

WTO - SPS Agreement - Rules/Exceptions - International Law as Interpretive Tool

EUROPEAN COMMUNITIES - MEASURES AFFECTING THE APPROVAL AND MARKETING OF

BIOTECH PRODUCTS. WTO Doc. WT/DS291,292,293/R. At

<http://www.wto.org/english/tratop_e/dispu_e/dispu_status_e.htm>.

World Trade Organization Panel, September 29, 2006 (adopted November 21, 2006)

In what was by far the longest panel report in the WTO's history,¹ a WTO Panel ruled last September that various parts of the European Communities² regulatory regime for the approval and marketing of "biotech products" (that is, products that contain, or are made from or with, genetically modified organisms (GMOs))³ violated the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The Panel report was not appealed and was adopted by the WTO Dispute Settlement Body on November 21, 2006.

In recent years, a heated international debate has developed regarding the production and consumption of food made from or with GMOs. Among the key players in this debate, the United States government, supported by many companies who have developed GMO-based products, has pushed for their acceptance; by contrast, the European Communities and its member States, backed by consumer groups and other activists, have tried to restrict their use through various regulations.

¹ The Panel's reasoning and findings were over 800 pages long.

² According to the WTO, the European Union is "known for legal reasons as the European Communities in WTO matters." See http://www.wto.org/english/thewto_e/countries_e/european_communities_e.htm (visited February 17, 2007). As a result, the "European Communities" and the "EC" are the terms used to describe the European Union here.

³ More specifically, in this dispute the Panel used the term "biotech products" to refer to "plant cultivars that have been developed through recombinant deoxyribonucleic acid ('recombinant DNA') technology." Panel Report, European Communities - Measures Affecting the Approval and Marketing of Biotech Products, WTO Doc. WT/DS291,292,293/R (Sep. 29, 2006) (adopted Nov. 21, 2006) [hereinafter Panel Report], para. 2.2.

In 2003, Argentina, Canada and the United States brought a complaint under the WTO Dispute Settlement Understanding against various parts of the regulatory regime of the EC and certain of its member States for the approval and marketing of "biotech products." The complaints cited several WTO agreements, but focused on the SPS Agreement.⁴ The three complainants' claims varied slightly,⁵ but the following were the key measures at issue: (1) an alleged *de facto* moratorium imposed by the European Communities on the approval of new biotech products; (2) the alleged failure by the European Communities to approve specific biotech products for which applications for approval had been made; and (3) "safeguard" measures taken by six EC member States to prohibit certain biotech products that had been approved at the EC level. The WTO Panel hearing the case issued a mixed ruling, finding violations for some claims but rejecting a number of other claims. The Panel found the following violations: (1) the *de facto* moratorium on approvals of biotech products led to "undue delay" in the completion of the approval process, in violation of SPS Agreement Annex C(1)(a), first clause; (2) delays in the approval process for a number of specific products violated this same provision; and (3) the member State "safeguard" measures were not "based on" a "risk assessment," in violation of SPS Agreement Article 5.1, and these measures could not be justified under SPS Agreement Article 5.7.

The De Facto Moratorium

⁴ Apr. 14, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, in WORLD TRADE ORGANIZATION, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS: THE LEGAL TEXTS 69 (1995). Claims were also brought under the Agreement on Technical Barriers to Trade and the General Agreement on Tariffs and Trade (GATT) 1994. *Ibid.* at 138 and 486. The legal texts are available online at <http://www.wto.org/english/docs_e/legal_e/legal_e.htm>

⁵ See WT/DS291/23, May 13, 2003 (U.S. panel request); WT/DS292/17, May 13, 2003 (Canadian panel request); and WT/DS293/17, May 14, 2003 (Argentine panel request).

The complainants claimed that the EC was applying a *de facto* moratorium on the approval of new biotech products (some had been approved in the past). While there was no formal EC legislative or administrative act indicating that such approvals would not be granted, the complainants submitted evidence that, in their view, demonstrated the existence of such a moratorium. They argued that this moratorium violated a number of provisions of the SPS Agreement.

After concluding as a factual matter that such a moratorium existed between June 1999 and August 2003,⁶ the Panel rejected most of the substantive claims on the basis that the EC decision to apply a general moratorium on approvals was not an "SPS measure" within the meaning of SPS Agreement Annex A(1) or the specific provisions under which claims were made. In this regard, Annex A(1), after setting out four objectives pursued by SPS measures, provides that:

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.

⁶ Panel Report, *supra* note 3, paras. 7.438-1285.

The Panel explained that, based on this provision, whether a particular measure constitutes an SPS measure "is to be determined, according to the above definition, by reference to such criteria as the *objective* of the measure, its *form* and its *nature*." (emphasis added) With respect to the "nature" of SPS measures, the Panel said that the definition stipulates that SPS measures include "requirements and procedures," and then "goes on to mention, by way of example, a number of relevant substantive requirements ... and procedures" In this regard, the Panel noted that the decision to apply a general moratorium on approvals was "a procedural decision to delay final substantive approval decisions," and concluded that the decision did not impose a substantive "requirement" in relation to biotech products with pending or future applications, as it "neither approved nor rejected applications." Similarly, it said, the decision was not a "procedure," as it "did not itself establish a new procedure or amend the existing EC approval procedures." On this basis, the Panel concluded that the "nature" element was not satisfied and thus rejected all of the claims under the provisions for which the existence of an "SPS measure" is a necessary element.⁷

However, the Panel did find a violation of Annex C(1)(a), first clause (under which claims were brought by Canada and the United States), which states:

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
 - (a) such procedures are undertaken and completed without undue delay [...].

This provision is not limited to SPS measures, as it applies to "procedure[s] to check and ensure the fulfilment" of SPS measures. The Panel recalled its earlier finding that EC

⁷ Panel Report, *supra* note 3, paras. 7.1326-1465.

Directives 90/220⁸ and 2001/18,⁹ as well as EC Regulation 258/97,¹⁰ which set out the European Communities' regulatory framework for the approval procedures for biotech products, constitute SPS measures within the meaning of Annex A(1). In addition, the Panel said, these measures "set out procedures to check and ensure the fulfilment of one or more SPS requirements the satisfaction of which is a prerequisite for the approval to place a product on the market." As a result, it concluded that the procedures set out therein constitute procedures "to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1), and are thus subject to Annex C(1)(a), first clause. Therefore, the European Communities was required during the relevant time-period to "undertake and complete" the approval procedures "without undue delay." The Panel then explained that if the European Communities did not "undertake and complete" the approval procedures "without undue delay" for *any individual product*, the moratorium would be in violation of this provision. Considering the evidence in relation to one of the products at issue,¹¹ the Panel concluded that "undue delay" existed in respect of the approval process for this product. The Panel thus found that because of the *de facto* moratorium, the European Communities "has failed to observe the provisions of Annex C(1)(a), first clause."¹²

Approval for Specific Biotech Products

The complainants also challenged the failure by the European Communities and six member States to approve applications for *specific biotech products*. These claims

⁸ Directive 90/220/EEC, O.J. 8.5.1990 L117/15.

⁹ Directive 2001/18/EC, O.J. 17.4.2001 L106/1.

¹⁰ Regulation (EC) No. 258/97, O.J. 14.2.1997 L043/1.

¹¹ The product was MS8/RF3 oilseed rape.

¹² Panel Report, *supra* note 3, paras. 7.1466-1570.

were distinct from the claims against the general moratorium, although they were closely related in terms of their substance.¹³

As with the moratorium, the Panel rejected a number of claims on the basis that there was no "SPS measure" at issue in relation to the failure to approve specific products.¹⁴ However, just as it had done in relation to the moratorium, the Panel found violations under SPS Agreement Annex C(1)(a), first clause based on an "undue delay" in undertaking and completing the procedures. In this regard, the Panel considered 27 individual products, 24 of which it found had been subject to "undue delay," and three of which had not been. Thus, for the 24 delayed products the Panel found a violation of Annex C(1)(a), first clause.¹⁵

In addition, the Panel also considered two non-discrimination claims against the product-specific measures, under Annex C(1)(a), second clause (brought only by Argentina) and GATT Article III:4 (brought by Argentina and Canada, but Canada's claim was not addressed for reasons of judicial economy). The essence of Argentina's claims was: (1) biotech products had been treated less favorably than novel non-biotech products; and (2) prior to 1998, the European Communities granted approvals for the marketing of biotech products, whereas it had not done so since. The Panel rejected both of these claims, based on the view that Argentina had focused on specific sub-categories of the products, and had not shown that *imported* products as a group were treated less favorably than the comparable group of *domestic* products.¹⁶

¹³ Panel Report, *supra* note 3, paras. 7.1628-1633.

¹⁴ Panel Report, *supra* note 3, paras. 7.1680-1778.

¹⁵ Panel Report, *supra* note 3, paras. 7.1779-2391.

¹⁶ Panel Report, *supra* note 3, paras. 7.2392-2421 and paras. 7.2499-2517.

The Member State "Safeguard" Measures

Finally, the complainants made a series of claims concerning "safeguard" measures adopted by certain EC member States that allegedly prohibited the import, use of, or marketing of biotech products. Normally, where a biotech product has been approved for EC-wide marketing, member States may not prohibit or restrict trade in, or use of, that product in their respective territories. Exceptionally, however, member States "may provisionally adopt safeguard measures which prohibit or restrict trade in, or use of, biotech products which have been granted Community-wide marketing approval" under certain conditions, such as where "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," a member State has "detailed grounds for considering that a GMO as or in a product [...] constitutes a risk to human health or the environment [...]."¹⁷

The complainants made claims against nine different safeguard measures, taken by six different member States, each of which, the complainants alleged, prohibited the importation or marketing of various biotech products. The complainants claimed that these measures were not consistent with SPS Agreement Article 5.1, which requires that SPS measures be "based on" a "risk assessment,"¹⁸ and could not be justified under SPS

¹⁷ Panel Report, *supra* note 3, paras. 7.2529-2531.

¹⁸ Article 5.1 provides: "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."

Agreement Article 5.7, which allows "provisional measures" when "relevant scientific evidence is insufficient."¹⁹

After concluding that the measures at issue were "SPS measures,"²⁰ the Panel considered the relationship between Articles 5.1 and 5.7, which is not addressed explicitly in the SPS Agreement text. The Panel concluded that Article 5.7 "should be characterized as a right ... in relation to Article 5.1, rather than as an exception from a 'general obligation' under Article 5.1." As a result, it said, "in cases where a complaining party alleges that an SPS measure is inconsistent with Article 5.1, it is incumbent on the complaining party, and not the responding party, to demonstrate that the challenged measure is inconsistent with at least one of the four requirements set forth in Article 5.7."²¹

Turning to the facts of this case, the Panel found that for each safeguard measure, the measure was not "based on" a "risk assessment" under Article 5.1.²² Then, with regard to Article 5.7, the Panel found that because the first requirement of Article 5.7 -- which states that Members may provisionally adopt an SPS measure if this measure is imposed in respect of a situation where "relevant scientific evidence is insufficient" -- was not met, the safeguard measures were inconsistent with Article 5.7. Therefore, it

¹⁹ Article 5.7 provides: "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."

²⁰ Panel Report, *supra* note 3, paras. 7.2563-2922.

²¹ Panel Report, *supra* note 3, paras. 7.3000-3001.

²² Panel Report, *supra* note 3, paras. 7.3036-3213.

found, by maintaining the measures in question, the European Communities acted inconsistently with Article 5.1.²³

The Role of International Law in Interpreting the WTO Agreement

The WTO Agreement is not the only set of international rules that applies to GMOs and their regulation. As part of its defense, the European Communities contended that the WTO agreements at issue "must be interpreted and applied by reference to relevant rules of international law arising outside the WTO context, as reflected in international agreements and declarations."²⁴ In this regard, the Panel considered the relevance of the 1992 Convention on Biological Diversity (Convention on Biological Diversity),²⁵ the 2000 Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Biosafety Protocol)²⁶ and the precautionary principle. In doing so, the Panel first examined the possibility of using the Convention on Biological Diversity and the Biosafety Protocol as an interpretative element to be "taken into account" together with the "context," pursuant to Article 31(3)(c) of the Vienna Convention on the Law of Treaties (Vienna Convention), which refers to "any relevant rules of international law applicable in the relations between the parties."²⁷ The Panel concluded that these agreements need not be taken into account because they were not in force for certain WTO Members.²⁸ As to the "precautionary principle," the Panel explained that the "relevant rules of international law" to be taken into account under Article 31(3)(c)

²³ Panel Report, *supra* note 3, paras. 7.3215-3371.

²⁴ Panel Report, *supra* note 3, paras. 7.49-50.

²⁵ *Opened for signature* June 5, 1992, 1760 UNTS 79.

²⁶ 39 ILM 1027 (2000); UN Doc. UNEP/CBD/ExCOP/1/3, at 42 (2000).

²⁷ *Opened for signature* May 23, 1969, 1155 UNTS 331.

²⁸ Panel Report, *supra* note 3, paras. 7.74-75. For the Convention on Biological Diversity, the United States signed it in 1993, but has not ratified it; as to the Biosafety Protocol, Argentina and Canada have signed it, but have not ratified it, and the United States has not signed it.

include general principles of law and it noted the European Communities' contention that the precautionary principle "is a relevant principle of this kind." On this issue, the Panel stated: "Since the legal status of the precautionary principle remains unsettled, like the Appellate Body before us, we consider that prudence suggests that we not attempt to resolve this complex issue, particularly if it is not necessary to do so." It further stated, "[o]ur analysis below makes clear that for the purposes of disposing of the legal claims before us, we need not take a position on whether or not the precautionary principle is a recognized principle of general or customary international law," and therefore "we refrain from expressing a view on this issue."²⁹

However, while rejecting the use of these international law instruments and principles under Article 31(3)(c), the Panel also considered "whether other rules of international law could be considered by us in the interpretation of the WTO agreements at issue even if these rules are not applicable in the relations between the WTO Members and thus do not fall within the category of rules which is at issue in Article 31(3)(c)." In this regard, the Panel noted that pursuant to Article 31(1) of the Vienna Convention, the terms of a treaty must be interpreted in accordance with the "ordinary meaning" to be given to these terms in their context and in the light of its object and purpose. The Panel expressed the view that "in addition to dictionaries, other relevant rules of international law may in some cases aid a treaty interpreter in establishing, or confirming, the ordinary meaning of treaty terms in the specific context in which they are used." On this basis, the Panel stated that "a panel may consider other relevant rules of international law when interpreting the terms of WTO agreements if it deems such rules to be informative," but a panel "need not necessarily rely on other rules of international law, particularly if it

²⁹ Panel Report, *supra* note 3, paras. 7.76-89.

considers that the ordinary meaning of the terms of WTO agreements may be ascertained by reference to other elements." Applying this approach to the case at hand, the Panel "did not find it necessary or appropriate to rely on [the Convention on Biological Diversity and the Biosafety Protocol] in interpreting the WTO agreements at issue in this dispute."³⁰

The *EC - Biotech Products* Panel report is an important part of the legal and political debate over the regulatory treatment of GMOs around the world. However, while the report seems to have resolved the specific claims at issue (the parties were satisfied enough with the outcome, each having won some key points, that the report was not appealed), a number of questions remain.

With regard to the specific legal questions addressed by the Panel, three issues in particular stand out. First, in examining the term "SPS measure" in Annex A(1), the Panel divided the term into the separate sub-elements of (1) the form of the measure (laws, decrees and regulations) and (2) the nature of the measure (requirements and procedures). This interpretation is arguably contrary to the plain meaning of the text, which simply provides that various types of measures -- laws, decrees, regulations, requirements and procedures -- are covered, rather than identifying two separate required sub-elements. The Panel did not offer any explanation for why it took this approach, and it is possible that the Appellate Body would take a different view. Under a different interpretation, a conclusion that the moratorium and the product-specific measures were SPS measures might have been possible, which could have led to additional findings of violation.

³⁰ Panel Report, *supra* note 3, paras. 7.90-96.

Second, the Panel's treatment of the international law issues, in particular its exclusion of the Convention on Biological Diversity and the Biosafety Protocol from consideration as rules to be taken into account together with the context pursuant to Article 31(3)(c) of the Vienna Convention, is somewhat controversial. Specifically, it has been argued that the Panel's decision to exclude international law instruments which have not been adopted by all parties to the relevant WTO agreement could make it very difficult for such instruments ever to be considered.³¹

Finally, the Panel's examination of the relationship between SPS Agreement Articles 5.1 and 5.7, while arguably faithful to past Appellate Body rulings, raises questions about the consistency and appropriateness of the current WTO jurisprudence on rules and exceptions. In various contexts, the Appellate Body has taken different approaches to establishing provisions as either "exceptions" or "conditional rights," with important consequences for the burden of proof. In some of these cases, the approach taken arguably does not have much support in the text, and there is also a problem with the overall coherence of the rulings in this area.³² It may be difficult to sustain the existing approach and apply it to similar issues in the future without further guidance and clarification from the Appellate Body.

In addition to these specific legal interpretations, the broader controversy underlying trade in GMOs remains largely unresolved. This dispute dealt with the relatively simple issue of an alleged refusal to approve or allow the sale of GMO products. However, it is clear that there are more complex legal battles on the horizon.

³¹ See Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law, Report of the Study Group of the International Law Commission Finalized by Martti Koskenniemi, UN Doc. A/CN.4/L.682, Apr. 13, 2006, at paras. 448, 450 and 471.

³² See Tomer Broude, *Genetically Modified Rules: The Awkward Rule-Exception-Right Distinction in EC - Biotech*, Hebrew University International Law Research Paper No. 14-06, December 2006.

For example, the United States continues to express concern over labeling and traceability requirements for GMOs in food products.³³ The consideration of such requirements under WTO rules would be very different from the measures at issue in this case, and the outcome if such rules were challenged is not clear.

Furthermore, opponents of GMOs will no doubt continue to search for evidence disputing their safety. If they are able to generate credible evidence in this regard, a general ban on GMOs, similar to the measures at issue here, may surface again.

As a final point, it is likely that the debate will be resolved through negotiations rather than litigation. The science and the law in this area may take us only so far when the feelings on both sides are so strong. It may be that a negotiated solution, with rules that balance the views of both sides, is the only way to resolve the issue.

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³³ See United States Trade Representative's Office, 2006 National Trade Estimate Report on Foreign Trade Barriers, at 239.