's approach.[37] The Panel responded that "we do not consider that the rules of the Biosafety Protocol can be deemed to be applicable to the United States merely because the United States participates in the Protocol's Clearing-House Mechanism."[38] With respect, the Panel missed the point: the EC had not argued that the rules can be deemed to be applicable, but that the United States as a matter of fact must be taken to have no objection to the mechanism, even though it is not a party, and that could give

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32 Preamble and Article 8(g) of the Convention on Biological Diversity and Articles 1, 8, 10, 11, 15, 23, 26 and Annex III of the Biosafety Protocol. See para. 7.95.

33 Final Panel Report Para. 7.95.

34 Final Panel Report Para. 7.96.

35 Alice Palmer likewise observes that the Panel's use of interpretative sources available to it in accordance with DSU Article 3.2 was selective and arbitrary. Alice Palmer, note 22, page 7.

36 SPS Article 3(4).

37 Final Panel Report para.7.53.

38 Final Panel Report para.7.75.

the mechanism some added weight. The Panel should have assessed whether the risk assessments and approach of the Clearing-House Mechanism was relevant, and whether there was an aspect of State practice that should be taken into account. The Biosafety Protocol is specifically concerned with adverse effects on biological diversity, as well as risks to human health, arising from living modified organisms.[39] The Advance Informed Agreement procedure[40] of which the Clearing-House Mechanism is part is highly relevant to the issues before the Panel, and in addition the extensive State practice that has developed under the Protocol could and should have informed the Panel's deliberations.

The EC also argued that the Biosafety Protocol and the SPS Agreement should be interpreted and applied consistently with each other[41] and that the Protocol's provisions on precaution and risk assessment inform the meaning and effect of the relevant provisions of the WTO agreements.[42] It should be noted that this argument included the application of the Agreements. This argument has an obvious attraction, in that WTO Members participating in an MEA are bound as a matter of law to apply both the provisions of the MEA and the WTO agreements, so striving for harmonization is clearly desirable. The Parties to the Biosafety Protocol have developed specific expertise and procedures in LMO organisms and risk assessments in particular, so it would benefit the WTO to use this expertise in weighing risk assessments in GE organisms. Canada, however, argued that the only possible relevance of the Protocol to the dispute could be for interpretive purposes.[43] This is a surprising position for the country which holds the headquarters of the Biosafety Protocol, and particularly so when Canada also argued that there is no inconsistency between the obligations of the Biosafety Protocol and the WTO obligations relevant to the dispute.[45] Moreover, Canada argued that the Biosafety Protocol is concerned with the impact of LMOs (living modified organisms) on biodiversity, and has "no relevance" to the risk assessment of biotech products for food use.[46] As a signatory to the Biosafety Protocol, Canada has an obligation under the Vienna Convention on the Law of Treaties to refrain from acts which would defeat the object and purpose of the Protocol.[47] The stated objective of the Biosafety Protocol is in accordance with the precautionary approach, to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.[48] Canada's recorded position on the precautionary approach, risk assessments and the risks to human health sits uneasily with its obligations under international law.

The Panel found that "the rules of international law to be taken into account in interpreting the WTO agreements at issue in this dispute are those which are applicable in the relations between the WTO Members",[49] and of course the US, Canada and Argentina are not Parties to the Biosafety Protocol, although Canada and Argentina are.[50] It likewise said that Article 31(3)(c) requires "consideration of those rules of

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39 Biosafety Protocol, Article 1.

40 Biosafety Protocol, Article 7.

41 Final Panel Report para.7.55.

42 Final Panel Report para.7.55.

43 Final Panel Report para.7.60.

44 Cartagena Protocol on Biosafety, signed at Montreal, 29 January 2000, entered into force 11 September 2003, 39 ILM 1027, at http://www.biodiv.org/biosafety/protocol.asp.

45 Final Panel Report para.7.61.

46 Final Panel Report para.7.61.

47 Vienna Convention on the Law of Treaties, note 21, Article 18.

48 Biosafety Protocol, Article 1.

49 Final Panel Report para.7.68.

50 Canada signed the Protocol on 19 April 2001, and Argentina signed on 24 May 2000. See status of the Protocol at http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt.

51 Final Panel Report para.7.70.

52 Final Panel Report note 272.

international law which are applicable in the relations between all parties to the treaty which is being interpreted."[51] However, the Panel also noted that in a case where all disputing parties are parties to a convention, this fact would not necessarily render reliance on that convention appropriate.[52]

The Panel concluded that "[i]n view of the fact that several WTO Members, including the Complaining Parties to this dispute, are not parties to the Biosafety Protocol, we do not agree with the European Communities that we are required to take into account the Biosafety Protocol in interpreting the multilateral WTO agreements at issue in this dispute."[53] This rather enigmatic conclusion states only that the Panel is not *required* to take the Biosafety Protocol into account. The Panel did not decide that they *could* not do so, and more importantly, did not decide whether practice and standards developed under the Biosafety Protocol were relevant to the dispute. In failing to do so, they certainly did nothing to harmonize the two agreements, and left questions open that could have been answered. The result for the 134 Parties to the Biosafety Protocol[54] that are also Party to the SPS is that they are bound by the Biosafety Protocol provisions as well as the SPS provisions, and as such are caught between the two agreements and any inconsistency that there may be. The JPOI exhortation to strive for mutual supportiveness was ignored. It can be hoped that on any appeal the Appellate Body may address the issue with more rigour, but the decision clearly shows the necessity to search for solutions such as a joint compliance and dispute settlement mechanism for MEAs, arbitration or referral to international adjudication such as before the International Court of Justice which can by their terms of reference take into account both WTO and MEA rules.[55]

53 Final Panel Report para.7.75.

54 Ratifications are at http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt.

55 See a discussion of such options at: Adelphi Research, Friends of the Earth Europe and Greenpeace: *Is the WTO the Only way? Safeguarding Multilateral Environmental Agreements from international trade rules and settling trade and environmental disputes outside the WTO*, at http://www.greenpeace.org/raw/content/international/press/reports/is-the-wto-the-only-way.pdf.

3. The consequences for the nine safeguards measures and for similar actions by EU member States

The Panel found that the safeguard measures were not based on risk assessments, and that Article 5.7 of the SPS Agreement was not applicable, since the EU scientific committee reviews showed that enough scientific evidence was available to permit a risk assessment. So the Panel recommended that the Dispute Settlement Body (DSB) request the EC to bring the relevant member State safeguard measures into conformity with its obligations under the SPS Agreement.[56] There will be a DSB meeting within 30 days after the adoption[57] of the Panel or Appellate Body report, at which time the EU will need to inform the DSB of its intentions.[58] Of course, if there is an appeal, that date would be delayed and could still be quite distant.

Austria, France, Germany, Greece, Italy, and Luxembourg could bring their safeguard measures into compliance with the ruling by conducting risk assessments according to the SPS Agreement,[59] in particular Annex A(4),[60] and as described in the Report. Much will turn on whether there is an appeal.[61]

In particular, in order to make measures 'WTO proof', a risk assessment should take into account the likelihood of events of concern.[62] The Panel adopted the finding of the Appellate Body in *Australia-Salmon*[63] that "[i]t is not sufficient that a risk assessment conclude that there is a possibility of entry, establishment or spread of diseases and associated biological and economic consequences. A proper risk assessment of this type must evaluate the 'likelihood' i.e., the 'probability', of entry, establishment or spread of diseases and associated biological and economic consequences." So any risk assessment should take this into account.

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56 Final Panel Report para. 8.64.

57 Reportedly the United States and Argentina have asked WTO members to adopt the report. WTO Reporter, Monday, November 13, 2006.

58 DSU, Article 21(3).

59 The Final Report acknowledged that a risk assessment carried out after a measure's adoption could 'sufficiently warrant' or 'reasonably support' the measure. See para 7.3030.

60 Annex A(4) Risk assessment - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

61 The Parties have an opportunity to provide comments to the Panel on its findings and request changes, although significant changes are not expected. The final report will then be released in final form. The Parties will then have 60 days to appeal to the WTO Appellate Body (DSU Article 16(4)).

62 See discussion on page 15. This is not to prejudge whether Article 5(7) can have any application.

63 Australia —Measures Affecting Importation of Salmon, WT/D518/AB/R, adopted 6 November 1998, DSR 1998: VIII, 3327 ('Appellate Body Report, Australia — Salmon') paras. 123-124.

64 Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified micro-organisms and their derived products intended for food and feed use, adopted 17 May 2006, at http://www.efsa.europa.eu/en/science/gmo/gmo_guidance/gmo_guidance_ej374_gmm.html.

EFSA's Guidance Document on risk assessment[64] provides some guidance. It notes that "[w]hen scientific information is insufficient, inconclusive, or uncertain, or when there are indications that the possible effects on the environment, or human, animal, or plant health may be potentially dangerous and inconsistent with the chosen level of protection, the precautionary approach may be invoked."[65] Such a risk assessment may be found to be sufficient to maintain the SPS measure if the risk assessment contained a divergent view justifying the restriction.

Alternatively, European Member States could carefully document that their measures are provisionally adopted under Article 5.7 because scientific evidence is insufficient. They should take care to document that the measure is imposed in respect of a situation where relevant scientific evidence is insufficient and the measure is adopted on the basis of available pertinent information. Additionally the Member should seek to obtain the additional information necessary 'for a more objective assessment of risk' and should review the measure accordingly within a reasonable period of time. They should obtain careful legal advice on all these measures. With an eye to the future, they would also be well advised to work to strengthen the implementation of the precautionary approach in international law, and specifically in trade law.

The MON810 Bans

In September 2004, the EU authorised 17 different seed strains of Monsanto maize known as MON810 for planting and sale across EU territory.[66] Hungary, Poland and Greece banned the cultivation of MON810. The Commission added MON810 maize to the common EU catalogue of agricultural plant species.[67] In April 2005, the Greek authorities referred to the national safeguard clause concerning risk for the environment or for human health[68] and banned the marketing of all MON810 varieties in Greece. The Commission decided on 10 January 2006 to order the ban to be lifted.[69] Greece did so, but replaced the ban with another, covering the same and additional species.[70] Cited concerns included:[71]

- Development of resistance among the most damaging insects infesting Greek corn and cotton crops.
- Disruption of biodiversity among non-harmful and beneficial insects.
- Danger that genetically modified pollen will be transported to cultivations far from GM crop cultivations, due to the high prevalence of bee-keeping in Greece and the relatively small size of holdings.

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65 EFSA Guidance Document, page 59.

66 See Greenpeace briefing on National Bans on genetically engineered organisms, updated May 2006, http://www.greenpeace.eu/downloads/gmo/NationalBans0507.pdf. See opinion of the Scientific Committee on Plants 10 February 1998, at http://ec.europa.eu/food/fs/sc/scp/out02_en.html.

67 Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0053:EN:HTML.

68 Formerly Article 16 of Directive 90/220/EC, now Article 23 of Directive 2001/18/EC: Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GE organism as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GE organism as or in a product on its territory.

69 "Greece ordered to lift ban on Monsanto's corn seed", January 10, 2006, at http://www.checkbiotech.org/root/index.cfm?fuseaction=news&doc_id=11991&start=1&control=152&page_start=1&page_nr=101&pg=1.

70 See report 30 Jan 2006 at http://www.genet-info.org/genet/2006/Feb/msg00008.html.

71 Greenpeace applauds Greek ban on GMO corn, 30 January 2006, at http://www.ana.gr/anaweb/user/showplain?maindoc=3869485&maindocimg=1151649&service=8.

With respect to the Mon 810 ban, Hungary, Poland and Greece could likewise carry out compliant risk assessments with regard to MON 810 maize. In order to minimize legal risk for these measures, it would be advisable that the risk assessments be not only peer reviewed by scientists but checked by lawyers familiar with WTO jurisprudence. It may eventually be the course of least resistance for the EU to audit and as necessary amend its legislation to take into account the WTO decision and thus ensure that its procedures are WTO compliant, but it would be advisable to wait for this until any appeal is decided. Again, the EU would work to strengthen the role and implementation of the precautionary approach in international trade law so that in future precautionary policies can be adopted with less legal risk. The current EFSA consultation on hybrid GE plants[72] should also be noted by stakeholders.

Discussion and Background

SPS Article 5.1 provides that:

Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

Article 5.7 provides that:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

The Complaining Parties challenged nine state safeguard measures covering different types of maize and oilseed rape.[73] The nine safeguard measures were adopted under Directives 90/220 EEC,[74] which was replaced by Directive 2001/18,[75] and under Regulation 258/97.[76]

The object of the two Directives was to avoid adverse effects on human health and the environment which might arise from the deliberate release into the environment of products consisting of, or containing, GE organisms. The Directives established administrative procedures for granting consent to placing GE organism on the market. An applicant would make an application, which would be assessed by the competent authority of the Member State where the GE organism was to be placed on the market for the first time, and there were Community-level mechanisms for objections. A GE organism that had been approved for marketing under either Directive could not be prohibited, but a Member States could, under Article 23 of Directive 2001/18, adopt a safeguard measure where, on the new or additional information

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72 Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing. Submissions due 10 September 2006. See http://www.efsa.europa.eu/cf/consultation.cfm?doc=11 and press release at http://www.efsa.europa.eu/en/press_room/press_release/pr_gmo_hybridgmm.html.

73 (1) Austria — T25 maize; (2) Austria — Bt-176 maize; (3) Austria —MON810 maize; (4) France — MS1/RF1 oilseed rape (EC-161); (5) France — Topas oilseed rape; (6) Germany — Bt-176 maize; (7) Greece — Topas oilseed rape; (8) Italy — Bt-11 maize (EC- 163), MON810 maize, MON 809 maize and T25 maize; and (9) Luxembourg — Bt-176 maize. See Final Panel Report para. 7.2534. The Panel examined each measures in turn starting on para. 7.2560.

74 Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms" (repealed on 17 October 2002). The safeguard measures were all taken under Article 16 of Directive 90/220, except the measure by Italy on Bt-11 maize (EC-163), MON 810 maize, MON 809 maize and T25 maize, which was adopted on the basis of Article 12 of Regulation 258/97 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997R0258:EN:HTML. Final Panel Report para. 7.2535.

75 Directive 2001/18 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

76 Regulation 258/97 concerning novel foods and novel food ingredients.

made available since the date of the consent, it has detailed grounds for considering that a GE organism constitutes a risk to human health or the environment.[77] These safeguard measures can only be maintained on a provisional basis until a full assessment is made at the EC level,[78] and a decision is made resulting either in the modification of the marketing approval.[79]

The nine measures were adopted by six EC Member States: Austria, France, Germany, Greece, Italy, and Luxembourg. No decision had been taken on any of them at the European Community level as of the date of the Panel's establishment.[80] The Panel found that the measures, including consumer labelling requirements,[81] were SPS measures within the definition of the SPS Annex,[82] and that they were measures that may affect international trade.[83] The next question was whether the measures were to be assessed under Article 5.7 or 5.1 of the SPS Agreement. Article 5.7 provides that in cases where relevant scientific evidence is insufficient, SPS measures may be provisionally adopted on the basis of available pertinent information.

Existing WTO case law holds that there are four requirements for adopting and maintaining a provisional SPS measure under Article 5.7. They are that:[84]

(a) the measure is imposed in respect of a situation where "relevant scientific evidence is insufficient";
(b) the measure is adopted "on the basis of available pertinent information";
(c) the Member which adopted the measure "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and
(d) the Member which adopted the measure "review[s] the ... measure accordingly within a reasonable period of time".

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77 Under Article 16 of Directive 90/220, a Member State could prohibit a GE organism in its territory where it has justifiable reasons to consider that a product constitutes a risk to human health or the environment.

78 See Art 23(1) of Directive 2001/18 and Art 16(1) of Directive 90/220.

79 See Art 21 of Directive 90/220.

80 Article 21 of Directive 90/220; Article 30(2) of Directive 200 1/18; and Article 13 of Regulation 258/97. Each safeguard measure was notified to the Commission by the relevant member State with evidence allegedly supporting the adoption of the measure. The Commission in turn requested in each case the opinion of the relevant EC scientific committee on whether the information supplied by the member constituted relevant scientific evidence that would cause the committee to consider that the product(s) at issue constituted a risk for human health or the environment. For each measure, the relevant EC scientific committee reaffirmed its earlier assessment, or that of another EC scientific committee, that the products did not present any risks to human health or the environment. Final Panel Report para. 7.2536.

81 The Panel found that labelling to indicate the presence of GE organism imposed for the purpose of protecting human health from unanticipated effects of GE organism falls within the scope of Annex A(1)(b) or (c) of the SPS Agreement. Final Panel Report, para. 7.2650.

82 Para. 7.2923. Under Annex A(1), an SPS measure is defined as:
1. Sanitary or phytosanitary measure - Any measure applied:
(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
See Final Panel Report para 7.2598 as to the form and nature of the Austrian ordinance. Under Annex A(1), SPS measures include "all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria". The ordinance which prohibited the marketing of the maize was a 'requirement.' Final Panel Report para. 7.2599.

83 The Panel found that the Austrian ordinance prohibited imports of T25 maize. Final Panel Report, Para. 7.2609.

84 Appellate Body Report, Japan — Measures Affecting Agricultural Products, WT/D576/AB/R, adopted 19 March 1999, DSR 1999:1, 277 (Appellate Body Reports, Japan —Agricultural Products II,) para. 89; Japan - Measures Affecting the Importation of Apples, WT/DS245/AB/R, adopted 10 December 2003, at http://www.wto.org/English/tratop_e/dispu_e/245_abr_e.doc (Japan —Apples), para. 176. See Final Panel Report para. 7.2929.

The European Communities claimed that all the measures were provisional measures and fell to be assessed under Article 5.7.[85] The Panel said that Article 5.7 is applicable whenever the relevant condition is met, that is to say, in every case where relevant scientific evidence is insufficient.[86] It dismissed the EC's argument that a risk assessment was required only under Article 5.1, not 5.7.[87] The Panel found that provisional measures can only be adopted under Article 5.7 where relevant scientific evidence was insufficient.[88] Conversely, Article 5.1 can apply whether or not measures were provisionally adopted.[89] Article 5.7 is a right and not merely an exception[90] from a general obligation under Article 2.2[91] not to maintain a SPS measure without sufficient scientific evidence.[92] This has implications for the allocation of the burden of proof: the complaining party has the burden of establishing that a challenged measure is contrary to the provision permitting the behaviour.[93]

The Panel was quite specific:

"subject to compliance with the requirements set out in Article 5.7, SPS measures may be provisionally adopted and maintained under Article 5.7 even if these measures are not based on a risk assessment as defined in Annex A(4). Accordingly, we conclude that Article 5.7 permits Members to do, in certain circumstances, what they would not be permitted to do under Article 5.1."[94]

This is important since this means that there is a specific 'green light' for introducing and maintaining an SPS measure where the four requirements of Article 5.7 are present. Article 5.1 requires Members to base their SPS measures on a risk assessment, whereas pursuant to Article 5.7, in cases where relevant scientific evidence is insufficient, Members may provisionally adopt SPS measures on the basis of available pertinent information. "If a challenged SPS measure was adopted and is maintained consistently with the four cumulative requirements of Article 5.7, the obligation in Article 5.1 to base SPS measures on a risk assessment is not applicable to the challenged measure."[95]

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85 Final Panel Report para. 7.2933.

86 Final Panel Report para. 7.2939. The Panel cited Japan — Apples where the Appellate Body stated that "the application of Article 5.7 is triggered [...] by the insufficiency of scientific evidence" at para. 184.
The Panel meant that by 'applicable' they meant whether or not the right conferred by the first sentence of Article 5.7 is, in principle, available to a Member. In a specific case, a Member must still satisfy the various requirements set forth in Article 5.7 if it wishes to benefit from the right conferred by Article 5.7. Final Panel Report, note 1807.

87 Final Panel Report para. 7.2943.

88 Final Panel Report para. 7.2944, 7.2946, stating that Article 5.7 is applicable in every case where relevant scientific evidence is insufficient.

89 Final Panel Report para. 7.2948.

90 The Panel said that the term "exception" connotes freedom from, and hence inapplicability of, an obligation. Para 7.2972. The Appellate Body in *Japan Agricultural Products II* Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence" (para. 80).

91 This means that if a challenged SPS measure was adopted and is maintained consistently with the four cumulative requirements of Article 5.7, the situation is "as provided for in paragraph 7 of Article 5" (Article 2.2), and the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence is not applicable to the challenged measure. Final Panel Report para. 7.2974.

92 Final Panel Report para. 7.2969.

93 Final Panel Report para. 7.2976, citing Appellate Body Report, European Communities — Conditions for the Granting of Tariff Preferences to Developing Countries, WT/D5246/AB/R, adopted 20 April 2004 ('Appellate Body Report, EC — Tariff Preferences') para. 88. So when a complaining party presents a claim of violation under Article 5.1, the burden is on the complaining party to establish a *prima facie* case of inconsistency with both Articles 5.1 and 5.7. Final Panel Report para. 7.3000. One commentator has suggested that the misapplication of the burden of proof should provide a ground of appeal, insofar as the EC appears to have been required to show that there was insufficient scientific evidence. Alice Palmer, note 22, page 12.

94 Final Panel Report para. 7.2993.

95 Final Panel Report para. 7.2997.

Relevant scientific evidence is "insufficient" within the meaning of the first sentence of Article 5.7 if it does not allow the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A(4).[96]

The Panel therefore said the critical legal issue is whether the relevant safeguard measures meet the requirements set out in the text of Article 5.1, not whether they are consistent with Article 5.7.[97] The Panel said the approach is to see if the measure meets the requirements in Article 5.7, then if not, to examine whether this measure is consistent with the requirements of Article 5.7.

A risk assessment is described in Annex A(4):

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

An SPS measure may be based on a risk assessment conducted by another Member, or an international organization; it need not be undertaken by the Member concerned.[99] In this case, the risk assessments had been carried out by the lead Competent Authority (CA)[100] and the EC Scientific Committee.[101] The measure must be 'based on'[102] the risk assessment, in the sense of there being a rational relationship between a risk assessment and the measure taken,[103] and measures must be based on an assessment of risks which is 'appropriate to the circumstances'[104] existing at that time.[105] A corollary of this is that a change in relevant circumstances could in some cases render a completed risk assessment no longer 'appropriate to the circumstances'.

The Panel assessed the documents advanced by the EC[107] and concluded that none of them were 'risk assessments' within the meaning of Annex A(4), for instance because they did not assess the likelihood of risks.[108]

The Panel then went on to examine whether the safeguard measures were consistent with Article 5.7. The Panel said that Article 5.7 reflects the precautionary principle, and that the precautionary principle as such has not been written into the SPS Agreement as a ground for justifying an SPS measure that

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96 Final Panel Report para. 7.2994.

97 Final Panel Report para. 7.3006

98 Final Panel Report para. 7.3007.

99 Final Panel Report para. 7.3024.

100 Articles 5 and 11 of Directive 90/220 and Articles 6 and 13 of Directive 2001/18.

101 Final Panel Report para. 7.3027.

102 SPS Article 5.1.

103 Final Panel Report para. 7.3028. The results of the risk assessment must "sufficiently warrant" or "reasonably support" the SPS measure at issue: EC Measures Concerning Meat and Meat Products (Hormones), WT/D526/AB/R, WT/D548/AB/R, adopted 13 February 1998, DSR 1998:1, 135 ('Appellate Body Report, EC-Hormones'), paras. 193-194.

104 SPS Article 5.1.

105 Final Panel Report para. 7.3028.

106 Final Panel Report para. 7.3031.

107 E.g. Final Panel Report para. 7.3086, finding that Austria's safeguard measure on Bt-176 maize cannot be considered to be "based on" the risk assessments performed by the lead CA or the risk assessments, which were conducted by the SCPE, the SCAN or the SCF in relation to Bt-176 maize.

108 See Final Panel Report paras. 7.3078 et seq.

is otherwise inconsistent with that Agreement.[109] The Panel assessed the measures against the four requirements of Article 5.7. The Panel found that they failed the first test being that the measure is imposed in respect of a situation where "relevant scientific evidence is insufficient". The Panel disagreed with the EU's argument that the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member.[110] In the case of the Austrian T25 maize safeguard, the SCP[111] had carried out risk assessments and later concluded that information provided by Austria did not constitute new scientific information, which could change its risk assessment, and effectively confirmed its risk assessment.[112]

7.1518 We note in this regard that if relevant scientific evidence were insufficient to perform a risk assessment as defined in Annex A(1) of the SPS Agreement and as required by Article 5.1 of the SPS Agreement, pursuant to Article 5.7 of the SPS Agreement, a Member may provisionally adopt an SPS measure on the basis of available pertinent information. Contrariwise, in situations where relevant scientific evidence is sufficient to perform a risk assessment, a Member must base its SPS measure on a risk assessment. Of course, the mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (e.g., uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken. In view of these uncertainties, a given risk assessment may well support a range of possible measures. Within this range, a Member is at liberty to choose the one which provides the best protection of human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonably supported by the risk assessment and not inconsistent with other applicable provisions of the SPS Agreement, such as Article 5.6.

In essence, since the relevant EC scientific committee had reviewed the arguments and the evidence submitted by the Member State to justify the prohibitions, and did not consider that such information called into question its earlier conclusions, it considered that sufficient scientific evidence was available to permit a risk assessment as required by the SPS Agreement.[113] However, as one commentator has observed, these risk assessments failed to assess the full range of risks, in light of inadequacies identified by Member States.[114]

The Panel also considered whether any risk assessment had been provided by the relevant member States, which would reasonably support the prohibition of the biotech products at issue. Although some of the member States did provide scientific studies, in no case did they provide an assessment of the risks to human health and/or the environment meeting the requirements of the SPS Agreement.[115]

For each of the products affected by a national safeguard measure, the EC had given its EC-wide approval based on an evaluation of the potential risks to human health and/or the environment that all Parties agreed was a risk assessment under the SPS Agreement.[116] The relevant EC scientific committee subsequently also reviewed the arguments and the evidence submitted by the member State to justify the prohibition, and did not consider that such information called into question its earlier conclusions.

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109 Final Panel Report para. 7.3220, citing Appellate Body Report, EC — Hormones, para. 124.

110 Final Panel Report para. 7.3246.

111 Scientific Committee for Plants, later replaced by the scientific panel on genetically modified organisms established by the European Food Safety Authority (the "EFSA"), which was created pursuant to Regulation 178/2002.

112 Final Panel Report para. 7.3259.

113 Final Panel Report para. 8.9.

114 See Alice Palmer, note 22, page 8.

115 Final Panel Report para. 8.10.

116 Conclusions and Recommendations, para. 8.9.

Sufficient scientific evidence was available to permit a risk assessment as required by the SPS Agreement, and thus no recourse may be had to Article 5.7. The risk assessments undertaken by the EC scientific committees could not provide reasonable support for a prohibition of the biotech products at issue.[117]

The Panel found that none of the member States provided an assessment of the risks to human health and/or the environment meeting the requirements of the SPS Agreement.[118] Therefore the Panel has concluded that each of the safeguard measures taken by the relevant member States failed to meet the obligations of the European Communities under the SPS Agreement.

The Panel said that new scientific information[119] made available since the date of the consent and affecting the environmental risk assessment is not enough to satisfy SPS requirements.[120] The Panel required that the EC level assessment must contain a divergent view[121] to justify an EC Member States' provisional restriction or prohibition of the use and/or sale of the relevant biotech product.

"Where a given risk assessment sets out a divergent opinion and this opinion comes from qualified and respected sources, it can be reasonably said that an SPS measure which reflects the divergent opinion is "based on" the risk assessment in question inasmuch as the divergent opinion is expressed in that risk assessment."[122]

The implications for the application of the precautionary principle are at best confused. The Panel said that the fact that a Member has decided to follow a precautionary approach could have a bearing on a panel's assessment of whether an SPS measure is "based on" a risk assessment as required by Article 5.1.[123] If there are factors, which affect scientists' level of confidence in a risk assessment they have carried out, a Member may take this into account in determining the measure to be applied for achieving its appropriate level of protection from risks.[124] However, there is a 'but': "even if a Member follows a precautionary approach, its SPS measures need to be "based on" (i.e., "sufficiently warranted" or "reasonably supported" by) a risk assessment."[125]

In saying so, the Panel has permitted the precautionary principle under Article 5.1 to be a factor in risk management. Some policy managers may find this at best confusing: there needs to be sufficient scientific information to found an SPS-compliant risk assessment, but there may be sufficient uncertainty about that scientific information to allow application of an SPS measure taking the precautionary principle into account.

The Appellate Body has already said that Article 5.7 reflects the precautionary principle.[126] Yet the approach of the Panel all but ignored the relevance of the precautionary principle and held that scientific evidence is 'insufficient' within the meaning of the first sentence of Article 5.1 only if it does not allow the performance of an SPS-compliant assessment of risks.[127] So the test is not whether scientific information is insufficiently reliable to permit an adequate assessment of risks, but whether it permits an assessment at all. A consequence of this, *if it stands on any appeal*, as the Centre for International Environmental Law (CIEL) analysis has noted, is that "Members would be forced to make decisions on the basis of information that cannot ascertain the risks to human, animal, or plant life or health in a manner adequate to the level of protection they have chosen."[128]

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117 Final Panel Report Conclusions and Recommendations para. 8.10.

118 Final Panel Report Conclusions and Recommendations para. 8.10.

119 Article 23 of Directive 2001.

120 Final Panel Report para. 7.3061.

121 The Panel used the term"divergent opinion" or "divergent assessment" to refer to an opinion or assessment which argues for, and supports, a significantly different overall conclusion. See Final Panel Report, Note 1897.

122 Final Panel Report para. 7.3060.

123 Final Panel Report para. 7.3065.

124 Final Panel Report para. 7.3065.

125 Final Panel Report para. 7.3065.

126 Appellate Body Report, EC-Hormones, para. 124, and see Japan — Agricultural Products II, para. 81.

127 See Final Panel Report, para. 7.2995.

128 *CIEL Overview and Analysis of the Panel's Interim Repor*t, page 43.

129 Final Panel Report, para. 1852. See discussion on page 20.

This also effectively robs Article 5.7 of its reflection of the precautionary principle, and indeed of much of its meaning. Its very nature is that it is provisional, and therefore it is appropriate that in case of scientific uncertainty, that the precautionary principle can be invoked in the sense that provisional measures can be implemented under Article 5.7 until a risk assessment can be carried out. But the approach taken by the Panel means that if a risk assessment can be carried out according to the criteria in the Panel report, then Article 5.7 has no application, and risk managers cannot act in the common-sense situation where scientific information is insufficiently reliable to permit an adequate assessment of risks and so base provisional measures based on Article 5.7. Instead, measures must be based on a risk assessment and must be permanent.

The failure of the Panel to appreciate the role and status of the precautionary principle is seen too in its observation that if new scientific evidence comes to light which conflicts with available scientific evidence it might provide a justification to suspend all final approvals pending an appropriate assessment of the new evidence.[129] On that basis, new scientific evidence may even justify a moratorium on approvals, yet the precautionary principle would not.

The implications of the ruling for developing and Central and Eastern European countries which are currently developing restrictions on genetically engineered crops

The ruling, *if upheld on any appeal*, will in legal terms have a dampening effect on countries which want to control genetically engineered crops, as it creates further requirements that countries must follow in order to ban or restrict those crops. An emphasis on labelling aimed at consumer preference will assist in directing any WTO complaints towards the TBT rather than the SPS Agreement, though such a programme would, on the basis of the Panel report, need to avoid any link to human health in its expressed objectives.[130] The recent Polish ban on the sale and registration, but not planting, of GE seeds[131] relied on[132] Article 16(2)(b) of EU Directive 2002/53/EC, which allows prohibition of planting, upon application to the Commission, where the variety is not suitable for cultivation in any part of its territory because of its type of maturity class.[133] This ban is therefore not directly affected. It is important to stress, moreover, that restricting and banning genetically engineered crops remains decidedly possible. Greenpeace expects more restrictions and bans to be imposed as more farmers, consumers and governments reject genetic engineering.

130 See discussion on page 190.

131 Polish GM bill 'violates EU regulations', 4 May 2006, at http://www.cee-foodindustry.com/news/ng.asp?n=67435-gm-polish-crops.

132 EU backs Poland's GM crop ban, 10 May 2006, at http://www.cee-foodindustry.com/news/ng.asp?n=67593-gm-commission-poland.

133 See report at http://www.genet-info.org/genet/2006/May/msg00030.html.

4. The panel's interpretation of the notion of risk assessment and consequences of that interpretation

The Panel focused on risk assessment almost at the exclusion of risk management.[134] The EC brought the distinction to the attention of the Panel, saying that risk assessment is the task of the scientific committees, while risk management is the function of the Regulatory Committee.[135] Risk management[136] issues are broader than risk assessment issues. The Panel did say that the pursuit of a risk management objective would not justify a delay in the completion of an approval procedure and hence would be inconsistent with Annex C(1)(a).[137] But other than saying that procedural delay could not be used in managing risks, the Panel did not address risk management in any meaningful way. This is not surprising, since the Appellate Body in the Beef Hormones case rejected a distinction under the SPS between risk assessment and risk management.[138]

The Panel observed that an assessment of risk is, at least with respect to risks to human life and health, a "scientific" examination of data and factual studies; it is not, in the view of the Panel, a "policy" exercise involving social value judgments made by political bodies. The Panel describes the latter as "non-scientific" and as pertaining to "risk management" rather than to "risk assessment". We must stress, in this connection, that Article 5 and Annex A of the SPS Agreement speak of "risk assessment" only and that the term "risk management" is not to be found either in Article 5 or in any other provision of the SPS Agreement. Thus, the Panel's distinction, which it apparently employs to achieve or support what appears to be a restrictive notion of risk assessment, has no textual basis. The fundamental rule of treaty interpretation requires a treaty interpreter to read and interpret the words actually used by the agreement under examination, and not words, which the interpreter may feel should have been used.

However, the Appellate Body did instead espouse a broad concept of risk assessment:

It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.[139]

However, even such a broad understanding of risk assessment does not answer the question: how does a Member manage the potential for adverse effects? SPS Article 3.3 allows Members to introduce or

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134 For a discussion of risk management and risk assessment in the SPS, see David G. Victor, "The Sanitary and Phytosanitary Agreement of the World Trade Organization: An Assessment after Five Years," *New York Journal of International Law and Politics* 32(4), 865-937, (2000).

135 Final Panel Report Para 7.1052.

136 A definition of risk management is "the process of identifying, evaluating, selecting and implementing actions to reduce risk to human health and to ecosystems," The Presidential/Congressional Commission and Risk Management, (1997) at http://www.riskworld.com/nreports/1997/risk-rpt/html/epajan1.htm.

137 Final Panel Report Para 7.1517.

138 Appellate Body Report, EC-Hormones, para 181. See Walker, "Keeping the WTO from becoming the 'World Trans-science Organisation': Scientific Uncertainty, Science Policy and Factfinding in the Growth Hormones Dispute," (1998) 31 *Cornell ILJ* 251, 255-272, 303-304.

139 Appellate Body Report, EC-Hormones, para. 187.

maintain sanitary or phytosanitary measures to achieve a level of sanitary or phytosanitary protection: risk management in any other terms. The essence of the Beef Hormones decision, being that the EU measure was not based on a risk assessment, has been widely criticized for its narrow interpretation given to 'base',[140] in the absence of other justification in the SPS agreement for such an approach.

In order to be "WTO-safe", it is thus critical for member States to firstly conduct WTO-compliant risk assessments, or properly to invoke Article 5.7 according to the criteria described above, and secondly to invoke SPS Article 3.3 to introduce measures to manage that risk. The right of a Member to establish its own level of sanitary protection under Article 3.3 of the SPS Agreement is an autonomous right and not an 'exception' from a 'general obligation' under Article 3.1.[141] The point made in Beef Hormones is that compliance with the risk assessment requirements in Article 5.1 is required for Article 3.1.[142] The Appellate Body said that "the concept of "risk management" is not mentioned in any provision of the SPS Agreement and, as such, cannot be used to sustain a more restrictive interpretation of "risk assessment" than is justified by the actual terms of Article 5.2, Article 8 and Annex C of the SPS Agreement."[143] Nevertheless, once compliance with Article 5.1 is achieved, Articles 3.1 and 3.3 provide an important tool for risk management. If risk management is not mentioned as such in the SPS then it is not prohibited by the SPS. However, the conservative view may be that in exercising risk management, Member States should comply with Articles 5.1, 5.7, 3.1 and 3.3 of the SPS.

The Panel did acknowledge that a given risk assessment may well support a range of possible measures, and a Member can choose the measure which provides the best protection of human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonably supported by the risk assessment and not inconsistent with other applicable provisions of the SPS Agreement, such as Article 5.6.[144] In doing so, it implicitly accepted a certain freedom to exercise risk management within the SPS, but this freedom is heavily dependent on the risk assessment, and due to the lack of specific reference to risk management in the SPS Agreement and the consequent rejection in Beef Hormones of a distinction in the SPS between risk management and risk assessment, meaningful and practical guidance on risk management is unlikely to be forthcoming within the SPS framework.

Implications of Delay of Approval

The Panel found that the European Communities applied a general de facto moratorium on approvals of biotech products between June 1999 and 29 August 2003 but that the moratorium was not itself an SPS measure within the meaning of the SPS Agreement. However, it affected the operation and application of the EC approval procedures, which the Panel found to be SPS measures. This resulted in a failure to complete individual approval procedures without 'undue delay,' and hence gave rise to an inconsistency with Article 8 and Annex C of the SPS Agreement.[145] The Panel found undue delay in the completion of the approval procedure with respect to 24 of the 27 products awaiting approval.[146] However, the Panel noted that

7.1852 Before undertaking this task, we wish to note that our conclusion above should not be construed to mean that it would under no circumstances be justifiable, in the light of the provisions of Annex

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140 SPS Agreement Article 5.1 and 3.1.

141 Final Panel Report para. 7.2965, Appellate Body Report, EC — *Hormones*, para. 172.

142 See EC – *Hormones*, para. 177.

143 *EC – Hormones*, para. 206.

144 Final Panel Report para. 7.1525.

145 Final Panel report para.8.6.

146 Final Panel Report para. 8.7. See Final Panel Report para 7.1567, 7.1570. Article 8 requires Members to observe the provisions of Annex C.

C(1)(a), first clause, to delay the completion of approval procedures by imposing a general moratorium on final approvals of biotech products. We consider that there may conceivably be circumstances where this could be justifiable. For instance, if new scientific evidence comes to light which conflicts with available scientific evidence and which is directly relevant to all biotech products subject to a pre-marketing approval requirement, we think that it might, depending on the circumstances, be justifiable to suspend all final approvals pending an appropriate assessment of the new evidence. The resulting delay in the completion of approval procedures might then be considered not "undue".

While encouraging in situations where new scientific evidence comes to light, the Panel's decision leaves great uncertainty as to what scientific evidence would qualify as justifying delay, and moreover, this approach ignores the precautionary principle. As has been noted by one observer,[147] what constitutes 'undue' delay should have been informed by practice under the Biosafety Protocol, which is specifically concerned with approval procedures.

The EU had approved one of the GM foods in question during the panel proceedings, Bt-11 sweet corn, thus ending the moratorium.[148] The Panel reversed its interim report decision not to make any recommendation on the general moratorium because approval by the EC of a 'relevant biotech product' in 2004 ended the moratorium,[149] and recommended that the Dispute Settlement Body request the EC to bring the general de facto moratorium on approvals into conformity with its obligations under the SPS Agreement, if, and to the extent that, that measure has not already ceased to exist.[150]

The Panel recommended that the Dispute Settlement Body (DSB) request the EC to bring the four product-specific measures challenged by Canada[151] into conformity with its obligations under the SPS Agreement.[152]

Scope of the SPS Agreement

The Panel took a very broad view of the scope of the SPS Agreement with regard to the four categories in Annex A(1)(a)-(d), both with respect to measures with respect to genetically engineered organisms and with respect to labelling. Since much labelling is intended to inform the consumer or allow the consumer to make a choice, it is not desirable or appropriate that it falls to be analysed under the SPS Agreement.

The TBT Agreement does not apply to SPS measures.[153] The purpose of the measure defines the scope of application of the SPS Agreement. SPS measures are defined in Annex A, which distinguishes four types of SPS measures according to their purpose. It defines SPS measures as -

Any measure applied:

(a) to *protect animal or plant life or health* within the territory of the Member from risks arising from the *entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms*;

(b) to *protect human or animal life or health* within the territory of the Member from risks arising from *additives, contaminants, toxins or disease-causing organisms* in foods, beverages or feedstuffs;

(c) to *protect human life or health* within the territory of the Member from risks arising from *diseases carried by animals, plants or products thereof*, or from the *entry, establishment or spread of pests*; or

147 Alice Palmer, note 22, page 6.

148 Final Panel Report, paras. 4.396, 7.506.

149 Panel Report 8.16 (US) and 8.36 (Canada) and Final Panel report para. 8.16 and 8.36.

150 Panel Report 8.16, 8.36.

151 M58/RF3 oilseed rape, RR oilseed rape (EC-70), MS1/RF1 oilseed rape (EC-89), and MS 1/RF2 oilseed rape.

152 Final Panel Report para. 8.40.

153 TBT Agreement, Article 1(4).

(d) to *prevent or limit other damage* within the territory of the Member from the *entry, establishment or spread of pests*.

The Panel analyzed the risks that Directives 90/220 and 2001/18 seek to avoid, and found that they are all risks covered by one or more of the sub-paragraphs of Annex A(1).

Annex A(1)(a):[154] .the Panel found that a considerable number of adverse effects identified in Annex II.C.2.1 of Directive 2001/18 fell within Annex A(1)(a)[155] as measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms.

Annex A(1)(b):[156] The Panel found[157] that genetically engineered organisms can be 'additives',[158] as substances[159] intentionally added at the stage of seed development and production can be considered to be added in the manufacture of the food plant.[160] The Panel then said that it considered genetically engineered organisms can be a 'contaminant', when they are proteins unintentionally produced in genetically engineered plants which are eaten or used in the production of food or feedstuffs,[161] and that the term could encompass herbicide residues present in foods or feedstuffs.[162]

With respect to 'toxins', the Panel found that a poisonous substance, which is produced during the metabolism or growth of a gene crop could qualify as a toxin,[163] and a genetically engineered plant, which is grown in a field may be eaten as food by wild fauna.[164] While the SPS has no specific reference to 'allergens', the Panel found that the Directives can in our view, be considered as measures applied to protect human or animal life or health from risks arising from toxins produced in GM plants which are foods or feedstuffs.[165]

The Panel did not decide whether allergens which could be in GE organisms could be considered 'disease-causing organisms', since it had already found that they were toxins and additives.[166] The Panel concluded that potential adverse effects of genetically engineered organisms addressed by Annex II[167] and Annex D.2[168] of Directive 2001/18 fell within Annex A(1)(b) of the SPS Agreement.

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154 Annex A(1)(b) includes measures "to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms."

155 See list in para. 7.285.

156 Annex A(1)(b) includes measures "to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs."

157 Final Panel Report para. 7.301.

158 In terms of Annex A(1)(b).

159 A gene was considered a 'substance', which the Panel defined as defined as the "real physical matter of which a person or thing consists". Panel Report 7.298, citing the Concise Oxford Dictionary.

160 Final Panel Report 7.299, applying the Codex definition of 'additive' in the Codex Procedural Manual 14th edition (Reference A), p. 43.

161 Final Panel Report para. 7.416.

162 Final Panel Report para. 7.417.

163 Final Panel Report para. 7.323.

164 Final Panel Report para. 7.323.

165 Final Panel Report para. 7.340.

166 Final Panel Report para. 7.342.

167 Of the of the potential adverse effects of GMOs identified in Annex II of Directive 2001/18, the following fell within the scope of Annex A(1)(b) of the SPS Agreement:
— "disease to humans including allergenic or toxic effects"
— "altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors"
— "compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine".

168 Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GE organism and any products derived from it, if it is intended to be used as animal feed. Final Panel Report para. 7.344.

Annex A(1)(c):[169] The Panel discussed potential allergenicity of genetically engineered (GE) organisms and GE-induced increased use of pesticides under this heading. The Panel found that if interaction with, and exposure to, GE organisms other than as or in a food produced allergenic effects in persons, the GE organisms in question could be viewed as "pests" within the meaning of Annex A(1).[170] So even harvested plants could continue to be 'pests' even after they were no longer living.[171]

The panel found that to the extent that Directives 90/220 and 2001/18 seek to avoid adverse effects on human health which arise from changes in management practices associated with the introduction into the environment of GE organisms, the Directives can be viewed as measures applied to protect human life or health from risks arising indirectly from the entry, establishment or spread of weeds qua "pests.[172] So 'disease to humans including allergenic or toxic effects' within Annex II of Directive 2001/18 fell within the scope of Annex A(1)(c) of the SPS Agreement.[173]

Annex A(1)(d):[174] Finally, the Panel assessed whether potential effects of GE organisms could be said to give rise to 'other damage', which must be damage other than damage to the life or health of plants, animals or humans.[175] It could include economic damage and[176] damage to biodiversity.[177] To the extent that Directives 90/220 and 2001/18 seek to avoid adverse effects arising from management techniques associated with GE organisms other than damage to the life or health of non-target organisms, the Directives can be considered as measures applied to prevent or limit "other damage" resulting indirectly from the entry, establishment or spread of weeds qua "pests".[178] So 'effects on the dynamics of populations of species in the receiving environment' and 'effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material' fell within the scope of Annex A(1)(d).

In conclusion, the Panel took a very broad view of the scope of the Annex A(1) of the SPS Agreement. This is likely to lead to uncertainty as to the applicability of the TBT and SPS agreements.[180] Another consequence of this is likely to be to increase the emphasis on the SPS rather than the TBT agreement. This has implications for developing States, in that GE organisms exporting States can pressure the importing States to approve GE organism imports by insisting that they are subject to SPS rather than TBT requirements, which are additionally burdensome, particularly in the light of this Panel report.[181] This broad approach is particularly evident in the discussion on labelling, which follows.

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169 Annex A(1)(c) includes measures "to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests."

170 Final Panel Report para. 7.350.

171 Final Panel Report para. 7.350.

172 Final Panel Report para. 7.360.

173 Also, within Annex D.2 of Directive 2001/18 with respect to genetically modified higher plants (GMHP), 'possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMPHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s)' fell within Annex A(1)(c).

174 Annex A(1)(d) includes measures applied "to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests."

175 Final Panel Report para. 7.369.

176 Final Panel Report para. 7.370.

177 Final Panel Report para. 7.372.

178 Final Panel Report para. 7.378.

179 Final Panel Report para. 7.379. Annex II of Directive 2001/18. Similarly, Annex D.2 concerns with respect to GMHPs could fall within Annex A(1)(d). Para 7.380.

180 So much so that one observer said that its expansive reading of the SPS purposes threatens to make TBT Agreement redundant. Alice Palmer, note 22, page 7.

181 Alice Palmer, note 22above, observed that the United States has suggested that India's GMO regulations be notified to the SPS Committee, as well as the TBT Committee. See minutes of the meeting of the Committee on Technical Barriers to Trade, of 7-9 June 2006, G/TBT/M/39, 31 July 2006, para 9, commenting on G/TBT/N/IND/12 and G/TBT/N/IND/17.

Labelling

The Panel found the SPS Agreement can apply to labelling measures under dispute. The Panel found that there is a rational relationship between the labelling requirement in Directive 2001/18 and the purpose of protecting human health and the environment.[182] So labelling requirements imposed for the purpose of protecting plant, animal or human health from the risks covered in Annex A(1)(a) and (c), or for the purpose of preventing or limiting other damage from the risk covered in Annex A(1)(d), would likewise be subject to the disciplines of the SPS Agreement.[183]

The Panel said that a purpose in Regulation 258/97 is to avoid that foods containing or consisting of GE organisms "mislead the consumer".[184] At first sight this is a TBT purpose. However, the Panel decided that they were "labelling requirements directly related to food safety" under para. 1 of Annex A, since they applied to protect human health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods under para (b).[185] The Panel did not analyse whether the labelling requirements were 'directly' related to food safety. The Panel analysed the requirements in Regulation 258/97[186] including labelling to inform the consumer of 'the presence of an organism genetically modified by techniques of genetic modification', and found that Regulation 258/97 is to ensure that those consumers who have a preference for food not containing or consisting of GE organisms are not misled into purchasing food containing or consisting of GE organisms.[187] To the extent that to the Regulation 258/97 is applied to ensure that novel foods not mislead the consumer, it does not constitute a measure applied to protect the life or health of consumers from risks arising from, e.g., additives or contaminants in foods and falls outside the scope of Annex A(1).[188] Nor is the purpose to ensure that foods are not 'nutritionally disadvantageous' within Annex A.[189]

The Panel considered that labelling requirements related to food safety are labelling requirements which are applied to protect human health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods.[190] The first purpose of Regulation 258/97, ensuring that novel foods not present a danger for the consumer, is on this analysis a measure which is applied for the purpose identified in Annex A(1)(b) and therefore meets the purpose requirements for an SPS measure.[191] The Panel did say that to the extent a labelling measure aims at other purposes, such as to ensure either that novel foods not mislead the consumer or that they not be nutritionally disadvantageous for the consumer,[192] it is not an SPS measure to the extent that it is applied for those purposes,[193] this is meaningless if the measure as a whole is considered under the SPS Agreement.

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182 Final Report para.7.389. Identification of the presence of a GMO may result in consent holders and competent authorities being better informed, than they otherwise would be of unanticipated risks of a GMO to human health and the environment, allowing them to determine whether additional measures are necessary to protect human health and the environment. Para. 7.387. Note that the Final Panel Report varied from the Interim Report on labelling, after para. 7.385.

183 Final Panel Report para. 7.390.

184 Final Panel Report para. 7.408.

185 Final Panel Report para. 7.410.

186 Final Panel Report para. 7.411.

187 Final Panel Report para. 7.411.

188 Final Panel Report para. 7.412.

189 Final Panel Report para. 7.414.

190 Final Panel Report para. 7.410.

191 Final Panel Report para. 7.415.

192 Final Panel Report para. 7.416, 7.727, 7.732, 7.734.

193 Final Panel Report para. 7.736.

If this decision stands, labelling requirements which are not completely unrelated to human health may fall within the SPS Agreement, even if their primary purpose is consumer information and includes interests wider than human health. So even if only one purpose is related to human health – such as ensuring that novel foods not present a danger for the consumer – it could fall under the SPS Agreement, on the test applied by the Panel.[194] An appeal is likely to focus on the failure of the Panel to analyse whether the labelling requirements were 'directly related' to food safety, rather than merely 'related to food safety'.[195]

So it can be seen that the Panel took a broad view of the applicability of the SPS Agreement. If the broad scope of the SPS Agreement is upheld – such as the finding that harvested plants are, and could continue to be 'pests', even after they were no longer living - then the SPS may be far more applicable than was previously thought. No further light was shed on the relevance of the TBT Agreement, as the Panel found that it did not need to make findings on whether the product specific measures challenged by Canada and Argentina breached the TBT Agreement.[196]

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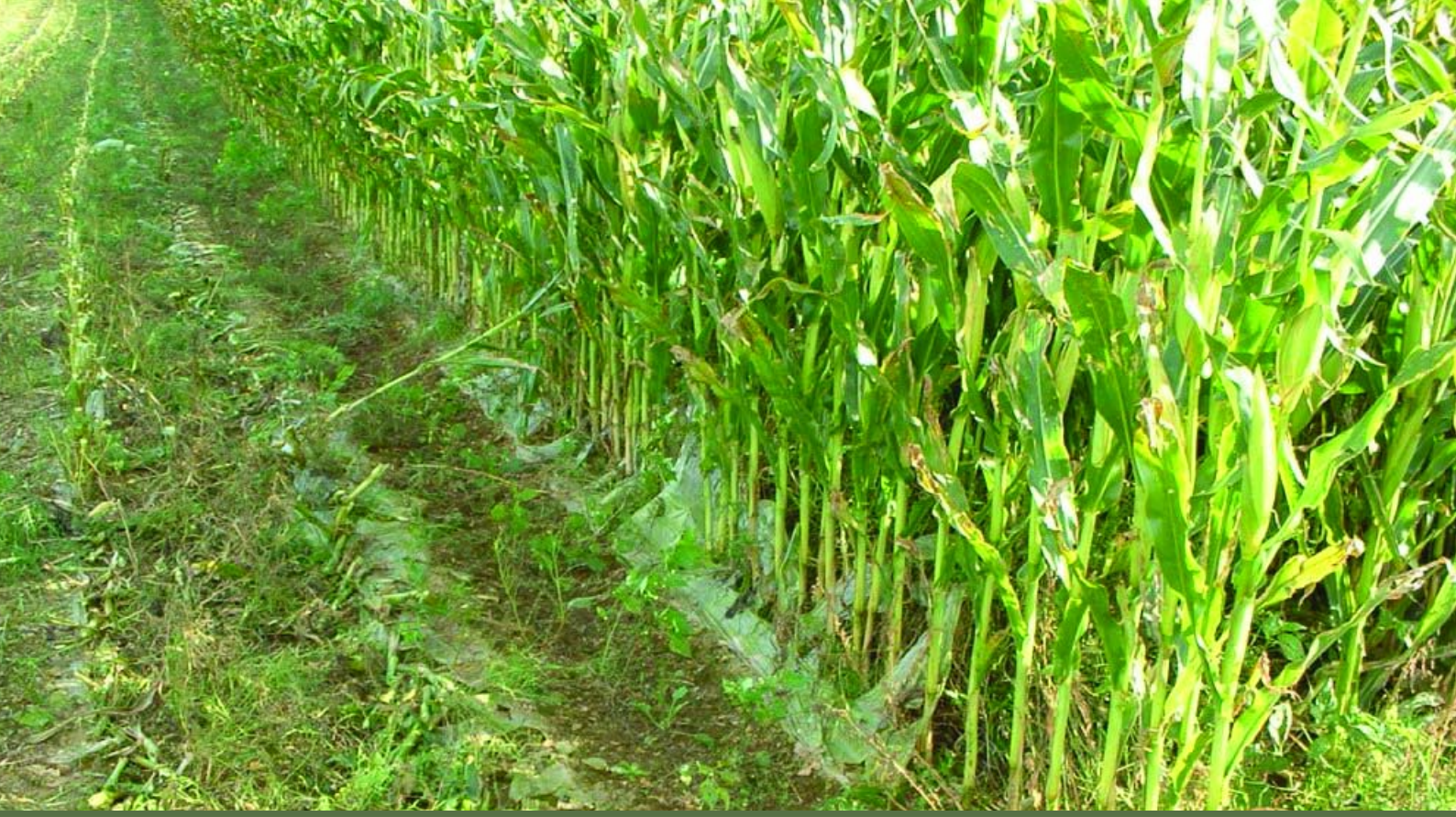
194 Final Panel Report para. 7.415, 7.756.

195 Final Panel Report, para. 7.410.

196 Final Panel Report para. 7.2527, 7.3412, 7.3413. Canada had challenged the measures under Arts 2.1, 2.2 and 2.9 of the TBT Agreement.



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