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The Transatlantic GMO Dispute Against the European Communities

Some Preliminary Thoughts

David A. Wirth[1]

I. Introduction

On 13 May 2003 the United States requested consultations with the European Communities (EC) under the auspices of the World Trade Organization (WTO) concerning "a moratorium on the approval of biotech products."[2] Canada and Argentina also made similar requests. On 4 March 2004 the Director-General of the WTO established a three-member panel to consider the three disputes simultaneously. This initiation of a formal dispute settlement proceeding in the WTO was the latest step in a long-standing political and legal controversy concerning the approval of genetically-engineered plants and foodstuffs by the EC and access to European markets by overseas firms.

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2. Letter from Linnet F. Deily, Permanent Representative of the United States to the World Trade Organization, to Carlo Trojan, Permanent Representative of the European Commission to the World Trade Organization, 13 May 2003.

To date,[3] the United States has filed its initial substantive submission to the panel,[4] the EC has also made a first submission,[5] and the United States has presented a rebuttal submission.[6] Canada's initial submission is also publicly available.[7] In the meantime, the panel has taken a decision to consult with technical experts and all four parties have requested additional time to develop their submissions to the panel. Consequently, the panel's report is currently expected to be produced at the earliest in the summer of 2005.

This analysis attempts to identify the likely legal issues in the dispute as they have evolved to date. Because the dispute is ongoing as of this writing, any commentary at the present moment must necessarily be preliminary and inevitably will involve an element of conjecture. The overall outlines of the dispute and the likely contours of the issues to be raised have, however, been the subject of considerable public debate. Accordingly, based on the information presently available this paper (1) describes the EC's regulatory programs addressing genetically modified organisms (GMOs); (2) sets out the international legal requirements governing GMOs; (3) identifies the principal legal bases that the complaining parties have or might have asserted; (4) assesses the relevant precedents in WTO law; and (5) evaluates the likely outcomes and the long-term implications of this dispute.

3. The manuscript of this article was completed on 24 November 2004.
4. *European Communities — Measures Affecting the Approval and Marketing of Biotech Products* (WT/DS291, 292, & 293): First Submission of the United States (April 21, 2004) http://www.ustr.gov/assets/Trade_Agreements/Monitoring_Enforcement/Dispute_Settlement/ WTO/Dispute_Settlement_Listings/asset_upload_file720_5542.pdf
5. *European Communities — Measures Affecting the Approval and Marketing of Biotech Products* (DS291, DS292, DS293): First Written Submission by the European Communities (May 17, 2004) http://www.trade-environment.org/output/theme/tewto/EC_submission_biotech.pdf
6. *European Communities — Measures Affecting the Approval and Marketing of Biotech Products* (WT/DS291, 292, & 293): Rebuttal Submission of the United States (July 19, 2004) http://www.ustr.gov/assets/Trade_Agreements/Monitoring_Enforcement/Dispute_Settlement/WTO/Dispute_Settlement_Listings/asset_upload_file909_5542.pdf
7. *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (WT/DS292) (April 21, 2004) http://www.genewatch.org/WTO/Submissions/Canada_WTO_Submission.pdf.

II. Regulation of GMOs in the European Communities

Since October 2002 the principal vehicle for addressing GMOs in the EC has been Directive 2001/18,[8] governing the deliberate release into the environment of genetically modified organisms. Directive 2001/18 replaces Directive 90/220,[9] which was similar in many respects. Directive 2001/18 mandates a prior, affirmative regulatory approval on a case-by-case basis before a genetically modified organism may be released into the environment or placed on the market. After approval, the GM product may be sold in any of the EC's 25 Member States.

The approval process is initiated when the manufacturer or importer submits a "notification" or application to the competent authority of the EC Member State where a GMO is to be marketed for the first time. The notification must provide general information on the nature of the GMOs, the conditions of their release, and a full risk assessment of the possible hazards for human health and the environment. The competent authority of the Member State concerned, after evaluating the notification, may approve the application if the competent authority is satisfied that the release is safe for human health and the environment. Alternatively, the competent authority may request additional information, may attach conditions to the release, or may disapprove the notification.

In cases in which the Member State proposes to provide written consent to the release, the competent authority must forward a dossier supporting the Member State's decision to the European Commission. The Commission then forwards the dossier to the other Member States. If another Member State raises an objection to the release that could not be resolved with the Member State that received the notification, then the Commission must make a determination. The Commission first requests the opinion of its Scientific Committees, composed of independent experts in medicine, nutrition, toxicology, biology, chemistry or other relevant disciplines.[10] If the scientific opinion is favorable, the Commission proposes a

8. OJ 2001, L106/1.
9. OJ 1990, L 117/15, as amended by Directive 94/15, OJ 1994, L 103/20, and Directive 97/35, OJ 1997, L 169/72.
10. Directive 2001/18, in contrast to its predecessor Directive 90/220, specifies that consultation with the relevant Scientific Committee or Committees is obligatory. The standard to be applied by the Scientific Committees in reviewing notifications is less than clear, with the most illuminating insight provided by Article 16, paragraph 2, which directs the Scientific Committees to establish criteria and information requirements for approved GMOs sufficient "to ensure a high level of safety to human health and the environment."

decision to a Regulatory Committee composed of representatives of the Member States acting by weighted majority voting. If the committee's opinion is favorable, the Commission's proposal is adopted.

If the Regulatory Committee rejects the Commission's proposal, that proposal then goes to the Council for consideration by qualified majority voting. If the Council fails to act within 3 months, the Commission may adopt its proposal. After the receipt of written consent, all Member States are obliged to take measures to assure compliance with any conditions imposed on the release. A final approval must also establish labeling requirements, which at a minimum include an indication that the product contains genetically modified organisms.

Prior to the mid-1990s, 18 products were granted final consent under Directive 90/220. In response to public concerns, since October 1998 five or six EC Member States, including Denmark, France, Greece, Italy, and Luxembourg, are alleged to have blocked further approvals under Directive 90/220 and its successor instrument, Directive 2001/18. The United States' request for consultations identified more than 20 notifications for products that had not been acted upon and are currently said to be pending, some dating from as long ago as 1996. Some of these have been resubmitted under Directive 2001/18.

Under Article 16 of Directive 90/220, the so-called "safeguard clause," even after written consent had been given pursuant to this process, a Member State that nonetheless believes that the GMO in question may pose a risk to health or the environment could provisionally restrict or prohibit use or sale in its territory. The U.S.'s request for consultations identified 6 such actions taken by Austria, France, Germany, Greece, Italy and Luxembourg. These cases were examined by the Scientific Committee on Plants, which concluded that the information submitted by the Member States in question did not justify the bans. Consequently, the Commission has informed these Member States that they should withdraw their bans and apply, if anything, the new safeguard clause of Directive 2001/18.

Effective 18 April 2004, a new instrument, Regulation 1830/2003,[11] complemented Directive 2001/18 to provide for the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, along with Reg-

11. OJ 2003, L 264/24.

ulation 1829/2003[12] on genetically modified food and feed. Together these instruments set up a harmonized EC system to trace GMOs, to introduce the labeling of genetically modified animal feed, and to reinforce the current labeling rules, which since 1997 have required labeling for the presence of GMOs. The traceability provisions include (1) requirements for tracking from whom products are obtained and to whom products are sold; (2) a requirement for transmission of specified information on the identity of the individual GMO that a product contains in the case of GMOs intended for deliberate release into the environment; (3) a requirement for food and feed produced from GMOs that enterprises inform purchasers that the product is produced from GMOs; and (4) a requirement to retain records and produce them upon governmental request for 5 years. The new labeling requirements apply to all GM food or feed, whether or not genetically modified DNA or protein can be detected. As these two regulations took effect after the date that the United States, Canada, and Argentina initiated their requests for consultations, the new regulations are not included in the pending dispute in the WTO.

The EC's regulatory treatment of "novel" foods, which include but are not limited to GMOs, under Regulation 258/97[13] is similar. The novel foods regulation applies to food products derived from raw agricultural commodities, such as tomato paste or ketchup made from a genetically-engineered tomatoes. The U.S. request for consultations identified 11 requests which had not been approved under the novel foods regulation.

The United States[14] and Canada[15] filed their first submissions to the WTO panel on April 21, 2004. The U.S. submission is confined exclusively to arguments under the WTO Agreement on the Application of Sanitary and Phytosanitary Standards (SPS Agreement)[16] and argues that the pattern of inaction and prohibitions with respect to GMOs amounts to a "general moratorium." The submission does not challenge the EC regulatory scheme as such, but instead attacks the cumulative effect of the actions taken under it. The alleged moratorium, according to the submission, has resulted in undue delay in the approval process, violates the scientific disciplines of the SPS Agreement, results in arbitrary or unjustifiable distinctions in the EC's levels of protection against risk, arbitrarily or unjustifiably discriminates among WTO members, and is a disguised restriction

12. OJ 2003, L 268/1.
13. OJ 1997, L43/1.
14. See *supra* n. 4.
15. See *supra* n. 7.
16. http://www.wto.org/english/docs_e/legal_e/15sps_01_e.htm

on international trade. Analogous arguments are made in the case of the Member State actions under the safeguard provisions. Canada in its submission makes similar arguments to those of the United States, and in addition addresses the individual product applications, the applicability of GATT 1994, particularly Article III requiring national treatment, and the requirements of the WTO Agreement on Technical Barriers to Trade (TBT Agreement).[17]

The European Communities in their initial submission[18] emphasize the precautionary nature of their scheme requiring prior approval for GM crops and foods. The Communities also challenge the characterization of the pattern of actions under the EC legislation as a general moratorium, stressing the necessity of examining the approval process for each application individually. Relying on the text of its internal legislation, the EC argues that application of safeguard measures by Member States is provisional only and therefore governed by a provision specifying special treatment for provisional measures in the SPS Agreement. In response to the near-exclusive reliance on the SPS Agreement by the United States, the EC asserts that only a portion of its actions challenged in the dispute fall within the scope of that Agreement – namely, its actions designed to protect human, animal, or plant life or health – while the EC's actions directed at protection of the environment and biological diversity are not governed by the SPS Agreement. The EC submission also explains why, in its view, Article III of GATT 1994 does not apply and why, even it if does, the EC's actions are justified by Article XX.

III. International instruments addressing GMOs

As demonstrated by the instant dispute, the issue of biotechnology acquires an international dimension in part as a result of differences in national regulatory approaches. International responses can be considered consequences or artifacts of attempts by national governments to harmonize domestic regulatory strategies. Trade in, and market access for, genetically engineered products can then be understood as one of the principal driving forces behind much of the international debate.[19] Inter-

17. http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm.
18. See *supra* n. 5.
19. See generally S. Charnovitz, "The Supervision of Health and Biosafety Regulation by World Trade Rules", *Tulane Environmental Law Journal* 13 (2000), p. 271.

national standard-setting processes designed to overcome or harmonize national disparities address a variety of regulatory strategies for biotechnology.[20] This section addresses two such efforts, the Cartagena Protocol on Biosafety and standards adopted by the Codex Alimentarius Commission.

A. The Cartagena Protocol on Biosafety

The Biosafety Protocol[21] is a legally binding international agreement adopted in January 2000 as ancillary instrument to the 1992 United Nations Convention on Biological Diversity.[22] After entry into force in 2003, the first meeting of the conference of the parties to the Protocol was held in Kuala Lumpur, Malaysia in February 2004. The European Communities, all of its 15 pre-enlargement Member States, and most of the 10 new Member States are currently parties to the instrument. Canada and Argentina have signed but not ratified, and the United States has not signed the agreement.[23]

The principal regulatory vehicle in the Protocol is the requirement for "advanced informed agreement" (AIA). The Protocol requires as a first step in the AIA process advance notice to the state of import before the first exportation of a living modified organism (LMO). The state of import then has right to permit, deny, or impose conditions on the importation of the LMO in question, and must ensure that a risk assessment has been performed. The other principal substantive aspect of the Biosafety Protocol concerns the establishment of a Biosafety Clearinghouse designed to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms, with particular attention to the needs of developing countries.

The Protocol regulates "transboundary movement... of all living modified organisms [LMOs] that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."[24] LMOs as defined in the Protocol include those intended

20. See generally S.D. Murphy, "Biotechnology and International Law", *Harvard International Law Journal* 42 (2001), p. 47.
21. Cartagena Protocol on Biosafety, 29 Jan. 2000, *International Legal Materials* 39 (2000), p. 1027.
22. Convention on Biological Diversity, 22 May 1992, *International Legal Materials* 31 (1992), p. 822.
23. See http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt.
24. Biosafety Protocol, *supra* n. 21, Article 4.

for release into the environment, such as seeds, as well as those intended for human food or animal feed. As a general matter, the Protocol does not govern pharmaceuticals. LMOs intended for direct use as food or feed are not covered by AIA procedure. As to LMOs intended for food, feed, or processing, the Biosafety Clearinghouse must be notified within 15 days of a decision regarding domestic use, including domestic marketing with a potential for exportation.

Negotiation of the Biosafety Protocol was lengthy, complex, and acrimonious, characterized by the emergence of a number of negotiating groups: the EC, which tended to argue most strenuously for strict procedures; the so-called "Miami Group," consisting of agricultural exporting countries (Australia, United States, Canada, Argentina, Uruguay, and Chile); a "Like-Minded Group" of developing countries; a "Compromise Group" including Norway, Japan, Switzerland; and a group consisting of Central and Eastern European states. Among the more difficult aspects of the negotiations were the need for AIA itself; the desirability of special rules for LMOs intended for direct use as food, feed, or processing; standards for decision-making, including science, socio-economic considerations, and the precautionary principle; liability; and relationship to international (GATT/WTO) trade rules. Because of the difficulty of these issues, many are resolved in ambiguous manner in the text of the Protocol, or deferred for further action by the Parties to the Protocol after entry into force.[25]

B. Codex Alimentarius

The Codex Alimentarius Commission is a joint undertaking of the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The Commission, membership in which is open to all FAO and WHO member states and now numbers more than 130, is charged with two potentially competing functions: "protecting the health of consumers and ensuring fair practices in the food trade."[26] To this end, the Commission is specifically charged with adopting non-binding or advisory multilateral "good practice" standards on such matters as the composition of food products, food additives, labeling, food processing techniques, and inspection of foodstuffs and processing facilities.

25. See generally S. Safrin, "The Biosafety Protocol", *International Lawyer* 34 (2000), p. 708.
26. See Understanding the Codex Alimentarius, http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/w9114e/W9114e06.htm.

Activity in Codex on GMOs is now occurring primarily in two committees. An Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology has adopted three instruments:

- Principles for the risk analysis of foods derived from modern biotechnology;
- Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants; and
- Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms.[27]

Of these, the first – which establishes labeling and "tracing of products for the purpose of facilitating withdrawal from the market when a risk to human health has been identified or to support post-market monitoring" – is the most relevant to the present dispute. Second, the Codex Committee on Food Labeling is considering proposed draft recommendations for the labeling of foods obtained through certain techniques of genetic modification/genetic engineering.[28] The current draft of guidelines emerging from the latter group anticipates labeling of GMOs for content if they are different from naturally occurring foods, as well as for production methodology, as in "Product of Gene Technology."

The work product of the Codex Commission is textually linked to the WTO Agreement on Sanitary and Phytosanitary Standards, discussed below, which specifies that domestic measures that conform to Codex standards are presumptively valid. Otherwise, the WTO member maintaining the measure must justify its action by reference to a scientific test. Codex standards are then a "floor" from which deviation must be justified. Consequently, Codex standards, although ostensibly voluntary "good practice" guidelines, have the capacity to limit governments' regulatory options with respect to GMOs through the operation of the WTO agreements.

IV. WTO disciplines

In contrast to the Biosafety Protocol, which establishes obligations for states parties to regulate international trade in GMOs, and the Codex Alimentarius, which establishes non-binding minimum good practice standards, the World Trade Organization suite of agreements generally

27. See http://www.fao.org/es/ESN/food/risk_biotech_taskforce_en.stm.
28. See http://www.codexalimentarius.net/ccfl32/fl04_01e.htm.

contain "negative" disciplines, in the sense of constraining the capacity of WTO members to regulate in ways that would constitute barriers impeding international trade. It is these disciplines which are at issue in the transatlantic dispute over GMOs.

A. Basic nondiscrimination disciplines: GATT 1994

As a general matter, national measures directed at preservation of the environment and protection of public health are subject to the generic requirements of GATT 1994. Fundamental GATT obligations that apply in these areas, as in others, include

- the most-favored-nation (MFN) principle contained in Article I, which requires non-discrimination among imported products on the basis of their national origin;
- the national treatment discipline set out in Article III, which requires non-discrimination between foreign and domestic products; and
- a prohibition on quantitative restrictions for imports or exports articulated in Article XI.

Article XX of GATT 1994 contains a number of exemptions from the General Agreement for specific categories of national measures. Of particular importance in the fields of environment and public health are two express exceptions in Article XX of GATT 1994:[29]

- paragraph (b), applying to measures "necessary to protect human, animal or plant life or health;" and
- paragraph (g), exempting measures "relating to the conservation of exhaustible natural resources if such measures are made effective in

[29] The relevant passage provides in full as follows:

"Article XX
General Exceptions

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

....

(b) necessary to protect human, animal or plant life or health; [or]

....

(g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption."

conjunction with restrictions on domestic production or consumption."

B. Uruguay Round of Multilateral Trade Negotiations

The Uruguay Round of Multilateral Trade Negotiations in GATT, completed in December 1993, contains two new texts addressing standards relevant to the protection of environment and public health: (1) an Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)[30] addressing such domestic regulations as those designed to protect the food supply from contamination; and (2) an Agreement on Technical Barriers to Trade (TBT Agreement),[31] which applies to domestic standards other than sanitary and phytosanitary measures.

1. Agreement on the Application of Sanitary and Phytosanitary Measures

The Uruguay Round SPS Agreement governs a particular and specific category of measures known as "sanitary and phytosanitary standards,"[32] defined by the objective of the measure and the source of the hazard regulated. The Agreement expresses a preference for multilaterally-agreed,

30. See *supra* n. 16.
31. See *supra* n. 17.
32. Paragraph 1 of Annex A of the SPS Agreement, *supra* n. 15, defines "sanitary or phytosanitary measure" as:
"Any measure applied:
– 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;
– 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;
– 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
– to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety."

harmonized standards,[33] which in the area of human food safety are established primarily by the Codex Alimentarius, and in other areas are set out by the International Office of Epizootics and the Secretariat of the International Plant Protection Convention. The benefits of international standards from a trade point of view are relatively obvious: producers in one country readily obtain market access to any other country with the same standards. There has also been a reciprocal concern, however, that multilateral standards may reflect a least-common-denominator consensus responsive to those countries that are the least, and not the most, aggressive in protecting public health from food-related risks.

The SPS Agreement provides that under certain specified circumstances a WTO member may adopt measures more stringent than international standards, such as those established by the Codex. As a first step in this process, the SPS Agreement introduces the concept of a WTO member's "appropriate level of sanitary or phytosanitary protection."[34] This concept appears at its core to be a social value choice based on national policy priorities.[35] Once a WTO member has determined that it desires a level of protection in excess of that provided by harmonized multilateral standards, the measures chosen must be "based on" a risk assessment.[36]

33. SPS Agreement, *supra* n. 16, Arts. 3.1-3.3.

34. *Ibid*., Arts. 3.3 & 5.3-5.6 & Annex B, para. 3(c). Noting that "[m]any Members... refer to this concept as the 'acceptable level of risk,'" paragraph 5 of Annex A defines "[a]ppropriate level of sanitary or phytosanitary protection" as "[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."

35. The U.S. Government's interpretation at the time of the domestic approval of the Uruguay Round expressly affirms that the SPS Agreement's definition of appropriate level of protection "explicitly affirms the right of each government to choose its levels of protection, including a "zero risk" level if it so chooses. A government may establish its level of protection by any means available under its law, including by referendum. In the end, the choice of the appropriate level of protection is a societal value judgment. The Agreement imposes no requirement to establish a scientific basis for the chosen level of protection because the choice is not a scientific judgment."
Uruguay Round Agreements Act, Statement of Administrative Action, at 89, reprinted in H.R. Doc. No. 103-316, 103d Cong., 2d Sess. 656, p. 745.

36. SPS Agreement, *supra* n. 16, Art. 5.1. Paragraph 4 of Annex A to the Agreement defines "risk assessment" as
"The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages, or feedstuffs."

Assuming that international standards are not applicable or dispositive, the principal workhorse of the SPS Agreement is then a series of scientific tests requiring that a sanitary or phytosanitary measure, among other things:

- "is based on scientific principles" (article 2.2);
- "is not maintained without sufficient scientific evidence" (article 2.2);
- has "a scientific justification" (article 3.3);[37]
- is "based on [a risk] assessment" (article 5.1); and
- "take[s] into account available scientific evidence." (article 5.2)

Violation of any one of these requirements will result in an adverse finding by a panel or the Appellate Body, as the case may be.

2. *Agreement on Technical Barriers to Trade*

The Uruguay Round also contains an Agreement on Technical Barriers to Trade (TBT Agreement) which elaborates the requirements of the Tokyo Round Standards Code for technical regulations and standards,[38] with the exception of sanitary and phytosanitary measures, which are governed by the Uruguay Round Agreement on that subject. Unlike the earlier Standards Code, this new Agreement is an integral component of the Uruguay Round that must be accepted by all WTO members. As in the case of the Tokyo Round Standards Code, the new Agreement establishes trade disciplines to distinguish those domestic standards, including those designed to preserve the environment and to protect public health, that could act as non-tariff barriers to trade. The TBT Agreement could potentially apply to a wide variety of regulatory requirements that have environmental or public health implications, but that are not sanitary or phytosanitary standards. Specifications for consumer products and children's toys, appliance efficiency criteria, and vehicle fuel efficiency standards might all be governed by the Uruguay Round TBT Agreement.

Unlike the Uruguay Round SPS Agreement, the technical barriers agreement contains no scientifically-based trade disciplines. Like the Tokyo

37. According to a note to this provision, "there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection."

38. The Uruguay Round TBT Agreement is somewhat broader in coverage than that of the Tokyo Round Standards Code. The new Agreement specifies that it applies to both mandatory and advisory requirements not only for products, but also for "related processes and production methods." Annex 1, paras. 1-2.

Round Standards Code, the Uruguay Round TBT Agreement articulates a basic test of non-discrimination and retains the central notion of an unnecessary obstacle to international trade. This latter concept is elaborated by the requirement that product standards "shall not be more trade-restrictive than necessary to fulfil a legitimate objective," [39] such as protection of the environment or public health. Also like the earlier Standards Code, the new text encourages the use of international standards where they exist.[40] Because of the much broader range of legitimate objectives, such as consumer protection, in standards covered by the new TBT Agreement, and in distinct contrast to the Uruguay Round SPS Agreement, national regulations that are more stringent or rigorous than comparable international standards need not meet a scientific test.

V. Application of the WTO disciplines to the EC GMO scheme

The requests for consultations from the United States and the other complaining parties allege that the EC's actions with respect to non-approval of genetically modified food and agricultural commodities are inconsistent with the following WTO requirements:

- GATT 1994, Articles I, III, X and XI;
- SPS Agreement, Articles 2, 5, 7, and 8, and Annexes B and C;
- TBT Agreement, Articles 2 and 5; and
- WTO Agriculture Agreement, Article 4.

This section identifies and evaluates the most plausible of those claims, beginning with the Uruguay Round SPS Agreement, the sole authority for which the U.S. has elaborated its arguments in its first submission.[41]

39. TBT Agreement, *supra* n. 17, Art. 2.2.
40. *Ibid.*, Art. 2.4 & Annex 3, para. F. The Uruguay Round TBT Agreement, like the Uruguay Round SPS Agreement, articulates the concept of a "level of protection" chosen by each state member. *Ibid.*, preamble, para. 5 & Annex 3, para. F.
41. The transatlantic dispute over GMOs is the first in the WTO on this subject matter to proceed to this stage in the dispute settlement process. In 2000 Thailand requested consultations with Egypt over the latter's prohibition of importation of tuna canned with genetically modified soybean oil, but that dispute does not seem to have progressed beyond the consultation stage.

A. Uruguay Round SPS Agreement

The Appellate Body's jurisprudence interpreting the SPS Agreement to date consists of four reports, all of which were adverse to the responding party, challenging:

- An EC prohibition on the sale of imported and domestically manufactured meat and meat products derived from cattle treated with growth-promoting hormones.[42]
- Australia's ban on importation of fresh chilled or frozen salmon to protect the domestic salmon population from disease.[43]
- Japan's requirement to test each variety of certain agricultural products to protect against the introduction of coddling moths.[44]
- Japan's prohibition on the importation of mature, symptomless apples in an effort to prevent the spread of fire blight, a plant disease.[45]

Of these, only the first raises implications for human health. The measures at issue in the subsequent cases are fairly straightforward quarantines to protect the integrity of economically valuable domestic agricultural commodities. Agricultural quarantines are fundamentally different in kind and motivation from regulatory actions designed to protect human health or ecosystem viability. To the extent that the Australian and Japanese cases embellish requirements under the SPS Agreement, it is consequently unclear to what extent those precedents may or may not apply to the GMO dispute. The EC hormone dispute, moreover, was clearly understood to be the paradigmatic situation addressed in the SPS Agreement, which had something of the quality of a legislative solution to this clearly-defined situation. The instant situation concerning GMOs as a result has the air of a case of first impression, as the earliest dispute to raise human health concerns and/or ecological considerations that was not the express target of the SPS Agreement at the time it was adopted.

The EC GMO dispute raises a number of unusual and challenging questions of interpretation and application of the SPS Agreement, including the following: (1) the scope of the Agreement, particularly as it applies to

42. *European Communities — Measures Concerning Meat and Meat Products*, Doc. WT/DS26/AB/R & WT/DS48/AB/R, 16 January 1998.
43. *Australia – Measures Affecting Importation of Salmon*, Doc. WT/DS18/AB/R, 20 October 1998.
44. *Japan – Measures Affecting Agricultural Products*, Doc. WT/DS76/AB/R, 22 February 1999.
45. *Japan – Measures Affecting the Importation of Apples*, Doc. WT/DS245/AB/R, 26 November 2003.

environmental and ecosystem effects, as opposed to public health; (2) the potential for the Biosafety Protocol to articulate international standards that might operate through the SPS Agreement; (3) the identification of a measure to which the SPS Agreement applies in a system, such as the EC's for GMOs, requiring prior governmental approval for entry into commerce; and (4) the relevance, if any, of a precautionary perspective in the context of a prior approval scheme.

1. Scope of the SPS Agreement

The threshold jurisdictional question in the application of the SPS Agreement is whether the refusal to import GMOs is a "sanitary or phytosanitary measure" as defined by Annex A of the Agreement. SPS measures include food safety laws and regulations, but also include governmental actions to protect animal or plant life or health from pests, toxins, contaminants and the like. The application of the definition turns upon a two-part test consisting of the purpose of the measure, both in terms of its public policy goals – protection of health – and the specific source of the threat as enumerated in the definition – for example, pesticides, additives, contaminants, plant pests, or disease-causing organisms.

To the extent concerns about GMOs relate to the protection of human health from the ingestion of GM foods, such as from food allergies unusual to GM foods, there would appear to be little doubt that the EC's import prohibitions are SPS measures. Insofar as the objections might be more generally ecological or environmental, as from potential cross-pollination of GM crops or dispersal into the environment more generally, the application of the definition is less clear. The EC has specifically highlighted this jurisdictional question, asserting that at most a portion of its actions related to GMOs are governed by the SPS Agreement.[46]

The cases decided by the Appellate Body so far deal with human health and the well-being of commercially important, cultivated animal or plant species; the Appellate Body has not had occasion to opine on the application of the SPS Agreement to broader ecosystem effects. To the extent that measures falling in the latter category are not governed by the SPS Agreement, they might nonetheless be subject to the disciplines of the TBT Agreement (section V.C below). To the extent that the SPS Agreement applies to a particular measure, the TBT Agreement does not.[47]

46. First Written Submission by the European Communities, *supra* n. 4, para. 433.
47. TBT Agreement, *supra* n. 16, Art. 1.5.

Given that the SPS Agreement establishes among the most rigorous disciplines in the WTO suite of agreements, the EC appears to have a valid point. In other words, the SPS Agreement ought to be strictly confined to the subject matter identified in the definitions to the Agreement, and ambiguities should be resolved in a way that limits rather than expands the scope of that Agreement.[48] That conclusion, moreover, would be entirely consistent with the structure of both the SPS Agreement and the interrelationships among WTO agreements. One of the very clear tests in the SPS Agreement is intent as to a measure's coverage; to the extent that intent is lacking, a WTO member cannot be said to have agreed to the application of the SPS Agreement. A conclusion that the SPS Agreement covers only a portion of the challenged measure or measures in any event would not take those actions outside the disciplines of the corpus of WTO agreements as a whole. In such a situation, presumably the TBT Agreement, which like the SPS Agreement disciplines measures that are nondiscriminatory, would apply to the portion not covered by the SPS Agreement.

2. *International Standards*

The EC GMO dispute also appears to raise a novel legal question with respect to the first step in the analysis under the SPS Agreement, the requirement under Article 3.1 that Members "shall base their sanitary or phytosanitary measures on international standards, guidelines, or recommendations" except as otherwise provided in the Agreement. The most obvious candidate for international standards governing trade in GMOs would be the Biosafety Protocol, which provides parties to that agreement with the right to prohibit the importation of some GMOs under certain circumstances. The Biosafety Protocol consequently has the capacity to act as a "shield" that tends to justify the EC measures, in contrast to a "sword" which would tend to undermine their legitimacy.

Because of its binding multilateral character, the Biosafety Protocol might be considered a source of international standards as that term is used in the SPS Agreement. The Biosafety Protocol, however, contains obligations that are more procedural than substantive, such as pesticide residue limitations adopted by the Codex Alimentarius. The Biosafety Protocol also is not included in the list of specifically enumerated sources of

48. Cf. R.E. Hudec, "Science and 'Post-Discriminatory' WTO Law", *Boston College International & Comparative Law Review* 26 (2003), p. 185 (criticizing extension of WTO disciplines to "post-discriminatory" science-based tests in SPS Agreement).

international standards, but in any event that list is non-exclusive.[49] In any event, the EC has not argued that the Biosafety Protocol serves as an international standard within the meaning of the SPS Agreement, but only that it is "the international agreement which is most directly relevant" to the dispute.[50]

The United States is not a party to the Biosafety Protocol, so that agreement does not govern the relationship between the two parties. The situation with respect to Canada and Argentina is slightly more complicated because they have signed but not ratified.[51] In any event, if the Biosafety Protocol were considered to set out "international standards," then the rights and obligations set out in the Biosafety Protocol in effect could be imported into the present dispute and might well be dispositive in insulating the EC's action from further scrutiny.[52]

49. Paragraph 3(d) of Annex A to the SPS Agreement specifies that international standards may include "for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the [WTO SPS] Committee." The question whether there is a formal need for designation in order for states to rely on international standards has not yet been decided by the Appellate Body, although WTO members seem to believe that formal designation is necessary. Procedures for identifying additional sources of international standards, whether by consensus or by a voting process, would then be relevant in a situation such as the Biosafety Protocol, which has not been universally accepted.

50. First Written Submission by the European Communities, *supra* n. 4, para. 457.

51. Signature of a multilateral agreement that provides for ratification *ad referendum* is a preliminary indication of an intent to be bound, perfected by subsequent ratification. Vienna Convention on the Law of Treaties, 22 May 1969, *International Legal Materials* 8 (1969), p. 679, art. 18, para. 2, of the Vienna Convention, which is also generally considered to codify the customary international law of treaties, provides that "[a] State is obliged to refrain from acts which would defeat the object and purpose of a treaty when... it has signed the treaty or has exchanged instruments constituting the treaty subject to ratification, acceptance or approval, until it shall have made its intention clear not to become a party to the treaty..." Consequently signature of the Biosafety Protocol pending ratification can create inchoate legal obligations. In the present context, for example, Canada's and Argentina's signature might be taken as an indication of an acceptance of the basic premises of the Protocol by those parties in the context of the WTO dispute settlement proceeding.

52. The fact that the complaining parties in the WTO dispute — the United States, Canada, and Argentina — are not parties to the Biosafety Protocol is not necessarily a legal impediment to the agreement's application through the SPS Agreement. If non-binding standards such as those of the Codex Alimentarius can operate through the SPS Agreement, then binding standards establishing broad-gauge normative expectations for states might well be considered at least as effective in establishing international minimum standards, whether or not the complaining state is a party to the instrument in question.

There is some suggestion in the literature that the Biosafety Protocol and the SPS Agreement contain conflicting rights and obligations,[53] in which case the Protocol might be considered a poor candidate as a source of international standards to be applied through the SPS Agreement. The better view, however, is probably that the two instruments can and should be harmonized and interpreted in a manner consistent with one another. The Vienna Convention on the Law of Treaties directs that successive treaties on similar subject matter ought to be harmonized to the extent possible.[54] A conclusion that such treaties are incompatible is appropriate only as a last resort after all interpretive options that would give full effect to both have failed. These basic principles are particularly compelling in the context of two agreements, the SPS Agreement and the Biosafety Protocol, both of which have potentially universal application. Because the Biosafety Protocol refers to principles of science in general and risk assessment in particular, it is entirely possible to read the two agreements as complementary rather than incompatible.[55]

3. *Identification of the measure or measures*

The SPS Agreement, like the WTO agreements generally, applies to a "measure." In the application of the WTO dispute settlement process, it is consequently essential to identify the measure at issue as a first step in

53. E.g., S. Safrin, "Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements", *American Journal of International Law* 96 (2002), p. 606.

54. The obligations in international agreements ought to be harmonized where possible to give effect to all commitments simultaneously, an approach that counsels reconciling agreements with each other where possible. Article 30, paragraph 3, of the Vienna Convention, supra note 49, specifies that "[w]hen all the parties to the earlier treaty are parties also to the later treaty but the earlier treaty is not terminated or suspended in operation under Article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the latter treaty." Article 59, paragraph 1(b), provides that "[a] treaty shall be considered as terminated if all the parties to it conclude a later treaty relating to the same subject-matter and... the provisions of the later treaty are so far incompatible with those of the earlier one that the two treaties are not capable of being applied at the same time." In other words, a later treaty will supersede an earlier agreement for parties to both only to the extent that the later agreement is inconsistent with the earlier. Such supersession by implication is not to be presumed, however, and the preferred option is to give effect to both. Cf. The Schooner Charming Betsy, 6 U.S. (2 Cranch.) 64, 118 (1804) (harmonize domestic statute with international law where possible).

55. See O. Rivera-Torres, "The Biosafety Protocol and the WTO", *Boston College International & Comparative Law Review* 26 (2003), p. 263.

the analysis. The EC GMO dispute raises two novel questions concerning the characterization of the measure: (1) the identification of the measure in a scheme requiring prior governmental approval as a condition precedent a new product's entry into commerce; and (2) an argument advanced by the complaining parties which seeks to characterize the totality of the EC's actions under the relevant directives as a single measure in the form of a "general moratorium."

a. Identification of the measure in a prior approval scheme

As described in section II above, the EC scheme requires prior governmental authorization before a GMO may be "plac[ed] on the market."[56] This structure is common to regulatory schemes in place in many WTO member countries for such substances as drugs, food additives, and pesticides, but the validity as a matter of principle of such an approach has not yet been considered by the WTO Appellate Body. The EC framework for approving GMOs is typical in requiring a private party applicant, such as a manufacturer, to demonstrate that the substance meets a test of safety or the absence of adverse effects.

In the EC hormone dispute and the three subsequent cases dealing with agricultural quarantine requirements, the measure is relatively easy to identify: the governmentally-established requirements or prohibitions on hormones, entry of certain products, and the like. But as highlighted in this section, there is a somewhat uncomfortable structural fit between the disciplines in the SPS Agreement and a scheme, such as the EC's for GMOs, requiring prior approval of products before their entry into commerce. A principal difficulty in such a scheme is the precise identification of a "measure," which is the governmental action reviewed in the WTO dispute settlement process. This structural attribute raises two rather difficult subsidiary questions: (1) the application of the SPS Agreement's science-based disciplines in situations in which a notification is disapproved; and (2) the applicability of the SPS Agreement's prohibition in undue delay in cases in which a notification has not been acted upon.

(1) *Disapprovals*

The principal discipline in Annex C relevant to prior approval schemes,

56. Art. 1, para. 4 of Directive 2001/18, *supra* n. 8, defines "placing on the market" as "making available to third parties, whether in return for payment or free of charge."

such as the EC's for GMOs, is a prohibition on "undue delay."[57] But speed alone is of little utility either to the private party applicant or to the complaining parties in the dispute, the United States, Canada, and Argentina. In a prior approval scheme, it is often in the applicant's interest for the governmental authority to request more information instead of disapproving the application, perhaps prematurely. The U.S., Canada, and Argentina in reality are consequently complaining not of undue delay *per se*, but of undue delay *in approving* particular notifications. In effect, the complaining parties equate disapproval of a notification with undue delay. That interpretation is fundamentally incompatible with the EC's regulatory framework for GMOs – and, indeed, any prior approval scheme – because determining suitability for approval cannot be presumed in a particular – or, indeed, any – case without disrupting the inherent purpose of the scheme.

Approval of a GM product for the purposes of placing it on the market is clearly a "measure," although certainly one of little interest to the complaining parties in the present dispute. Situations in which, by contrast, the governmental authority declines to take an action affirmatively allowing market entry in response to an application from a private party raise considerable conceptual and practical difficulties. First, the "measure," at least by comparison with an affirmative approval, has a much stronger component of inaction. In disapproving notifications for GM foods and crops, the EC is not affirmatively impeding the entry into commerce of those products, which in any event were already prohibited by the directives establishing the regulatory framework for GMOs.[58] Rather, the EC is merely making a determination that the applicant has not yet met the ap-

57. SPS Agreement, *supra* n. 16, Annex C, para. 1(a). A strict reading of the introductory language, which limits this requirement to "any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures," might very well lead to the conclusion that this discipline is inapplicable by its terms. A prior approval scheme, strictly speaking, is not designed to "check and ensure the fulfilment of" a normative standard in an enforcement mode; rather a prior approval scheme is itself a normative process in which a governmental authority is requested to determine the appropriateness of entry into commerce.

58. An alternative conceptual approach would be to consider the framework directives themselves to be the "measure" under review. The SPS Agreement, however, provides no textual support for such an interpretation, and none of the complaining parties have attacked the structure of EC scheme as inconsistent with the SPS Agreement. Given the prevalence of prior approval schemes at the national level in a wide variety of countries for numerous categories of products, as noted in section V.A.3 above, it is highly unlikely that the drafters of the SPS Agreement intended to subject the structure of those regulatory schemes, as distinct from the actions taken under them, to review by WTO panels.

propriate standard established by those directives. In the hormone case, unlike the GMO dispute, the EC directives intervened in what otherwise would have been an unregulated market affirmatively to prohibit the use of six enumerated hormones, an action that much more clearly amounts to a "measure." Second, a disapproval is not necessarily final, as the private party applicant may supplement its notification with additional data until the regulatory test is satisfied.

It is difficult to make sense of the scientific tests in the SPS Agreement identified in section IV.B.1 above as applied to a prior approval scheme at the juncture of a negative governmental response. Consideration of the SPS Agreement's requirement for "sufficient scientific evidence" in Article 2.2 is perhaps the most revealing. Under a prior approval scheme such as the EC's for GMOs, a private party applicant's failure to provide sufficient information is one legitimate reason that a governmental authority might disapprove that application. To ask whether the governmental authority had "sufficient scientific evidence" to disapprove the application under such circumstances is to turn the structure of the prior approval scheme, which requires the private party applicant to provide sufficient evidence to support a governmental approval, on its head.[59] In such a situation, the governmental authority might well have determined that scientific evidence sufficient to support an approval is lacking, leading to the default conclusion from a policy point of view that the product may not enter commerce. While it might be possible for a third-party dispute settlement process such as that in the WTO to reexamine a decision resulting from a prior approval scheme to allow a product to enter commerce from a scientific point of view, to engage in such reevaluation of a disapproval resulting from a failure or omission of another entity not subject to the disciplines of the SPS Agreement by reference to that Agreement leads to incoherence. Applying the same reasoning to each of the scientific tests identified in section IV.B.1 above leads straightforwardly to the same conclusion.

(2) *Inaction*

An additional consideration in a case such as this one involving a prior approval scheme might be the potential for inordinate delay in processing an application that could in effect amount to a disapproval. As discussed in this section, there are principled difficulties with attempting to identify a generic test to address this situation.

59. The SPS Agreement does not discipline the actions of private parties, such as the industry submitter of a notification under the EC's directives on GMOs.

Domestic legal systems have evolved doctrines effectively to address review of both inaction by governmental authority and governmental actions that appear to lack finality.[60] Apart from the prohibition on "undue delay," the text of the SPS Agreement makes no textual reference to this learning. As a consequence, the disciplines in the SPS Agreement are poorly adapted to a situation of prior approval, and particularly situations in which a governmental authority is alleged to have in effect disapproved an application without formal action.

The principal textual requirements applicable to the EC GMO dispute stem from Annex C, entitled "Control, Inspection and Approval Procedures." The title of this passage itself is revealing as to the difficulty of applying the SPS Agreement to prior approval frameworks. Control and inspection procedures are enforcement and implementation actions taken by governments. Those actions are fundamentally different not only in kind but in structural context from a scheme of prior approval, which is a framework for taking normative or regulatory decisions by placing the burden on the applicant to generate data of sufficient quality to reach a substantive determination of a product's suitability for entry into commerce.

As demonstrated in the previous section, in cases of disapproval by an EC Member State or as a result of a recommendation of a Scientific Committee, there would be an affirmative governmental act, a "measure," that would be amenable to scrutiny by the WTO dispute settlement process by reference to the scientific disciplines in the SPS Agreement. A governmental approval in response to a private party's application would clearly amount to a "measure," as demonstrated in particular by the potential inclusion in many such schemes, including the EC framework for GMOs, of regulatory conditions on the subsequent use of the product. Those conditions, if any, would then be amenable to challenge through the WTO's dispute settlement processes.

Review of measures at an earlier stage in the governmental decision making process, before outright approval or disapproval, raises considerably more difficulties. In such a situation, a panel or the Appellate Body would need to develop a test to determine when review would be premature, or not yet "ripe" for consideration, because there would not have been an opportunity for a definitive scientific determination on the part of the EC's governmental apparatus. The prohibition on "undue delay" is the

60. See, e.g., Heckler v. Chaney, 470 U.S. 821 (1985).

most obvious textual basis to which an interpretive gloss might be attached, but it is difficult to imagine crafting a generic test that would apply even in the context of a single dispute such as the present one, involving as it does numerous applications characterized by divergent contexts. In cases in which the Scientific Committee has given a positive assessment but the approval has been subsequently rejected by the Regulatory Committee composed of representatives of the Member States, the EC would appear to be particularly vulnerable, as the reasons for maintaining the prohibition at least at first blush would seem to be impermissible under the SPS Agreement. Beyond that, it is difficult to make generalizations, particularly because the EC's decision making scheme has a number of steps, performed in a highly decentralized manner by a variety of actors – the Member State competent authority, other Member States, the Scientific Committees, the Regulatory Committee, the Commission, and the Council of Ministers – counseling caution on the part of the panel or Appellate Body to refrain from reviewing an action that is not yet final at a premature stage of the domestic regulatory process.

b. The "general moratorium" as a single measure

The first U.S. and Canadian submissions attempt to establish a pattern of denials and inaction, which are then characterized as a "general moratorium."[61] This appears to be a novel argument, certainly under the SPS Agreement, but also more generally in GATT/WTO jurisprudence. A "measure" need not be a law or regulatory action, but it is not clear to what extent a collection of individual governmental decisions may or may not amount to a measure. The utility of the argument from the point of the view of the challenging party is apparent: if successful, it would result in a wholesale finding on the merits that all of the EC actions with respect to GMOs either are or are not consistent with the SPS Agreement. There are, moreover, express statements of member countries that suggest they have acted in concert to achieve such a result.

This characterization of the measure as a *de facto* moratorium, however, is by no means necessary to resolving the dispute, which is more plausibly analyzed *a priori* as a challenge to multiple individual decisions with respect to each product, with varying circumstances and attributes that lend each a unique character. For instance, some notifications may have been considered by a Scientific Committee, a juncture which might provi-

61. First Submission of the United States, *supra* n. 4, paras. 81-84; First Written Submission of Canada, *supra* n. 7, paras. 152-59.

de meaningful insights into the application of the science-based tests in the SPS Agreement, whereas others may not. Since the argument is not necessary, since the long-term implications as to its effect on broader WTO jurisprudence are unclear, and since its acceptance would appear to be a wholesale challenge to the EC's regulatory scheme as opposed to individual decisions taken under it, the Appellate Body would probably be wise to refrain from proceeding on this basis.

This suggests that the U.S. allegation of a *de facto* across-the-board "moratorium" is overly simplistic and that the panel and the Appellate Body should segment the allegation into its component pieces, as the EC directives do. The panel and the Appellate Body can and should decide that what is really at issue is not the regulatory strategy itself, but its outcomes and application to individual notifications, applications, and requests with respect to specific products. Because of the prevalence of these schemes for prior approval in many national legal systems, the Appellate Body is unlikely to, and certainly would be poorly advised to, focus on the validity of the regulatory structure as such. Any number of WTO members have had prior approval schemes in place for some time, and the potentially problematic application of the SPS Agreement to requirements for affirmative governmental approval of private party applications was understood at the time the Agreement was drafted.

4. Precaution and SPS Article 5.7

The instant dispute is further complicated by the consideration that the requirement for prior approval has the hallmarks of a generalized precautionary approach, which the Appellate Body in the EC hormones case found to be precluded except on the very limited terms that the SPS Agreement specifically authorizes in Article 5.7.[62] While the motivation for Article 5.7 appears to be similar to that of a public policy based on precaution, they are not entirely the same. Salient divergences are readily

62. *European Communities — Measures Concerning Meat and Meat Products*, *supra* n. 42, paras. 120-25 & 253(c). Article 5.7 of the SPS Agreement provides as follows:
"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."

apparent when the text of Article 5.7 is juxtaposed with that of Principle 15 of the Rio Declaration on Environment and Development.[63]

A precautionary perspective acknowledges that some uncertainties may be irreducible or fundamental, in the sense that they cannot be removed relying on currently-available scientific methodologies, and counsels an early, proactive policy response nonetheless. By contrast, Article 5.7, speaks of an "insufficient" scientific predicate, a narrow subset of the "lack of full scientific certainty" addressed by a precautionary methodology, and allows a WTO member to maintain a measure relying on this provision only on an interim basis pending development of sufficient information. At least according to the text of that provision, for a measure justified by Article 5.7 a necessary component of a policy response is the collection of more scientific information until the scientific basis for the action can be determined to be either sufficient – in which case the measure may presumably maintained indefinitely – or insufficient – in which case is must presumably be removed, in both instances consistent with the requirements of the remainder of the SPS Agreement. Article 5.7 says nothing about a third, and very real, possibility involving fundamental or irreducible uncertainties, a situation expressly anticipated by a precautionary methodology. The Appellate Body has never found a measure to be justified by Article 5.7 despite litigation of this question in the two Japanese SPS disputes.[64] The Appellate Body's interpretations of this provision, which emphasize its very narrow applicability,[65] further underscore divergences between Article 5.7 and a genuine precautionary outlook.

This insight suggests that the EC may have missed an opportunity in its litigation posture in the WTO GMO dispute. As demonstrated in section V.A.3 above, both as a matter of principle as well as from the point of view of the SPS Agreement, approval and disapproval are not symmetrical governmental actions. Approval is clearly a measure, whereas disapproval is an interim decision more akin to inaction which is not necessarily final. That characterization suggests that the EC might have found it useful to

63. *International Legal Materials* 31 (1992), p. 876. Principle 15 reads in full as follows: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

64. *Japan – Measures Affecting Agricultural Products*, *supra* n. 44; *Japan – Measures Affecting the Importation of Apples*, *supra* n. 45.

65. E.g., *Japan – Measures Affecting Agricultural Products*, *supra* n. 44, para. 80.

argue that disapprovals are governed by Article 5.7 of the SPS Agreement. To the extent it is a "measure" disciplined by the Agreement, a disapproval arguably satisfies the tests of Article 5.7:

- Disapprovals of necessity are appropriate "[i]n cases where relevant scientific evidence is insufficient," namely when the private party applicant has failed to supply sufficient evidence;
- The measure, in the form of the disapproval, is "provisionally adopt[ed]," pending the private party's submission of sufficient information;
- By virtue of the structure of the prior approval scheme, a disapproval is simultaneously a decision by the WTO member to "seek to obtain the additional information necessary for a more objective assessment of risk," to the extent that information is available from the private party applicant; and
- The WTO member will presumably "review the... measure... within a reasonable period of time," provided the private party submits the necessary additional information.

B. Basic nondiscrimination disciplines: GATT 1994

The basic GATT disciplines of Articles I, III, and XI in essence are obligations to refrain from maintaining discriminatory measures in international trade. A legal question in the instant dispute might have been whether the EC's prohibition on importation of GMOs is discriminatory by reference to non-GM crops and foodstuffs. The United States has not proceeded on this basis in its submissions to the panel, but the two other complaining parties have raised, analyzed, and argued issues connected with these provisions in their presentations.

1. Article III

The best legal authority for resolving the applicability of Article III of GATT 1994, the national treatment requirement, is a dispute in which the WTO's Appellate Body reviewed a challenge initiated by Canada to a French decree banning the importation of asbestos and products containing all forms of that substance.[66] The WTO panel that initially considered

66. *European Communities – Measures Affecting Asbestos and Asbestos – Containing Products*, Doc. WT/DS135/AB/R, 12 March 2001. See generally D.A. Wirth, "International Decisions", *American Journal of International Law* 96 (2002), p. 435.

the dispute determined that non-asbestos alternatives to asbestos and asbestos-containing products are "like products" within the meaning of Article III:4 of GATT 1994.[67] The panel had applied a test for "likeness" that turns on four factors designed to evaluate the competitive relationships between and among products: (1) the properties, nature, and qualities of the products; (2) end uses of the products; (3) consumers' perceptions and behavior; and (4) the tariff classification of the products. In applying this test, the panel stressed a market-access approach and concluded that asbestos and alternatives to it are "like products" because they have the same functions and can be interchanged from the point of view of performance. Similarly, end uses for both categories would be similar or identical. In light of this conclusion, the panel found it unnecessary to examine the third and fourth criteria, consumer preferences and tariff classifications. Significantly, the panel expressly declined to consider health risks as relevant to the "like product" determination.

The Appellate Body's report[68] approved the test identified by the panel for determining "likeness," but disagreed with the application of that standard. In reversing the panel's conclusion that asbestos and alternatives to it are "like products," the Appellate Body emphasized the necessity of examining all the evidence in context, including the need to scrutinize physical characteristics as distinct from end uses. Among those physical properties, "carcinogenicity, or toxicity, constitutes... a defining aspect of the physical properties of chrysotile asbestos fibres,"[69] by comparison with non-asbestos alternatives. The toxic character of the product is also relevant to the analysis of consumer preferences. The Appellate Body did not say, however, that risk or hazardous characteristics are dispositive in determining "likeness," even in the case of asbestos for which there is ample evidence of toxicity.

67. *European Communities–Measures Affecting Asbestos and Asbestos-Containing Products*, Doc. WT/DS135/R, 18 September 2000. Article III:4 of GATT 1994 provides:
"The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product."

68. *European Communities–Measures Affecting Asbestos and Asbestos-Containing Products*. Doc. WT/DS135/AB/R, 12 March 2001.

69. *Ibid.*, para. 114.

Canada and Argentina argue that the EC's measure, an across-the-board ban on both importation and domestic marketing of GMOs, is a violation of Article III, the national treatment obligation. The basic argument is that GMOs are "like" products by comparison with their non-GM analogues, in which case the import ban would be a prohibited quantitative restriction. The Appellate Body's report in the asbestos case anticipates the possibility that products might be "like" even if they are not identical. Three of the four factors identified by the Appellate Body – the properties, nature, and qualities of the products; the end uses of the products; and the tariff classification of the products – suggest a conclusion of "likeness." Genetically-engineered foods and crops are intended to be, and in fact are, used for the same or similar purposes as their non-GM counterparts. Based on the widely-reported lack of receptivity of European consumers to GM foodstuffs, the fourth factor, consumers' perceptions and behavior, would tend to counsel the opposite conclusion. The challenging parties could well respond that consumers in other parts of the world, such as North America, seem to have accepted GM products as interchangeable with their non-GM counterparts.

The well-documented health risk from asbestos was a factor the Appellate Body considered to be of significant importance to, although not entirely dispositive of, its conclusion that alternatives to asbestos were not "like" asbestos itself. Risks, if any, from GMOs are uncertain, and considerably more so than in the case of asbestos, for which toxicity has been amply demonstrated. In the posture of the GMO dispute, moreover, the EC seems to have at least arguably conceded the absence of risk, at least of the sort that can be clearly documented. As many as sixteen of the "blocked" notifications under Directive 2001/18 that form the basis of the U.S. complaint appear to have received favorable assessments from the relevant Scientific Committees, as have least some of the requests submitted under the novel foods regulation. At least with respect to those notifications, the apparent lack of scientific objection tends to weaken the EC's position. With respect to the application of the basic GATT disciplines, the question of "likeness" consequently could well turn upon whether consumer opposition alone is sufficient to justify the distinction made by the EC between GM and non-GM products.[70]

70. Article III:4, which applies to "laws, regulations or requirements," also raises questions as to the nature of the measure similar to those encountered with respect to the SPS Agreement discussed in section V.A.3 *supra*.

2. Article XX

Even if a panel were to find that GM products are "like" products by comparison with their non-GM counterparts, the EC prohibition can still be justified by the exceptions in Article XX of GATT 1994. In that case, the EC would have to be prepared to argue that with respect to human, animal or plant life or health, the prohibition is "necessary." Alternatively, the bans could be validated as "relat[ed] to the conservation of exhaustible natural resources." The latter test in the current context would presumably apply to concerns about ecological effects resulting from the cultivation and release of genetically-modified organisms to the environment.

The Appellate Body's jurisprudence, beginning with its first case challenging a U.S. regulation on reformulated gasoline[71] and continuing at least through the turtle/shrimp dispute,[72] has tended to relax the rigor of its application of the tests under paragraphs (b) and (g) of Article XX that had characterized earlier GATT panel reports. The legal effect of this jurisprudential development has been to shift the emphasis to the *chapeau* or introductory language to Article XX, where a measure must also withstand scrutiny as to whether it constitutes "arbitrary or unjustifiable discrimination."

Neither GATT panels nor the WTO Appellate Body have expressly articulated a scientific test for the application of any of the tests in Article XX. But at least in the case of those notifications under Directive 2001/18 and requests pursuant to the novel foods regulation that have received favorable assessments from the relevant Scientific Committee or Committees, the EC's prohibitions would appear to be legally vulnerable as not "necessary" or "relat[ed] to the conservation of exhaustible natural resources," as the case may be. Even if the import prohibitions were to clear either or both of those hurdles, maintaining them against the backdrop of a favorable scientific evaluation could well run afoul of the *chapeau*'s prohibitions on "arbitrary or unjustifiable discrimination" or, as is more likely in a case such as this in which the measure is nondiscriminatory, "disguised restriction[s] on international trade."

71. *United States – Standards for Reformulated and Conventional Gasoline*, Doc. WT/DS2/AB/R, 20 May 1996, *International Legal Materials* 35 (1996), p. 603.
72. *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, Doc. WT/DS58/R, 15 May 1998, para. 3.135.

The Appellate Body has not addressed this precise question in the context of its interpretation of the phrase "arbitrary or unjustifiable discrimination" in the *chapeau* to Article XX, and jurisprudence on the meaning of "disguised restriction on international trade" is very limited and not illuminating in the context of the EC GMO dispute.[73] It is nevertheless at least a plausible to assert that a measure designed to protect public health and the environment that lacks a scientific foundation amounts either to arbitrary or unjustifiable discrimination or a disguised restriction on international trade. In other words, the challenging party would assert the irrationality of the measure by reference to a scientific test, leading to a conclusion that the measure is prohibited by the *chapeau*'s prohibition on "disguised restriction on international trade." This reasoning process also suggests the junctures at which a panel or the Appellate Body would have to make legal and policy determinations concerning the meaning of "disguised restriction" in the context of the *chapeau* to Article XX. If social factors, cultural considerations, or consumer preferences were to play a role in that determination, scientific considerations might well not be dispositive.

73. In *Standards for Reformulated and Conventional Gasoline*, *supra* n. 71, at 24-25, the Appellate Body stated:
""Arbitrary discrimination", "unjustifiable discrimination" and "disguised restriction" on international trade may, accordingly, be read side-by-side; they impart meaning to one another. It is clear to us that "disguised restriction" includes disguised *discrimination* in international trade. It is equally clear that *concealed* or *unannounced* restriction or discrimination in international trade does *not* exhaust the meaning of "disguised restriction." We consider that "disguised restriction", whatever else it covers, may properly be read as embracing restrictions amounting to arbitrary or unjustifiable discrimination in international trade taken under the guise of a measure formally within the terms of an exception listed in Article XX. Put in a somewhat different manner, the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to "arbitrary or unjustifiable discrimination", may also be taken into account in determining the presence of a "disguised restriction" on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX." (emphasis in original).
That language, however, is arguably *obiter dictum* as the Appellate Body found that the measure in question violated the *chapeau*'s prohibition on "arbitrary or unjustifiable discrimination."

C. Uruguay Round TBT Agreement

As described in section V.A above, to the extent that the EC's actions with respect to GMOs do not fall within the SPS Agreement – for instance, actions to protect the environment or ecosystems generally, as opposed to human, animal, or plant life or health – those measures could be disciplined by the TBT Agreement.[74] The TBT Agreement does not contain an explicit scientific test with the vigor of those in the SPS Agreement, and Appellate Body jurisprudence under the Agreement consists primarily of a successful challenge by Peru to an EC labeling requirement limiting the species that could be described as "sardines" by reference to a Codex standard.[75]

The primary discipline that might be applicable to the EC GMO dispute would appear to be Article 2.2, which prohibits "unnecessary obstacles to international trade."[76] Despite the lack of Appellate Body jurisprudence, this requirement is probably less rigorous than the requirements in the SPS Agreement from a scientific point of view. Governmental actions reviewed under this standard that are based on social or cultural, as opposed to scientific, considerations are commensurately more likely to withstand scrutiny. The labeling requirements of Directive 2001/18 for approved products have not been litigated in the present dispute. If the labeling portion of the Directive were to be subjected to scrutiny, that would most likely occur under the TBT Agreement, as labeling has been generally understood not to be an SPS measure. A strict reading of the SPS Agreement nonetheless does not rule out the possibility that labeling requirements that meet the other criteria of the definition of an SPS measure would not be treated under that Agreement.

74. Art. 4 of Directive 2001/18 identifies as its purpose "to avoid adverse effects on human health and the environment."

75. *European Communities – Trade Description of Sardines*, Doc. WT/DS231/AB/R, 26 September 2002.

76. Art. 2.2 provides in full:
"Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products."

V. Conclusion

The dispute over GMOs between the United States, Canada, and Argentina as complaining parties and the European Communities as respondent raises novel questions of trade law and policy. Chief among these is the application of the WTO Agreement on the Application of Sanitary and Phytosanitary Standards to a regulatory system requiring governmental approval of new products prior to their entry into commerce. While many national governments apply such prior approval schemes to other products such as human drugs, the fit between those domestic frameworks and the SPS Agreement is uncomfortable from both a structural and a legal point of view. In particular, it is unclear as to what precisely is the measure in cases of disapproval of a request for governmental approval or in cases of governmental inaction on such a request. Presumably this is one reason that the United States has sought to characterize the EC's treatment of multiple applications as a single measure in the form of a general moratorium. That characterization, however, finds no textual basis in the WTO suite of agreements and, moreover, risks further distorting the application of the SPS Agreement to a variety of distinct procedural contexts – approval, disapproval, and delay, for example – as well as treatment of applications with substantially divergent substantive attributes – favorable consideration by a Scientific Committee or not, for instance.

Additional issues of first impression include the scope of the SPS Agreement as applied to a measure with multiple motivations, protection of public health and preservation of ecosystem integrity, only one of which falls within the subject matter disciplined by the Agreement. To avoid a substantive creep into areas into which the rigorous scientific disciplines of the SPS Agreement were not intended to apply, it would be wise strictly to confine application of that Agreement by segmenting the component pieces of the measures at issue depending on their purpose. The Biosafety Protocol is unlikely to qualify as a formal matter for treatment as an international standard under the SPS Agreement, but the very existence of this question amounts to a recognition of the need for a considerably more systematic integration of WTO and non-WTO law and policy on related questions, such as GMOs. The Appellate Body has had prior occasion to address the applicability of a precautionary perspective in the case of the kind of measure expressly anticipated by the SPS Agreement. But a scheme requiring prior governmental approval for market entry of new products, employed by many WTO members including at least two of the complaining parties, raises the issue of precaution, widely accepted

at least in principle by WTO members, in a much more pointed manner. This attribute suggests the need for a more nuanced treatment of precaution than found in the Appellate Body's prior jurisprudence on this subject.