U.S. vs. EC Biotech Products Case

WTO Dispute Backgrounder

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ABOUT THIS PUBLICATION
Backgrounder on WTO Dispute: U.S. vs. EC BioTech Products Case

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Introduction

By the end of October 2005, the World Trade Organization dispute panel hearing the "European Communities Measure Affecting the Approval and Marketing of Biotech Products" (EC Biotech Products) case is scheduled to issue its ruling, first to the parties to the dispute, followed by publication of the ruling about a month later. The date of the ruling's issue has been postponed twice due to "several import new issues raised by the parties" and by "a vast amount of material" that requires review as a result of consultation with experts.[1] An interim ruling could come out as early as September with a final ruling handed down in October.[2] The panel and ruling combine the cases of the United States (DS 291/17), Canada (DS 292/17) and Argentina (DS 293/17) against the European Communities. This short analysis reviews the main issues drawn from available U.S. and EC submissions plus related documents.

What's at stake?

The stakes in the outcome of this ruling—all but certain to be appealed—are very high. If the panel rules against the EC and the appellate body upholds the ruling, the plaintiffs will be able to seek at least two forms of redress. First, they are eligible to seek monetary reward in the form of tariffs imposed on EC exports in the amount of negotiated damages due to EC regulations on genetically modified organisms (GMOs). Already as of 2002, the U.S. State Department had claimed at least $300 million in lost sales of genetically modified corn and soy products.[3] A no doubt larger claimed amount of damages would likely be negotiated downward in the compliance phase of a ruling favorable to the plaintiffs.

Secondly, the victorious plaintiffs will be able to seek changes to the EC regulatory regime that would presumably make that regime more like the U.S. regime, which the EC has characterized as "laissez-faire," or a deregulatory regime.[4] Any changes to the EC regulatory regime would come at a politically difficult moment when the European Commission is struggling to enforce its legislation on GMOs in the face of six EC member state bans on GMOs.[5] The commission is seeking to overturn EC member state marketing and import bans both through the European Court of Justice and through fostering greater cooperation between member state scientific bodies and the European Food Safety Agency. Recent votes on regulatory committees to lift marketing or import bans on GMOs have been defeated by narrow margins, in a process in which each EC member state receives votes based on its population size.[6] However, on June 24, 22 of 25 EU member states voted against eight commission proposals to end GMO bans in the member states. As a result, the commission may introduce a totally new law to end the bans, rather than submit further proposals through the existing regulatory system.[7]

Finally, and most importantly, the ruling will very likely be treated as a precedent by future WTO panels ruling on food safety, public health and environmental health measures applied to international traded goods and services. Developing countries, many of which have yet to establish regulatory regimes for GMO crops, will be particularly affected by the ruling. Also, the ruling could impact the regulation of other industries. For example, aspects of the ruling could be cited if the U.S. decides to launch a WTO case against draft EC rules to test certain industrial chemicals for their public health consequences. The Bush administration charges that the rules would cost the United States $20 billion annually in lost chemical trade to Europe. The administration and the State Department have joined the U.S. chemical industry in an extensive campaign to weaken those rules.[8]

The WTO case against the EC regulatory regime comes at a highly charged political moment when the constitutional viability of the EC is in question only months after the expansion of the EC from 10 to 25 members. The panel decision will come in the midst of U.S. charges that new EC GM testing requirements, as a result of recent illegal U.S. GM corn exports to Europe, will result in the loss of hundreds of millions of dollars of sales of U.S. corn gluten feed.[9] In addition, the European press has widely covered the recent discovery of internal studies by Monsanto that a variety of GM corn, Mon 863, under consideration to be commercialized in the EC, when fed to rats, caused changes in the blood composition and reduced kidney size.[10] While such revelations fall outside the period of EC regulatory review against which the U.S. has brought charges, the EC's ability to implement the WTO ruling will certainly be affected by the ongoing "surprises" about GMOs not revealed in the U.S. approval process for biotech products.

Overview:
Four central questions in the case

1. **Will the EC and other WTO members be able to develop and maintain a regulatory system for GMOs that allows for the use of precautionary measures (see "The precautionary principle," below) to protect consumer, animal and/or plant health when there is insufficient scientific evidence to assess the risks of a biotech product presented to governments for commercialization approval?** If the panel rules that the EC regulatory system violates provisions in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), the U.S. may demand changes to the EC regulatory review system to make it more like the U.S. system, which the EC has characterized as laissez-faire or deregulatory. An adverse ruling will be weaken the EC's ability to use a precautionary approach in regulating to meet public health, safety and environmental objectives.

2. **Will the panel agree with the EC that some of its regulatory objectives for GMOs fall outside of the competence of WTO agreements and are covered by other international agreements (e.g. the objective to preserve biodiversity against plant species invasion by GM varieties)?** The EC argues that measures to preserve biodiversity are the competence of the Cartagena Protocol on Biosafety, to which the U.S. is not a party. The WTO does not recognize the protocol as containing presumptively authoritative standards. Indeed, WTO members have not allowed the secretariat of the Convention on Biological Diversity, to which the protocol is appended, to be an observer at the WTO Committee on Trade and Environment. If the panel disagrees with the EC argument that part of the U.S. complaint concerns measures outside the WTO's competence and that of the standard setting organizations referenced in its agreements, then an international public law controversy will arise about the scope of the application of WTO rules. However, if the panel invokes the first WTO appellate body ruling that the General Agreement on Tariffs and Trade (GATT) "is not to be read in clinical isolation from international public law," then the panel may rule that the Protocol is a *lex specialis* useful for interpreting more general WTO rules.[11]

3. **How will the panel document its use of expert opinion in determining the factual matters that pertain to the main legal issues of the dispute?** Determining whether the EC has violated the provision against "undue delay" in its regulatory review procedures will depend on how the panel interprets the "vast amount of materials" about GMOs submitted by the experts. Determination of violation will also depend on how the panel interprets the answers from experts to questions put to them and to the disputing parties by the panel. Panelists are not required to use expert opinion to make their ruling and the U.S. argued unsuccessfully that no expert opinion was needed to decide the dispute. However, since the panel has requested expert opinion, it is vital to the credibility of the ruling that the experts' opinions, the documentary basis for the opinion and questions put to the experts be appended to the ruling.

4. **How will the panel use previous WTO dispute panel and appellate body rulings on "scientific uncertainty" to justify its ruling?** The disputants interpret past WTO rulings differently to support their arguments. Particularly important is how the panelists rule on the relation of "insufficient scientific information" to "scientific uncertainty" as that relation was ruled in the case of a dispute over SPS measures that Japan took to prevent fire blight in apples. If the panel rules against the EC that there is no basis in the SPS agreement for "scientific uncertainty" resulting from "insufficient scientific information," then the EC likely will not be able to defend itself against the U.S. charge of "undue delay" in its regulatory review procedures.

The precautionary principle

Since the EC has taken a number of steps to revise its regulatory system to commercialize GMOs, the U.S. objectives in bringing the dispute are not entirely clear. One underlying objective is to get a dispute panel and/or appellate body ruling that there is no basis in the WTO agreements to support EC's argument "that states have the right to adopt a precautionary approach when dealing with GMOs."[12] In support of this argument, the EC cites articles 10(6) and 11(8) of the Cartagena Protocol on Biosafety, an international public law agreement to which none of the plaintiffs are parties.

The "precautionary approach" derives from German air pollution legislation in 1968 as a result of suggestive but not conclusive evidence that industrial air pollution was damaging the environment. In addition to justifying the government's authority to take preventative action against environmental damage, the legislation required that the regulatory actions be "proportional" to the potential for harm and that there be an assessment of the costs and benefits of action and inaction.[13] Subsequent formulations of the precautionary principle, including those applied to the risk analysis of GMOs, have specified the relation between scientific evidence and a typology of scientific uncertainty, and the need to shift the burden of proof to the technology developer to demonstrate the safety of a new technology ("harmful until proven safe").[14]

An EC Communication describes precaution as a risk management tool which is part of a risk analysis framework rather than the overall guide to its (i.e., the framework's) implementation. According to this argument, precautionary action should only be taken after experts prepare an "objective" quantitative risk assessment. Precaution is seen as a temporary measure pending further risk assessment."[15] The commission's interpretation of the precautionary principle is clearly an attempt to make its application conform with the provisions of the SPS agreement. A great deal of the commission's work has been to analyze the application of precautionary approaches to government regulation over a wide range of products and over a time frame much longer than the decade since the commercialization of the first GM crops.[16]

U.S. corporations have taken a strong stand against a precautionary approach to the regulation of new goods and services.[17] Additionally, the current head of the U.S. Office of Information and Regulatory Affairs in the president's Office of Management Budget has sought to pervert the precautionary principle by assuming that new products are safe until proven otherwise and putting a prohibitive cost-benefit analysis against most regulation. Given the antipathy of the White House and major U.S. corporations to the precautionary approach, most regulatory applications of precautionary approaches have occurred at the sub-federal level.

Background

On May 13, 2003, the United States informed the European Commission that it would seek WTO consultations to end an alleged EC moratorium on the approval for commercialization of agricultural biotechnology products. The United States claimed that the alleged moratorium violated provisions of the WTO agricultural, technical barriers to trade (TBT) and sanitary/phytosanitary (SPS) agreements, as well as the General Agreement on Trade and Tariffs (GATT). To its complaint the U.S. appended a list of biotech product applications for commercialization that had been submitted to EC member states from April 1996 through July 2001, all of which either were pending approval or which had been withdrawn. The majority of the plaintiffs' claims of EC violations of WTO rules concern the SPS agreement, which is the focus of this analysis. However, the panel will almost certainly rule on the violations charged under other agreements. The U.S. further justified its complaint by contending that biotech products were necessary to feed developing countries.[18]

The EC characterized the filing of the complaint as "legally unwarranted, economically unfounded and politically unhelpful [with regard to EC efforts to develop a regulatory system for GMOs]."[19] Two weeks later, President George Bush brought the trade dispute to wider public attention by charging that the alleged moratorium on GMO approvals was hindering efforts to reduce hunger in Africa.[20]

Because the EC consultations with the U.S., Canada and Argentina did not result in the ending of the alleged moratorium, in August 2003 the WTO Dispute Settlement Body (DSB) announced the formation of a single panel to rule on the case. In March 2004, the three panelists were named and in April, the first submissions of evidence began. In addition to the three plaintiff WTO members, Australia, Brazil, Chile, Colombia, India, Mexico, New Zealand and Peru requested consultations with the European Communities and reserved their rights as third parties to benefit from the ruling.[21]

Since at least as early as July 1999, an interagency task force of U.S. officials had been debating under which provisions of which WTO agreements the U.S. should charge that the EC regulatory review process violated WTO rules. In June 1999, five EC member states had declared that they would not approve biotech products for commercialization until new EC legislation (Directive 2001/18) concerning the labeling and traceability (ability to document and verify each step in food and animal feed production from the farm to the consumer) of GMOs had been adopted by member states. That declaration triggered U.S. charges of a general moratorium on GMO approvals. Because the EC had not rejected, but only classified as pending, an individual application for commercialization of a biotech product, U.S. officials decided that the most likely provision under which the U.S. could win a WTO dispute would be under article 8 and annex C of the SPS agreement. These provisions seek to ensure that approval and control procedures for products entailing SPS measures be undertaken "without undue delay." At the time of the filing in 2003, the EU had not approved a new GMO crop since 1996. Even then, one industry official thought it would be difficult for the U.S. to win on that basis, noting that it took the U.S. 50 years to approve imports of avocadoes.[22]

In general, the U.S. has argued that there are no scientific issues relevant for assisting the dispute panel: "no dispositive issue in this dispute [U.S. underlining] turns on these abstract scientific questions. In particular, regardless of the answer to abstract questions regarding the purported risks of biotech products, the EC is obligated to complete its approval procedures without 'undue delay.'"[23] The EC countered, "The independent expertise is needed to determine whether the time actually used in the specific cases [of alleged 'undue delay'] to address the actual issues which arose was 'undue.'"[24]

In spite of U.S. objections, in August 2004, the dispute panel decided that it would seek expert advice and began the process of selecting experts and drafting questions for them. The panel is not required by the WTO dispute settlement understanding to take into account expert advice in issuing their ruling, nor does the panel have to append to the ruling questions put to experts, their answers and bibliographical references to document their answers. Nevertheless, the panel has opened the door to allow experts to comment on scientific issues that the EC regards as relevant and the U.S. regards as irrelevant to determining the outcome of the case.[25]

The main issues

The status of "facts"

The first U.S. submission to the dispute panel largely comprises a "statement of facts," followed by a legal discussion that focuses on the SPS agreement. It is not clear what, if any, evidentiary weight the dispute panel will give to U.S. assertions as "facts." In some instances, the U.S. represents as facts claims that are controversial within the scientific community. Consider the claim, documented by an un-cited, presumably commercialization-applicant study, alleging a 21 metric ton reduction in U.S. pesticide use in 2001 due to use of genetically engineered seeds.[26] How will the panelists weigh such an undocumented claim as evidence, if it is contrasted to the first detailed analysis of U.S. Department of Agriculture data documenting an increase in U.S. pesticide use on GM crops since 1999?[27] In general, how will the panel judge blanket assertions about the environmental safety of GMOs when the U.S. National Research Council concludes, "claims concerning the lack of effects from the tens of millions of hectares of transgenic crops that have been planted in the United States during the last three years are nonscientific. There has been no environmental monitoring of these transgenic crops, so any effects that might have occurred could not have been detected"?[28]

Will the panelists give greater evidentiary weight to an EC Research Directorate press release, cited by the U.S., declaring the safety of biotech products[29] than it would to a U.S. commercialization approval letter for GMOs? Will the panelists consider the U.S. approval process, which is offered as a WTO conforming, science-based regulatory system? The U.S. does not verify the safety of any biotech product, but approves products based on the "safety and nutritional assessment" submitted by biotech companies and based on the company's conclusion that its findings "do not raise issues that would require pre-market approval."[30] (See "Sample U.S. Food and Drug Administration biotech product commercialization approval," page 8.) How will panelists be able to compare WTO member compliance with the SPS agreement provisions on approval and control procedures if the U.S. allows biotech companies to de facto self-approve, while the EC requires independent verification by a competent authority of the company's claims for its products?[31]

Legal issues

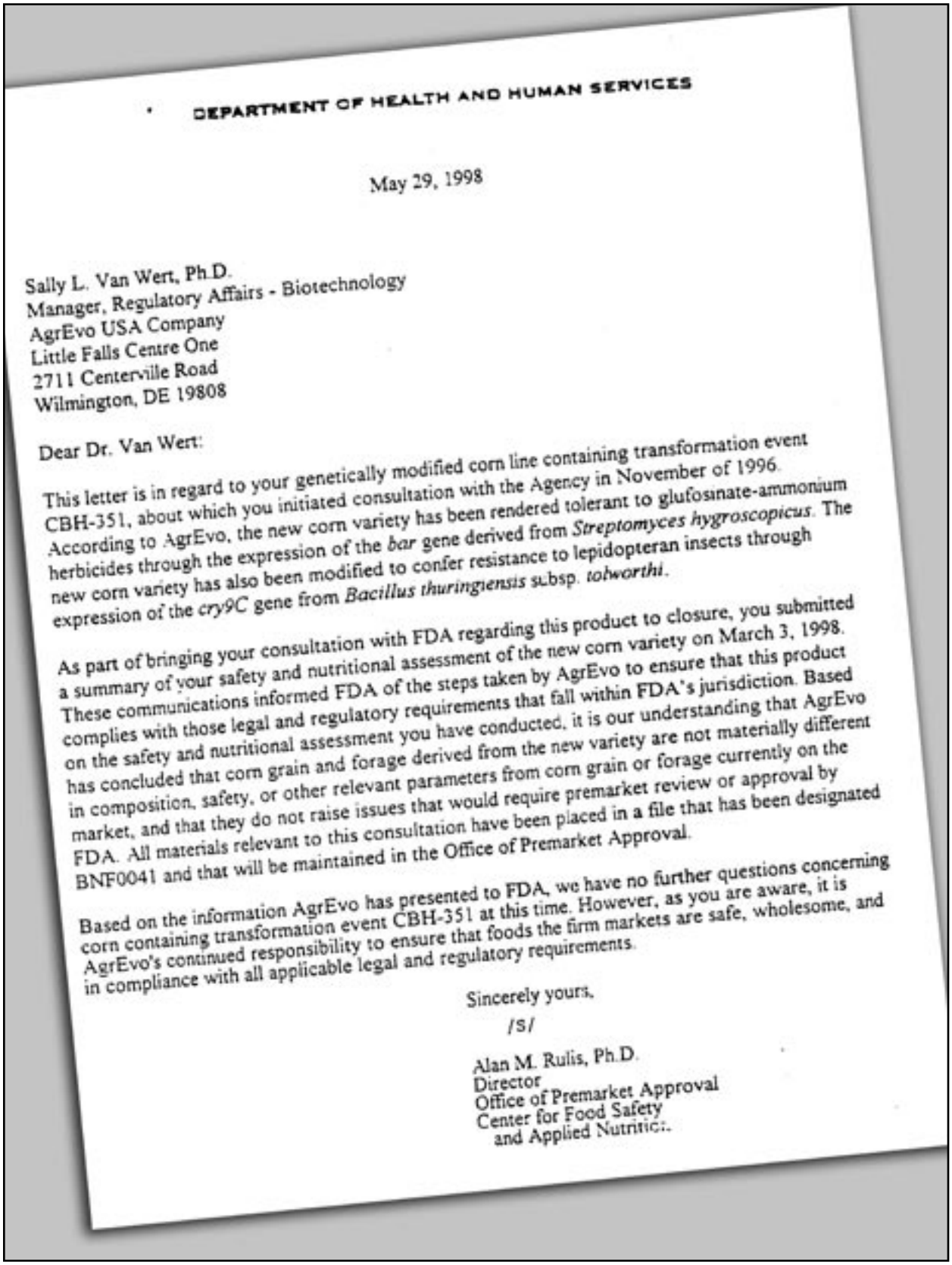
The structure of the U.S. legal argument is in three parts: "1) General Moratorium Violates the SPS Agreement; 2) Product-Specific Moratoria Violate the SPS Agreement: and 3) EC Member State Marketing or Import Bans Violate the SPS Agreement." With slight variations, the U.S. claims the same violations of the SPS Agreement in each of the three parts. The United States claims:

1. The existence of alleged moratorium is a violation of the SPS rules against "undue delay" in SPS agreement approval procedures.

2. Failure to notify the moratorium as an SPS measure is a violation of SPS agreement rules on transparency of rule-making and notification of domestic SPS measures to the WTO SPS committee.

3. The EC and EC member states failed to publish risk assessments on the likelihood of harm resulting from biotech products, as required by article 5.1.

Sample U.S. Food and Drug Administration biotech product commercialization approval



DEPARTMENT OF HEALTH AND HUMAN SERVICES

May 29, 1998

Sally L. Van Wert, Ph.D.
Manager, Regulatory Affairs - Biotechnology
AgrEvo USA Company
Little Falls Centre One
2711 Centerville Road
Wilmington, DE 19808

Dear Dr. Van Wert:

This letter is in regard to your genetically modified corn line containing transformation event CBH-351, about which you initiated consultation with the Agency in November of 1996. According to AgrEvo, the new corn variety has been rendered tolerant to glufosinate-ammonium herbicides through the expression of the *bar* gene derived from *Streptomyces hygroscopicus*. The new corn variety has also been modified to confer resistance to lepidopteran insects through expression of the *cry9C* gene from *Bacillus thuringiensis* subsp. *tohworthi*.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new corn variety on March 3, 1998. These communications informed FDA of the steps taken by AgrEvo to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that AgrEvo has concluded that corn grain and forage derived from the new variety are not materially different in composition, safety, or other relevant parameters from corn grain or forage currently on the market, and that they do not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF0041 and that will be maintained in the Office of Premarket Approval.

Based on the information AgrEvo has presented to FDA, we have no further questions concerning corn containing transformation event CBH-351 at this time. However, as you are aware, it is AgrEvo's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/S/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

4. The alleged moratoria are maintained without "sufficient scientific evidence" in violation of article 2.2.

5. By regulating biotech products, such as genetically engineered seeds, more strictly than biotech processing agents, such as enzymes used in food manufacturing, the EC violates article 5.5, which seeks to ensure that WTO members apply SPS measures indiscriminately to domestic and imported products "in comparable situations."

In its first submission to the dispute panel, the EC deployed various defenses against the U.S., et al., complaint of "undue delay." First, the EC states that "the alleged delay in completing the approval procedures for certain applications does not, itself, constitute a sanitary or phytosanitary measure, and thus, these provisions [of the SPS agreement that the U.S. charges the EC violates] do not apply."[32] But even if delays in regulatory review of applications of the commercialization of GMOs were considered to be measures, the EC argues that they are not "undue" but that the delays are due to legitimate requests for information from applicants and due to the implementation process for Directive 2001/18.

In its first and second submissions, the EC outlines reasons for the delays in final approvals to commercialization applications to member states. Most of the delays, the EC contends, resulted from lack of applicant response or incomplete response to member-state regulator questions about GMOs. For example, regarding an application to commercialize genetically modified oilseed rape (canola), the EC points to delays in receiving information requested of the applicant, including information related to "the impact of herbicide regimes associated with the cultivation of GM herbicide tolerant oilseed rape, on farmland biodiversity, and population dynamics and life cycles in the farming ecosystem (risk issues which obviously go beyond the scope of risk assessment under the SPS agreement)."[33] According to the U.S., the scope of the application of SPS measures in the SPS agreement, annex A, paragraph 1, covers all the issues raised by the EC and its members states and, hence, no EC directive nor member-state legislation or regulation is exempt from the claim of violating the "undue delay" provision.[34] For the EC, the delay cannot be "undue" if it pertains to an issue for risk assessment not covered in the SPS agreement.

The relevance of international SPS standards versus the Biosafety Protocol

More generally, the EC submits, "The SPS Agreement was not intended to address the prevention of risks to the environment." The common and ordinary meaning of "environment" is broad and includes the protection of biodiversity. It extends beyond the narrow definitions to be found in annex A of the SPS agreement.[35] The EC claims that some of those aspects of the EC regulation of GMOs not covered by the SPS agreement are contained in the Cartagena Protocol on Biosafety.[36] The United States not only dismisses the relevance of the protocol to the panel's decision, [37] but asserts that the panel's determination of environmental risks covered by the SPS agreement need not be "controlled" by the definitions of such risks, adduced by the EC, from the Codex Alimentarius Commission and the International Plant Protection Convention (IPPC).[38]

Since the Convention on Biological Diversity, to which the protocol belongs, is not even allowed to be an international observer at the meetings of the WTO Trade and Environment Committee, much less mentioned in the SPS agreement, the panel may dismiss or at least not rule on the relevance of the protocol

to the case. However, with notable exceptions, the SPS agreement requires WTO members to base their SPS measures on international standards (article 3.1). Codex and the IPPC are designated as international standard-setting organizations in which WTO members are to participate (article 3.4). Therefore, it is unlikely that the panel will ignore the normative weight of Codex and IPPC definitions employed in the EC argument. Nor can the panel ignore that the SPS agreement calls on members to take into account "available scientific evidence" in assessing risks, including "relevant ecological and environmental conditions" (article 5.2).

"Undue delay" and EC officials' calls to "lift the moratorium"

Perhaps most counterintuitively, the EC argues, "No evidence on the existence of a 'moratorium' [on the approval of GMOs] has been identified."[39] The EC dismisses the evidentiary validity of statements by EC officials, such as Commissioners David Byrne and Margaret Wallström, adduced by the United States, about the existence of a "de facto moratorium" by EU member states on approvals of GMOs.[40] According to the EC argument, evidence of a moratorium would be an official EC communication declaring a moratorium, and no such communication was issued.[41]

The U.S. contends that what the EC calls "alleged delay" is in fact a "general moratorium [that] is one component of the EC's biotech regime ... [which] is unquestionably an SPS measure"[42] subject to the disciplines of the SPS agreement. According to the U.S., "The statements of European Commission officials acknowledge not only the existence of the moratorium but also that it is maintained without scientific or legal justification."[43] Whether or not the dispute panelists decide that statements by EC officials in favor of GMOs[44] and in support of lifting the alleged moratorium have the force of law, and therefore have evidentiary relevance, is difficult to predict.

"Undue delay" and "risk assessment"

Panelists will decide the validity of the U.S. argument that the alleged moratorium in its entirety must be justified by a risk assessment, per article 5.1 of the SPS agreement. The EC charges "the Complainants' strategy is to avoid dealing with individual applications or looking at the scientific and risk assessment related reasons that has arisen in each case. Instead they apply a superficial attempt to reduce the whole case to a generalized and indiscriminate moratorium."[45] The EC further points out that the Codex principles for the risks analysis of "Foods Derived from Modern Biotechnology" (CAC/GL 44-2003, points 13-14) advises that all risk analysis should be performed on a case by case and not on the basis of a general regulatory framework.[46] However, the status of Codex texts, like all expert opinion as evidence, is only advisory, so, according to the dispute settlement understanding, the panels are not required to take them into account in issuing their ruling. [47]

The U.S. argues that a general moratorium requires a risk assessment, based its interpretation of an appellate body ruling concerning a U.S. case against EU restrictions on the import of meat from animals raised with growth hormones.[48] The panel is likely to rule on this argument because it concerns an interpretation of WTO case law that will bear on the future interpretation of the SPS agreement.

Just as importantly, the panel may decide to set a precedent by ruling on the U.S. argument that the entire

regulatory risk analysis framework (since the U.S. claims that the alleged moratorium is an SPS measure), and not just specific biotech products, must be justified by a risk assessment.[49] If the panel rules in favor of the U.S. on this argument, general regulatory frameworks, such as the U.S. "substantial equivalence" measure that assumes GMOs to be "substantially equivalent" to their "conventional counter-parts" unless proven otherwise, could be challenged as having lacked a risk assessment. The regulatory approval of a transgenic event shown not to be "substantially equivalent"[50] could be challenged as illegal for having lacked a risk assessment.

The most compelling U.S. argument against the EC is that "undue delay" occurs when EC member states issue marketing or imports bans to a biotech product despite having received a positive risk assessment from an EC scientific committee. Article 5.1 of the SPS agreement requires that SPS measures are "based on" a risk assessment, as defined in the SPS agreement. According to the U.S., "Because the member States failed either to put forth their own risk assessment or to provide sufficient information to overturn the European Communities' earlier positive assessments, the member States have violated Article 5.1."[51] If the panelists decide that an import or marketing ban is an SPS measure covered under the SPS agreement, then they will have to decide whether a positive risk assessment must lead to a final approval for commercialization of a biotech product.

The EC rebuts the U.S. argument that a positive risk assessment requires the EC or an EU member state to give final approval for commercialization of a biotech product. The EC states that EC scientific opinions are not legally binding on member states, as the U.S. believes they are, and that "scientific opinions are limited in scope, and, therefore, often do not conclude the risk assessment process, even in the narrow sense."[52] Furthermore, the EC argues that article 5 of the SPS agreement refers to risk management and risk communication elements of risk analysis. The article makes "it clear that in making an assessment of risks Members are entitled, and indeed obliged ('Members shall'), to take into account not only scientific but also economic and regulatory considerations."[53] When scientific knowledge is insufficient to assess a risk, a precautionary approach to risk analysis entitles governments to apply risk management options, such as a traceability scheme "to detect and identify any negative impact that was unforeseen or unidentified in the initial process of risk assessment."[54]

For the EC to defend its regulatory regime against the charge of violating article 5.1, the panel must agree with the EC that the rendering of a positive risk assessment by an EC scientific commitment is not in and of itself sufficient as to require a final approval of a biotech product for commercialization. The U.S. and its allies have successfully blocked Codex work that would advise governments on risk analysis,[55] so the panelists have no international standard to which to refer in judging the EC argument about the components of risk analysis.

The interpretation of provisional measures in SPS article 5.7 in relation to the rest of the agreement

Much of the EC defense of its regulatory regime for GMOs depends on how article 5.7 is interpreted in relation to several other articles that the U.S. charges the EC violates. The EC appears to concede that the member state import and marketing bans are SPS measures, but characterizes them as provisional measures whose consistency or lack of consistency should be judged not under article 5.1, but under article 5.7 on provisional measures applied while sufficient information is gathered to perform "a more objective

assessment of risk."[56] If the panelists agree with the EC that the complaints against the EC regulatory regime should be judged under article 5.7, then the likelihood that EC can defend that regime improves considerably.

The U.S. does not charge the EC with violating article 5.7, but argues that the EC cannot defend its alleged moratoria as provisional measures resulting from insufficient scientific evidence.[57] The U.S. reads the relation of article 5.7 as subordinate to the article 2.2 requirement to base an SPS measure on "sufficient scientific evidence" and the article 5.1 requirement to base an SPS measure on a risk assessment as defined by the SPS agreement.

The EC reads article 5.7 as exclusionary from the article 2.2 and 5.1 requirements. For the EC, article 5.7 allows WTO members to establish a provisional SPS measure without a risk assessment precisely because of the insufficiency of scientific evidence and uncertainty about risks that makes it impossible to carry out a full risk assessment.[58] Regulatory review delays resulting from requests by regulators to obtain sufficient relevant scientific evidence to perform a risk assessment, to design risk management measures, such as traceability system and risk communication measures, such as labeling of GMOs, should therefore not be characterized as "undue delays" in violation of the SPS agreement.[59] The EC notes as an example of the delay required by thorough regulatory review the three-year delay in Canada to approve Monsanto's application to commercialize genetically engineered wheat.[60]

However, "the United States does not agree that the 'sufficiency of relevant scientific evidence' depends on the level of protection [sought by a government for its consumers, plants or animals] or nature of the risks." The U.S. bases this statement on its reading of an appellate body passage in the *Japan-Apples* ruling concerning SPS measures to combat apple blight (WT/DS245/AB/R, paragraph 179).[61] The EC states that the *EC-Biotech Products* case is "very different from the circumstances of the *Japan-Apples* case." The EC notes that the appellate body ruling on the lack of justification for a provisional measure was because the nature of the risks of fire blight for apples, the sufficiency of relevant scientific evidence and the SPS measures to combat it had been known for about 200 years. In contrast, "GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain—and potentially much more far reaching."[62]

If the dispute panel determines that a judgment about the sufficiency of relevant scientific evidence on which to base an SPS measure can be made regardless of the nature and severity of the risks of a product and regardless of the level of protection that a government seeks for its consumers, plants and animals, then the panel likely will rule in favor of the U.S. If the dispute panel agrees that the material facts of *EC-Biotech Products* (i.e., the risks of the technology and the SPS measures used to prevent harm to human, plant and animal health) are different from the material facts, the risks and measures for fire blight in *Japan-Apples*, then the EC might prevail.

Risk assessment, "sufficiency of evidence" and scientific uncertainty

The U.S. believes that WTO case law is clearly on its side in the dispute over the relevancy and interpretation of Article 5.7. The U.S. maintains, "The EC's general discussion of themes such as 'uncertainty,' however, does not help the EC in the development of any argument under Article 5.7."[63] The U.S. then adduces as support for its argument, this passage from the appellate body ruling on the *Japan-Apples* case:[64]

The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to "cases where relevant scientific evidence is insufficient," not to "scientific uncertainty." The two concepts are not interchangeable. Therefore, we are unable to endorse Japan's approach of interpreting Article 5.7 through the prism of "scientific uncertainty."

The U.S. then remarks, "The Panel should do the same here with respect to the EC suggestion." [65] If the panel does as the U.S. recommends, and does not endorse the EC interpretation of article 5.7, it will do so not just to uphold the *Japan-Apples* "precedent" ruling on article 5.7. To accept the *Japan-Apples* ruling on "scientific uncertainty," the panel would need to find that there was no more "scientific uncertainty" in determining the risks of biotech products and applying SPS measures to control than there is in determining the risks of and measures to control fire blight.

Regulatory consistency in the application of SPS measures

Article 5.5 aims to ensure regulatory consistency in the application of SPS measures to achieve the appropriate level of protection (ALOP) that WTO members set. The article is sufficiently controversial so that the SPS committee took five years of negotiations to work out voluntary guidelines for implementation of this article.[66] These guidelines not withstanding, implementation of 5.5 presents difficulties in interpreting what are "comparable situations" in the application of SPS measures to meet a designated ALOP. For the U.S., the EC violates article 5.5 when it allows commercialization of biotech food processing agents but maintains a moratorium against other biotech products, such as genetically modified seeds.[67] According to the U.S., "In contrast to new biotech processing aids, which are not regulated, the EC has imposed a general moratorium on other new biotech products, resulting in an appropriate level of protection of zero risk."[68] The U.S. maintains that this contrast results in "arbitrary or unjustifiable" differences in the appropriate level of protection, a violation of article 5.5.

The EC defense against this claim of violation is not a factual one concerning the differences between processing aids and the biotech products submitted for commercialization approval, largely GM seeds and crops. Rather, the EC defense relies, again, on the argument that article 5.5 does not apply to the case because it concerns final SPS measures, and not the delays or interim SPS measures under article 5.7. The EC argues, "WTO members must necessarily enjoy more flexibility in cases where they lack elements to assess the nature or extent of the risk."[69]

An NGO brief on scientific uncertainty

An NGO amicus brief concedes the appellate body's distinction between "insufficient evidence" and "scientific uncertainty" but then notes that "WTO jurisprudence is not clear as to the influence of uncertainty in determining whether the scientific evidence is insufficient in a given situation."70 The brief then goes on to outline different kinds of scientific uncertainty about GMOs and how such uncertainties influence the determination about when scientific information is insufficient. For example, the amicus brief characterizes the uncertainty arising from "unintended effects of genetic modification arising from the random nature of rDNA techniques."71 The brief states, "Random and unpredictable genetic modification techniques thus lack a cardinal feature of both scientific method and reliable commercial technologies—repeatability."72

The brief also outlines the problem of determining the sufficiency of evidence to verify the safety of GMOs when a large portion of the studies asserting safety are applicant studies that are not peer-reviewed in scientific journals, but are classified often as confidential business information available to nobody outside the firm but government regulators.73 Finally, the NGOs argue "Uncertainty may not allow, in qualitative terms, the performance of an adequate risk assessment, thus making scientific evidence 'insufficient' within the meaning of Article 5.7."74 Therefore, concludes the brief, "the first condition under Article 5.7, the 'insufficiency' of relevant scientific evidence is met by the EC measures challenged in the present case."75

The NGO amicus brief offers to the panel the means to refine the appellate body ruling on Japan-Apples regarding article 5.7. If the panel takes into account the NGO brief, the EC defense of the reasons for its delays and interim SPS measures stands a better chance of withstanding the U.S. challenge.

Conclusion:
Significance of *EC-Biotech Products*

Whether or not the United States wins the *EC-Biotech Products* case, it is likely that the U.S. will file another case against the Directive 2001/18 on labeling and traceability of GMOs. As one industry official put it, "removal of the moratorium is 'utterly useless' if it is replaced by labeling and traceability rules."[76] However, the likelihood that the United States, et al., will file another case against the EC on its GMO regulations in no way diminishes the impact of this case. The U.S. is seeking a ruling, rather than a negotiated settlement, in *EC-Biotech Products* to establish a legal precedent, particularly to make it extremely difficult to use article 5.7 to defend domestic SPS measures.[77] While the ruling cannot reverse European consumer distaste for GMOs and growing preference for organic products, the ruling can lead to enforcing commission support for planting GM crops and thereby reducing the availability of non-GM products from which to choose.

Furthermore, if the panel rules against the EC's invocation of the precautionary principle, either in the EC context or in the Cartagena Protocol on Biosafety,[78] the viability of successfully using a precautionary principle-based defense (e.g., against a threatened U.S. WTO case concerning the new EC chemicals assessment regime[79]) is reduced. For the EC, "Article 5.7 of the SPS Agreement is of course one expression of the precautionary principle. ... This is another reason why Article 5.7 is an autonomous right that is also recognized in the Biosafety Protocol."[80] However, the panel well may dismiss the relevance of or evidentiary status of the precautionary principle in its ruling on the article 5.7 defense. A repudiation of the precautionary principle alone may justify to the U.S. the negative civil society reaction that is very likely to follow an *EC-Biotech Products* ruling in favor of the plaintiffs.

The fact that the commission is working very hard to promote the technology,[81] as well as to defend their regulatory system, in the face of considerable public opposition to agricultural biotechnology, does not diminish the importance of the case.[82] Former EC Trade Commissioner and incoming WTO Director General Pascal Lamy believes victory for the plaintiffs to lift the moratorium would only result in the status quo, in view of the restarting of approvals for GM products in Europe. However, such a victory could have far more serious precedential consequences for WTO members attempting to justify measures to protect public and environmental health in the context of international agreements for which the highest public policy criterion is the promotion of trade, allowing protective measures only insofar as they can be demonstrated to be "least trade restrictive."

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To read:

U.S. dispute documents, go to: http://www.ustr.gov/TradeAgreements

EC dispute documents and NGO amicus briefs are at http://www.genewatch.org.uk and at http://www.foeeurope.org/biteback

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