



**EC-BIOTECH:
OVERVIEW AND ANALYSIS OF THE PANEL’S INTERIM REPORT¹**

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Executive Summary

On February 7, 2006, a Dispute Settlement Panel at the World Trade Organization (WTO) issued the interim report in the European Communities – Measures affecting the Approval and Marketing of Biotech Products (EC-Biotech) case. Interim reports in the WTO contain all of the elements of a final report, but are released only to the parties to the dispute. This tendency towards secrecy and a closed-door approach is endemic to dispute settlement in the trade sector and has permitted the misrepresentation of the findings of the WTO Panel. The lack of transparency is particularly worrisome in cases where public health and the environment are at stake. As of this writing, the EC-Biotech report is still officially interim and secret, but has been made available to the public by Friends of the Earth Europe, which obtained a leaked report.

The objective of the present note is to provide an overview of the main findings and reasoning in the Panel’s Interim Report. In its report, the Panel addressed the various categories of European Communities (EC) and EC Member State measures challenged by the United States, Canada, and Argentina, and found each type of measures was – at least in certain respects – inconsistent with WTO rules. The measures in question were categorized into three types: an alleged EC moratorium on approvals of biotech products, product-specific EC measures related to the approval of biotech products, and measures related to the import and/or marketing of specific biotech products. The Panel found most of the challenged measures to fall under the scope of the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), an agreement with much more stringent risk assessment and science requirements than other agreements under the WTO such as the General Agreement on Tariffs and Trade (GATT) or the Agreement on Technical Barriers to Trade (TBT Agreement) that could also have been found applicable.

First, the Panel concluded that the general *de facto* moratorium and product-specific measures affecting product approval had resulted in a failure to complete individual approval procedures without undue delay, and hence gave rise to an inconsistency with Article 8 and Annex C of the SPS Agreement. The Panel did not find the general moratorium to be substantive SPS measures subject to the science and risk assessment provisions of the SPS Agreement. Rather, the Panel regarded these measures collectively to be a procedural decision to avoid making final decisions about product approvals, and thus subject only to the SPS procedural requirement not to cause “undue delay” in the approval procedure for biotech products. Although the Panel found there were no legitimate reason or justification for the delay in the present case, it also considered that the decision to delay the completion of approval procedures by imposing a general moratorium on final approvals of biotech products might be justifiable in other cases.

Second, the Panel found that the measures taken by some EC Member States restricting the import, use, and marketing of certain biotech products - safeguard measures taken in relation to products already approved at the EC level - failed to meet the requirements of the SPS Agreement. In particular, the safeguard measures were found to be inconsistent with the obligation for SPS measures to be based on a risk assessment. The Panel found that the safeguard measures fell outside the scope of Article 5.7 of the SPS Agreement,

which allows members to adopt provisional SPS measures where relevant scientific evidence is insufficient. The scientific evaluation of the products at issue at the European level, which all Parties agreed constituted risk assessments under the SPS Agreement, had, in the view of the Panel, proved that scientific evidence was “sufficient.” Moreover, because this scientific evaluation had resulted in the approval of the products - it could not justify measures to restrict them. Other scientific evidence presented by EC Member States was considered not to meet the characteristics of a risk assessment under the SPS Agreement. As a result, the safeguard measures were found not based on a risk assessment as required by Article 5.1 and thus were found inconsistent with the SPS Agreement.

Finally, the Panel rejected the EC’s argument that the Panel should take the 1992 Convention on Biological Diversity (CBD) and the 2000 Cartagena Protocol on Biosafety (Biosafety Protocol) into account when interpreting the relevant WTO rules in this specific case. The Panel found that according to the Vienna Convention on the Law of Treaties it did not have the obligation to take these treaties into account when interpreting WTO rules since not all parties to the dispute were parties to the CBD and the Biosafety Protocol. Moreover, the Panel indicated, without taking a definitive position, that the Vienna Convention’s obligation to take other agreements into account when interpreting WTO rules might only come into play in situations where *all* WTO Members are parties to the other agreement. The Panel also noted, however, that while there was no obligation to take into account other agreements, panels were nevertheless free to take into account other relevant agreements when wishing to do so. In this case, however, the Panel, without much explanation, concluded that it was not useful to take the CBD or the Biosafety Protocol into account.

I. Introduction

On February 7, 2006, a Dispute Settlement Panel at the World Trade Organization (WTO) issued the interim report in the European Communities – Measures affecting the Approval and Marketing of Biotech Products (EC-Biotech) case.² In its report, the Panel addressed the various categories of European Communities (EC) and EC Member State measures challenged by the United States, Canada, and Argentina, and found that each of these types of measures were inconsistent with WTO rules - in particular the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement). Nevertheless, the Panel emphasized that its report did not examine the safety of biotech products and that it had not examined the legitimacy of current EC legislation. Indeed, a spokesperson for Peter Mandelson, trade commissioner of the European Union, characterized the interim report as “largely of historical interest” as it would not affect or alter the European decision-making system or framework in relation to biotechnology products.³ Given distorted press statements and understanding of the Interim Report, however, concerns regarding the content of the ruling and its potential impact on the ongoing debate on biotechnology both in the European Union and in other countries remain.

The objective of the present note is to provide an overview of the main findings and reasoning in the Panel’s Interim Report. The claimants in EC-Biotech challenged three types of measures taken by the EC and EC Member States, all of which were dealt with in the ruling:

- *An alleged EC moratorium on approvals of biotech products:* The claimants did not request the Panel to make findings on the WTO-consistency of the EC regulations on the approval of biotech products, but rather argued that there had been a de facto suspension of such approvals. The EC denied the existence of a general moratorium on the approval of biotech products and submitted that the alleged practice alone, not based on a formal or informal instrument, would not constitute a measure under WTO agreements.
- *Various product-specific EC measures related to the approval of biotech products:* The claimants argued that the failure of the EC to consider specific applications for approval of biotech products also constituted a violation of WTO rule. In response, the EC argued that failing to deal with product applications within a specified timeframe could not be considered a measure, and thus would only be subject to provisions dealing with the application, rather than development of a measure.
- *Various EC Member State measures related to the import and/or marketing of specific biotech products:* The claimants challenged measures enacted by some EC Member States, including France, Germany, Italy, and Greece, arguing these

² On 4 March 2004, the Director-General composed the panel with Christian Haberli (Switzerland), Mohan Kumar (India), and Akio Shimizu (Japan).

³ Raphael Minder and Edward Alden, “EU shrugs off GM foods censure,” *Financial Times*, February 9, 2006.

measures were not based on scientific evidence, as required by WTO rules. The ‘safeguard measures,’ permitted by EC regulations, allow EC Member States to limit the importation or marketing of certain biotech products already approved by the EC. The EC, on its part, claimed these measures, given their provisional nature, were in full compliance with relevant WTO disciplines.

This note will analyze the Panel’s findings in relation to these three categories of challenged measures, as well as address certain crosscutting issues in the Interim Report. This note will not cover in its entirety the arguments of the Parties or the findings of the Panel. Instead, it will focus on the points of the reasoning of the Panel most relevant for the challenged measures and for broader discussions on the relationship between WTO rules and biosafety and biotechnology regulations.

Following the introduction, Section II will address concerns regarding transparency and public participation in the WTO Dispute Settlement Process raised by the EC-Biotech process and Interim Report, including the Panel’s treatment of several *amicus curiae* briefs presented by various groups and experts. Although the Panel accepted these briefs, it found it unnecessary to consider them, in spite of the fact that the dispute involves issues that directly affect public policy concerns such as environmental protection and human health.

Section III will provide a brief background to the measures challenged by the claimants and addressed by the Panel. Then, Section IV will begin looking at the Panel’s reasoning in the Interim Report, specifically in relation to the scope of the SPS Agreement. According to the Panel, the purpose and targeted concerns of the challenged measures fall within the scope of the SPS Agreement.⁴ This conclusion is important because the SPS Agreement is arguably stricter than other potentially applicable agreements, such as the General Agreement on Tariffs and Trade (GATT) or the Agreement on Technical Barriers to Trade (TBT Agreement).

Section V will provide an overview of the claims of inconsistency made by the complaining parties regarding the general moratorium and the product-specific measures, as well as of the relevant findings of the Panel. Sections VI, VII, and VIII will then expound on particular aspects of the Panel’s reasoning, in relation to the general moratorium and product specific measures.

Section VI will address the Panel’s consideration of the definition of “SPS measure” and the consequences for the challenged measures. In particular, the Panel determined that the general moratorium and the product-specific measures were not SPS measures within the meaning of Annex A (1) and any of the substantive provisions of the SPS Agreement at issue, which thus were considered not to apply.

Section VII will analyze the Panel’s findings in relation to the question of “undue delay.” The Panel concluded that the general moratorium was inconsistent with Annex C and Article 8 of the SPS Agreement, which require that procedures to check and ensure the

⁴ Paragraph 7.428.

fulfillment of SPS measures are undertaken and completed without undue delay. Section VIII will describe another important issue addressed in relation to the general moratorium: the implication of special and differential treatment in the SPS Agreement. The Panel indeed rejected claims that the EC, through its general moratorium, had failed to take account of Argentina's special needs as a developing country and thus acted inconsistently with Article 10.1 of the SPS Agreement.

Section IX will subsequently analyze the Panel's findings in relation to the safeguard measures enacted by EC Member States. In contrast to the general moratorium and the product-specific moratoria, which were found to violate procedural rules only, in the case of these national measures the Panel found substantive violations of SPS provisions. The Panel decided that every challenged national safeguard measure violated the SPS Agreement's science-related provisions. In particular, the Panel found each measure in violation of Article 5.1, which requires that a measure be based on a risk assessment. It also found that the national safeguard measures did not fall within the scope of Article 5.7, which applies in cases "where relevant scientific evidence is insufficient," and which allows Members to adopt provisional sanitary or phytosanitary measures on the basis of available pertinent information. By implication, the Panel also found a violation of Article 2.2 of the SPS Agreement, which requires that a measure be based on scientific principles and not maintained without sufficient scientific evidence.

Section X will then analyze another critical element of the Panel's reasoning and findings: the relevance of multilateral environmental agreements and other international law in interpreting WTO rules. In the Interim Report, the Panel rejected the idea that it was required to take into account either the Convention on Biological Diversity (CBD) or the Cartagena Protocol on Biosafety (Biosafety Protocol), in light of the fact that several WTO Members, including the complaining parties to the dispute, were not parties to the agreements in question.

Finally, Section XI will bring to a close this note by offering some concluding remarks on the legal reasoning of the Panel, as well as on the potential implications of the reasoning and findings in the Interim Report on the challenged measures, the EC regulations, and biotechnology and biosafety laws and policies more generally.

II. Transparency and Public Participation

A. Transparency

WTO panels release interim reports only to the parties to the dispute. When the secret interim panel report in the EC-Biotech case was issued to the disputing parties, journalists around the world tried to get hold of it — apparently without success. The news coverage was entirely based on hearsay, and special interest groups, including certain government officials, were able to completely misrepresent the WTO panel's findings. Because the report was secret, no one could challenge the distorted representations.

Interim reports contain all of the elements of a final report (the revised descriptive part, the findings, the conclusions and the recommendations, and, as the case may be, suggestions for implementation). Although parties are entitled to make comments and may also request a meeting of the panel to further argue specific points, it is rare for the parties to ask the panel to completely overturn its interim decision. As a result, the content of the report does not generally vary upon finalization. This case shows that this phase of secrecy is dangerous as it can lead to the manipulation of information in matters that are of direct concern to all WTO Members as well as to the public, globally.

According to the timetable established by Appendix III of the DSU, after the issuance of the interim report, parties have one week to ask for a review. If so, the period of review must not exceed two weeks, during which time, the Panel may hold additional meetings with the two sides. A final report is then submitted to the two sides and three weeks later, it is circulated to all WTO members.

As of this writing, the EC-Biotech report is still officially interim and secret, but has been made available to the public by Friends of the Earth Europe, which obtained a leaked report. This note is based on that text.

B. Public participation

Another important issue is public participation. In the context of the WTO, the role of *amicus curiae* briefs (written submissions by ‘friends of the court’) is particularly important when disputes involve issues that directly affect the residents of disputing parties, such as environmental protection or public health, or even other people. In the EC-Biotech case, the Panel confirmed jurisprudence concerning its power to accept *amicus curiae* briefs. Adding to a troubling trend, however, the Panel also found it unnecessary to consider the *amicus curiae* briefs that it accepted.

The Panel accepted the three unsolicited *amicus curiae* briefs from: a group of university professors; a group of non-governmental organizations, represented by the Foundation for International Environmental Law and Development (FIELD); and a group of non-governmental organizations represented by the Center for International Environmental Law (CIEL).⁵ The Panel noted that the briefs were submitted prior to the first substantive meeting of the Panel with the parties, and the parties and that third parties were given an opportunity to comment on these briefs. In line with previous jurisprudence, the Panel reiterated that it has the ‘discretionary authority either to accept and consider or to reject any information submitted to it, whether requested by a panel or not’ and that in this case it accepted the three submissions. However, in rendering its decision, it stated that it ‘did not find it necessary to take the *amicus curiae* briefs into account.’⁶ To date, panels and the Appellate Body have expressly taken into account only *amicus curiae* briefs that were attached to parties’ submission. In *Shrimp/Turtle I*, for example, the Appellate Body accepted for consideration three briefs from non-governmental organizations that the United States had attached to its appellate submission. Similarly, in *U.S. – Shrimp/Turtle*

⁵ Paragraph 7.10

⁶ Paragraph 7.11

21.5, both the panel and the Appellate Body accepted and considered the attached *amicus* briefs, but did not do the same with briefs that were not attached.

Given that the Panel had no expertise regarding the science relating to GMOs, it sought information from the secretariats of the CBD, Codex, Food and Agriculture Organization, International Plant Protection Convention, OIE, United Nations Environment Programme and World Health Organization, inviting these to ‘identify appropriate standard references (scientific or technical dictionaries, documents adopted or circulated by the relevant international organization, etc.) that would assist the Panel in ascertaining the meaning of certain terms and concepts.’⁷ Other than that, it seems the Panel did not solicit the views or specific expertise of any of these organizations.

C. Preliminary conclusions

The deficits of democracy in the WTO are augmented by the secrecy of interim rulings and the failure of dispute settlement panels or the Appellate Body to consider *amicus curiae* briefs. In that regard, accepting *amicus curiae* briefs only to neglect them afterwards further underscores the closed door characteristics of dispute settlement in the trade arena, which ultimately leads to reasoning and decisions of lesser quality. Cases involving public health and the environment cannot afford poorly reasoned decisions.

III. **Background on Challenged Measures**

As mentioned, three types of measures taken by the EC and EC Member States were challenged in the EC-Biotech case: an alleged EC moratorium on approvals of biotech products; various product-specific EC measures related to the approval of biotech products; and several EC Member State measures related to the import and/or marketing of specific biotech products. This section will provide a brief overview of these measures, as well as a short explanation of the EC approval procedures for biotechnology products, which are relevant for all three categories of measures.

A. EC approval procedures for biotechnology products

In the Interim Report, the Panel gave a detailed description of the EC-approval procedures. It stressed at the outset that the complaining parties had not challenged these procedures *as such*, but rather the *application* of these procedures. In its analysis the Panel examined the legal instruments that were in force on or before the date of establishment of the Panel, *i.e.*, on 29 August 2003. These are:

- Directive 90/220/EEC “on the deliberate release into the environment of genetically modified organisms” (repealed on 17 October 2002);
- Directive 2001/18 “on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC;” and

⁷ Paragraph 7.31

- Regulation 258/97 “concerning novel foods and novel food ingredients.”⁸

The two directives on the deliberate release into the environment of genetically modified organisms (GMOs) - Directives 90/220 and 2001/18 - aim to avoid adverse effects on human health and the environment which might arise from the deliberate release into the environment of products consisting of, or containing, GMOs. Among other things, these Directives establish administrative procedures for granting consent for the placing on the market of GMOs. Directive 2001/18 replaced Directive 90/220. According to the Panel, the administrative procedures laid down by Directive 2001/18 are more efficient, but overall, the two administrative procedures are very similar.

The stages of approval procedures include the submission of application by applicant and assessment by the competent authority of the Member State where the GMO is to be placed on the market for the first time, as well as community-level mechanisms in case of objections. Where a GMO used as, or in, a product has been approved for marketing under Directives 90/220 or 2001/18, Member States ordinarily may not prohibit or restrict trade in, or use of, that product. Exceptionally, however, Member States may provisionally adopt safeguard measures. Pursuant to Article 16 of Directive 90/220, a Member State may provisionally restrict or prohibit the use and or sale of a product in its territory where it has justifiable reasons to consider that a product constitutes a risk to human health or the environment. Article 23 of Directive 2001/18 provides that a safeguard measure may be adopted where, on the new or additional information made available since the date of the consent, a Member State has detailed grounds for considering that a GMO constitutes a risk to human health or the environment. The safeguard measures taken pursuant to these Directives may be maintained on a provisional basis only, until a full assessment at EC level is made,⁹ and a decision is made resulting either in the modification of the marketing approval or in the termination of the safeguard measure.¹⁰

Regulation 258/97 concerns the placing on the market of products to be used as a novel food or a novel food ingredient. These products include foods and food ingredients containing or consisting of GMOs within the meaning of Directives 90/220 and 2001/18. They also include foods and food ingredients produced from, but not containing, GMOs. The main purpose of Regulation 258/97 is to ensure that the novel foods and food ingredients do not present a danger for the consumer; do not mislead the consumer; and do not differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous to the consumer. Regulation 258/97 sets out the administrative procedures for granting consent for the placing on the market of the products foods and food ingredients containing or consisting of GMOs. These administrative procedures are similar to those under Directives 2001/18 and 90/220, including in regards to safeguard measures.

⁸ Directive 2001/18 and Regulation 258/97 are in force.

⁹ Article 16(1) of Directive 90/220 and Article 23(1), 3rd paragraph of Directive 2001/18.

¹⁰ Article 21 of Directive 90/220.

B. General *de facto* moratorium on approval of biotech products

The complaining parties asserted that the EC had maintained a *de facto* moratorium on the approval of biotech products since October 1998. The EC contested its existence, noting no instrument or other text through which such a “moratorium” is brought into effect had been put forth and all of the complainants’ claims were in reality complaints about delay. As a consequence, the Panel examined at length and in detail whether the evidence supported the complaining parties’ assertion.

Among other things, the Panel examined whether the EC showed intention to suspend approvals and whether there was in fact an absence of approvals. It also examined a large number of documents and statements referring to a moratorium, including documents of the European Commission and statements by individual European Commissioners.¹¹ Moreover, the Panel examined the facts and histories of a number of individual approval procedures, examining the exact points where the approval process was inhibited by omissions or actions by the Commission and EC Member States.

Important considerations included that not a single biotech application under consideration between October 1998 and August 2003 had been approved on or before the date of establishment of the Panel. Moreover, the Panel considered the so-called ‘June 1999 declaration by the Group of Five countries’ as direct evidence of an intention on the part of the relevant five Member States (Denmark, Italy, France, Greece and Luxembourg) to do what was within their power to prevent the approval of applications, pending the adoption of EC rules concerning labeling and traceability of biotech products.

The Panel found that because of the June 1999 declaration, the Commission had reason to believe that it could no longer approve applications with the (qualified majority) support of the Member States. The Panel found it logical that the systematic opposition by the Group of Five countries might have affected the Commission’s readiness to make full use of the relevant procedures to complete the approval process.

Together with the above considerations and the numerous documents and statements by EC or EC Member States regarding a general moratorium, the Panel concluded that a moratorium on approvals was in effect in the EC between June 1999 and August 2003, when the Panel was established. It concluded that this moratorium was applied *de facto*, *i.e.*, without having been adopted through a formal EC rule- or decision-making process and, more particularly, that the final approval of applications was prevented by the Group

¹¹ The European Commission is one of the institutions participating in the decision-making process of the European Union. The European Commission was created to represent the European interest common to all Member States of the Union. It has a right of initiative in the legislative process, proposing the legislation on which the European Parliament and the Council decide. It is also responsible for implementing common policies and administers the budget and manages the European Union’s programs. The word ‘Commission’ can refer to both the institution and to the college of Commissioners. The college of Commissioners is made up of one Commissioner from each Member State.

of Five countries and/or the Commission through their actions and/or omissions.¹² Specifically, the Panel stated:

Based on the foregoing observations, the Panel considers that between June 1999 and August 2003 the Group of Five countries and the Commission did follow a common ‘plan or course of action.’ The relevant ‘plan’ consisted in preventing the final approval of applications pending the adoption of new EC rules on labeling and traceability. The fact that the Commission might have disliked the ‘plan,’ or sought to change it, is immaterial as long as the Commission did not actually follow a different ‘plan.’ As noted, there is no indication that this was the case.¹³ (Footnotes omitted)

The Panel’s findings regarding the existence of a *de facto* moratorium are interesting in that they show what issues may come up in the various phases of the EC approval procedures, which involve a number of different entities. However, the fact that the Panel found that the EC had applied a *de facto* moratorium probably will have little significance for biotech approval procedures more generally.

According to the EC, the finding of a general *de facto* moratorium on approvals between June 1999 and August 2003 should not automatically mean that the Panel may, or should, make findings on the WTO-consistency of the general moratorium. The EC questioned whether the moratorium was a challengeable measure under WTO rules. If the moratorium were regarded as challengeable measure, then the Panel should nevertheless refrain from making findings on the WTO-consistency of the measure because the moratorium ceased to exist after the date of establishment of the Panel, making the remaining questions of the WTO-consistency of the general moratorium moot.¹⁴

Referring to the Appellate Body’s definition of a ‘measure’ as “any act or omission attributable to a WTO Member,” the Panel concluded that both *de jure* measures and *de facto* measures were covered by the term ‘measure’ as used in the *Understanding on the Settlement of Disputes (DSU)*. Moreover, the Panel found itself competent to make findings on the WTO-consistency of the moratorium on approvals even though the moratorium ceased to exist subsequent to the establishment of the Panel.¹⁵

¹² Paragraph 7.1264

¹³ Paragraph 7.1273

¹⁴ Paragraph 7.1278

¹⁵ The Panel noted that the DSU gave it the authority to make findings on a measure within its terms of reference even if that measure had ceased to exist. The Panel then stated it would make use of that authority because findings in relation to the general moratorium – in spite of it no longer being in force – would secure a positive solution to the dispute. In particular, it considered the continuing EC member State opposition to approvals and the possibility of the re-imposition of a *de facto* moratorium justified addressing the WTO-consistency of the measure (Paragraph 7.1311).

C. Product-specific measures related to the approval of biotech products

In addition to the claims in relation to the general moratorium on approvals, the complaining parties also challenged a number of product-specific measures. These alleged failures to consider for approval certain specific applications were considered by the complaining parties as separate yet similar and related measures to the general moratorium. In particular, the United States made claims in respect of twenty-seven applications. Canada and Argentina requested findings in relation to four and seventeen applications, respectively. The Panel considered all these product-specific measures, except for the one concerning GA21 maize, since the relevant application had been withdrawn before the establishment of the Panel. The Panel deemed useful to offer findings for cases in which the applications were withdrawn or approved after the establishment of the Panel, but any recommendations would not apply.

D. National measures related to the import and/or marketing of specific biotech products

In *EC-Biotech*, the complaining parties made a series of claims in relation to measures adopted by EC Member States, alleging these measures prohibit the import, use of, or marketing of certain biotech products. These measures, which are referred to by the Panel as “safeguard measures” or “member State measures,” were adopted on the basis of Directives 90/220 and 2001/18, as well as on the basis of Regulation 258/97 – all of which are described above. In particular, the complainants made claims with respect to nine different safeguard measures (the United States challenged all nine, while Canada and Argentina challenged five and six, respectively). These measures were adopted by six EC Member States, namely Austria, France, Germany, Greece, Italy, and Luxembourg. Although safeguard measures are subject to a review under relevant EC legislation, the Panel found that as of the date of its establishment, no decision had been taken on any of them at the European Community-level.

IV. Scope of the SPS Agreement

As mentioned, the EC had questioned the applicability of the SPS Agreement – at least in part – to all challenged measures. The Panel, however, found the SPS Agreement to apply, in one way or another, to each of these measures. This conclusion was most important since it thus required the measures would have to fulfill the disciplines of the SPS Agreement, which are generally considered more stringent than the disciplines under the TBT Agreement or the GATT. Moreover, the TBT Agreement does not apply to SPS measures.

The SPS Agreement sets out specific scientific requirements, including the requirement to base measures on an assessment of risks, elements not present in the GATT or the TBT Agreement. As of February 2006 four cases involving the SPS Agreement have been considered by the Appellate Body, and in all four cases, the defending Member lost and was found to violate SPS disciplines.

A. Scope of application of the SPS Agreement as defined by Annex A (1)

The scope of application of the SPS Agreement depends on the definition of SPS measures in Annex A of the SPS Agreement. Annex A (1) defines a sanitary or phytosanitary measure with respect to the *purpose* of the measure. Annex A thus distinguishes four types of SPS measures according to their purpose. It defines SPS measures as:

Any measure applied:

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

A footnote specifies that “[f]or the purpose of these definitions, ‘animal’ includes fish and wild fauna; ‘plant’ includes forests and wild flora; ‘pests’ include weeds; and ‘contaminants’ include pesticide and veterinary drug residues and extraneous matter.”

Also, according to Annex A (1), 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 labeling requirements directly related to food safety.

The Panel analyzed the scope of the SPS Agreement particularly in relation to the EC approval procedures, which it were found to be SPS measures. The issue was also addressed in regard to each of the national measures, however, which were also found to be SPS measures.

B. EC-Approval Procedures and the SPS Agreement

While the EC acknowledged that its approval procedures fall in part within the scope of the SPS Agreement, it also insisted that, in part, the approval procedures fell outside the scope of the SPS Agreement. While accepting the concept that a measure could

incorporate both SPS as well as other measures simultaneously,¹⁶ the Panel rejected most of the EC arguments in this respect, concluding that most aspects of the EC approval procedures fell under the SPS Agreement. Overall, the Panel provided a broad interpretation of the definition of SPS measures, thus expanding the scope of application of the more stringent SPS Agreement.¹⁷

For example, the EC argued that, while Annex A (1)(b) of the SPS Agreement concerns certain things “in foods, beverages or feedstuffs,” a genetically modified (GM) seed destined to be planted in the ground, not eaten by humans or fed to animals cannot be considered to be a “food, beverage or feedstuff.” As a consequence the EC concluded that the definition of Annex A (1)(b) could not apply. The EC further argued that although the term “disease” appears in both Annex A of the SPS Agreement and the EC legislation, a genetically modified organism (GMO) is not infected or an infection and is not, in itself, a “disease” within the meaning of Annex A (1), making Annex A (1) inapplicable. The Panel rejected all of these interpretations. Furthermore, with regard to the term “pest” as used in the definition in Annex A (1), the Panel rejected the EC claim that, in order for a GMO to be a pest within the meaning of the SPS Agreement, the relevant GMO would have to be “pathogenic” or “injurious” – that is, it would have to do more than merely interact in some way with humans, animals or plants, and that accordingly, a GMO could not fall under the definitions of Annex A 1 (a), (c) or (d), all of which refer to pests and/or diseases.

The EC also noted that Directives 90/220 and 2001/18 repeatedly list as one of their purposes the protection of the environment. The EC contrasts this with Annex A of the SPS Agreement which it claims does not address environmental protection, unlike Article 2.2 of the TBT Agreement, for example, which expressly refers to “the environment.” According to the EC, it is clear that when the drafters used a term in one instrument but not in another, the drafter intended to exclude that term from the latter instrument. The EC concluded from this that the SPS Agreement was not intended to address the prevention of risks to the environment.¹⁸ The Panel, however, found that Annex A (1)(a) and (b) of the SPS Agreement covered measures applied to protect animal and plant life or health from certain risks. Thus, to the extent Directives 90/220 and 2001/18 were applied to protect animals and plants as part of their purpose of protecting the environment, they were not *a priori* excluded from the scope of application of the SPS Agreement.¹⁹

1. *Identifying the types of risks covered by Directives 90/220 and 2001/18*

In examining the application of the SPS Agreement to EC approval procedures, the Panel, with respect to Directives 90/220 and 2001/18, noted that the central purpose was

¹⁶ Paragraphs 7.150 - 7.173

¹⁷ The Panel, in line with the approach of all disputing Parties, treated each the three EC approval procedures as constituting one single SPS measure, rather than constituting more than one SPS measure (Paragraph 7.425).

¹⁸ Paragraph 7.198

¹⁹ Paragraph 7.203

to protect human health and the environment when placing on the market GMOs in themselves or in products, and to avoid adverse effects on human health and the environment which might arise from the deliberate release of GMOs. The Panel also observed that while neither of the directives explicitly identified what potential risks for human health and the environment had to be assessed prior to a release of GMOs into the environment, they nevertheless identified the information required in an application for marketing approval. Such information encompassed, for instance, the characteristics of the GMO, such as, toxic or allergenic effects, information on pathogenicity, communicability, host range, antibiotic resistance patterns, and the potential for excessive population increase in the environment or the competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s). The Panel also considered the fact that Directive 2001/18 addresses the methodology to be followed to perform an environmental risk assessment, which mentions that potential adverse effects of GMOs may include, for instance, disease to humans including allergenic or toxic effects; disease to animals and plants including toxic, and where appropriate, allergenic effects, among others.

2. *Purposes of Directives 90/220 and 2001/18 and application of the SPS Agreement*

The Panel examined in great detail whether Directives 90/220 and 2001/18 fell within the scope of Annex A (1), and considered the meaning and scope of some of the terms and phrases used in Annex A (1)(a)-(d) to determine whether certain potential effects of GMOs identified in the Directives meet the definition of these terms and phrases.

The Panel began its analysis with an examination of **Annex A (1)(a)** which covers measures “to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms.” Notably, the Panel considered that the term “pest” in Annex A (1) had to be understood to cover plants in addition to animals.

In applying the concept of pest to the EC Directives, the Panel assessed three situations referred to by the disputing parties, including:

- (a) situations where GM plants grow where they are undesired, *e.g.*, as a result of seed spillage or persistence or invasiveness;
- (b) situations of unintentional gene flow or transfer from a GM plant ("out-crossing"), leading to cross-breeds between GM plants and other plants, whether conventional crops or wild flora, which have undesired introduced traits (such as herbicide or insect resistance) and may establish or spread; and
- (c) situations where pesticide-producing (*e.g.*, insecticide-producing) GM plants increase the potential for the development of pesticide-resistance in target organisms, notably insects.²⁰

²⁰ Paragraph 7.235

The Panel found that the risk of ‘pest’ (which – according to the SPS definition includes ‘weeds’) was inherent to all of the three situations. It also stated several times that there is nothing in the text of Annex A (1) to suggest that the product subject to an SPS measure – such as a pesticide-producing GMO to be released into the environment – need itself be the pest which gives rise to the risks from which the measure seeks to protect.²¹

The Panel also addressed the question whether other potential adverse effects of GMOs include effects on non-target organisms and biogeochemical cycles. It concluded that, to the extent that Directives 90/220 and 2001/18 sought to avoid adverse effects on the environment which involve adverse effects on the life or health of non-target organisms (animals and plants) and which arise from the management techniques associated with GMOs, the Directives could be viewed as measures applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds, and consequently “pests.”²²

The Panel also examined whether Directives 90/220 and 2001/18 fall within the scope of **Annex A (1)(b)** of the SPS Agreement, covering measures “to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs.”

As with its previous analysis, the Panel analyzed the specific terms and phrases used in Annex A (1)(b), including “foods, beverages or feedstuffs,” “additives,” “contaminants” and “toxins.” Here too, the Panel took a rather broad approach to interpretation. For example, it concluded that ‘feedstuff’ could include a GM crop that had been grown for a different purpose, but is eaten by animals, including wild fauna, and thus could be considered to be a “food” for that animal. According to the Panel, this would include, for example, pollen of the GM crop that is consumed by insects and GM plants consumed by non-target insects, deer, rabbits or other wild fauna. The Panel found:

“Contrary to the European Communities, we think GM seeds used for sowing purposes could also be considered animal “food”, for instance if these seeds are spilled next to a field or on a farm and are subsequently eaten by birds, etc.”²³

The Panel also rejected the EC’s interpretation of the term ‘additive,’ which the EC based on the Codex Alimentarius Commission definition of an additive as a substance that is added to “food.”²⁴ Based on this definition, the EC argued that the definition could not be a substance which is added to plants and which may find its way into food. Hence, it

²¹ Paragraph 7.258

²² Paragraph 7.268

²³ Paragraph 7.285

²⁴ The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

concluded that genes could not be considered substances, but rather instructions for the creation of substances.²⁵ The Panel rejected this interpretation and noted:

“A "substance" is defined as the "real physical matter of which a person or thing consists". It is our understanding that genes may be considered as "real physical matter". We do not dispute that genes contain and encode instructions for the creation of various substances. However, this does not exclude that genes may themselves constitute substances.”²⁶

With respect to **Annex A (1)(c)** (which covers measures “to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests”) the Panel concluded that to the extent a GM plant produces allergenic effects other than as a food, it would be a plant which causes harm to the health of humans and, as such, would qualify as a “pest.”²⁷

Finally, in the context of **Annex A (1)(d)** covering measures to prevent or limit other damage within the territory of a Member from the entry, establishment or spread of pests, the Panel considered the meaning of the term “other damage” used in Annex A (1)(d) and addressed whether certain potential effects of GMOs could be said to give rise to “other damage.” The Panel concluded that “other damage” included physical damage to property or economic damage, as well as damage to the environment other than damage to the life or health of living organisms (*i.e.*, animals or plants). In this context, the Panel noted, however, that damage to “biodiversity” implied damage to living organisms that would more likely qualify as the type of risks referred to in Annex A (1)(a) and (b).²⁸

3. *Purposes covered by Regulation 258/97 and application of the SPS Agreement*

The Panel also examined whether the risks or concerns identified in Regulation 258/97 were risks that fall within the scope of the definition of an SPS measure provided in Annex A (1) of the SPS Agreement. Regulation 258/97 concerns novel foods and food ingredients, including foods and food ingredients containing or consisting of GMOs, and foods and food ingredients produced from, but not containing, GMOs. The Panel pointed to Article 3(1) of the Regulation, which states that foods and food ingredients falling within the scope of the Regulation must not (1) present a danger for the consumer, (2) mislead the consumer, and (3) differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.²⁹

The Panel concluded that to the extent the Regulation seeks to achieve the first of the three purposes – *i.e.*, ensuring that novel foods not present a danger for the consumer – it

²⁵ Paragraph 7.288

²⁶ Paragraph 7.291, footnotes omitted.

²⁷ Paragraph 7.345

²⁸ Paragraph 7.365

²⁹ Paragraph 7.386

could be considered as a measure which is applied for the purpose identified in Annex A (1)(b), thus qualifying as an SPS measure.³⁰ It concluded, however, that to the extent Regulation 258/97 is applied to achieve the second and third purposes – *i.e.*, ensuring that novel foods not mislead the consumer, and that they not be nutritionally disadvantageous for the consumer – the regulation was not a measure applied for one of the purposes mentioned in Annex A (1), thus not qualifying as an SPS measure. The Panel concluded:

“Since the Regulation does not meet one of the constitutive elements of the definition of the term "SPS measure", it follows that Regulation 258/97 is not an SPS measure within the meaning of Annex A (1) to the extent it is applied to ensure either that novel foods not mislead the consumer or that they not be nutritionally disadvantageous for the consumer.”³¹

C. National safeguard measures and the SPS Agreement

The applicability of the SPS Agreement was also analyzed in relation to the national safeguard measures. The United States argued that the purpose and nature of safeguard measures as SPS measures could be inferred from the text of the EC regulations on which they were based. Nevertheless, the Panel found that the mere invocation or reference to these regulations did not in itself demonstrate that a particular measure had the purpose and nature that qualified it as an SPS measure.³² As a result, the Panel examined the purpose, form and nature, and effect on international trade of each of the nine challenged measures individually to determine if they were SPS measures as described in the SPS Agreement. To a large degree, the legal reasoning described above in relation to the EC approval regulations was applied in the analysis of the safeguard measures. In each case, safeguard measures were found to constitute SPS measures.

D. Preliminary conclusions

The interpretation of Annex A (1), which provides the definition of SPS measures, determines the scope of application of the said agreement. The Panel for the purposes of the SPS Agreement provided broad interpretations of the key terms of the SPS measure definition. Accordingly, the Panel found that most of the purposes covered by the EC approval procedures, as well as the national safeguard measures, qualified as purposes covered by the SPS Agreement. This approach provides for a broad application of the SPS Agreement and its disciplines, which are arguably more stringent than the disciplines under other WTO agreements. At the same time, in the context of Regulation 258/97, the Panel clearly said that measures aimed at mere consumer information were not covered by the SPS Agreement.

³⁰ Paragraph 7.389

³¹ Paragraph 7.408

³² Paragraph 7.2550. The Panel stated, however, that the fact that the member States involved these regulations, together with other elements, could support the conclusion that these measures were applied with the purpose to protect against risks to human health or the environment.

In line with this conclusion, the Panel found that one measure incorporating different purposes could fall within the scope of application of more than one WTO agreement. It remains unclear, however, what happens when there is such an overlap. To the extent that a purpose falls under the SPS Agreement, that agreement would apply, and to the extent that a purpose is not covered by the SPS Agreement, another agreement (probably the TBT Agreement or the GATT) would apply. A measure could be found consistent with the TBT Agreement, but not with the SPS Agreement.

In this scenario, a Member should arguably be able to continue to maintain its measure. These considerations are particularly important in the context of labeling requirements, for instance, which were not at the center of the EC-Biotech dispute and discussed only superficially in the Panel's decision.

V. **Alleged Inconsistencies of General Moratorium and Product-Specific Measures with WTO Rules**

The complaining parties presented several different inconsistencies in relation to the European Communities' general *de facto* moratorium on final approvals and to the product-specific measures related to the approval of biotechnology products.

In relation to the general *de facto* moratorium, the United States alleged the following violations under the SPS Agreement:

- Annex C (1)(a) and, consequently, Article 8;
- Annex C (1)(b) and, consequently, Article 8;
- Annex B (1) and, consequently, Article 7;
- Article 5.1 and, consequently, Article 2.2; and
- Article 5.5 and, consequently, Article 2.3.

Canada alleged the following violations under the SPS Agreement:

- Article 5.1 and, consequently, Article 2.2;
- Article 5.6 and, consequently, Article 2.2;
- Article 5.5 and, consequently, Article 2.3;
- Annex C (1)(a) and, consequently, Article 8; and
- Annex B (1) and consequently, Article 7.

Finally, Argentina alleged the following violations under the SPS Agreement:

- Article 5.1 and, consequently, Article 2.2
- Article 5.5 and, consequently, Article 2.3
- Article 7 and Annex B (1); and
- Article 10.1.

In relation to the product-specific measures, the United States alleged the following violations under the SPS Agreement:

- Annex C (1)(a) and, consequently, Article 8;
- Annex B (1) and, consequently, Article 7;
- Annex C (1)(b) and, consequently, Article 8;
- Article 5.1 and, consequently, Article 2.2; and

- Article 5.5.

Canada alleged the following violations of WTO rules:

- Article 5.1 and, consequently, Article 2.2 of the SPS Agreement;
- Article 5.6 and, consequently, Article 2.2 of the SPS Agreement;
- Article 5.5 and, consequently, Article 2.3 of the SPS Agreement;
- Annex C (1)(a) and, consequently, Article 8 of the SPS Agreement;
- Article III:4 of the GATT 1994; and
- In the alternative, Articles 2.1, 2.2, 5.1.2, and 5.2.1, first part, of the TBT Agreement.

Finally, Argentina alleged the following violations of WTO rules:

- Article 5.1 and, consequently, Article 2.2 of the SPS Agreement;
- Article 5.5 and 5.6 of the SPS Agreement;
- Annex C (1) (a), (b), (c), and (e) and, consequently, Article 8 of the SPS Agreement;
- Article III:4 of the GATT 1994; and
- In the alternative, Articles 2.1, 2.2, 5.1.1, 5.1.2, and 5.2.1, 5.2.2, and 12 of the TBT Agreement.³³

Claims under the SPS Agreement covered both procedural and substantive requirements. An overview of the Panel findings in relation to claims under the SPS Agreement is provided in the table below. The general moratorium and product-specific measures, the Panel found, were decisions concerning the application, or operation, of procedures, and thus were not SPS measures subject to the substantive requirements relating to risk assessment and science more generally. This issue will be addressed in Section VI. The Panel, however, found that inconsistencies with procedural requirements under Article 8 and Annex C (1) (a) of the SPS Agreement, discussed under Section VII. Finally, the Panel addressed Argentina's claims on special and differential treatment under Article 10.1, but did not find inconsistencies.

The Panel did not look at claims under the GATT and TBT Agreement.

General Moratorium: Claimed inconsistencies with SPS Agreement and Panel Findings		
SPS Agreement	Text	Panel Findings
Article 2.2 <i>(Article 2: Basic Rights and Obligations)</i>	Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not	Since the EC has not acted inconsistently with Article 5.1, and since the complaining parties' claims under Article 2.2 are premised on the existence of a breach of Article 5.1 by the

³³ In other words, both Canada and Argentina stated the Panel should examine the product-specific measures under the SPS Agreement. However, if the Panel were to conclude the SPS Agreement was not applicable, then Canada and Argentina claimed the measures were inconsistent with the requirements of the TBT Agreement.

General Moratorium: Claimed inconsistencies with SPS Agreement and Panel Findings		
SPS Agreement	Text	Panel Findings
	maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.	<p>EC, the complaining parties' claims under Article 2.2 cannot succeed.</p> <p>[The individual complaining parties challenged different parts of Article 2.2.]</p> <p>Conclusion: The complaining parties have not established that the EC acted inconsistently with its obligations under Article 2.2 of the <i>SPS Agreement</i> by applying a general <i>de facto</i> moratorium on approvals between June 1999 and August 2003.</p>
<p>Article 2.3</p> <p><i>(Article 2: Basic Rights and Obligations)</i></p>	Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.	<p>Since the EC has not acted inconsistently with Article 5.5, and since the complaining parties' claims under Article 2.3 are premised on the existence of a breach of Article 5.5 by the EC, the complaining parties' claims under Article 2.3 cannot succeed.</p> <p>Conclusion: The complaining parties have not established that the EC acted inconsistently with its obligations under Article 2.3 of the <i>SPS Agreement</i> by applying a general <i>de facto</i> moratorium on approvals between June 1999 and August 2003.</p>
<p>Article 5.1</p> <p><i>(Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection)</i></p>	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.	<p>The general <i>de facto</i> moratorium on approvals is not an "SPS measure" within the meaning of Annex and Article. Thus, Article 5.1 is not applicable to the general <i>de facto</i> moratorium on approvals. Conclusion: the EC has not acted inconsistently with</p>

General Moratorium: Claimed inconsistencies with SPS Agreement and Panel Findings		
SPS Agreement	Text	Panel Findings
		Article 5.1.
Article 5.5 <i>(Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection)</i>	With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.	The general de facto moratorium on approvals is not an "SPS measure" within the meaning of Annex A (1) and Article 5.5. Thus, Article 5.5 is not applicable to the general de facto moratorium on approvals. Conclusion: the EC has not acted inconsistently with Article 5.5.
Article 5.6 <i>(Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection)</i>	Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.	The general de facto moratorium on approvals is not an "SPS measure" within the meaning of Annex A (1) and Article 5.6. Thus, Article 5.6 is not applicable to the general de facto moratorium on approvals. Conclusion: the EC has not acted inconsistently with Article 5.6.
Article 7 <i>Transparency</i>	Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.	Given that Annex B (1) does not apply to the general <i>de facto</i> moratorium on approvals, there can be no inconsistency with Article 7.
Annex B (1) <i>(ANNEX B: Transparency of</i>	Members shall ensure that all sanitary and phytosanitary regulations, which have been adopted, are published promptly in such a manner as to enable	The general <i>de facto</i> moratorium on approvals is not an "SPS regulation" within the meaning of Annex B (1) or an

General Moratorium: Claimed inconsistencies with SPS Agreement and Panel Findings		
SPS Agreement	Text	Panel Findings
<i>Sanitary and Phytosanitary Regulations</i>	interested Members to become acquainted with them.	SPS measure within the meaning of Annex A(1). Thus, the provisions of Annex B (1) are not applicable to the general <i>de facto</i> moratorium on approvals Conclusion: The EC has not acted inconsistently with Annex B(1).
Article 8 <i>Control, Inspection and Approval Procedures</i>	Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.	Given that the EC has acted inconsistently with Annex C(1)(a), it has also acted inconsistently with its obligations under Article 8 of the <i>SPS Agreement</i> .
Annex C (1)(a) <i>(Annex C: Control, Inspection and Approval Procedures)</i>	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 and in no less favorable manner for imported products than for like domestic products;	The application by the EC of a general <i>de facto</i> moratorium on approvals led to "undue delay" in the completion of the approval procedure concerning MS8/RF3 oilseed rape and, consequently, to a breach of the European Communities' obligations under Annex C(1)(a), first clause, of the <i>SPS Agreement</i> . Conclusion: The EC has acted inconsistently with Annex C(1)(a), first clause, of the <i>SPS Agreement</i> .
Annex C (1)(b) <i>(Annex C: Control, Inspection and Approval Procedures)</i>	1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: ... (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an	The United States has not established that the EC has acted inconsistently with its obligations under Annex C(1)(b) of the <i>SPS Agreement</i> and, consequently, with its obligations under Article 8 of the <i>SPS Agreement</i> by applying a general <i>de facto</i> moratorium

General Moratorium: Claimed inconsistencies with SPS Agreement and Panel Findings		
SPS Agreement	Text	Panel Findings
	application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;	on approvals between June 1999 and August 2003.
Article 10.1 <i>(Article 10: Special and Differential Treatment)</i>	Article 10.1 In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.	Argentina has not established that the EC has acted inconsistently with its obligations under Article 10.1 of the <i>SPS Agreement</i> by applying a general <i>de facto</i> moratorium on approvals. [Only Argentina brought a claim under Article 10.1.]

VI. General Moratorium, Product-Specific Measures, and the Definition of an SPS Measure

A. Non-applicability of the substantive requirements of the SPS Agreement: Article 5.1

The Panel began its analysis in relation to the general moratorium with an examination of whether the EC acted inconsistently with Article 5.1, which requires SPS measures to be based on risk assessment. The EC countered claims by complaining parties by noting they were not complaining about an SPS measure, but about its application. Since Article 5.1 did not contain obligations relating to the application of an SPS measure, the alleged general moratorium on approvals thus was not subject to Article 5.1. The EC further argued that SPS measures as defined in Annex A (1) of the SPS Agreement presuppose the existence of an act. The EC submitted that the complaining parties' assertions about a moratorium were in reality complaints about delay in the completion of approval procedure. Delay of this kind could not constitute an SPS measure within the meaning of

Annex A (1). Rather delay was a failure to act in a timely manner, to be reviewed under the procedural obligations set out in Article 8 and Annex C (1) of the SPS Agreement as an issue of the application of an SPS measure (in this case, the EC approval system).³⁴

Overall, the Panel came to the same conclusion. Addressing questions relating to the application of Article 5.1 to the *de facto* moratorium, the Panel examined the definition of an SPS measure contained in Annex A (1) of the SPS Agreement. It noted that the second paragraph of Annex A (1) referred to “requirements and procedures,” but not to the “application” of “requirements and procedures.” The Panel concluded:

This omission suggests that whereas requirements and procedures as such may constitute SPS measures, the application of such requirements and procedures would not, itself, meet the definition of an SPS measure. The provisions of the SPS Agreement support the view that the omission of a reference to "application" is deliberate ...³⁵

In order to establish whether the general *de facto* moratorium on approvals constituted an “SPS measure” within the meaning of Annex A (1) and Article 5.1, the Panel set out to determine whether the general moratorium is a substantive SPS “requirement,” a “procedure,” or a measure of a different nature.³⁶ In this context, the Panel asked the question of whether the decision to apply a general moratorium on approvals was a decision to reject all applications or whether it predetermined such rejections. The Panel found that the EC had not given a negative substantive reply to the question of whether biotech products with pending or future applications could be marketed in the EC. Rather, the EC’s response was that certain conditions needed to be met before it could provide positive substantive replies. On this basis, the Panel concluded that the decision to apply a general moratorium was a procedural decision not to make final and favorable substantive decisions on applications until certain conditions were satisfied.³⁷ Thus, the Panel found that the EC's decision to apply a general moratorium on approvals could be properly characterized as a decision to delay final positive approval decisions. It rejected the idea brought by the complaining parties that the European Communities' decision to apply a general moratorium on approvals was a decision to impose an effective marketing ban on all biotech products subject to approval, or that it established a new procedure, or amended the existing EC approval procedure.

The Panel found that this procedural decision did not impose a substantive “requirement” in relation to biotech products with pending or future applications. According to the Panel, the procedural decisions “neither approved nor rejected applications.” Moreover, the Panel was of the view that the decision to delay final substantive approval decisions cannot appropriately be viewed as providing for a “procedure,” stating: “the mere fact

³⁴ Paragraph 7.1322

³⁵ Paragraph 7.1328

³⁶ Paragraph 7.1331

³⁷ Paragraph 7.1335

that the decision in question related to the application, or operation, of procedures does not turn that decision into a procedure for the purposes of Annex A (1).”³⁸

Thus, the Panel concluded that the EC decision to apply a general moratorium on approvals was a decision concerning the application, or operation, of procedures, as such, it did not provide for “requirements [or] procedures” within the meaning of Annex A (1).³⁹ As a consequence the EC decision to apply a general moratorium on approvals was not an “SPS measure” within the meaning of Article 5.1 and Annex A (1), and thus the provisions of Article 5.1 were not applicable to the general EC moratorium.

Similarly, in relation to the product specific measures, the Panel also found that Article 5.1 was not applicable. The Panel considered that since the general moratorium was not an SPS measure, neither would the acts and/or omissions through which relevant EC entities were giving effect to the decision to apply it.⁴⁰ The Panel concluded that the measures did not establish new requirements or procedures that would qualify them as SPS measures under Annex A (1). In addition, the Panel found that the product-specific measures would not, themselves, have been measures applied for achieving the EC’s appropriate level of SPS protection and, thus, could not be considered SPS measures within the meaning of Article 5.1.⁴¹

B. Other substantive requirements of the SPS Agreement

With respect to alleged inconsistencies with Articles 5.6, 5.5, 2.3, and 2.2, the Panel used the same reasoning as in its analysis of Article 5.1 both for claims in relation to the general moratorium and to the product-specific measures. It determined that since these were not SPS measures within the meaning of Annex A (1) and any of the listed provisions, those provisions were not applicable to the EC’s general moratorium or product specific measures. Accordingly, the Panel did not find it necessary to continue its analysis of complaining parties’ claims under these Articles. As a consequence, the Panel concluded that the EC had not acted inconsistently with its obligations under Articles 5.6, 5.5, 2.3, and 2.2 of the SPS Agreement by applying a general *de facto* moratorium on approvals between June 1999 and August 2003 or the challenged product-specific measures.

Similarly, when analyzing the consistency of the challenged measures with Article 7 and Annex B (1) of the SPS Agreement, the Panel found that the earlier conclusion that they were not SPS measures within the meaning of Annex A (1) to be appropriate in the context of Annex B (1). Since the complaining parties had sought to establish an inconsistency with Article 7 on the basis of the alleged inconsistency with Annex B (1), which the Panel found to not be applicable, the Panel considered there could be no inconsistency of the general moratorium or the product-specific measures with Article 7.

³⁸ Paragraph 7.1375

³⁹ Paragraph 7.1376

⁴⁰ Paragraph 7.1682

⁴¹ Paragraph 7.1692

The Panel's analysis in relation to Article 8 and Annex C (1) (a), as well as Article 10.1 of the SPS Agreement is considered in Sections V and VI below.

C. Preliminary Conclusions

The Panel characterized the general moratorium as a procedural decision not to make final substantive decisions, which did not itself constitute an SPS measure. In addition, the Panel found that the product-specific measures, as acts and/or omissions through which relevant EC entities were giving effect to the decision to apply the general moratorium, were also not SPS measures. Thus, given that the Panel found that the general moratorium and the product-specific measures were not SPS measures as defined by the SPS Agreement, it refrained from examining their consistency with any of the science-related provisions of the SPS Agreement. As a consequence, the Panel rejected all of the complaining parties' allegations relating to the scientific justification of the moratorium and product-specific measures and did not address most of the issues that the complaining parties wished to see addressed.

Among other things, the Panel said nothing with respect to the consistency of EC approval procedures with the SPS Agreement. It only looked at the way in which those approval procedures had been applied from June 1999 to the establishment of the Panel in August 2003. Thus, the Panel decision should not affect current EC regulation relating to biotech. Violations found in connection with the approval process relate solely to the procedural requirement not to cause "undue delay" (described below).

VII. **The Question of Undue Delay and Consistency of the General Moratorium with Article 8 and Annex C (1)(a), First Clause, of the SPS Agreement**

The United States and Canada claimed that the general *de facto* moratorium on approvals had led to a failure by the EC to comply with the requirements of Article 8 and Annex C (1)(a), first clause, of the *SPS Agreement*. All three complaining parties argued inconsistencies with Article 8 and Annex C (1)(a), first clause, in regards to product-specific measures. Nevertheless, the present section will focus on the analysis of the Panel in the context of the general moratorium, where the question of undue delay was primarily addressed. The analysis in regards to the product-specific measures was directed to the consideration of whether claims such as the failure of the European Commission to re-convene the Regulatory Committee for a vote on a draft measure; the failure of the European Commission to submit a draft measures to the Council; and delays at the Member State level demonstrated that the time taken had been unjustifiably long.

Article 8 of the SPS Agreement

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and

otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

Annex C (1)(a), first clause, of the *SPS Agreement*

1. Members shall ensure, with respect to any procedure to check and ensure the fulfillment of sanitary or phytosanitary measures, that:

(a) such procedures are undertaken and completed without undue delay [...].

A. Determining “undue delay”

In relation to the general moratorium, the United States and Canada argued the EC approval procedures for biotech products had to be undertaken and completed ‘without undue delay.’ The Panel first examined the meaning of the phrase “undertake and complete.” It found:

“The verb "undertake" makes clear that Members are required to begin, or start, approval procedures after receiving an application for approval. The verb "complete", on the other hand, indicates that approval procedures are not only to be undertaken, but are also to be finished, or concluded. Thus, in our view, the phrase "undertake and complete" covers all stages of approval procedures and should be taken as meaning that, once an application has been received, approval procedures must be started and then carried out from beginning to end.”⁴²
(Footnotes omitted)

The Panel then found that Annex C (1)(a), first clause, did not cover every delay in the undertaking or completion of approval procedures. Rather it covered only “undue” delay. Regarding the meaning of the phrase “undue delay,” the Panel found the dictionary meaning of the term “delay” as “(a period of) time lost by inaction or inability to proceed” as pertinent. With respect to the term “undue,” the Panel considered the following two dictionary meanings relevant:

- “[g]oing beyond what is warranted [...]" and
- “unjustifiable.”

It concluded that based on the ordinary meaning of the phrase “without undue delay” requires that approval procedures be undertaken and completed with no unjustifiable loss of time.⁴³

To determine whether there was undue delay or ‘unjustifiable loss of time’ the Panel found that both the reason for a delay and its duration were relevant factors. It noted:

⁴² Paragraph 7.1487.

⁴³ Paragraph 7.1488

“... what matters is whether there is a legitimate reason, or justification, for a given delay, not the length of a delay as such. Accordingly, if a Member causes a relatively short, but unjustifiable delay, we do not consider that the mere fact that the delay is relatively short would, or should, preclude a panel from finding that it is "undue". Similarly, we do not consider that a demonstration that a particular approval procedure has been delayed by, say, two years would always and necessarily be sufficient to establish that the relevant procedure has been "unduly" delayed. Having said this, we note that a lengthy delay for which no adequate explanation is provided might in some circumstances permit the inference that the delay is "undue".”⁴⁴

To this, the Panel added that the determination of whether a particular approval procedure had been undertaken and/or completed “without undue delay” had to be made on a case-by-case basis and that it was not possible to define the reasons which would render a given delay “undue,” and those which would not.⁴⁵

The Panel also noted that Members applying approval procedures had to be allowed to take the time that was reasonably needed to determine with adequate confidence whether their relevant SPS requirements were fulfilled. Based on this, the Panel described Annex C (1)(a), first clause, “as a good faith obligation requiring Members to proceed with their approval procedures as promptly as possible, taking account of the need to check and ensure the fulfillment of their relevant SPS requirements.”⁴⁶ The Panel offered the example in which new or additional information were to become available at a late stage in an approval procedure. It found that in that case, it might be justifiable for the Member to delay the completion of the procedure and give itself the additional time needed to assess the information.⁴⁷

The Panel also noted that a Member had to act “as expeditiously as could be expected of it in the circumstances” and that otherwise the delay would be “undue.” It found support for this interpretation in the preamble of the *SPS Agreement*, which states that its purpose includes “the establishment of a multilateral framework of rules and disciplines to guide the [...] enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade.”⁴⁸

B. Panel’s findings on the general moratorium and undue delay

The Panel proceeded with its analysis by attempting to determine the reason behind the application of the general EC moratorium. In this context, the Panel considered the June 1999 declaration by the Group of Five countries, which stated that, pending the adoption of new EC rules ensuring labelling and traceability of GMOs and GMO-derived products, in accordance with preventive and precautionary principles, the Group of Five countries

⁴⁴ Paragraph 7.1489

⁴⁵ Paragraph 7.1490

⁴⁶ Paragraph 7.1491

⁴⁷ Paragraph 7.1491

⁴⁸ Paragraph 7.1492

would take steps to have any new authorizations for growing and placing on the market suspended. The Panel inferred from this that the Group of Five countries perceived the EC approval legislation in force at the time as inadequate and considered that in these circumstances prudence and caution warranted the suspension of new final approvals. The Panel also noted that although the Commission probably did not support the decision of the Group of Five countries, it “nonetheless effectively (*de facto*) co-operated with the Group of Five countries by not making full use of the relevant, mandatory procedures to complete the approval process.”⁴⁹

The Panel then examined whether (i) the perceived inadequacy of then-existing EC approval legislation and (ii) evolving science and the application of a prudent and precautionary approach would provide a justification for delays that resulted the application of the general EC moratorium.

Addressing the first of these two inquiries (perceived inadequacies), the Panel explained that delays in the completion of approval procedures might have occurred as a result of the lack of EC-level legislation ensuring labelling and traceability of GMOs and GMO-derived products and that the EC had suspended its approval procedures pending the adoption of new EC legislation.

In deciding whether this justified the delays in the approval process, the Panel considered three aspects. First, it noted that the application of the approval legislation in question had never been suspended by a formal EC decision, *e.g.*, by the Commission or the Council and European Parliament. Nor had the granting of final approvals ever been suspended by a formal EC decision.⁵⁰ It noted that if the EC considered its existing legislation inadequate, it could have taken other steps, such as granting approvals subject to additional requirements of the type set out in the future EC legislation ensuring labelling and traceability of GMOs and GMO-derived products.

Second, the Panel referred to the time-consuming legislation process. In this context, the Panel voiced its concern that if a Member could suspend and, consequently, delay the granting of final approvals essentially every time it completed and updated its approval legislation, there might be frequent and long periods of time during which final approval decisions are suspended.⁵¹

Finally, the Panel noted that it was not recommended to use procedural delay as an instrument to manage or control risks as a substitute for a substantive risk management measure. It noted:

“If procedural delay could be used, directly or indirectly, as an instrument to manage or control risks, then Members could evade the obligations to be observed in respect of substantive SPS measures, such as Article 5.1, which requires that SPS measures be based on a risk assessment. Clearly, we cannot interpret Annex

⁴⁹ Paragraph 7.1501

⁵⁰ Paragraph 7.1505

⁵¹ Paragraph 7.1509

C(1)(a), first clause, in a manner which would nullify or impair the usefulness and intended effect of other provisions of the *SPS Agreement* ... Indeed, as we see it, a central purpose of Annex C(1)(a), first clause, is precisely to prevent a situation where Members avoid the substantive disciplines which Articles 2 and 5 of the *SPS Agreement* impose with respect to substantive SPS decisions by not reaching final substantive decisions on applications for marketing approval.”⁵²

Based on these considerations, the Panel concluded that the lack of EC legislation ensuring labelling and traceability of GMOs and GMO-derived products did not provide a justification for delays in the completion of approval procedures.⁵³

The Panel then addressed the second inquiry, that is, whether evolving science and the consequent application by the European Communities of a prudent and precautionary approach would provide a justification for delays which may have occurred due to the EC’ general suspension of final approvals between June 1999 and August 2003.

The Panel first noted that Annex C (1)(a), first clause, did not preclude the application of a prudent and precautionary approach to identifying, assessing and managing risks to human health and the environment arising from GMOs and GMO-derived products. The Panel also added, however:

“... application of a prudent and precautionary approach is, and must be, subject to reasonable limits, lest the precautionary approach swallow the discipline imposed by Annex C(1)(a), first clause. Indeed, if a Member could endlessly defer substantive decisions on the grounds of a perceived need for caution and prudence in the assessment of applications, Annex C(1)(a), first clause, would be devoid of any meaning or effect. In applying the provisions of Annex C(1)(a), first clause, it is therefore important always to bear in mind that Annex C(1)(a), first clause, implies as a core obligation the obligation to come to a decision on an application.”⁵⁴

The Panel recalled that if relevant scientific evidence were insufficient to perform a risk assessment as defined in Annex A (1) of the *SPS Agreement* and as required by Article 5.1 of the *SPS Agreement*, pursuant to Article 5.7 of the *SPS Agreement*, a Member could provisionally adopt an SPS measure on the basis of available pertinent information. The Panel noted that a Member was thus free to choose a measure providing the best protection of human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen was reasonably supported by the risk assessment.⁵⁵

However, the Panel stressed that evolving science, scientific complexity and uncertainty, and limited available scientific information or data were not, in and of themselves,

⁵² Paragraph 7.1510

⁵³ Paragraph 7.1511

⁵⁴ Paragraph 7.1516

⁵⁵ Paragraph 7.1518

grounds for delaying substantive approval decisions. It added that, even in cases where relevant scientific evidence did not permit the performance of a risk assessment, the *SPS Agreement* envisaged that Members take substantive SPS decisions.⁵⁶ It noted that this notion also fit well with Articles 5.1 and 5.7, and that the *SPS Agreement* nowhere stated that substantive decisions on applications needed “to give a straight yes or no answer to applicants.” For example, the Panel suggested that Members could grant time-limited approvals or approvals subject to other appropriate conditions, or they could reject an application subject to the possibility of a review of that decision in case of changes in circumstances, such as the state of scientific knowledge.⁵⁷

Based on these considerations, the Panel concluded that the perceived inadequacy of the existing EC approval legislation and evolving science and the application of a prudent and precautionary approach did not provide a justification for delays which might have occurred as a result of the application of the general EC moratorium on final approvals.⁵⁸

At the same time, however, the Panel explicitly stated that in some cases to delay the completion of approval procedures by imposing a general moratorium on final approvals of biotech products might be justifiable. This would be the case, for instance, where new scientific evidence came to light which conflicted with available scientific evidence and which were directly relevant to all biotech products subject to a pre-marketing approval requirement. The resulting delay in the completion of approval procedures in such a case might then be considered not “undue.”⁵⁹

Subsequently the Panel considered whether the general EC moratorium on final approvals actually led to undue delay by examining one approval procedure conducted under EC legislation, *i.e.*, the approval procedure concerning MS8/RF3 oilseed rape. It concluded that the time taken by the Commission to convene the Regulatory Committee for a further meeting was unjustifiably long, and that it could reasonably be inferred that the Commission's inaction was a consequence of the general moratorium on approvals.

Thus, the Panel concluded that the application by the EC of a general *de facto* moratorium on approvals led to “undue delay” in the completion of the approval procedure concerning MS8/RF3 oilseed rape and, thus, to a breach of Annex C (1)(a), first clause, of the *SPS Agreement*⁶⁰ and, consequently, of Article 8 of the *SPS Agreement*.⁶¹

C. Preliminary Conclusions

In examining the nature of the EC *de facto* moratorium, the Panel concluded that the suspension of approvals was not in itself an SPS measure as defined in the SPS

⁵⁶ Paragraph 7.1519

⁵⁷ Paragraph 7.1520

⁵⁸ Paragraph 7.1523

⁵⁹ Paragraph 7.1525

⁶⁰ Paragraph 7.1560

⁶¹ Paragraph 7.1563

Agreement. As a consequence, the Panel did not examine the substantive provisions of the SPS Agreement, such as the requirements relating to science. However, it did examine the consistency of the moratorium with the SPS provision relating to the “Control, Inspection and Approval Procedures.” In that context, the Panel found that the EC had acted with undue delay in the completion of the approval procedure concerning biotech products.

In interpreting the term “undue delay,” the Panel did not find the *exact duration* of the delay a determining factor. While stating that Members had to act “expeditiously,” it also added “as could be expected of it in the circumstances.” This gives ample flexibility to Members, including developing country Members who may not always have the capacity to deal with applications as fast as certain industrialized countries.

The Panel’s assessment of undue delay focused on issues relating to due process. The Panel concentrated on the question of whether there was a *legitimate reason or justification*, for a given delay. In this context, it rejected the notion that the EC delay could be justified based on the fact that the EC found the then-existing EC approval legislation as inadequate. Particular emphasis was placed in this respect to the irregular procedure applied to delay application. This conclusion could be relevant for other countries that are in process of revising their legal framework relating to biotech or adopting new laws. The Panel seemed to indicate that this would not justify inaction or delays in approval processes. However, the Panel also indicated that there were other ways for Members to deal with approval schemes pending new legislation, including, for instance, subjecting approval grants to conditions.

Further, the Panel examined whether evolving science and the consequent application by the EC of a prudent and precautionary approach could justify a delay. It found that evolving science, scientific complexity and uncertainty, and limited available scientific information or data were not, in and of themselves, grounds for delaying substantive approval decisions. This conclusion should *not* be understood, however, as inhibiting countries from adopting measures to protect human health and the environment, including precautionary measures. According to the Panel, Annex C (1)(a), first clause, says nothing that would prohibit this. All it does is to impose on Members to come to a decision on an application. The question as to what extent members can adopt precautionary measures needs to be determined instead under the substantive SPS provisions, including Article 22, 5.1, and 5.7, among others.

VIII. Developing Countries, Special and Differential Treatment, and Article 10.1 of the SPS Agreement

In the EC-Biotech case, Argentina claimed that the EC, through its general moratorium, had failed to take account its special needs as a developing country and thus acted inconsistently with Article 10.1 of the SPS Agreement. With the vast majority of acreage of genetically modified crops limited to a handful of countries, most developing countries are more concerned with the relationship between SPS provisions and their domestic regulations than with ensuring that biosafety frameworks in developed countries take into

account the needs of developing country biotechnology exporters. Nevertheless, the reasoning and findings of the Panel in its Interim Report remain significant in relation to developing countries' more general concerns as agricultural exporters. Since there is little information on the extent to which the special and differential treatment provided for in Article 10.1 has been provided to developing countries, and there is no previous jurisprudence or decision of a competent WTO body, the conclusions in *EC-Biotech* could set an important precedent.

<p>SPS Agreement</p> <p>Article 10</p> <p>Special and Differential Treatment</p> <p>1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.</p>

A. Interpretation of the SPS requirement to “take account” of the needs of developing countries

In particular, the Interim Report addressed the fundamental issue of whether the obligation to “take account of” the needs of developing countries requires positive action in favor of developing countries – as argued by Argentina – or merely calls for the consideration of these needs among a range of relevant factors – as argued by the EC. The Panel, relying on the Oxford Dictionary’s definition of the expression “take account of,” found that Article 10.1 does not prescribe a specific result to be achieved. More specifically, “Article 10.1 does not provide that the importing Member must invariably accord special and differential treatment in a case where a measure has led, or may lead, to a decrease, or a slower increase, in developing country exports.”⁶² The Panel found nothing in Article 10.1 to suggest that in weighing and balancing the various interests at stake, the EC had to necessarily give priority to the needs of Argentina as a developing country over, for instance, other legitimate interests such those of its own consumers and its environment.⁶³ As a result, the Panel considered that the fact that the EC did not accord Argentina special and differential treatment *vis-à-vis* other developed country exporters did not demonstrate, by itself, an inconsistency with Article 10.1.

The Panel also analyzed the burden of proof in relation to Article 10.1. Argentina argued that the EC had not provided any evidence proving that it had taken into account Argentina's special needs as a developing country when preparing and applying its legislation – for example, the legislation contains no reference to the special needs of developing countries. Moreover, Argentina claimed that, for the entire period of application of the general moratorium on approvals, there was no evidence leading to the

⁶² Interim Report, paragraph 7.1613.

⁶³ Interim Report, paragraph 7.1614.

conclusion that the EC had taken account of its special needs. The Panel, however, found that it was incumbent on Argentina – as the complaining party – to prove its claim that the EC did not take account of developing countries’ needs.⁶⁴ In this regard, it considered that the mere lack of reference in the EC approval legislation to the special needs of developing countries was insufficient to prove the legislation failed to take account of these needs. On the absence of other relevant evidence, the Panel stated it was unclear what efforts Argentina had undertaken to collect such evidence, since Article 10.1 does not specifically require the importing Member to document its compliance.⁶⁵ As a result, the Panel found that Argentina had failed to establish its claim that the EC had acted inconsistently with Article 10.1 because of the way it has applied its approval legislation between October 1998 and August 2003.⁶⁶

B. Preliminary Conclusions

Interestingly, the Panel itself applied certain degree of special and differential treatment in its analysis of Argentina’s claims under Article 10.1 of the SPS Agreement. Noting that Argentina’s submissions on this issue were less than fully clear, the Panel analyzed the claim it understood Argentina intended to make – that the general *de facto* moratorium on approvals constituted the relevant SPS measure to consider – in addition to the one the Panel considered was more accurate or appropriate. Specifically, the Panel assumed that Argentina also intended to make the claim that the EC approval legislation constituted a relevant SPS measure.⁶⁷

The EC-Biotech WTO Panel’s interpretation of the provision in the SPS Agreement relating to special and differentiated treatment appears to limit its scope. Indeed, the Panel found that Article 10.1 does not necessarily prescribe more favorable treatment for developing countries or the express consideration of the needs of developing countries in the preparation and application of SPS measures. In particular, these findings would seem to contradict the spirit of special and differential treatment proposals currently being discussed by the SPS Committee. These proposals include, for instance, the submission that Article 10.1 should require developed countries to identify names of the developing countries that could be affected by the application of the measures and – if the developing country identifies specific problems in complying with the measure – to enter into consultations with a view to finding a mutually satisfactory solution, including for concerns such as securing and enhancing current levels of exports from the developing country.⁶⁸

In addition, it also appears the Panel, by acknowledging that countries must consider various legitimate interests in developing and implementing SPS measures, including

⁶⁴ Interim Report, paragraph 7.1615.

⁶⁵ Interim Report, paragraph 7.1615.

⁶⁶ Interim Report, paragraph 7.1619.

⁶⁷ Interim Report, paragraph 7.1605.

⁶⁸ SPS Committee, “Report on Proposals for Special and Differential Treatment,” WTO document G/SPS/35, 7 July 2005.

those relevant to developing countries, to consumers, and to environmental and public health protection, has taken a step forward towards more balanced SPS policies.

IX. Safeguard Measures: Science and Precaution in the EC-Biotech Interim Report

The EC-Biotech Interim Report is quite explicit: It did not examine or determine whether biotech products are safe or not.⁶⁹ Science, nevertheless, remains at the core of the decision. Indeed, the Interim Report, although not itself considering the range of scientific and technical issues raised by Parties and experts,⁷⁰ does address the extent and manner in which WTO Members may take these issues into consideration in their national measures and policies. As a result, the Interim Report is significant not only for its impact on the challenged EC measures, but also for its interpretation of the role of science and precaution in the SPS Agreement.

The SPS Agreement, while recognizing the right of governments to maintain appropriate sanitary and phytosanitary protection, aims to restrict the unjustified use of relevant measures for protectionist purposes. In particular, it seeks to reduce possible arbitrariness of decisions by requiring that “any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence.”⁷¹ If “scientific evidence is insufficient,” however, a Member may still adopt SPS measures, provided that they are taken on the basis of available pertinent information and on a provisional basis and reviewed “within a reasonable period of time.”⁷²

This science-based approach, unique among WTO agreements, is considered to pose quite a high justificatory burden, but WTO jurisprudence has – for the most part – established wide parameters for determining the existence of a risk assessment, the relationship between the measure and the risk assessments, and the insufficiency of scientific evidence.⁷³ Such an approach adequately recognized the difficulty of comprehensively describing risks in strictly scientific terms, the need to avoid burdensome procedural requirements, and – most importantly – the right of WTO

⁶⁹ Paragraph 8.3

⁷⁰ In its discussion of the Panel's decision to consult individual scientific experts and certain international organizations, the Interim Report cites relevant articles, including Article 11.2 of the *SPS Agreement*, the May 2004 request by the EC for the Panel to seek advice from scientific and technical experts at an appropriate stage, and the August 2004 Panel decision to seek expert advice for various scientific and/or technical issues, including the scientific or technical grounds for the comments and/or objections raised by EC member States and the differences in the risks arising to human, plant or animal health, or to the environment, from the consumption and use of: products of biotechnology approved by the European Communities prior to October 1998; comparable novel non-biotech products. Paragraph 8.18.

⁷¹ Article 2.2

⁷² Article 5.7

⁷³ However, it must be noted that – despite fairly positive language regarding flexibility in Articles 2.2, 5.1, and 5.7, the majority of measures challenged under those provisions have been found not to meet their requirements. For a comprehensive analysis of WTO jurisprudence on science and precaution, see Nathalie Bernasconi-Osterwald, Daniel Magraw, María Julia Oliva, Marcos Orellana, and Elisabeth Tuerk, ENVIRONMENT AND TRADE: A GUIDE TO WTO JURISPRUDENCE (Earthscan 2005).

Members to adopt and maintain the level of sanitary and phytosanitary protection they deem adequate. The Interim Report, as will be analyzed below, can be described as a mixed outcome in this regard, with some language moving to consolidate the policy space recognized by the SPS Agreement, and with other interpretations raising serious concerns as to the leeway for WTO Members to protect their environment and public health.

SPS Agreement

Article 2.2

“Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.”

Article 5.1

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

Article 5.7

“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.”

All three types of measures addressed in the dispute – the alleged EC moratorium on approvals of biotech products, the various product-specific EC measures related to the approval of biotech products, and the various EC Member State measures related to the import and/or marketing of specific biotech products – were challenged as inconsistent with the science-based requirements of the SPS Agreement. As mentioned above, in relation to the general moratorium, the Panel found these requirements did not apply. In particular, the Panel characterized the general moratorium as a procedural decision not to make final substantive decisions,⁷⁴ which as a result did not itself constitute an SPS measure.⁷⁵ Thus, Articles 5.1 and 2.2, which establish that SPS measures must be based

⁷⁴ Paragraph 7.1335

⁷⁵ Paragraphs 7.1385 and 7.1386. Please note, however, that the Panel notes that, where the SPS Agreement establishes requirements for the application of SPS measures, the application does become a measure in itself. That explains why the general moratorium is found to be an SPS measure for the purposes of Annex C (1) (a), first clause and, consequently, inconsistent with provisions of Article 8.

on scientific principles and specifically on a risk assessment, were found not to apply.⁷⁶ Moreover, since the Panel considered the product-specific measures are essentially acts or omissions giving effect to decision to apply general moratorium, it applied the same reasoning, finding these were also not SPS measures and thus were not subject to Articles 5.1 and 2.2.⁷⁷

A. Panel's Findings

The safeguard measures enacted by some EC Member States, including France, Germany, Italy, and Greece, however, were all found inconsistent with SPS Agreement requirements. In particular, the Panel found that since the safeguard measures were not based on a risk assessment as required by Article 5.1 and were not consistent with the requirements of Article 5.7, the EC, by maintaining them, had acted inconsistently with its obligations under Article 5.1. By implication, given that Articles 5.1 and 2.2 are read in concert, the Panel found the EC had also acted inconsistently with the second and third requirements in Article 2.2.⁷⁸

In terms of the existence of risk assessments, there was common ground among the Parties to the dispute that the assessments carried out by the national competent authority and by the relevant EC scientific committee in respect of the products before their approval did constitute "risk assessments" within the meaning of SPS Agreement,⁷⁹ but none of the other studies or documents relied upon by Member States were found to be acceptable.⁸⁰ Given the favorable findings of the only studies considered by the Panel to be risk assessments, moreover, none of the safeguard measures were found to be warranted – or more specifically to be based on risk assessments as required by the SPS Agreement. In addition, because these studies did constitute risk assessments under the SPS Agreement, the Panel found that the measures fell outside the scope of Article 5.7, which would – according to the Panel – only apply in cases where there was insufficient evidence to conduct such risk assessment.

1. *Risk assessment*

Under the SPS Agreement, measures to protect human, animal, and plant life and health must be based on a risk assessment. As a result, the determination of what constitutes a risk assessment within the meaning of the SPS Agreement is not merely a definitional question, but one that has direct implications for national environmental and health measures. WTO cases such as EC-Hormones seemed to recognize the importance of

⁷⁶ Paragraph 7.1433

⁷⁷ Paragraph 7.1682

⁷⁸ Page 1035.

⁷⁹ Page 924. Paragraph 7.302

⁸⁰ In general, these documents were considered to not provide in themselves an evaluation of the potential for adverse effects on human or animal health arising from the products in question, to analyze only the possibility and not the probability of likelihood of such adverse effects, or to call for further assessment instead of providing actual analysis. Moreover, several of the studies were rejected for having been conducted after the date of establishment of the Panel.

establishing an adequately broad scope for risk assessments.⁸¹ More recent cases, including EC-Biotech, seem to have adopted a much more restrictive view – rejecting all assessments that do not strictly match the elements of the definition of risk assessment contained in Annex A (4) of the SPS Agreement.

SPS Agreement

Annex A (4)

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

Indeed, though commentators speculated that the Panel would be particularly considerate in light of the unique challenges posed by biotechnology,⁸² the Interim Report contains very little recognition of the flexibility previous WTO cases had recognized was essential in the SPS Agreement. For example, the EC had argued that all the safeguard measures were based on a risk assessment “appropriate to the circumstances” within the meaning of Article 5.1. The EC had also highlighted that the circumstances in the case included the fact that relevant scientific evidence was insufficient from the perspective of the Member States.⁸³ The Panel stated that:

“We need not determine whether relevant scientific evidence was or is insufficient for Austria, and if so, whether this would be a relevant circumstance. Even if this were the case, the flexibility which the phrase ‘as appropriate to the circumstances’ may in some situations provide does not relieve Austria from the requirement in Article 5.1 to base its safeguard measure on a risk assessment which meets the definition of Annex A (4).”⁸⁴

The Panel then limits the applicability of the phrase “as appropriate to the circumstances” to how the elements of the Annex A (4) definition are satisfied. Moreover, it also completely ignores the relevance of the precautionary principle in determining the scope of risk assessments by not addressing the issue of insufficiency of scientific evidence.

The Interim Report similarly reflects a restrictive interpretation on when a measure is “based on” a risk assessment. In EC – Hormones, the relationship between the scientific

⁸¹ María Julia Oliva, “The Cartagena Protocol On Biosafety and the Agreement on Sanitary and Phytosanitary Measures: What will Decisions Regarding GMOs have to be Based on?” *International Legal Perspectives*. Fall, 2002.

⁸² María Julia Oliva, “Science and Precaution in the GMO Dispute: A brief analysis of the first US submission,” BRIDGES. Year 8 No.5 May 2004.

⁸³ Page 930. Paragraph 7.3043

⁸⁴ Page 931. Paragraph 7.3044

conclusion yielded by a risk assessment and the measure was of course considered relevant, but not to the exclusion of everything else. Moreover, it was made clear that WTO Members could base their measures on minority scientific opinions without eliminating the reasonable relationship between the measure and the risk assessment. In the Interim Report, the Panel states the EC-Hormones statement was related to a hypothetical situation where divergent views were expressed as part of the same risk assessment.⁸⁵ As a result, according to the EC-Biotech Panel the divergent view must be in the same risk assessment in order to warrant the measures.

The analysis in the Interim Report then again limits the reflection of the precautionary principle in Article 5.1. The EC asserted that each of the safeguard measures at issue in the dispute was based on the precautionary principle and a bearing on a panel's assessment of whether an SPS measure is "based on" a risk assessment as required by Article 5.1. The Panel, while agreeing with the thrust of the EC argument, considered that a precautionary approach could only influence the measure chosen to achieve appropriate level of protection, but not the rational relationship required between the measure and the risk assessment. In particular, if any uncertainties or limitations arise in relation to a risk assessment, it would only justify a Member deciding to adopt a measure where others would not, or adopting a stricter measure than others. In either case, however, the Panel found that the SPS measures would still need to be "based on" the risk assessment.

2. *Scope of Article 5.7 and the right to take precautionary measures*

Article 5.7 of the SPS Agreement allows WTO Members to provisionally adopt SPS measures in cases where relevant scientific evidence is insufficient, and as such has been interpreted to reflect the precautionary principle. However, the scope of Article 5.7 only extends to provisional measures and Members are obliged to attempt to obtain additional information to review the measure within a reasonable period of time. As a result, Article 5.7 has been characterized by previous WTO cases as a "qualified exemption" from the Article 2.2 obligation for Members to base and maintain SPS measures on sufficient scientific evidence. In an amicus brief presented to the EC-Biotech case, however, the Center for International Environmental Law (CIEL) and other civil society organizations argued that:

"Article 5.7 is not an exception within the SPS Agreement. It is one of the Members' basic rights in the SPS Agreement's comprehensive approach towards ensuring that no Member is prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health. Under the SPS Agreement, Members have the right to determine the level of protection they find appropriate within their territories and to take measures to attain and maintain that level of protection. Article 5.7 allows Members to take provisional measures when scientific evidence is insufficient for an adequate assessment of the risks

⁸⁵ Page 932. Paragraph 7.3050

and thereby safeguards their right to protect their citizens and the environment under those circumstances.”⁸⁶ (*Footnotes omitted*)

The nature of Article 5.7 was raised by the EC, which argued that Article 5.7 is an autonomous right, and not an exception to Articles 2.2 and 5.1. The adequate characterization of Article 5.7 is critical to recognizing the precautionary principle as a rational and objective response to insufficient scientific evidence, rather than as an exceptional approach. In addition, the nature of Article 5.7 also affects the burden of proof in WTO dispute settlement, and thus has profound implications for the outcomes of specific cases. In the EC-Biotech case, the EC was seeking support for its view that the safeguard measures should thus not be assessed under Article 5.1. The Panel found Article 5.1 to be applicable – it was considered the “critical legal issue.”⁸⁷ Nevertheless, it did agree that Article 5.7 is an autonomous right, not an exception, in the SPS Agreement.⁸⁸

In the Interim Report, the Panel explained its reasoning. First, it analyzed the relationship between Article 2.2 and Article 5.7.⁸⁹ Following the test established in EC-Tariff Preferences, the Panel found that the relationship could indeed be characterized as one where one provision (Article 5.7) permits, in certain circumstances, behavior that would otherwise be inconsistent with an obligation in another provision (Article 2.2). The same test had been used to consider the relationship between Articles 3.1 and 3.3 in EC-Hormones, where it was found that the right of a WTO Member to establish its own level of sanitary protection under Article 3.3 of the SPS Agreement is an autonomous right and not an exception.⁹⁰

Then, the Panel analyzed whether the same relationship existed between Article 5.1 and Article 5.7. Because it concluded that Article 5.7 permits Members to do, in certain circumstances, what they would not be permitted to do under Article 5.1, the Panel found that Article 5.7 is also an autonomous right in this context – it is not an exception to Article 5.1. However, the relationship between Article 5.1 and 5.7 as interpreted by the

⁸⁶ Center for International Environmental Law (CIEL), Friends of the Earth – United States (FOE-US), Defenders of Wildlife, the Institute for Agriculture and Trade Policy (IATP), and the Organic Consumers Association (OCA), Amicus Curia Brief to European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS/291, 292, and 293), June 1st, 2004.

⁸⁷ Since consistency with Article 5.1 was considered the critical issue, and following previous analysis in WTO cases, the Panel’s analysis was structured as follows: It began considering consistency with Article 5.1. If the measures had been found consistent, analysis would not have gone further. Because they were not, consistency with Article 5.7 is looked at. If the measures had been found consistent, then Article 5.1 would not have applied. Because they were not, Article 5.1 was found to apply, making the measures inconsistent with SPS Agreement.

⁸⁸ Pages 910 and 918. Paragraphs 7.2960 and 7.2989.

⁸⁹ Page 908. Paragraph 7.2952

⁹⁰ The Panel noted considered the significant textual similarities between Article 3.1 and Article 2.2, but pointed out that a WTO Member can, subject to compliance with applicable requirements, choose whether to base an SPS measure on a relevant international standard in line with Article 3.1 or, alternatively, to avail itself of the qualified right not to do so provided in Article 3.3. In contrast, in cases where the relevant scientific evidence is insufficient, *e.g.*, because none is available, a Member who wishes nonetheless to take a precautionary SPS measure could not meet the requirement in Article 2.2 to ensure that this measure “is not maintained without sufficient scientific evidence”.

Panel in EC-Biotech also proves to have negative consequences: It significantly narrows the scope of Article 5.7. In particular, the Panel found implicit cross-references between Article 5.1 and Article 5.7 that led to its conclusion that scientific evidence is “insufficient” within the meaning of the first sentence of Article 5.7 only if it does not allow the performance of an assessment of risks as defined in Annex A (4).⁹¹

As a result, Article 5.7 would seem to exclude, in spite of previous WTO jurisprudence, all consideration of situations where, although the quantity of scientific research allows for a risk assessment under the SPS Agreement, the quality of scientific evidence is not sufficiently reliable to permit an *adequate* assessment of risks.⁹² Moreover, if such cases are not considered within the scope of Article 5.7, WTO Members would be forced to make decisions on the basis of information that cannot ascertain the risks to human, animal, or plant life or health in a manner adequate to the level of protection they have chosen.⁹³

The Panel’s interpretation in this regard is particularly clear in the discussion of whether the sufficiency of the scientific evidence must be assessed by reference to a Member’s appropriate level of sanitary or phytosanitary protection, in its analysis of Article 5.7. The EC argued that the concept of “insufficiency” in Article 5.7 is “relational” and had to be linked with the right of WTO Members to establish the level of protection they deem appropriate for their territory, and specifically with the aims of legislators in relation to a particular measures. The Panel did not agree, stating that:

“We note that the Appellate Body in *Japan – Apples* referred to the insufficiency of available scientific evidence to perform an ‘adequate’ assessment of risks. The European Communities appears to rely on the Appellate Body’s use of the term ‘adequate’, for it argues that an ‘adequate’ assessment of risks is one which is ‘adequate for the purposes of the legislator’. The Appellate Body failed to define or explain the term ‘adequate’. Moreover, the term ‘adequate’ nowhere appears in Article 5.1, Article 5.7 or Annex A (4). In these circumstances, we are not convinced that we should attach much significance to this term. Indeed, the term ‘adequate’ may have been intended as nothing more than a reference to the definition in Annex A (4). On this view, a risk assessment would be “adequate” if it meets the standard and definition provided in Annex A (4).”⁹⁴ (*Footnotes omitted*)

Consequently, the level of protection chosen by a WTO Member is considered by the Panel to be irrelevant in determining the sufficiency of scientific evidence – although it will be only with sufficient qualitative certainty that a Member will be able to identify the measure necessary to achieve its chosen level of protection. According to the Interim

⁹¹ Page 917. Paragraph 7.2986

⁹² For an analysis of uncertainty and the quality of scientific evidence in Article 5.7, see the above-mentioned CIEL et al amicus brief.

⁹³ The relationship between Article 5.7 and the level of protection is also addressed in the CIEL et al amicus brief.

⁹⁴ Paragraph 7.3226

Report, if there are factors in the risk assessment that affect the level of confidence of the scientists conducting the evaluation, then they may be taken into account in determining the measure to be applied under Article 5.1 for achieving the appropriate level of protection.⁹⁵ The acceptable level of risk identified by WTO Members, however, would not be relevant for the determination of the sufficiency of scientific evidence or for the assessment of the existence and magnitude of risks.

In WTO jurisprudence, the Appellate Body has recognized that Members have an autonomous right to determine the level of risk they consider acceptable within their territory, which may even consist of “zero risk.” However, the interpretation of the Panel seems to deprive Members of the right to establish the level of protection they deem appropriate for their territory in cases of scientific uncertainty: If a risk assessment has been carried out, then any measure taken must be permanent and based on that assessment, even if it does not provide enough conclusive or reliable information for the measure to achieve the Members’ level of protection.

B. Preliminary conclusions

As mentioned, the reasoning and findings of the Interim Report may have a range of potential implications. First, the conclusions of the Panel are of course significant for the challenged measures, which were found inconsistent with WTO rules. Nevertheless, a request for the EC to bring the relevant measures into conformity with its WTO obligations – which the Panel recommends the Dispute Settlement Body formulate – would not necessarily entail a withdrawal of the safeguard measures at issue. The inconsistencies found by the Panel related to these measures not being based on a risk assessment as required by Article 5.1 and not being consistent with the requirements of Article 5.7. As a result, Austria, France, Germany, Greece, Italy, and Luxembourg would be able to bring their safeguard measures in compliance with the ruling by conducting or putting forth risk assessments – as delineated by the SPS Agreement – that warranted these measures.⁹⁶ In this regard, it is worth mentioning that a review of the EC level risk assessment and of the new and additional information raised by the EC Member States in relation to these safeguard measures is already scheduled to take place pursuant to European regulations.

Second, the Interim Report has implications for the EC regulations themselves. Here, it must be emphasized that the Panel was not asked to consider and did not address the consistency of any EC regulations with WTO rules. Nevertheless, the Panel noted that for each of the products affected by a national safeguard measure, the EC had given its EC-wide approval based on an evaluation of the potential risks to human health and/or the environment that all Parties agreed was a risk assessment under the SPS Agreement. This is significant for two reasons: First, according to the Panel in the Interim Report, such an assessment would exclude the application of Article 5.7. As a result, EC

⁹⁵ Page 977. Paragraph 7.3231

⁹⁶ As noted by the Interim Report: “[B]oth a risk assessment carried out before the adoption of a particular safeguard measure and a risk assessment carried out after its adoption could ‘sufficiently warrant’, or ‘reasonably support’, the maintenance of that measure.”

Member States could not justify any safeguard measures on the basis of the precautionary principle as reflected in that SPS Agreement provision; and second, unless the EC level assessment contains a divergent view to justify an EC Member states' provisional restriction or prohibition of the use and/or sale of the relevant biotech product, it is not sufficient for these safeguard measures to be based on "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,"⁹⁷ as required by EC Regulation. The findings of the Interim Report would require, instead, a risk assessment that fulfilled requirements of Article 5.1 and Annex A (4).

Finally, the Interim Report is significant due to its interpretation of the role of science and precaution in the SPS Agreement, and thus the scope for WTO Members to adopt measures to achieve and maintain the level of protection they deem appropriate. Unfortunately, in its analysis of the risk assessment requirements of the SPS Agreement, the Panel espoused a narrow perspective of the term "risk assessment," with little recognition of the flexibility previous WTO SPS cases had considered was essential. In regards to the Article 5.7 analysis, the acknowledgement of its nature as an autonomous right should have a positive impact on environmental and health regulation by recognizing the importance of the precautionary principle in the advancing SPS objectives and adequately allocating the burden of proof. Nevertheless, the Interim Report, by excluding all cases where a risk assessment has been conducted from the scope of Article 5.7, regardless of the uncertainty or inconclusiveness of its results, raises serious concerns for the right of WTO Members to adopt and maintain their chosen level of SPS protection.

X. Interpreting WTO Law and the Relevance of Multilateral Environmental Agreements (MEAs)

In the EC-Biotech case, the EC argued that the WTO agreements had to be interpreted and applied by reference to relevant rules of international law arising outside the WTO context. It criticized the approach by the complaining parties to treat the legal issues concerning the authorization and international trade of GMOs as though they were regulated exclusively by WTO rules, making no reference whatsoever to the relevant rules of public international law which have been adopted to regulate the concerns and requirements which arise from the particular characteristics of GMOs.⁹⁸ The EC referred to the US – Shrimp decision – in which the Appellate Body looked at several treaties, including treaties, which at least one party to the dispute had not signed or had signed but not ratified.⁹⁹ In line with the Appellate Body's approach the EC argued that the Panel in the EC-Biotech case had to take the 1992 CBD (ratified by the EC, Argentina and Canada; and signed by the United States) and the 2000 Biosafety Protocol (ratified by the EC and signed by Argentina and Canada) into account when interpreting the relevant WTO rules. Specifically, the EC argued that the rules of international law reflected in the

⁹⁷ Article 23, Directive 2001/18.

⁹⁸ Paragraph 7.49

⁹⁹ Paragraph 7.52

Biosafety Protocol on the precautionary principle and on risk assessment should be taken into account to inform the meaning and effect of the relevant provisions of the WTO agreements.

CIEL's *amicus curiae* brief also argued that customary rules of interpretation of public international law, recognized by the WTO dispute settlement system, require that WTO agreements be considered as a part of the broader corpus of international law and principles. Moreover, the Appellate Body has emphasized the importance, in certain circumstances, of interpreting terms in the WTO Agreements in light of the "contemporary concerns of the community of nations." CIEL's submission also noted that international law and principles may provide particularly significant interpretative guidance to the Panel in the present case for two reasons. First, the concerns of the international community regarding the transboundary movement of GMOs are reflected in the first comprehensive international agreement on the subject at issue, the Biosafety Protocol. Second, the precautionary principle reflected in the SPS Agreement, and particularly in Article 5.7, provides critical interpretative guidance for regulators and adjudicators in cases where uncertainty renders scientific evidence insufficient to adequately determine sanitary and phytosanitary risks.

A. The Panel's reasoning & findings

The Panel confirmed, in line with previous jurisprudence, that it had to interpret the WTO agreements "in accordance with customary rules of interpretation of public international law" reflected, in part, in Article 31 of the Vienna Convention.¹⁰⁰

Vienna Convention on the Law of Treaties

Article 31 General rule of interpretation

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:
 - (a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;
 - (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.
3. There shall be taken into account, together with the context:
 - (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
 - (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;
 - (c) any relevant rules of international law applicable in the relations between the parties.

¹⁰⁰ Paragraph 7.65

In this context, the Panel concentrated primarily on the meaning of Article 31 (3)(c), which directs the interpreter to ‘take into account, together with the context’ ‘any relevant rules of international law applicable in the relations between the parties.’ It found that “rules of international law” seemed sufficiently broad to encompass all generally accepted sources of public international law, including treaties, customary international law, and the recognized general principles of law. With respect to the latter, it noted that the Appellate Body in *US – Shrimp* made it clear that pursuant to Article 31 (3)(c) general principles of international law are to be taken into account in the interpretation of WTO provisions.¹⁰¹

The Panel also addressed the phrase “applicable in the relations between the parties” in the same article. It found that this reference limited the application of Article 31 (3)(c) to the rules of international law applicable in the relations between all the parties to the treaty that is being interpreted. In the present case, this would cover those rules that are applicable in the relations between the WTO Members.¹⁰² However, the Panel did not take a position on the situation where the relevant rules of international law are applicable between all parties to the dispute, but not between all WTO Members.¹⁰³ As a consequence, the Panel rejected the idea that it was required to take into account either the CBD, or the Biosafety Protocol, in light of the fact that several WTO Members, including the complaining parties to this dispute, were not parties to the agreements in question.¹⁰⁴

The Panel also rejected the notion that it should consider the fact that some of the disputing parties, while not ratifying, had *signed* the agreement, and that pursuant to Article 18 of the Vienna Convention a State which has signed a treaty must refrain from acts which would defeat the object and purpose of that treaty. The Panel’s reasoning was based on the argument that “the ‘object and purpose’ of a treaty cannot be reasonably considered to constitute a ‘rule’ of international law.”¹⁰⁵

1. *The precautionary principle*

The EC argued that certain GMOs present potential threats to human health and the environment. It submitted that the existence of a potential threat justified the assessment of risks on a case-by-case basis and special measures of protection based on the precautionary principle.¹⁰⁶ Citing several international instruments incorporating the precautionary principle, the EC asserted that the precautionary principle was now a fully-fledged and general principle of international law.¹⁰⁷

¹⁰¹ Paragraph 7.66

¹⁰² Paragraph 7.68

¹⁰³ Paragraph 7.72.

¹⁰⁴ Paragraphs 7.73 - 7.75

¹⁰⁵ Paragraph 7.74, FN 200.

¹⁰⁶ Paragraph 7.77

¹⁰⁷ Paragraph 7.78

CIEL's *amicus curiae* brief further argued that scientific uncertainty is an essential component of the precautionary principle. In fact, it was the recognition that science does not have all the answers in certain circumstances that led to the acknowledgement that uncertainty could not be used to postpone measures that respond to serious and complex health and environmental problems, and to the development of the precautionary principle. CIEL also noted that while the precautionary principle may be worded differently in various instruments – not an uncommon characteristic in international customary law – the notion of inconclusive scientific evidence is at the core of each statement.

With respect to the precautionary principle, the Panel found that if the “precautionary principle” was a general principle of law, it should be taken into account.¹⁰⁸ Noting that the EC had not explained exactly what it meant by the term “general principle of international law,” the panel found that the term could be understood as encompassing either rules of customary law or the general principles of law recognized by States or both, and that it would consider whether the precautionary principle fit within either of these categories.¹⁰⁹ In doing so, the Panel relied primarily on the Appellate Body’s handling of this question in its report in EC-Hormones. In that case, the Appellate Body, noting that it was unclear whether the precautionary principle has been widely accepted by Members as a principle of general or customary international law, refrained from taking position on the status. In line with that approach, the EC-Biotech Panel also refrained from expressing a view on the issue.¹¹⁰

2. *Other International Law Rules*

Finally, the Panel examined whether it could consider, in interpreting WTO agreements, rules of international law that 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).¹¹¹ Referring to the EC argument that in *US – Shrimp* the Appellate Body interpreted WTO rules by reference to treaties that were not binding on all parties to the proceedings (including the CBD), the Panel concluded that it could consider such rules when interpreting the terms of WTO agreements if it deemed such rules to be informative. It stressed, however, that it need not necessarily rely on these.¹¹² To come to this conclusion, the Panel relied on Article 31 (1) of the Vienna Convention, according to which the terms of a treaty must be interpreted in accordance with the “ordinary meaning” to be given to its terms “in their context and in the light of its object and purpose.” It noted:

The ordinary meaning of treaty terms is often determined on the basis of dictionaries. We think that, in addition to dictionaries, other relevant rules of international law may in some cases aid a treaty interpreter in establishing, or

¹⁰⁸ Paragraph 7.76

¹⁰⁹ Paragraph 7.86

¹¹⁰ Paragraph 7.87

¹¹¹ Paragraph 7.90

¹¹² Paragraph 7.91-7.93

confirming, the ordinary meaning of treaty terms in the specific context in which they are used. Such rules would not be considered because they are legal rules, but rather because they may provide evidence of the ordinary meaning of terms in the same way that dictionaries do. They would be considered for their informative character. It follows that when a treaty interpreter does not consider another rule of international law to be informative, he or she need not rely on it.¹¹³

Applying these considerations to the EC-Biotech case, the Panel concluded without further explanation that it was not necessary or appropriate to rely on the particular provisions of the CBD and the Biosafety Protocol invoked by the EC in interpreting the WTO agreements at issue in this dispute.¹¹⁴

B. Preliminary conclusions

US – Shrimp has become the *leitmotiv* of those who believe that the WTO and MEA question has been cleverly resolved. Any concerns expressed that MEAs might not be adequately considered in a WTO dispute, were brushed off as irrelevant in light of the jurisprudence laid down by the Appellate Body in US-Shrimp. The EC-Biotech Panel's reasoning with respect to the MEA-WTO relationship and the relationship between the WTO and public international law more generally, serves as a wake-up call. The Panel rejected the notion that rules of interpretation might require that international conventions that were not ratified by all WTO Members be taken into account. Having to address the fact that the Appellate Body previously had taken into account treaties to which not all disputing parties were parties (and as a consequence not all WTO Members were parties), the Panel found that a treaty interpreter could rely on such a treaty only if found useful, but that under no circumstance was he or she obliged to do so.

As of February 21, 2006, 132 states had ratified the Biosafety Protocol and an additional 61 countries had signed it. To expressly and totally disregard the importance and relevance of the first comprehensive international agreement on the subject at issue in the dispute, the Biosafety Protocol, shows that there is indeed a reason to worry about the WTO's approach to MEAs.

While the Panel's interpretation of the reference in Article 31 (3) (c) of the Vienna Convention to 'rules applicable in the relations between the parties' may not be manifestly wrong, it does not contribute to building channels of dialogue in an increasingly fragmented international legal system. The Panel's apparent attempt to avoid conflicts between relevant rules of international law¹¹⁵ led it to conclude that the Vienna Convention did not establish a legal obligation for interpreting bodies to take into account treaties that were not ratified by all parties to the treaty being interpreted. However, this conclusion stands at odds with the responsibility of an interpreting body to take into account those treaties, especially when they address issues of global concern where the interests of the international community are involved.

¹¹³ Paragraph 7.92, footnotes omitted.

¹¹⁴ Paragraph 7.95

¹¹⁵ Paragraph 7.70.

While the particular wording of the Vienna Convention on the Law of Treaties may lead to differing interpretations, it should also be noted that the customary rules of treaty interpretation reflect a State-centered view of international law. Indeed, under such view, a State cannot acquire obligations that it has not consented to and the interpretation of rules applicable to it cannot take into account other rules the State has not consented to. In addition, the rules of interpretation in the Vienna Convention were developed at a time where most treaty-making activity focused on bilateral treaties, and where multilateral agreements were only beginning to appear. The limitations of this State-centered paradigm and its impact on the interpretation of the rules of treaty interpretation are particularly evident in regards to issues of common concern to humanity, such as those addressed by multilateral environmental agreements. Where the concerns of the international community are at stake, such as the preservation of biodiversity and life on planet earth, the State-centered paradigm and its rules of treaty interpretation must give way to the recognition of superior values and interests. In that regard, international environmental law must have an impact and be given proper weight in the interpretation of treaties.

In addition, the Appellate Body's preference for multilateralism in the situations involving global issues confirms the importance of multilateral environmental agreements and their relevance to the interpretation of WTO law. The Appellate Body's recognition that good faith negotiations will not always succeed in bringing all countries to adhere to a treaty should also be an indication that it considers all treaties and negotiations relevant and important.

Moreover, it is noteworthy that both the SPS and the TBT Agreements give strong preference to international standards. Such standards are not mandatory but nevertheless have legal consequences on questions of interpretation and the repartition of burden of proof. Not only are these rules relevant despite the fact that they are non-binding, but they additionally need not have been adopted by consensus (as long as membership is open to all WTO Members). This was explicitly confirmed in the EC-Sardines case. As a consequence, an international standard, as referred to in the SPS and the TBT Agreement can be relevant for determining rights and responsibilities, and *a fortiori* for WTO law interpretation, even where not all WTO Members agreed on the standard.

Finally, countries regularly refer to the concept of mutual supportiveness between trade and environment. Taking an MEA into account for the interpretation of WTO agreements and vice versa allows different regimes to co-exist and for one regime to support the other. This approach does not result, as the Panel appears to believe, in new obligations for WTO Members that are not party to the MEA. The attitude of the Panel to ignore the importance of internationally negotiated instruments outside the WTO runs counter to the notion of mutual supportiveness.

XI. Conclusion

A number of EC and EC Member States measures challenged in the EC-Biotech case were found – at least in certain respects – to be inconsistent with WTO rules. First, the Panel concluded that the general *de facto* moratorium resulted in a failure to complete individual approval procedures without undue delay, and hence gave rise to an inconsistency with Article 8 and Annex C of the SPS Agreement.

Second, with regards to the applications for certain specific biotech products, the Panel found that there was undue delay in the completion of the approval procedure with respect to 24 of the 27 relevant products. Therefore, the Panel concluded that, in relation to the approval procedures concerning these 24 products, too, the EC breached its obligations under Article 8 and Annex C of the SPS Agreement.

Finally, the Panel found that the nine safeguard measures taken by some EC Member States after products had been approved by the EC to be marketed EC-wide failed to meet the requirements of the SPS Agreement relating to risk assessment. The Panel concluded that Article 5.7 of the SPS Agreement (which allows members to adopt provisional SPS measures where relevant scientific evidence is insufficient) was not applicable. This conclusion was based on the finding that the evaluation and review of the products at issue by the relevant EC scientific committees proved that sufficient scientific evidence was in fact available to permit a risk assessment as required by the SPS Agreement.

At the same time, many of the complaining parties' claims against the challenged measures were dismissed in the Interim Report. In relation to the general moratorium and the product-specific measures, the Panel found the EC had not acted inconsistently with any of the allegedly violated substantive SPS Agreement requirements. This is primarily due to the fact that the Panel did not examine the EC approval legislation as such but rather scrutinized the general moratorium and the specific moratoria on approvals. The moratoria, the Panel found, were decisions concerning the application, or operation, of procedures, and thus were not SPS measures subject to the substantive requirements relating to risk assessment and science more generally.

In light of the distorted representations of the Panel's findings following the issuance of the Interim Report in early February 2006, it is important to point out that the Panel report is far from being the clear-cut victory for the complaining parties reflected in the press. According to the *Wall Street Journal*, for instance, U.S. officials characterized the ruling as an important warning to other parts of the world against establishing prohibitions for GMOs.¹¹⁶ Although the full implications of the EC-Biotech case remain unclear, both for the EC and for other WTO Members, the present overview and analysis of the Interim Report should serve to dispel some of the concerns raised by such statements.

While some aspects of the report are worrisome – such as the Panel's approach to the relationship of the WTO to multilateral environmental agreements, as well as its narrow definition of risk assessment – the report says nothing that would put into question WTO Members' rights to regulate GMOs, including through the adoption of import

¹¹⁶ *The Wall Street Journal*, "EU loses a round on biotech crops," 9 February 2006.

prohibitions and moratoria on the use and marketing of GMOs. The inconsistencies the Panel found related solely to the manner in which the EC approval procedures were applied. The Panel did not once question the validity of the EC approval legislation itself. The Panel's concerns centered on the fact that the EC had not given an answer to applicants, be it yes or be it no, leading to the described 'undue delay.' In short, nothing in the Interim Report indicates that the EC will have to make changes to its current GMO legislation.

With respect to the national safeguard measures, the Panel found that these were not based on a risk assessment as required by the SPS Agreement. However, the Panel did not question the right of EC Member States to take such safeguard measures. If in the future new risk assessments are conducted to support the adoption of the safeguard measures, these safeguard measures may become WTO-compliant. Indeed, the findings in EC-Biotech in regards to safeguard measures would not require any changes to the EC legislation. It remains unclear, however, whether the Panel's narrow interpretation of the notion of "risk assessment" in the SPS Agreement could leave sufficient space for members to take a precautionary approach.

Overall, the Panel avoided addressing many of the issues surrounding GMO trade. For example, it did not look at the question of whether biotech products are "like" their conventional counterparts. Nor did it examine whether the EC has a right to require the pre-marketing approval of biotech products, or whether the current EC approval procedures, which provide for a product-by-product assessment, are consistent with WTO obligations.

One much-awaited issue on which the Panel did elaborate, however, is on the relationship between the CBD and the Biosafety Protocol on the one hand and WTO rules on the other. The Panel found that neither of these conventions was useful for its interpretation of WTO rules, without explaining why it reached this conclusion. The Panel's approach to the relationship between MEAs and the WTO lacked much consideration of the concepts of mutual supportiveness and the general preference for addressing environmental concerns multilaterally. To neglect and brush off the importance and relevance of the only comprehensive international agreement on the GMOs, the Biosafety Protocol, shows that there is a reason to worry about the WTO's approach to MEAs.

Finally, the Panel continued the WTO's pattern of secrecy in issuing interim reports only to disputing parties, which led to misinformation about the content of the interim report. Moreover, the Panel accepted, but refused to consider, *amicus curiae* briefs, thus further removing WTO jurisprudence from being in the public interest. The first-mentioned problem requires a change in WTO procedures. The latter requires a broader understanding of the importance of public participation.