European Communities – Measures Affecting the Approval and Marketing of Biotech Products

(WT/DS291, 292, and 293)

Rebuttal Submission of the United States

July 19, 2004

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I. INTRODUCTION

1. The United States showed in its first submission that after October 1998, the European Communities adopted a moratorium on any further biotech product approvals. Particular product applications might make some progress through the EC approval system, but the EC failed to make a final decision on any biotech product application in the period between October 1998 and August 2003, when the terms of reference for this panel were established.

2. The United States in its first submission also showed that the EC's adoption of the moratorium – both across-the-board, and with respect to individual pending product applications – is inconsistent with the EC's obligations under the WTO Agreement, and in particular the *Agreement on the Application of Sanitary and Phytosanitary Measures*. While Members are allowed to maintain approval systems, the procedures under that system must be undertaken and completed "without undue delay." Although a determination of whether delay is "undue" may present challenges in other disputes, in *this* dispute there can be no question that the EC has not processed applications without undue delay. Certainly, if this SPS obligation is to have any meaning, the adoption of a moratorium of indefinite length -- without any basis other than the EC's own internal politics – must be considered "undue."

3. In addition to the moratorium on the approval of biotech products, six EC member States have adopted marketing or import bans on biotech products that previously have been approved by the European Communities. The EC's own scientific committees reviewed the purported basis for these bans, and found them without merit. Accordingly, these product-specific bans are thus inconsistent with the fundamental obligations under the WTO Agreement that SPS measures must have a scientific basis.

4. The EC's response to these clear showings of breaches of its WTO obligations have been remarkable: to date, the EC has failed to address the central issues. With regard to the moratoria, the EC's only defense is that no such measures ever existed. In taking this position, the EC asks the Panel to ignore the statements, and indeed actions, of the EC's political-level decisionmakers. The EC makes this argument even though it has informed the Panel that there indeed is a key political component in the EC approval system. By asking the Panel to find that the moratoria never existed, the EC is requesting that the Panel adopt – solely for the purpose of this dispute and based only on the assertions of the EC representative in this dispute – a factual finding that is directly contrary to reality as understood throughout the EC and the worldwide agricultural trade community. In so requesting, the EC would seek to undermine the credibility of the WTO dispute settlement system

5. Instead of acknowledging the reality of the moratorium and then attempting to justify it under the legal standards set out in the SPS Agreement, the EC has submitted a substantial volume of communications between member States and applicants for biotech approvals. None of this information, however, is inconsistent with the fundamental reality that the EC had adopted moratoria on biotech approvals. To the contrary, staff-level information exchanges regarding

product applications is entirely consistent with a moratorium adopted on a political-level, under which no product was allowed to reach final approval. Moreover, the very information that the EC has submitted confirms that certain member States simply were not going to allow final approvals, regardless of the underlying science.

6. With regard to the member States measures, the EC has asserted that there "may"[1] be scientific bases for the product bans, but to date the EC has failed to identify any of them. This is understandable, since – as the United States noted in its first submission – the EC's own scientific committees have reviewed the products and have found that they meet the requirements of the EC biotech approval system. In doing so, the United States has more than met its burden of showing that the member State measures are inconsistent with Articles 2.2 and 5.1 of the SPS Agreement. If the EC wishes to argue that other evidence rebuts the presumption established by the positive assessments of the EC's scientific committees, it is incumbent on the EC to identify such evidence and explain how it is relevant to this dispute. But the EC has not done so; accordingly the Panel should find that the member State measures are inconsistent with the obligations of the EC and the member States under the SPS Agreement.

II. THE EC'S STATEMENT OF FACTS IS MISLEADING

7. As the United States noted at the first meeting of the Panel, the contents of the Statement of Facts set out in the EC's first submission has little, if any, connection to the legal questions in dispute in this proceeding. Nonetheless, the factual portion of the EC submission is misleading in several respects. The United States will address below some central flaws in the EC's factual presentation.

A. The EC's Statement on the Purported Risks of Biotech Products is Misleading

8. In its first submission, the EC stresses the EC's view that biotechnology involves complexity and uncertainty.[2] As for most of its factual presentation, the EC does not describe how its assertions, even if true, would be relevant either to the legal issues in this dispute or to the products covered in this dispute. In particular, the EC does not claim, and indeed could not claim, that any of the scientific issues discussed in its background section justified either a general moratorium or the product-specific moratoria. Moreover, if the EC has scientific questions about biotechnology, those questions can be and should be addressed within the context of the EC's own approval system, and in a manner consistent with its WTO obligations. Indeed, this is how the EC approached scientific and technical issues for the biotech products that the EC approved prior to October 1998.

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[1] EC Responses to Questions from the Panel Following the First Substantive Meeting, para. 343.
[2] EC First Submission, paras. 36-64.

9. Nonetheless, even though the EC's factual presentation on biotechnology is not tied to the legal issues in this disputes, the United States would like to note that the EC's statements regarding the purported risks of biotechnology are fundamentally misleading. Contrary to the EC assertion, there has, in fact, been consensus over the types of risks potentially posed by agricultural biotechnology products since the late 1980's. The consensus among international experts is that, qualitatively, the types of risks potentially posed by products of modern biotechnology are essentially the same as those posed by similar products produced through other, more traditional technologies.

10. In other words, the types of risks that regulators assess for foods produced through biotechnology are qualitatively the same as for foods produced through other methodologies—for example, the production of toxins, significant changes in composition, and the presence of food allergens.[3] Similarly, the types of environmental risks – for example, the production of plant pests, and effects on beneficial non-target organisms – are not qualitatively different between biotechnology and non-biotechnology agricultural products.

11. In 1986, the OECD Ad Hoc Group on Safety and Regulations in Biotechnology concluded that any potential environmental impacts of recombinant DNA organisms are "expected to be similar to effects that have been observed with introductions of naturally occurring species or selected species used for agricultural applications."[4] In 1987 the U.S. National Academy of Sciences (NAS) published a white paper that stated that the risks posed by biotech organisms are the "same in kind" as those associated with organisms that have been modified through other techniques.[5]

12. In 1993, the OECD, through work commissioned by the Group of National Experts on Safety in Biotechnology, concluded that the risks potentially posed by plants produced through modern biotechnology should be approached within the context of the potential risks of plants produced through traditional plant breeding.[6] While the OECD and NAS may have been the earliest scientific bodies to come to these conclusions, the same conclusion has been reached by other international scientific organizations and national scientific advisory bodies. In 1996, a joint FAO/WHO expert consultation on biotechnology and food safety concluded that

> Food safety considerations regarding organisms produced by techniques that change the heritable traits of an organism, such as rDNA technology, are basically

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[3] Attachment I contains responses of the United States to the EC Answers to Panel Questions 23 and 24, which address, respectively, significant changes in composition and the presence of food allergens.

[4] *OECD, Recombinant DNA Safety Considerations*, Paris. 1986. p. 29 (Ex. US-110).

[5] National Academy of Sciences. *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues*. Washington, D.C. National Academy Press, at 22. (1987) (Ex. US-111).

[6] OECD, *Traditional Crop Breeding Practices: An Historical Review To Serve As A Baseline For Assessing The Role Of Modern Biotechnology*. Paris 1993 (Ex US-112).

> of the same nature as those that might arise from other ways of altering the genome of an organism, such as conventional breeding.[7]

The Royal Society of the United Kingdom came to essentially the same conclusion that:

> …as with genetic modification, conventional plant breeding technology (which can involve chemical or radiation-induced mutagenesis or cross-species hybridization) might also cause rearrangements of the genome, and therefore might also cause the activation of previously unknown toxins, anti-nutrients or allergens.[8]

The scientific advisory bodies of the European Union have also confirmed the conclusion that, for both food and environmental risks, plants produced through modern biotechnology do not present new or novel risks. In 2003, the Scientific Steering Committee of the European Commission acknowledged that both the Scientific Committee on Plants and the Scientific Committee on Food have concluded in their published risk assessment that for the "GM crops" reviewed no new safety issues to humans or the environment have been presented. The Scientific Steering Committee also stated that the "published review of data do not indicate the GM crops presently in cultivation pose any more risks for humans, animals and the environment than do their conventional counterparts."[9]

13. The level of scientific uncertainty claimed by the EC to exist around the risks posed by biotechnology products is both inconsistent with the history of the international discussion of this issue and with the actions of individual government regulatory authorities. In its 2003 report, the International Council for Science (ICSU) concluded after a synthesis of more than 50 independent scientific reviews that there is "convergence of science" that:

> Presently available genetically modified foods are safe to eat. GM foods presently on the market have been assessed for any risks of increased allergenicity, toxicity, or other risks to human health, using internationally agreed food safety standards. …This is the consensus view of several reports by national and international agencies.[10]

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[7] FAO/WHO, *Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety*, Rome, Italy, 30 September to 4 October 1996, at 4 (Ex. US-126).

[8] UK, The Royal Society, *Genetically Modified Plants for Food Use and Human Health – an Update*, Policy document 4/02, February 2002, p. 6 (Ex. US-22).

[9] EC, Scientific Steering Committee, Opinion of the Scientific Steering Committee accompanying the Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed, 7 March 2003, p. 2 (Ex. US-113) .

[10] International Council for Science. 2003. *New Genetics, food and Agriculture: Scientific discoveries-Societal Dilemmas.* Paris. p 19 (Ex. US-114).

In addition, government regulatory authorities with experience in regulating plants produced through modern biotechnology routinely use a case-by-case approach. For example, the United States, Canada, the EC, Japan, Australia, and South Africa have completed risk assessments on plants produced through biotechnology – essentially addressing the same types of risk assessment end points on a case-by-case basis.[11] The foundation for this case-by-case approach to the regulation of biotechnology plants is the widely held scientific consensus that: 1) the risks potentially associated with biotech plants are essentially the same as those of plants produced by other techniques and 2) the assessment of risk should not focus on the methodology used in the breeding process but rather on the results of that process; i.e., on the characteristics of the product itself.

14. To further illustrate the scientific consensus surrounding the types of risks potentially posed by biotech plants, both the Codex Alimentarius and the International Plant Protection Convention have adopted guidances that provide recommendations on the type of data that should be considered when conducting safety assessments for biotech plants. Both of these standard setting bodies were able to conclude these guidelines because of the already existing consensus on the types of risk issues that should be addressed in the risk assessment for biotech plants.

15. If scientific uncertainty concerning the risks of biotech plants has been as great as claimed by the EC, it is unlikely that any of these products would have successfully completed the regulatory process in any country. The assertion that the complexities—and uncertainties—of assessing the risks of the biotech plants currently in the EC system are far greater than non-biotech products is not born out by experience.[12]

B. Neither the Biosafety Protocol nor the Precautionary Approach Serves as a Defense to the EC in this Dispute

16. In the factual presentation of its first submission, the EC addresses at length both the Biosafety Protocol and what it considers to be a "precautionary principle" in international law. Once again, the EC's factual presentation is not in any way connected with the legal issues in this dispute.

17. Under the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (DSU), the Panel's terms of reference are to examine the matter at issue "in light of the relevant

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[11] United States Website: http://www.usbiotechreg.nbii.gov; Canada Website: http://www.inspection.gc.ca/english/plaveg/bio; Japan Website: http://www.s.affrc.go.jp/docs/sentan/; Australia Website: http://www.fodstandards.gov.au/whatsinfood/gmfoods; South Africa Website: http:// www.nda.agric.za/docs/geneticresources/geneticcontrol.htm (Ex. US-115). For a list of biotech products approved by the EC prior to the moratorium, see Exhibit US-97.

[12] The three amicus submissions received to date by the Panel to some degree address issues regarding scientific uncertainty. In Attachment III, the United States has provided its views on the three amicus submissions.

provisions . . . in the covered agreements cited by the parties to the dispute."[13] The matter is not to be considered in light of the provisions of the Biosafety Protocol, nor of other sources of international law.

18. The only way these other sources of international law could be pertinent to this dispute is if, under Article 3.2 of the DSU, those other sources of law would assist the Panel in "clarifying the existing provisions of the [covered] agreements in accordance with customary rules of interpretation of public international law."[14] As pertinent here, customary rules of interpretation of public international law are reflected in Article 31 of the Vienna Convention of the Law of Treaties. This provision states that in interpreting the terms of the treaty "in accordance with [their] ordinary meaning . . . in their context and in the light of [the treaty's] object and purpose",[15]

> 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.[16]

Thus, international law other than the WTO Agreement is only pertinent in so far as it would assist the Panel in interpreting the particular terms of the covered agreements at issue in this dispute. But in this dispute, the EC has not identified how the Biosafety Protocol or a "precautionary principle" would be of relevance to interpreting any particular provision of the WTO Agreement.

19. Moreover, in the *EC-Hormones* dispute, the Appellate Body examined at length nearly identical arguments presented by the EC regarding the relationship between a purported "precautionary principle" and the SPS Agreement. The EC has not presented, and cannot argue, that any different results should apply here. To summarize the Appellate Body's conclusions:

- The status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges. . . . [I]t is unnecessary, and

[13] DSU, Article 7.1.
[14] DSU, Article 3.2.
[15] Vienna Convention on the Law of Treaties, Article 31(1).
[16] Vienna Convention on the Law of Treaties, Article 31(3).

> probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question.
>
> - [T]he principle has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement.
>
> - [T]he precautionary principle indeed finds reflection in Article 5.7 of the SPS Agreement. . . . [T]here is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3.
>
> - [T]he precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement.
>
> - [T]he precautionary principle does not override the provisions of Articles 5.1 and 5.2 of the *SPS Agreement*.[17]

20. The United States submits that these findings by the Appellate Body are more than sufficient to address any relevance that a precautionary principle might have to the legal issues in this dispute. Thus, even if a precautionary principle were considered a relevant rule of international law under Article 31(3) of the Vienna Convention, it would be useful only for interpreting particular treaty terms, and could not override any part of the SPS Agreement. So, for example, the notion of precaution could not excuse the EC from complying with the requirement under Article 5.1 that SPS measures be based on risk assessments. Second, Article 5.7 of the SPS Agreement already allows for the EC to adopt a precautionary approach to regulating biotech products. The EC however, has not shown, nor even claimed, that its general or product-specific moratoria are covered by Article 5.7.

21. Just as the Appellate Body found it unnecessary and imprudent to make a finding on the status of the precautionary principle in international law, this Panel also should have no need to address this theoretical issue. Nonetheless, the United States notes that it strongly disagrees that "precaution" has become a rule of international law.

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[17] Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998 ("*EC – Hormones*"), paras. 123-125.

22. In particular, the "precautionary principle" cannot be considered a general principle or norm of international law because it does not have a single, agreed formulation.[18] In fact, quite the opposite is true: the concept of precaution has many permutations across a number of different factors. For example, the concept of "precaution" is associated with very different basic meanings, such as: 1) that scientific uncertainty should not be used as a reason not to take action with respect to a particular environmental concern; 2) that action should affirmatively be taken with respect to a particular environmental concern; or 3) that those engaging in a particular activity have the burden of establishing the absence of environmental harm.[19] Thus, the United States considers precaution to be an "approach," rather than a "principle" of international law.

23. Moreover, if – as the United States submits – precaution is not a *principle* of international law, then it is *a fortiori* not a *rule* of customary international law. Customary international law is a binding rule that results from: 1) a general, consistent, extensive, virtually uniform practice of States; 2) followed by them from a sense of legal obligation.[20] Precaution does not fulfill any of these requirements. Precaution cannot be considered a "rule" because it has no clear content and therefore cannot be said to provide any authoritative guide for a State's conduct. Second, it cannot be said to reflect the practice of States, as it cannot even be uniformly defined by those who espouse it.[21] Third, given that precaution cannot even be defined and, therefore, could not possibly be a legal norm, one could not argue that States follow it from a sense of legal obligation.

24. For the purposes of interpreting the WTO Agreement in accordance with the principles in Article 31(3) of the Vienna Convention, the United States also strongly disagrees with any notion that the Biosafety Protocol is a rule of international law. Under Article 31(3), the international rule must be "applicable in the relations between the parties." In this case, however, the Biosafety Protocol is not applicable to relations between the United States and the EC, because the United States is not a party to the Biosafety Protocol.

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[18] General principles of international law are primarily abstracted from rules that have been long and generally accepted. Examples include the principles of consent, reciprocity, equality of states, and good faith. Ian Brownlie, *Principles of Public International Law* (5th ed.)(1998) at 19 (Ex. US-116).

[19] John O. McGinnis, "The Appropriate Hierarchy of Global Multilateralism and Customary International Law: The Example of the WTO", 44 Va. J. Int'l L. 229, 272 (Fall 2003) (Ex. US-117). *See also*, David VanderZwaag, "The Precautionary Principle in Environmental Law and Policy: Elusive Rhetoric and First Embraces", 8 J. Envtl. L. & Prac. 355 (1999) (Ex. US-118) (describing substantial differences in definitions of the precautionary principle, including what should trigger the principle and its practical application).

[20] Article 38(1)(b) of the Statute of the International Court of Justice provides for "international custom, as evidence of a general practice accepted as law". There must be a recognition among states that a particular practice is obligatory, and not merely general practice. Ian Brownlie, *Principles of Public International Law* (5th ed.)(1998) at 4 (Ex. US-116).

[21] The EC has described the application of a precautionary approach by various countries in their domestic legislation, but even these approaches vary substantially. EC first written submission, paragraphs 79-80 (e.g., Australia has adopted the Rio Declaration Principle 15 formulation; Swiss law states that "dangers and harmful effects…are to be limited as early as possible"; New Zealand law requires consideration of the "precautionary need for precaution…where there is scientific and technical uncertainty…")

25. The EC's only argument to the contrary is entirely without merit. In particular, the EC notes that the United States participates in the Biosafety Protocol Clearing-House Mechanism, and from this the EC leaps to the conclusion that the United States must thus have no objection to the "approach" required by the Protocol.[22] Notwithstanding that the EC has provided no explanation of what is meant by the "approach," the U.S. good-faith effort to share information regarding living modified organisms that have completed regulatory review in the United States is in no way an endorsement of the Protocol itself. Again, the United States is not a party to the Biosafety Protocol, and has no obligations under it.

26. Finally, the United States would not agree that the Panel would need to look to the Biosafety Protocol in interpreting the WTO Agreement even in a dispute between WTO Members that were both parties to the Protocol. The Protocol has a clear and unequivocal statement that the Protocol does not change the rights and obligations under any existing international agreement.[23] In addition, the EC does not argue that any provision of the Protocol is in any way inconsistent with the EC's full compliance with its WTO obligations. The Biosafety Protocol foresees a functioning regulatory system in each Party country – a system that works in a predictable manner to make informed decisions on imports of "living modified organisms" within a specified timeframe. Nowhere does the Protocol require or even condone the adoption of moratoria on decisionmaking, or undue delays in such decisionmaking.

C. The EC's Description of Its Biotech Approval Regime is Inaccurate

27. In paragraphs 132 through 195 of its First Written Submission, the EC sets out what it calls the "EC Regulatory Framework." This section gives the impression that it is a complete and objective description of the key procedural steps that are laid down in Council Directives 90/220 and 2001/18 and Regulation 258/57. In fact, the EC is only telling part of the story: it conveniently leaves out a number of mandatory procedural steps, omits several deadlines by which specific action is required, and implies that the Commission has discretion – which the legislation does not grant – not to act on product notifications. But an accurate presentation of the EC system is important, because this serves as the baseline for understanding that the EC's delays under the moratorium are inconsistent with the EC's own laws. Although this dispute does not turn on whether or not the EC has complied with its own laws, the inconsistency of the EC's moratorium with the underlying biotech approval legislation further highlights that the delays resulting from the moratorium are undue.[24]

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[22] EC responses to Panel Questions following first panel meeting, of June 16, 2004, at para 19.

[23] Biosafety Protocol, Preamble ("*Emphasizing* that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements") (EC Ex. 1).

[24] In Attachment IV, the United States explains in detail the inaccuracies in the EC's description of its biotech approval procedures.

III. THE SPS AGREEMENT APPLIES TO ALL MEASURES IN THIS DISPUTE

28. In its first submission, the EC argues at length, and in the hypothetical, that the EC might adopt measures with respect to one or more biotech products that are not covered within the scope of the SPS Agreement.[25] But, once again, the EC discussion is not linked to any of the legal issues in this dispute.

29. The pertinent question is whether the measures that the EC has *actually* adopted, and that are covered in this dispute's terms of reference, are within the scope of the SPS Agreement. But the EC does not even appear to contest this fundamental point. First, the EC has not disputed that both its Novel Foods regulation and Deliberate Release directive are covered within the scope of the SPS Agreement. Furthermore, with respect to the member State measures, the EC acknowledges that each of the member State measures was adopted for "some reasons" that fall within the scope of the SPS Agreement.[26]

30. The EC's agreement that its measures were adopted for "some reasons" covered within the scope of the SPS Agreement is more than sufficient to bring those measures with the scope of that Agreement. SPS Agreement Annex A makes clear that "any measure" applied to protect against one of the enumerated risks falls within the scope the SPS Agreement. The Annex does not state that the measure needs to be *exclusively* applied to protect against only the enumerated risks. Nor does the SPS Agreement say that an SPS measure -- meaning a measure addressing a risk enumerated in Annex A -- somehow loses its status as an SPS measure if the adoption of the measure is also supported by other rationales. Thus, for example, even if some portion of the EC's basis for its actions is properly construed to fall outside the scope of the SPS Agreement, the moratorium would still be an SPS measure, and subject to the disciplines thereunder.

31. In fact, this is not the first SPS dispute in which a measure arguably was adopted for reasons both within and without the scope of the SPS Agreement. In the *EC-Hormones* dispute, the EC directive was not solely adopted to address alleged affects on human health. To the contrary, as the Appellate Body explained, the EC was also motivated to adopt its Hormones Directive by the perceived need to harmonize beef regulations in order to prevent distortions in the conditions of competition between producers in various EC member States.[27] The harmonization of product standards is a goal expressed in the *Agreement on Technical Barriers*

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[25] First EC Submission, paras. 388-433.

[26] First EC Submission, para. 578.

[27] *EC-Hormones*, para. 245 ("A major problem addressed in the legislative process of the European Communities related to the differences in the internal regulations of various Member States of the European Union (four or five of which permitted, while the rest prohibited, the use for growth promotion of certain hormones), the resulting distortions in competitive conditions in and the existence of barriers to intra-community trade. The necessity for harmonizing the internal regulations of its Member States was a consequence of the European Communities' mandate to establish a common (internal) market in beef.").

to Trade.[28] Yet, despite the variety of rationales, all parties in the *EC-Hormones* dispute agreed that the Hormones Directive fell within the scope of the SPS Agreement.

32. Although the detailed EC discussion purporting to classify various alleged risks of biotech products as within or without the scope of the SPS Agreement is not tied to the legal issues in this dispute and thus hypothetical, the United States notes that the EC's analysis is incorrect. In particular, the EC's analysis would result in an overly narrow scope of the measures intended to be covered by the SPS Agreement. Accordingly, in Attachment II to this submission the United States provides a detailed response to the EC's position regarding the types of risks covered by the SPS Agreement.

IV. GENERAL MORATORIUM VIOLATES THE SPS AGREEMENT

33. The EC's discussion of the general moratorium is remarkable in that it is concerned solely with whether or not the general moratorium qualifies as a "measure" under the SPS Agreement. Should the Panel find, as the complainants all submit, that the general moratorium is indeed a measure under the SPS Agreement, the EC has not contested that the general moratorium is inconsistent with the EC's obligations under the WTO Agreement.

34. In particular, the EC has not contested that the general moratorium:

- results in "undue delay" in breach of Article 8 and Annex C;
- is inconsistent with its obligations under Article 7 and Annex B to publish measures promptly;
- is inconsistent with its obligations under Article 8 and Annex C(1)(B) to keep applicants informed of the progress of applications;
- is not based on a risk assessment as required under Article 5.1; and
- results in arbitrary or unjustifiable distinctions in the levels of protection in breach of Article 5.5.

Indeed, in its answers to Panel's questions, the EC concedes that there was no overall risk assessment for biotech products that could serve as a basis for the general moratorium.[29] The EC's decision not to contest these central issues illustrates precisely why the United States,

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[28] *E.g.*, TBT Agreement, Article 2.6 (noting that Members should participate in international standardizing bodies "with a view to harmonizing technical regulations on as wide a basis as possible").

[29] EC Responses to Questions from the Panel following the First Substantive Meeting, para. 337 (agreeing that the EC "has not prepared any risk assessment which covers any and all biotech products as opposed to risk assessments covering only certain individual biotech products.").

Argentina, and Canada brought this dispute in the first place. In short, the complainants believe that a general moratorium on all biotech products is indefensible under the WTO Agreement.

35. The evidence that the general moratorium exists is overwhelming. To summarize the facts: Up to October 1998, the EC had approved at least ten biotech products. But between October 1998 and August 2003, the EC failed to approve a single biotech product under its novel foods or deliberate release legislation, even though many of those products had been favorably assessed by the EC's own scientific committees.

36. The moratorium became widely known no later than June 1999, when it was announced by Environment Ministers of five member States. In particular, at a Council Meeting of EC Environment Ministers in June 1999, Environment Ministers of Denmark, Greece, France, Italy and Luxembourg issued a Declaration stating: "in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms… they will take steps to have any new authorisations for growing and placing on the market suspended."[30]

37. The statements of Commission and member State officials confirm the existence of a moratorium. For example, as early as July 2000, European Environment Commissioner Margot Wallström publicly admitted the existence of a "moratorium," calling it "illegal and not justified."[31] This sentiment was reiterated at a press conference in October 2001 following a meeting of the Council of Environment Ministers when Commissioner Wallström reportedly "admitt[ed] that no end was in sight for the moratorium, which she said was an illegal, illogical, and otherwise arbitrary line in sand."[32]

38. European Commissioner for Health and Consumer Protection, David Byrne, stated in June 2000 that the reluctance of member States to approve the placing on the market of biotech products "has resulted in a complete standstill in the current authorisations and a de facto moratorium on the commercial release of GMOs."[33] Commissioner Byrne again acknowledged the existence of the moratorium in February 2003 when he implored member States that "we must lift the moratorium."[34]

39. And, the EC's official representative to the SPS Committee acknowledged the existence of the moratorium. At the meeting of the SPS Committee held on October 31-November 1,

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[30] "Declaration by the Danish, Greek, French, Italian and Luxembourg delegations concerning the suspension of new GMO authorisations," Council of the European Union, 2194th Council Meeting, Environment, Luxembourg, June 24/25, 1999 (Ex. US-76).

[31] "EU Moves to Break Gene Crop Deadlock," Reuters, July 13, 2000 (Exhibit US-33).

[32] "EU Moratorium on GMOs Could Last Until Traceability, Labeling Regime in Place," at A-8 (Exhibit US-2).

[33] "Biotechnology: Building Consumer Acceptance," Speech by David Byrne, European Commissioner for Health and Consumer Protection, European Business Summit, June 10, 2000, at 2 (Exhibit US-1).

[34] "Sine die postponement of inter-ministerial meeting planned on GMOs in Washington," Agence Europe, February 6, 2003 (Exhibit US-37).

2001, the United States and Canada expressed concerns about the EC's adoption of the moratorium. The summary of the meeting notes the following EC response:

> The representative of the European Communities reaffirmed the European Commission's interest and positive actions aimed at allowing the authorization procedures to continue. The recent meeting of the European Environmental Council had started a very important discussion on proposals presented by the Commission to *restart* the authorization procedure.[35]

The EC representative's statement that there were proposals to *restart* biotech authorization procedures is plainly an acknowledgment that those procedures had been suspended.

40. Commission documents also confirm the existence of the moratorium. A Commission Working Document dated November 2000 states "the current authorization procedure for commercial release of GMOs, including those that may end up in the food chain, has ground to a standstill."[36] A Commission Press Release dated July 2001 states that the adoption of new legislative proposals "will contribute towards the lifting of the de facto moratorium on the commercial release of GMOs."[37] An October 2001 internal Commission working paper states that "[t]his reluctance to go forward with authorizations of GMOs has resulted in a de facto moratorium on the marketing of new GMOs and impacted on product approvals under the sector-based legislation."[38] In July 2003, a Commission fact sheet on GMO regulation stated that "[t]he revised Directive [2001/18] and the two proposals for Regulations are expected to pave the way for a resumption of GM authorizations in the European Union."[39] A document issued by the General Secretariat of the Council of the European Union stated that the proposed rules on traceability and labeling of biotech products could "possibly lead to the lifting of the current moratorium."[40] Most recently, in an official Background document to the Agriculture and Fisheries Council of Ministers held on April 26, 2004, during which the Council of Ministers considered a Council Decision to authorize the placing on the market of Bt-11 sweet corn, the following statement appears: "The adoption of a decision to authorize Bt-11 would bring an end to the current *moratorium* on genetically modified food and feed in Europe."[41]

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[35] Committee on Sanitary and Phytosanitary Measures, Summary of the Meeting Held on 31 October-1 November 2001, Note by the Secretariat, para. 105 (G/SPS/R/25) (18 January 2002) (emphasis added).

[36] Advance Copy of Working Document of the Commission Services on Traceability and Labeling of GMOs and Products Derived from GMOs, ENV/620/2000, November 2000, at 1 (Exhibit US-93).

[37] Commission improves rules on Labeling and tracing of GMOs in Europe to enable freedom of choice and ensure environmental safety, Commission Press Release IP/01/1095, Brussels, 25 July 2001, at 2 (Exhibit CDA-39).

[38] EC Working Paper of DG Environment and DG Health and Consumer Protection: Resumption of the Authorization Procedure for GMOs, October 2001, at 1 [emphasis in original] (Exhibit 27).

[39] Question and Answers - July 2003, p. 12 (Exhibit US-107).

[40] Note from the General Secretariat - 3 July 2003 (Exhibit US-38).

[41] Background, Agriculture and Fisheries Council, 23 April 2004 (Ex. US-109).

41. Finally, official documents of the European Parliament confirm the existence of the moratorium. For example, a February 2001 Report on the future of the biotechnology industry repeatedly acknowledges the existence of a moratorium on biotech approvals:

> "Observes that the existing de facto moratorium particularly harms small and medium sized enterprises which, unlike multinational corporations, are often unable to perform their research work in countries outside the EU;"[42]
>
> "Welcomes the agreement reached between Council and Parliament in the conciliation committee on the amendment of the directive on the release of genetically modified organisms and the assurances given by the Commission in that connection with regard to Labeling and traceability, and considers that a clear framework now exists for the release of genetically modified organisms in Europe which will ensure maximum consumer protection and environmental protection, and that it would therefore not be justified to continue the de facto moratorium on the release of GMOs."[43]
>
> "Under this system approval takes an unacceptably long time. Article 16 of Directive 90/220 has been invoked by Member States to put a temporary ban on GM products for safety reasons. In some of these cases the Commission's Scientific Committees have judged that the ban was unjustified. Furthermore, no authorisations have been approved under this directive since October 1998. This demonstrates a lack of mutual recognition between Member States and a de facto moratorium on all development. It calls into question the political will in Europe to support this industry."[44]

42. More recently, a March 2003 resolution introduced in the European Parliament acknowledges the moratorium:

> whereas, in view of the risks which GMOs represent, there are no grounds for lifting the de facto moratorium on GMO authorisation, especially since no Labeling and tracing system has been introduced and no assessment has been carried out of the impact which GMOs may have on organic/conventional farming.[45]

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[42] European Parliament, Committee on Industry, External Trade, Research and Energy, Report on the Future of the Biotechnology Industry (2000/2100(INI)), 28 February 2001, at 12 (emphasis added) (Ex. US-119).

[43] *Id.* at 20 (Emphasis added).

[44] *Id.* at 20 (Emphasis added).

[45] European Parliament, Motion for a European Parliament resolution on the impact of genetically modified organisms (GMOs) on organic/conventional farming, 18 March 2003 (B5 0190/2003) (Ex. US-120).

The same resolution then goes on to urge the continuance of the moratorium pending the launch of "a broad public debate."[46]

43. The EC first submission in fact goes quite a long way toward conceding the existence of the moratorium. In particular, in the section of the EC submission providing background regarding the EC's modification of its Deliberate Release directive, the EC submission states:

> These issues [meaning issues relating to alleged scientific uncertainty] affected some of the pending applications as **a number of Member States made it clear that they were not in a position to vote in favor of granting market authorizations** for individual products without these issues being addressed first.[47]

This statement is quite close to a confirmation of the basic point that the complainants are making in this dispute: namely, that at a certain point in time, certain member States decided that they simply were not going to vote for new product approvals. Under the EC's rules of qualified majority voting, a minority of member States can block EC action. Blocks by qualified majority in the regulatory committee may be overridden by a simple majority vote in the Commission. But, as the record here shows, the EC has decided not to submit final decisions for a majority vote by the Commission.[48] In addition, if one of those "number of member States" that are unwilling to grant market authorizations were the original recipient of the application, then that single member State may block a Deliberate Release application all by itself.

44. The EC presents three arguments in its first submission as to why this Panel should nonetheless find that there is no general moratorium. First, the EC argues that it cannot be "legally affected" by "casual statements of any of its numerous representatives". But the complainants are not relying on "casual statements of numerous representatives"; the statement cited by complainants are statements made by the EC's highest officials, by its member States, and by its official bodies. Moreover, the EC itself concedes, as it must, that such statements can be considered as evidence of the existence of a measure.[49] And in this case, the numerous statements from every EC entity - member States, Commission, Council, and Parliament – are strong evidence indeed.

45. Second, the EC argues that even if the EC did adopt a general moratorium on approvals of biotech products, such a moratorium is legally precluded from qualifying as a "measure" under the SPS Agreement. This defense, too, is without any merit. The EC's argument is based on

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[46] *Id.*

[47] EC First Submission, para. 157 (emphasis added).

[48] See discussion of BT Cotton (Ex. EC-65) and Roundup Ready Cotton (Ex. EC-66) in the following section.

[49] EC First Submission, para. 556 ("There are cases where statements have constituted evidence of a Member's wrongful action.").

two panel reports that considered the status under the Anti-dumping and Subsidies Agreements of investigating authorities' so-called "practices".[50] Those reports, however, are inapposite to this dispute. The United States does not contend that the EC's suspension of its approval process constituted a "practice" as described in the *US - Steel Plate* and *US - Export Restraints* reports cited by the EC. Rather, the United States argues and maintains that the EC made a conscious decision to suspend the consideration of applications for, or granting of, approval of biotech products under the novel foods and deliberate release legislation. This definitive act is a measure evidenced by numerous public statements made by prominent EC and member State officials, and by the EC's failure to approve any new biotech products during the period covered in this dispute. Although the EC's measure was not adopted in a transparent manner and officially published as a formal law, decree or regulation, the EC's decision to indefinitely suspend its approval procedures falls within the SPS definition of a measure and blocks biotech approvals just as effectively as would a written amendment to EC legislation.

46. Third, the EC claims that the application histories for certain products covered in the U.S. panel request disprove the existence of the moratorium. In particular, the EC claims that this information shows that "none has been stalled and none has been subject to a general suspension of the approval process."[51] This assertion, however, is unsupported and baseless. To the contrary, the information submitted by the EC is entirely consistent with the EC's imposition of a general moratorium. First, the information submitted by the EC confirms that there were in fact no approvals of biotech products between October 1998 and the establishment of the Panel's terms of reference in August 2003. Second, not only do the product histories confirm that no product was submitted for final approval, many of the product histories illustrate just how the moratorium operated. In particular, some product histories have long, unwarranted gaps that could only be explained by the existence of the moratorium, and other histories include statements by member States to the effect that they simply will not approve the product until further legislation is actually adopted, regardless of whether the product meets the requirements of either existing or pending legislation. These product histories will be addressed in the following section on the product-specific moratoria.

47. Finally, at the first substantive meeting the EC appeared to present another defense: even if the EC adopted a moratorium on the consideration of applications for final approval, the moratorium ended when the EC approved Bt-11 sweet corn on May 19th of this year. Contrary to the EC's contention, the approval of this product in no way affects the issue in this dispute: whether the measure in existence at the time this Panel was established in August 2003 was consistent with the EC's WTO obligations.

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[50] Panel Report, *United States – Anti-Dumping and Countervailing Measures on Steel Plate from India*, WT/DS206/R and Corr.1, adopted 29 July 2002; Panel Report, *United States – Measures Treating Exports Restraints as Subsidies*, WT/DS194/R and Corr.2, adopted 23 August 2001.

[51] EC First Submission, para. 485.

48. To be clear, the United States would not view an approval of Bt-11 as a lifting of the EC's moratorium or as an indication that the EC will begin to meet its WTO obligations by making decisions on all other pending applications without undue delay. But any issues relating to whether or not steps taken by the EC after August 2003 have brought the EC into compliance with its WTO obligations are not before the Panel.

49. The United States would also note that the Bt-11 approval in May 2004 is entirely consistent with, and in fact supports, the existence of a general moratorium during the period covered within the Panel's terms of reference. As noted above, both the European Commission and the Council have stated that the entry into force of the EC's new traceability and labeling rules for biotech products might finally allow for the lifting of the moratorium. Those new rules went into effect on April 19, 2004. The fact that the Commission then approved Bt-11 just one month later is certainly no mere coincidence. To the contrary, this timing indicates that -- as the EC itself has acknowledged everywhere but in this proceeding -- the EC approval system was held up not by any problems with particular applications, but by events outside the scope of its approval legislation. Moreover, the EC Council itself acknowledges the existence of the "moratorium" – it uses this very word – in a statement concerning the scheduled Bt-11 approval.[52]

V. PRODUCT-SPECIFIC MORATORIA VIOLATE THE SPS AGREEMENT

50. With regard to the EC's product-specific moratoria, whether one views them as separate measures or simply as undue delay in the approval process of these individual products, the EC once again asserts that no such measures ever existed and that no application faced any undue delays. The EC makes this assertion even though, as explained above, no biotech products were approved between October 1998 and the establishment of the Panel's terms of reference in August 2003, and even though EC officials, official bodies, and member States acknowledged the existence of a moratorium.

51. The primary basis for the EC's denial of the product-specific moratoria is the vague statement that "what has happened in <u>many</u> of these applications is that, at different stages of the procedure, requests for additional information have been put to applicants."[53] The EC ignores, however, that product histories exhibiting requests for information are entirely consistent with the existence of a general and product-specific moratoria. The United States has not claimed that each and every application stopped all progress beginning in 1998. To the contrary, the moratorium was a decision by the EC not to move products to a *final* decision in the approval process. Certain progress in the process, short of final decision, is not the least bit inconsistent with a moratorium on final approvals.

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[52] EC First Submission, para. 157 (emphasis added).
[53] EC First Submission, para. 486 (emphasis added).

52. Moreover, the EC product histories provide further, compelling evidence of the existence of both a general and product-specific moratoria. First, a number of applications – particularly those nearing the final stage of approval – exhibit lengthy, unwarranted delays, unrelated to any requests for additional information.[54] Second, a number of product histories contain statements from member States acknowledging – in writing – that regardless of any scientific issues regarding he particular application at issue, the member State simply was not going to vote for approval unless and until the EC had adopted new forms of legislation. Such statements illustrate that, contrary to the EC assertions, the moratorium applied to each and every application, regardless of whether or not particular regulators had particular questions about individual applications. Both types of examples are illustrated below.

A. Examples of Applications which Faced Lengthy Delays, Without Any Pending Requests for Information

1. Oil-Seed Rape MS1, RF1 and Oil-Seed Rape, MS1, RF2

53. The U.S. submission noted that the two oil-seed rape products (MS1, RF1 and MS1, RF2) were subject to the general moratorium. The EC submission, however, writes to the contrary that these two products were approved for cultivation, import, and marketing under the 90/220 Directive at "Community level."[55] The key phrase here, however, is "Community level." The EC submission entirely fails to note that under Directive 90/220, the "Community level" approval is not effective unless and until the member State that initially received the application takes a final step of placing the product on the market. In this case, that member State, which was France, never allowed the product to be placed on the market. Thus, these products in fact were never approved for cultivation, import, and marketing in the EC. This is an example, of how in certain circumstances a single member State can block a product approval. And, more importantly, it is an example of how the EC's own submission does not contradict, and in many cases supports, the existence of the general moratorium.

54. In Question 99, the Panel asked the EC to confirm that France withheld its consent. The EC responded "Yes."[56] The EC then goes on to argue that, nonetheless, individuals "can directly assert his or her right by directly relying on the Community law in question."[57] This excuse is entirely unpersuasive. The EC does not assert that either of these products is in fact on the market in the EC; that EC Customs officials – in France or elsewhere – would admit either of these oil-seed products without the final step (the French consent) in the approval process; or that any biotech applicant has ever successfully asserted this right. Nor does the EC even attempt to

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[54] The United States submits that these delays, standing alone and without the need for any further examination of the record in this dispute, must be considered "undue delays" in contravention of the EC's obligations under Annex C of the SPS Agreement.

[55] EC First Submission, Paragraph 298 and Exhibits 89 and 90.

[56] EC Responses to Questions from the Panel Following the First Substantive Meeting, para. 313.

[57] *Id.,* para. 314.

explain what mechanism – such as a legal challenge – might be used to assert this right, or explain how a product can be considered approved if additional legal proceedings are required to allow the product to be placed on the market. In short, the EC has not presented any information to contradict the clear language of the Directive 90/220 stating that the sponsoring member State must take the final step in the approval process, and that France has not done so for either of these products.

2. BT-Cotton

55. Spain, the member State that initially received the application for BT-Cotton, forwarded it with a positive opinion to the EC in November 1997.[58] The EC's Scientific Committee on Plants made a favorable assessment in July 1998. The application then ran into trouble with the qualified majority voting rules of the EC's regulatory committee. In particular, in February 1999 the regulatory committee did not approve the application by a qualified majority vote. Like for all regulatory committee decisions, the EC did not provide the applicant with any reason for the regulatory committee's failure to achieve a qualified majority of votes in favor of the application. Moreover, under the EC's own rules, an application that fails to achieve a qualified majority of votes in the regulatory committee must be submitted to the EC Council for an additional vote, and such submission must be made, to quote Article 21 of the EC Directive, "without delay."

56. But that is not what happened in this case. The EC's own chronology states that the next action is nearly three months later, in May 1999. And the action taken is not, as required under EC legislation, the submission of the application to the EC Council. Instead, the chronology states: "Launching of Inter-Service Consultation on draft Council Decision." To the knowledge of the United States, this term, and this step, is not provided for under the EC's regulations. Moreover, there is no indication that this step is notified or explained to the applicant. The chronology is then blank until July of 2001. The United States would submit that "Inter-Service Consultation" is just another word for the moratorium.

3. Roundup Ready Cotton

57. Spain, the member State that initially received the application for Roundup Ready Cotton, forwarded it with a positive opinion to the EC in November 1997.[59] The EC's Scientific Committee on Plants made a favorable assessment in July 1998. In February 1999, the Roundup Ready cotton application, like Bt cotton, did not receive a qualified majority vote in the the regulatory committee. Like for Bt cotton, the next step in the EC chronology is the "Launching of Inter-Service Consultation on draft Council Decision" in May 1999. There is no further entry in the chronology until January 2003, which is more than two and one-half years later. Again,

[58] Bt Cotton is addressed in paragraphs 222 to 228 and Exhibit 65 of the EC First Submission.

[59] Roundup Ready Cotton is addressed in paragraphs 229 to 234 and Exhibit 66 of the EC First Submission.

this is another example of a major delay that was not caused, as the EC claims, by a pending request to the applicant for additional information.

4. Oilseed rape tolerant for glufosinate-ammonium

58. This oilseed rape product is covered in Exhibit 68 of the EC First Submission. According to the EC chronology, this product received a favorable opinion from the scientific committee on plants in November 2000. Under the EC's approval system, the next step should have been to submit the application for approval by the EC's Regulatory Committee. But the EC chronology shows that no action was taken on the application until November 2002, a full 2-year delay. And in November 2002, the chronology notes only a request for an update in light of the scheduled 2003 entry into force of Directive 2001/18 – there is no mention of any problem with the application, nor of any additional information needed for final approval. This 2-year gap belies the EC's assertions that under its supposed "interim approach," it was moving ahead on processing applications in advance of the entry-into-force of 2001/18.

5. Maize BT-11

59. Maize BT-11 is addressed in Exhibit 69 of the EC's first submission. The chronology of BT-11 is similar to that of oilseed rape tolerant for glufosinate-ammonium. In particular, there is no action on the application for 2 years after a favorable opinion of the Scientific Committee on Plants in November 2000. The next entry, an "evaluation of updates by the lead CA" in October 2002, is unexplained and unsupported by any exhibit or attachment.

B. Product Histories in Which Member States Acknowledge Opposition to Approval Regardless of the Merits of the Individual Application

60. The exhibits accompanying the product histories provide numerous examples in which member States noted in writing that they would oppose approvals until some type of new legislation was adopted, even though under EC law any objection had to be based on the merits of the application. These statements by member States stand in stark contrast to the EC's argument that it had adopted an "interim approach" under which final approvals were to be granted prior to the adoption of new legislation. They also directly contradict the EC's arguments that the delays with respect to individual products were justified by fact-specific considerations unique to the individual products, such as conflicting science, or delays on the part of applicants. In short, it is clear from these statements that irrespective of any other considerations, the products would not be allowed to reach a final decision until one or another type of revised legislation was in place. Below are some examples from the EC's own exhibits.

1. Novel Food and Feed Regulation

61. The EC has had a functioning system to conduct risk assessments under their Novel Foods directive (258/97), but some member States have used the implementation of new food

and feed regulations (which did not become effective until April 2004) as an excuse for halting this process. Analysis of the exhibits supplied by the EC reveals several instances in which member States cited the implementation of the new food and feed regulations as a condition for a lifting of the moratorium on reviews of biotech crops. Below are examples:

(a) EC Exhibit 74

62. EC Exhibit 74 provides a product chronology for Pioneer/Dow's Bt corn application. In it, the Austrian Federal Ministry of Health and Women, acting as the Austrian Competent Authority according to Directive 2001/18/EC, notes in its letter to the EU's DG XI, dated 24 October 2003, that any registration of Pioneer/Dow's product "should also take into consideration the two new EU regulations concerning traceability and genetically modified food and feed which will enter into force in April 2004."[60] This statement clearly demonstrates Austria's demand that the moratorium continue – without providing any scientific justification – until new regulations were in place.

(b) EC Exhibit 76

63. EC Exhibit 76, Roundup Ready corn (NK603), contains another clear statement by the Austrian government that they would stonewall the review process and continue the de facto moratorium until the new food and feed regulations took effect. In a letter from the Austrian Federal Ministry for Social Affairs and Generations to the EU's DG XI regarding Monsanto's application for Roundup Ready corn (NK603), the Ministry cites several scientific concerns, but plainly states that

> Irrespective of the above mentioned scientific objections raised, Austria is of the opinion, that products shall not be placed on the market before the new regulations concerning genetically modified food and feed as well as on traceability and Labeling of GMOs will enter into force. In addition the issue of co-existence of genetically modified, conventional and organic farming is at the moment under discussion and has to be resolved.[61]

(c) EC Exhibit 92

64. Syngenta's application to the EC for import approval for its Bt11 biotech sweet corn,, offers yet another example of member State unwillingness to allow the EC system to issue final decisions on biotech crop applications. Syngenta's Bt11 sweet maize application was for marketing the corn as a fresh vegetable or after processing, not for cultivation. Moreover, the corn line was derived from an already reviewed and approved version of Bt11 field maize. On

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[60] EC Exhibit 74, p. 71.
[61] EC Exhibit 76, p. 59.

10 February 1998, the Scientific Committee on Plants published an opinion in which it concluded that the use of seed carrying the Bt11 event was as safe as the use of seed from conventional corn varieties.[62] But on 10 August 2000, the French authorities cited the yet to be implemented food and feed regulations as a reason for withholding support for Bt11, choosing to disregard comprehensive scientific findings and instead continue the moratorium on biotech reviews.[63]

2. Traceability and Labeling Legislation

65. Member States opposed to re-starting the review process for biotech crops also used the proposed new traceability & labeling regulations (which also did not become effective until April 2004) as a reason for continuing the moratorium.

(a) EC Exhibit 69

66. In Syngenta's Bt-11 biotech sweet corn application, several member State competent authorities statements clearly require that the new traceability and labeling regulations be in place prior to the lifting of the moratorium on biotech reviews and approvals. The German competent authority's objections, dated September 26, 2003, provided that:

> "In accordance with the French position, the German CA is of the opinion that no consent should be given until both regulations are in force. In particular, the regulation on traceability and Labeling of GMOs will provide for additional transparency and the possibility of choice for consumers." [64]

67. Likewise, Denmark, in late September 2003 stated that its support for Bt-11 was contingent on the implementation of the new traceability and labeling regulations. In doing so, it reminded the EC authority of the March 2001 declaration of 6 member States (the "March 2001 declaration") reaffirming the moratorium until traceability and labeling rules, as well as a system for environmental liability, are adopted:

> Denmark also wants to draw attention to the declaration from March 2001 in which 6 Member States
>
> - "reaffirmed their intention, when exercising the powers conferred upon them, of ensuring that the new authorisations for cultivating and marketing GMOs are suspended pending the adoption of effective provisions concerning a complete traceability of GMOs that guarantees reliable Labeling of all GMO products;

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[62] EC Exhibit 92, attachment 17, p. 1 (referring back to the February 1998 SCP Opinion).
[63] EC Exhibit 92, attachment 10, p.2.
[64] EC Exhibit 69, p. 58 (the "regulations" referred to are the EC traceability and labeling regulations).

- call on the Commission to make rapid progress towards the establishment of a system of environmental liability to supplement the regulatory framework necessary for development in the field of biotechnologies, as in other environmental fields."[65]

68. Again in February 2004, the Danish competent authority cites the need for traceability and labeling regulations to be in place before Denmark can support the approval of Syngenta's Bt-11 corn: "Furthermore, Denmark finds that approval for placing on the market cannot take place before the regulation on traceability and Labeling is fully into force."[66]

(b) Exhibit 70

69. EC Exhibit 70, oilseed rape (GT-73), provides more examples of member States' unwillingness to acknowledge the strength of the scientific conclusions and lift the moratorium on biotech crop reviews and approvals. The Danish, Italian, Austrian and Belgian competent authorities all cite the need for traceability and labeling regulations to be in place before they will support the approval of any biotech crops.[67] Quoting the Austrian competent authority's assessment:

> As a matter of principle, this product should not be placed on the market before the entry into force of the Regulation of the European Parliament and of the Council concerning the traceability and Labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. In addition, further issues concerning liability and the coexistence of genetically modified, conventional and organic crops remain to be resolved.[68]

The "principle" referred to by the Austrian authority is nothing other than the general moratorium on biotech approvals.

(c) Exhibit 91

70. In EC Exhibit 91, the Roundup Ready corn (GA21) application under novel foods regulation, document EC-Ministeriet 180400, page 5, Denmark acknowledged that "the

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[65] EC Exhibit 69, p. 68.

[66] EC Exhibit 69, p. 94.

[67] EC Exhibit 70, pages 73,75, 87 & 101, respectively. In a letter of March 24, 2003, Italy expressed the belief "that it is unsuitable to proceed with the GMO authorization process in absence of the final normative on labeling and traceability..." Belgium noted in a letter of March 26, 2003, that "the official Belgian position ... is that [as long as rules on traceability and labeling are not in place] the conditions for risk management and public information are not fulfilled to authorize new GMOs under Directive 2001/18."

[68] EC Exhibit 70, p. 87.

assessment of the health and nutritional aspects of this application gives Denmark no reason to object to the approval of the GA21 maize nor to products derived from the maize." However, "in spite of the favourable assessment . . . , Denmark will submit a reasoned objection to the approval of the genetically modified GA21 maize, reference being made to the statement submitted by this country and four other member states at the Environmental Council on 24 and 25 June 1999 [declaring a suspension of new GMO authorizations until labeling and traceability rules are adopted]."

(d) Exhibit 92

71. With respect to the Bt-11 sweet corn application under the novel foods regulation, attachment 12, Denmark states that "[w]ith regard to the issue of food safety as such, Denmark sees no problem in allowing the Bt11 maize for food purposes . . . Apart from this however, Denmark will refer to the Declaration concerning the suspension of new GMO authorisations made by five member States (France, Greece, Italy, Luxembourg, and Denmark) at the Environmental Council of 24 and 25 June 1999. With reference to this Declaration, Denmark therefore wishes to submit a reasoned objection concerning the Bt11 maize."[69]

3. Co-Existence and Environmental Liability Legislation

72. Several member States have used the lack of coexistence and environmental liability laws as a reason to continue the moratorium. As detailed below, these member States have stated that without coexistence or liability rules in place, authorizations of biotech products will continue to be suspended under the moratorium. The issues of coexistence and environmental liability are questions of economics for farmers and producers in certain areas who wish to grow organic or conventional products, with no biotech commingling. Such rules have no bearing on decisions or assessments regarding the environment or human or animal health or safety, and a desire for such rules cannot justify delay. Otherwise, a Member could always say it would like a better regulatory regime in other aspects and delay approvals indefinitely, rendering the SPS "undue delay" discipline meaningless.

(a) Exhibit 69

73. In EC Exhibit 69, glufosinate tolerant and Bt resistant (Bt-11) corn, the Austrian competent authority (CA) states:

> 2. Objection
>
> As this product is in particular destined for cultivation in all countries of the European Union, Austria – apart from the need for further information – raises an

[69] EC Exhibit 92, document 12, p. 3.

> objection against the putting of this product on the market, as long as all conditions for coexistence with GMO-free cultivation methods are not cleared in a sound legal way.[70]

74. Belgium makes the same objection for the same product:

> *Coexistence*
>
> Belgium is of the opinion that the placing on the market of this product should not be granted before a coexistence regulation is not yet entered into force.[71]

75. Denmark once again recites the March 2001 declaration of 6 member States reaffirming the moratorium until traceability and labeling rules, as well as a system for environmental liability, are adopted.[72]

(b) Exhibit 70

76. As discussed above in relation to traceability and labeling objections raised by member States, Austria also objected to Roundup Ready oilseed rape GT73, as a "matter of principle," requiring that "further issues concerning liability and the coexistence of genetically modified, conventional and organic crops remain to be resolved."[73]

77. On March 24, 2003, Denmark objected, citing the March 2001 declaration.[74]

(c) Exhibit 75

78. The Austrian CA, as late as Oct. 17, 2003, objected to the placing on the market of Pioneer/Dow AgroSciences Bt corn (Cry1F 1507), citing coexistence. The specific reasons cited by the CA are generally economic in nature, rather than issues of environmental safety:

> 2.1. *Co-existence*
>
> Import, processing and cultivation of GM 1507 maize will result in the presence of adventitious and/or technically unavoidable GMO traces in non GMO maize. Although maize has limited capabilities to survive, disseminate or outcross, this may lead to effects on the implementation of co-existence of different agricultural systems (with or without GMO). As long as the conditions for co-existence are

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[70] EC Exhibit 69, p. 48, Sept. 26, 2003.
[71] EC Exhibit 69, p. 85, Feb. 26, 2004.
[72] EC Exhibit 69, p. 68, September 29, 2003.
[73] EC Exhibit 70, p. 87.
[74] EC Exhibit 70, p. 73.

not clarified on the EU level, Austria holds the opinion that no consent for the placing on the market of 1507 maize should be given.[75]

(d) Exhibit 76

79. With regard to Roundup Ready corn (NK603), Austria states that not only should biotech product approvals continue to be suspended until feed and traceability and labeling legislation becomes effective, but also, that no biotech products may be placed on the market without coexistence rules: "In addition the issue of co-existence of genetically modified, conventional and organic farming is at the moment under discussion and has to be resolved. (EC Exhibit 76, p. 59). Denmark also objects, again citing to the March 2001 declaration. (EC 76, p. 69, March 24, 2003)

C. The EC Product Histories Are Incomplete

80. The EC relies almost exclusively on its product histories to support its claim that – despite the statements and actions of EC officials – there were in fact no general or product-specific moratoria. But the EC product histories are incomplete in three important ways. First, the product histories do not cover any products that were withdrawn prior to establishment of the Panel. These failed product applications are direct, compelling evidence of the existence of a general moratorium. These applications languished in the approval process for years, for no apparent reason other than the EC's moratorium, and the withdrawals evince the applicants' frustration with the EC's suspension of its approval process. In its first submission, the United States noted that applications under both the environmental release and novel food legislations had been indefinitely delayed by the general moratorium and consequently withdrawn, and gave 9 specific examples (U.S. First Submission, paras. 52, 53, 56). For these products, the EC has failed to provide any chronologies or exhibits, and has decided only to provide copies of the letters of withdrawal.[76]

81. The EC's product histories are also incomplete in that the EC has not provided the underlying documentation for each step in the process. Instead, in selecting what exhibits to provide to the Panel, the EC has picked and chosen among the various chronological entries.

82. Finally, the product histories are incomplete in that they do not include every step in the product histories. Although only the applicants and the EC have access to all correspondence,

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[75] EC Exhibit 75, p. 40.

[76] In addition, the EC has failed to submit any chronologies for four products whose applications were pending at the time at panel establishment but were withdrawn after these proceedings were underway. These are Roundup Ready Corn (GA21) (withdrawn September 15, 2003), Bt and Roundup Ready corn (MON 810 x GA21) (withdrawn September 15, 2004), Roundup Ready sugar beet (withdrawn April 16, 2004), and Roundup ready sugar beet (under the novel foods legislation) (withdrawn April 16, 2004). In addition, the EC has failed to submit product chronologies for transgenic radicchio and transgenic green hearted chicory, which were withdrawn on May 27, 2003.

the United States has learned that at least some of the product histories are missing significant entries. For example, EC Exhibit 64 provides the application history for Fodder beet A5/15, a product which received a favorable opinion from the Scientific Committee on Plants over **six** years ago - in mid-1998. The EC's chronology excludes a reference to at least one significant document. In particular, at a point in the process where the applicant believed that it had complied with all outstanding information requests, the chronology omits a letter from the lead competent authority to the applicant, stating that: "Since we met the new directive [2001/18] has been adopted and as you probably already know Denmark and five other member states have confirmed their opinion on suspending new authorizations for cultivation and marketing until effective provisions concerning complete traceability which guarantees reliable labeling has been adopted."[77]

VI. MEMBER STATE MEASURES VIOLATE THE SPS AGREEMENT

83. The nine measures imposed by six member States are sanitary or phytosanitary measures which are not "based on" "risk assessment[s]" as required by Article 5.1 of the SPS Agreement.[78] Although each of the six member States that have imposed bans on approved biotech products offered reasons for their measures – though unjustified according to the scientific committees – none of the member States put forth a "risk assessment" as defined in Annex A, paragraph 4. Rather, the justifications offered by the member States typically expressed concerns about adverse effects of the banned products, or biotech products in general, but there is no basis for believing that the objections were based on any risk assessments.

84. In response to the Panel's question 107 following the first substantive meeting asking the EC to explain its conclusion that the member State safeguard measures are based on a risk assessment as required under Article 5.1, the EC claimed that "the Member States have made their own assessments and further risk assessments *may* be forthcoming" (emphasis added). The United States submits that, in fact, no such risk assessments supporting the member State measures have been provided.

85. In particular, the EC has provided on their second CD-ROM a folder titled "Safeguard Measures," in which the EC purports to provide EC member State justifications for the member State measures. Although the United States has only received translations of all of these

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[77] Letter from the Danish Ministry of Environment and Energy (2001) (Ex. US-128).

[78] In its first submission, the EC makes the outlandish argument that SPS Article 5.1 does **not** require that measures be based on a risk assessment as defined in Annex A. The sole basis for the EC's position is that article 5.1 uses the phrase "assessment . . . of the risks", as opposed to "risk assessment." This argument would make the Annex A definition of "risk assessment" all but meaningless, and is directly contrary to every panel and Appellate Body report that has considered Article 5.1. *See, e.g.*, *EC – Hormones*, at para. 193 ("The requirement that an SPS measure be "based on" a risk assessment is a substantive requirement that there be a rational relationship between the measure and the risk assessment.").

documents within the last few days, a review of the documents confirm that none of the member State bans are based on a risk assessment.

86. With regard to the member State bans, the Panel will recall that the EC scientific committees had rejected the information provided by the Member States to justify their bans and reaffirmed their original, favorable risk assessments. This rejected information is included in the chronologies and attachments provided by the EC in its latest CD-ROM. The EC has also submitted on this CD-ROM some "new" scientific information allegedly relied upon by some Member States, which post-date the EC scientific committees' reaffirmation of their risk assessments.

87. The United States has reviewed these documents; none of them constitute risk assessments for the banned products. Accordingly, none of the member State bans bear a "rational relationship" to the only relevant risk assessments on the record in this dispute, which are the EC scientific committees' positive opinions.

88. The only documents in the folder that warrant any further discussion are two opinions from France's Biomolecular Engineering Committee, one issued February 16, 2001 and a second issued February 13, 2004, concerning France's ban of the marketing and importation of oilseed rape MS1/RF1. The first opinion apparently was requested in July 2000 by the French Ministry of Agriculture and Fisheries and the Ministry of National and Regional Development and of the Environment, a full 2 years after France issued its ban.[79]

89. The conclusion of the Committee's 2001 opinion with regard oilseed rape was that "even if cultivating genetically modified oilseed rapes which are tolerant to herbicides does not present any direct risks for the environment, a transitional phase of two years would make it possible, by carrying out experiments on areas of different scale, to validate the forms of management which are proposed for weed control and for coexistence . . . ."[80] This document talks about the need for development of management plans for cultivation, but does not contain a specific analysis of risks associated with the marketing and importation of oilseed rape.

90. Subsequently, in June 2003, just as this 2 year transitional phase was to end, the French government again asked the Biomolecular Engineering Committee for a new opinion that took into account new information and studies that had occurred since 2001.[81] The Committee issued this second opinion on February 13, 2004, and once again called for the establishment of management plans. This document is notable in further concluding that "with respect to the particular case of importation, the Biomolecular Engineering Committee believes that the importation for the transformation and consumption by animals of canola grains that have been genetically modified to be resistant to an herbicide, does not present any more risks to the

[79] EC CD-ROM, Folder C-UK-94-M1-1, attachment 4, p. 3.
[80] EC CD-ROM, Folder C-UK-94-M1-1, attachment 7, p. 19.
[81] EC CD-ROM, Folder C-UK-94-M1-1, attachment 9, p. 4; attachment 4, p. 4.

environment than other commercially available varieties of canola." Thus, this document most certainly cannot be viewed as a risk assessment supporting a ban on the importation of herbicide-tolerant oilseed rape.[82]

91. In fact, the only risk assessments put forth for the banned products are the positive scientific assessments rendered by member States to which the products were submitted, and then by the EC's own scientific committees. In the case of each member State ban, these favorable assessments were reaffirmed when the scientific committees considered and rejected the information provided by the member States. Thus, the member State measures do not bear a "rational relationship" to the EC's positive risks assessment, and are not "based on" a risk assessment, in violation of SPS Articles 5.1 and 2.2.

92. The EC's argument in defense is that each of the member State measures fall within the scope of Article 5.7 of the SPS Agreement. But the EC does not specify how Article 5.7 might apply. Its only argument is that under the terms of the EC legislation, the member State measures are labeled as "provisional." The mere label of a measure, however, is most certainly not sufficient to bring it within the scope of Article 5.7. Instead, in order to be covered by Article 5.7, a measure must meet each of the criteria set out in that paragraph.

93. Before turning to the specific criteria of Article 5.7, the United States would note that the EC is incorrect in claiming that the United States was obliged to include an explicit Article 5.7 argument in its first submission, and since the United States has not done so, the Panel must necessarily find that the member State measures are covered by Article 5.7. This argument fundamentally misunderstands the structure of the SPS Agreement. The United States in its first submission most certainly did explain that the member State measures are inconsistent with SPS Article 2.2, and this necessarily means that the United States submits that Article 5.7 does not apply. In other words, Article 5.7 provides not the basis for a claim of an alleged breach of a WTO obligation, but acts as a defense to shield measures that would otherwise violate Articles 2.2 and 5.1.[83] As explained by the Appellate Body in *Japan – Agricultural Products II*:

> it is clear that Article 5.7 of the SPS Agreement, to which Article 2.2 explicitly refers, is part of the context of the latter provision and should be considered in the interpretation of the obligation not to maintain an SPS measure without scientific evidence. Article 5.7 allows Members to adopt provisional SPS measures '[i]n cases where relevant scientific evidence is insufficient' and certain other requirements are fulfilled. Article 5.7 operates as a qualified exemption from the

[82] EC CD-ROM, Folder C-UK-94-M1-1, attachment 9, pp. 11-12 (Unofficial Translation).

[83] Article 5.7 provides an exception to Article 5.1 as well as Article 2.2, as these two articles "should constantly be read together." *See* Appellate Body Report, *EC – Hormones*, para. 180.

> obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence.[84]

94. In *Japan – Agricultural Products II*, as well as in *Japan – Apples*, another dispute in which Article 5.7 was considered, the Respondent invoked the provision to defend the challenged measure against alleged violations of Articles 2.2 and 5.1.[85] The Complainant (the United States in both cases) did not assert Article 5.7 as an independent claim in either dispute, nor did the Panels suggest that the Complainant should have invoked Article 5.7. Indeed, the United States is not aware of any dispute in which the Complainant has based a claim on the Respondent's violation of Article 5.7. In short, having established that the member State measures are inconsistent with Articles 2.2 and 5.1, the question of whether Article 5.7 applies to the member State measures is now before the Panel. As the United States explained at the first substantive meeting, however, in the face of *positive* risk assessments with respect to each product subject to a member State measure, the EC has no basis for arguing that Article 5.7 nonetheless applies.

95. Article 5.7 states:

> [i]n cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information …. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of the risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

96. The EC member State measures do not meet any of these criteria set out in Article 5.7. First, the scientific evidence with respect to the products subject to the member State measures is not "insufficient". Scientific evidence is "insufficient," according to the Appellate Body, if it "does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement."[86] Here, the evidence is plainly sufficient to perform a risk assessment, because the EC itself has conducted positive risk assessments for each product subject to a member State measure.

97. The EC tries to avoid this plain truth by arguing that the sufficiency of the scientific evidence must be viewed from the "specific perspective" of the "national legislator."[87] According to the EC, therefore, scientific evidence can be insufficient even it there is no dispute

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[84] Appellate Body Report, *Japan – Agricultural Products II*, para. 80 (emphasis in original) (footnote omitted).

[85] *See* Panel Report, *Japan – Agricultural Products II*, para. 8.48 ("We note that Japan invokes Article 5.7 in support of its varietal testing requirement"); Panel Report, *Japan – Apples*, para. 8.203.

[86] Appellate Body Report, *Japan – Apples*, para. 179.

[87] EC First Written Submission, para. 596.

among scientists that the evidence is adequate to perform a risk assessment, as long as a national legislator believes that the evidence is insufficient to perform such an assessment. Further, the EC maintains that the complainants bear the burden of proof to show the sufficiency of the evidence, i.e., that the national legislators imposing the measure do not believe that the scientific information is insufficient.[88] This is an impossible standard to meet, and the EC presents no basis for its suggestion that the SPS Agreement should be construed so as to turn on the subjective beliefs of particular decisionmakers.

98. Second, the member State bans were not adopted 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."[89] As the United States noted in its First Written Submission, the relevant Scientific Committee in the EC reviewed each of the member State bans and concluded in each case that the information provided by the member State did not warrant any change in the Scientific Committee's earlier favorable risk assessment.[90] Thus, the EC's own scientific committees have confirmed that the member State measures are not based on "available pertinent information."

99. Third, the member States have not sought "to obtain the additional information necessary for a more objective assessment of risk." In fact, there is no information in the record that the Member States have sought to perform any risk assessments that would support their bans. To the contrary, as noted above, the EC's additional CD of documents contains no new information that could constitute an assessment of the risks by the member States."

100. Fourth and finally, neither the member States nor the European Commission has reviewed the import and marketing bans within a reasonable period of time. When asked by the Panel whether the member State measures were "reviewed within a reasonable period of time," the EC answered, without providing any evidence or elaboration, that the "measures are constantly subject to review."[91] The conclusory statement that a measure is "constantly subject to review" does not come close to meeting the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption.

101. In sum, the record in this dispute is clear in showing that the member State measures do not meet *any* of the four criteria necessary to bring them within the scope of Article 5.7 of the SPS Agreement.

VII. CONCLUSION

[88] EC Responses to Panel Questions, para. 356.
[89] SPS Agreement, art. 5.7.
[90] U.S. First Written Submission, para. 170.
[91] EC Responses to Panel Questions, para. 324; *see also* EC First Written Submission, para. 599.

102. For all the reasons set forth above and in the prior oral and written submissions of the United States in this dispute, the United States submits that this Panel should find that the EC measures covered in the U.S. panel request are inconsistent with the obligations of the European Communities under the SPS Agreement and the GATT 1994.

ATTACHMENT I

RESPONSES TO EC'S ANSWERS TO PANEL QUESTIONS 23 AND 24

Question 23

The European Communities states at paras. 26-28 of its first written submission that none of the current biotech gene transfer methods are able to precisely control where the foreign gene will insert into the recipient cell's genome, or whether that insertion will be stable, and further describes the screening for the desired traits. How do the points described here compare with the results of conventional selective breeding techniques?

United States Response to EC Answer

1. The EC answer fails to note that there are non-biotech breeding techniques in which chromosomal rearrangements do commonly occur, such as somaclonal variation. The EC also ignores the presence of "transposons" in plants, which "jump" around and can cause genes to turn on or off. The multi-colored kernels in Indian corn are the result of such transposons. The EC also does not mention that the environment and physiological stress can affect how mutations are expressed as well as the frequency of hopping by transposons in traditional cultivars.

2. While narrow crosses between closely related elite varieties are unlikely to result in chromosomal rearrangements, that may not be true for wide crosses with wild relatives that have not been so domesticated as to have lost most of their transposons. The EC also ignores the fact that in traditional plant breeding, especially in wide crosses with non-food-use relatives, the breeder will be introducing a great many unknown genes along with the desired trait. What effect those other genes may have, and under what circumstances, poses potential safety questions that are arguably much more difficult, and certainly no less difficult, to evaluate than that posed by the introduction of a single or a few genes via bioengineering.

3. Moreover, none of the hypothetical risks described by the EC are newly discovered. They all were known at the time the EC evaluated and approved biotech crops prior to instituting its moratorium. And, none of the described risks are precluded from occurring with other breeding techniques. There are well-known examples in which conventional breeding has led to the introduction of an unexpected vulnerability into a crop, to be discovered only under particular environmental or pest-infestation conditions. For example, in 1970, much of the US corn crop was destroyed by an infestation of Southern corn leaf blight. The corn was susceptible to the blight because of a genetic change introduced into corn through traditional breeding, but that susceptibility was discovered only after exposure to the blight.

Question 24

How does the potential for allergenicity to be introduced through biotech foods (e.g., as described by the European Communities at para. 45 of its first written submission) compare with the potential for its introduction through non-GM novel foods?

United States Response to EC Answer

4. The EC raises a number of issues regarding potential allergenicity of biotech foods and whether that potential is fundamentally different from that of non-biotech foods. However the fundamental point is that any new protein introduced into food poses some risk of being an allergen, just as any new food introduced into the diet may turn out to be allergenic. There are well-established ways to evaluate that allergenicity potential. In fact, the EC used essentially the same scientific approach to evaluating potential allergenicity of new proteins in the biotech foods that the EC supported for adoption by the Codex Alimentarius Commission in 2003 that it used in its review and approval of biotech foods prior to the moratorium. There has been no evidence, nor has the EC presented any evidence, to suggest that biotech foods that were approved prior to the moratorium, or that the EC stopped reviewing during the moratorium, present a risk of allergenicity to consumers.

5. The United States recognizes that different methods are needed to evaluate allergenicity of a food or protein that has not been in the diet before than are used to evaluate foods or proteins that have been in the diet. However, that is true whether the new protein is introduced into the diet through bioengineering, or through conventional breeding (for example, in bringing in new traits from wild relatives of common food plants when the wild relatives are not edible). In fact, even conventional foods that are *processed* differently can have significantly different allergenic profiles. Thus, there is no basis for the EC to claim that "conceptually, the two cases are therefore radically different."

6. But again, the significant issue is not whether one can hypothesize a rationale for arguing that there could in theory be an allergenicity issue with a biotech food that would not occur with a non-biotech food; it is whether the foods under review by the EC raise allergenicity (or other food or environmental) issues that are beyond the power of scientists to evaluate. The EC has not even attempted to make such a claim, and indeed it is not true as a matter of science.

7. The United States also would note that the EC itself provides an example (in paragraph 106 of the EC Answers to Questions) of the fact that there are established methods for evaluating allergenicity that are successful in protecting human health. Developers wanted to determine whether the protein they had transferred from a Brazil nut to a soybean was one of the proteins responsible for the allergenicity of Brazil nuts. They had picked the protein because of its nutritional profile, and recognized that because it came from a food that is allergenic, the transferred protein might be an allergen. Using the established assessment strategy, they determined that it was indeed an allergen to people sensitive to Brazil nuts, and discontinued the project. This variety was never commercialized for any use.

8. The EC also makes the point that "fusion proteins" may be more likely to occur in bioengineered food than in conventionally-bred food. Whether that is true is beside the point. The EC presents no basis, nor could it, for arguing that fusion proteins cannot be evaluated for allergenicity by the very same methods as are used for non-fusion proteins. Furthermore, the EC acknowledges that fusion proteins can occur in non-biotech foods. (The EC neglects to mention, however, that fusion proteins are rarely looked for and are hard to detect because one generally wouldn't know which proteins to examine).

ATTACHMENT II

RESPONSE TO EC'S CATEGORIZATION OF SPS AND NON-SPS RISKS

1. To support its argument that some of its actions at issue in this dispute fall outside of the disciplines of the SPS agreement, the EC asserts that various risk considerations are wholly excluded from the agreement. To make this argument, the EC bypasses the ordinary meaning of the language of the agreement, in favor of definitions adopted by international standard setting bodies, albeit frequently disregarding how those bodies have actually applied and interpreted the definitions.

2. As a general matter, the US would agree that the SPS agreement was intended to only apply to measures adopted to address the enumerated risks in Annex A. Consequently, the determination of whether a particular measure is an SPS measure is necessarily a fact-specific exercise. However, the text of the agreement clearly does not support the categorical exclusions the EC proposes – for example, that "risks to the environment" fall wholly outside the scope of the SPS agreement. Indeed, all of the examples the EC presents in paragraphs 398-432 fall within the scope of the SPS agreement based on the explicit language of the agreement and the ordinary meaning of its terms.

The Environmental Effects of Biotech Plants Fall Within the Scope of Annex A

3. The EC argues that the concept of the "environment" is broader than the risks enumerated in Annex A of the SPS agreement, and consequently, some of the effects relating to any invasiveness of biotech plants fall outside of the agreement.[1] Specifically, the EC argues that the SPS agreement only addresses "risks to life or health of a particular animal or plant," contrasting that with the "environment," which it asserts takes into consideration a whole range of living organisms and the entire ecological balance. In this context, they rely heavily on the IPPC definition of a "pest, " although they disregard how that body has interpreted and applied that term.

4. The text of Annex A directly contradicts the EC's interpretation, clearly encompassing the full range of adverse environmental effects that a biotech plant might present. A biotech plant can only damage biodiversity or the ecological balance of an area through its ability to adversely affect, directly or indirectly, the wild flora or fauna of the area. Any damage to biodiversity or the ecological balance of an area would typically occur due to alterations in the invasiveness or persistence of a certain plant species, thereby causing changes in the relative abundances of different plant species that may secondarily have a negative impact on animal life. Such changes, should they occur, would be caused by the new plant species (i.e., the biotech plant), or its hybrid progeny, establishing or spreading into new areas and outcompeting and

[1] EC First Submission, paras. 420, 426; EC Answers to Panel Questions 28, 104.

displacing wild flora thereby potentially altering the availability of resources such as food and shelter used by wild fauna.[2]

5. Paragraph 1(a) specifies that measures taken to protect animal or plant life or health from "risks arising from the entry establishment of pests" are SPS measures. The intended breadth of these risks is confirmed by Footnote 4, which specifies that, for purposes of the definitions in Annex A, "'animal' includes fish and wild fauna; 'plant' includes forests and wild flora." Any other environmental effects relating to biodiversity that the biotech plant might present, fall within paragraph 1(d), which specifically provides that measures taken "to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests" are SPS measures. (Emphasis added.)

6. The WTO Agreement is to be interpreted "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."[3] Definitions or other international standards adopted by international standard setting bodies are therefore not dispositive of the scope of the terms under the SPS agreement. They may provide additional evidence of the ordinary meaning of those terms, or provide evidence of how those terms have been interpreted and applied, but they cannot restrict the meaning of terms that ordinarily have a broader or more extensive meaning.

7. A pest is defined as "any thing or person that is noxious, destructive, or troublesome."[4] This definition captures many of the effects that the EC has identified in its first submission, as "concerns that may arise in connection with [biotech products]."[5] For example, any plant that displaces or eliminates existing flora would fairly be considered "destructive or troublesome." Likewise, any plant that damaged the "ecological balance" could reasonably be characterized as destructive. Nothing in this definition supports the limited interpretations that the EC proffers or otherwise substantiates the EC's unsupported assertion that a biotech product can never be a

[2] Nothing in the EC's response to Panel question 29 contradicts this conclusion. The examples presented do not demonstrate that no adverse effect on wild flora or fauna occurs, but merely that the flora and fauna are adversely affected "indirectly" or secondarily. In determining whether an effect "arises from" a biotech plant, the relevant issue is not merely whether the initial interaction adversely affects the flora or fauna, but rather, whether injury may ultimately result from the presence of the organism. This is distinct from the related question of how precisely the harmful effect is produced, which is what the EC's four examples present. Even though there may be intermediate effects that occur before the effect of concern appears, the risks "arise from" the biotech plant in that it is the presence of the plant that triggers the necessary sequence of events. Indeed, in all of the examples presented, risks to plant and animal life or health would necessarily occur.

[3] Vienna Convention on the Law of Treaties, Article 31(1).

[4] The Compact Oxford English Dictionary, Oxford University Press, 24th Printing, 1971, page 2145 (Ex. US-121).

[5] EC First Submission, para. 418, n.282.

pest.[6] Nor does any other provision of the SPS agreement contradict or otherwise modify the ordinary meaning of this term.[7]

8. Similarly the IPPC definition of a pest is much broader than the EC suggests. The IPPC defines a pest as: "any species, strain or biotype of plant, animal, or pathogenic agent, injurious to plants or plant products."[8] This definition is clearly not restricted to plants that present "a short term risk to the life or health of a particular plant, " nor to plants that only cause direct injury to plants.[9]

9. It is worth noting the IPPC standards that elaborate on this point. ISPM 11, *Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Effects and Living Modified Organisms* contains the following discussion:

> COMMENTS ON THE SCOPE OF THE IPPC IN REGARD TO ENVIRONMENTAL RISKS
>
> The full range of pests covered by the IPPC extends beyond pests directly affecting cultivated plants. **The coverage of the IPPC definition of plant pests includes weeds and other species that have indirect effects on plants, and the Convention applies to the protection of wild flora**.
>
> The scope of the IPPC also extends to organisms which are pests because they:
>
> - *directly affect uncultivated/unmanaged plants*
>
> Introduction of these pests may have few commercial consequences, and therefore they have been less likely to be evaluated, regulated and/or placed under official control. An example of this type of pest is Dutch elm disease *(Ophiostoma novo-ulmi*).
>
> - *indirectly affect plants*

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[6] EC response to question 104.

[7] The EC correctly interprets the requirement in Article 5.2 to consider "relevant ecological and environmental conditions" as compelling Members to consider how ecological and environmental conditions affect the risk to be assessed. EC Answer to Panel's Question 104. But nothing in this provision compels a conclusion that this is the extent of the requirement. It certainly would not be inconsistent with the ordinary meaning of the language to consider this provision as a requirement to include in the risk assessment consideration of how the risk affects ecological and environmental conditions. The US has not argued that this provision would overcome any clear exclusion in Annex A. However, Annex A contains no such exclusion, and under its plain terms, encompasses all of the risks the biotech products at issue in this dispute might present to the environment. Thus, the requirement to consider "relevant environmental and ecological conditions" can be considered to confirm the conclusion that the risks covered under Annex A include effects on the environment caused, for example, by a pest.

[8] IPPC, Article II.10 (Ex. US-122); ISPM No. 5, p. 13 (1999)(Ex. US-127).

[9] EC First Submission at para 417, 424.

> In addition to pests that directly affect host plants, there are those, like most weeds/invasive plants, which affect plants primarily by other processes such as competition (e.g. for cultivated plants: Canada thistle (*Cirsium arvense*) [weed of agricultural crops], or for uncultivated/unmanaged plants: Purple loosestrife (*Lythrum salicaria*) [competitor in natural and semi-natural habitats]).
>
> - *indirectly affect plants through effects on other organisms*
>
> Some pests may primarily affect other organisms, but thereby cause deleterious effects on plant species, or plant health in habitats or ecosystems. Examples include parasites of beneficial organisms, such as biological control agents.[10]

In addition, sections 2.3.1.1 and 2.3.1.2 of ISPM 11 describes some of the potential effects that can be considered in determining whether an organism is a quarantine pest:

> In the case of the analysis of environmental risks, examples of direct pest effects on plants and/or their environmental consequences that could be considered include:
>
> - reduction of keystone plant species
> - reduction of plant species that are major components of ecosystems (in terms of abundance or size), and endangered native plant species (including effects below species level where there is evidence of such effects being significant)
> - significant reduction, displacement, or elimination of other plant species.
>
> Specified examples of indirect pest effects on plants and/or their environmental consequences to be considered include:
>
> - significant changes in ecological processes and the structure, stability or processes of an ecosystem (including further effects on plant species, erosion, water table changes, increased fire hazard, nutrient cycling, etc.)[11]

While not dispositive of the scope of the term "pest" under the SPS agreement, the specific inclusion of such damage in ISPM 11, by the body explicitly recognized by the SPS Agreement as responsible for international standards for plant health, is additional evidence that the ordinary

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[10] ISPM 11, Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Effects and Living Modified Organisms, at 34 (Ex. US-123).

[11] *Id.* at 19.

meaning of the term "pest" certainly includes a biotech plant that cross-breeds with existing flora, and consequently, adversely affects biological diversity.

Effects from the spread of herbicide tolerant or pesticide producing genes to other plants.

10. The remainder of the EC's attempts to exclude certain effects based on an unduly narrow interpretation of a "pest" are equally without merit. In all of the examples raised, the EC acknowledges that the adverse effect of concern arises from an "invasive" plant: a plant that displaces or eliminates existing flora. Such plants fall within the definition of a weed, and thus would be considered a "pest," as that term is defined both under the SPS agreement and under the IPPC.

11. The stated concern is that, assuming the two species are growing in proximity, herbicide tolerance or pesticide producing genes from a crop plant might cross-breed with wild relatives or other sexually-compatible plants and transfer the gene. While most studies to date indicate that the plants containing these genes do not have increased fitness characteristics that would lead to increased invasiveness, the concern has been raised that the gene would confer a selective advantage on the off-spring. One resulting risk, should that occur, would be that the herbicide-tolerant or pesticide-producing offspring would eventually eliminate the existing flora, or otherwise result in a loss of biological or genetic diversity, either in the plant species, or by affecting the larger ecosystem. In the event of such a circumstance, the plant would present a risk of "invasiveness," or "weediness," and thereby meet the definition of a pest under the SPS agreement.

12. Footnote 4 of the SPS agreement provides that for purposes of the definitions in Annex A, "'pests' include weeds." A weed is defined as a "herbaceous plant not valued for use or beauty, growing wild and rank, and regarded as cumbering the ground or hindering the growth of superior vegetation."[12] Thus, the agreement flatly contradicts the EC's argument that the elimination of existing wild flora as a result of cross-breeding with a biotech product, falls outside of the agreement because the "plant doesn't injure the flora, it cross-breeds with them."[13] As an initial matter, it is difficult to conceive how one can argue that a plant responsible for the elimination of flora does not injure the flora. In any event, a plant that displaces, or outcompetes, the native flora would fairly be considered to "hinder[] the growth of superior vegetation."[14] And such a risk would fall squarely within the ambit of paragraph 1(a) as a "risk to plant life or health arising from...a pest."

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[12] The Compact Oxford English Dictionary, 1971, page 3725 (Ex. US-121).

[13] EC First Submission at para 424.

[14] While the biotech plant would generally be considered useful in the agricultural context, that does not mean that the plant is necessarily excluded from the definition of a weed. Value is generally a relative concept, and in this example, the plant's value is generally diminished outside of the agricultural setting, in comparison to the existing native flora.

13. Moreover, as noted above, the IPPC also defines weeds as a pest. In this context, it is worth noting that under ISPM 11, the spread of insect resistance genes into wild flora would be considered relevant to the determination of whether a plant presents a phytosanitary risk. Annex 3, provides:

> Potential phytosanitary risks for LMOs may include:
>
> a. Changes in adaptive characteristics which may increase the potential for introduction or spread, for example alterations in:
>
> - tolerance to adverse environmental conditions (e.g. drought, freezing, salinity etc.)
> - reproductive biology
> - dispersal ability of pests
> - growth rate or vigour
> - host range
> - pest resistance
> - pesticide (including herbicide) resistance or tolerance.
>
> b. Adverse effects of gene flow or gene transfer including, for example:
>
> - transfer of pesticide or pest resistance genes to compatible species
> - the potential to overcome existing reproductive and recombination barriers resulting in pest risks
> - potential for hybridization with existing organisms or pathogens to result in pathogenicity or increased pathogenicity."[15]

14. The EC also argues that the spread of insect resistance trait into wild flora is not covered under the SPS agreement, because although "invasive," the plant would "primarily damage insects and other organisms of the trophic chain."[16] First, as noted above, a pest is defined as "any thing or person that is noxious, destructive, or troublesome."[17] Thus, any biotech crop adversely affecting non-target organisms could be fairly considered to be a "pest" within the meaning of the SPS Agreement, pursuant to Annex A, paragraph 1(a). Further, to the extent the plant is "invasive," as noted above, it presents a risk to "plant life or health" and would fall within the scope of paragraph 1(a).

[15] ISPM 11, Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Effects and Living Modified Organisms, at 36 (emphasis added) (Ex. US-123).

[16] EC First Submission at paragraph 426.

[17] The Compact Oxford English Dictionary, 1971, page 2145 (Ex US-121).

15. Adverse effects on non-target organisms can be covered under even the more narrow definition of a "pest" contained in the IPPC. ISPM 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, provides in Annex 3:

> Potential phytosanitary risks for LMOs may include: …
>
> c. Adverse effects on non-target organisms including, for example:
>
> - changes in host range of the LMO, including the cases where it is intended for use as a biological control agent or organism otherwise claimed to be beneficial
> - effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)
> - capacity to vector other pests
> - negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants."[18]

Risks to Wild Fauna

16. The EC also argues that any risks to wild animal health from increased pesticide use or the use of more toxic alternatives fall outside of the SPS agreement because the risk is either (a) a "risk arising from steps taken to prevent the spread of a pest," or (b) a risk arising from the use of the herbicide, rather than a risk arising from a pest. As an initial matter, the US notes that the EC raised these risks on the grounds that they are associated with the biotech products at issue in this dispute.[19] They cannot now rely on an artificial distinction about the cause of the risks to avoid compliance with the disciplines of the SPS agreement. If the risks do not "arise from" the biotech product, then the risks are not relevant to the approval of the product, and the EC cannot rely on them as the basis for its decisions with respect to these products.

17. In any event, this argument relies on a misreading of the phrase "arising from." This phrase does not require a demonstration that the risk be direct or immediate. The critical question is whether the risk results from the presence of the organism, rather than the related but distinct question of how precisely the harmful effect is produced. Even though there may be intermediate effects that occur before the effect of concern appears, the risks "arise from" the organism in that it is the presence of the organism that triggers the necessary sequence of events.

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[18] ISPM 11, Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Effects and Living Modified Organisms, at 36 (emphasis added) (Ex. US-123).

[19] EC First Submission at para 418, , n.282.

Potential for insects to develop resistance to Bt

18. The articulated concern here is that consistent exposure to Bt, either due to the spread of the pesticide gene to wild flora, or from the constant exposure in the agricultural crop, will cause insects to develop resistance. If those individual insects carrying the resistance trait were to become established or spread throughout the population, the concern is that more toxic chemical pesticides might be applied to control the Bt-resistant insect, causing greater environmental damage. The EC argues that such effects fall outside the SPS agreement because resistance is unrelated to the spread or establishment of a pest. In this instance, the pest against which the measure was directed would be the Bt crop rather than the resistant insect. It is the Bt crop that is ultimately responsible for increased potential for risks to animal or plant life or health resulting from the increased use of more toxic pesticides, because the Bt crop would have been responsible for the need to apply the more toxic pesticides. Such risks are clearly covered the SPS Agreement, pursuant to paragraph 1(a) – "risks to animal or plant life or health arising from...a pest."

19. In this regard, it is worth noting IPPC standards that address this point. Section 2.3.1.2 of ISPM 11 includes among the potential "indirect pest effects" that can be considered in determining whether an organism is a quarantine pest, "environmental and other undesired effects of control measures, [as well as] feasibility and cost of eradication or containment."[20] In addition, as noted above, ISPM 11 specifically identifies "direct or indirect negative effects on non-target organisms from plant-produced pesticides" as a potential phytosanitary risks for biotech products.[21]

Antibiotic Resistance

20. The EC raises several arguments in support of its allegation that any risks relating to the antibiotic resistance marker genes in several of the products at issue in this dispute, fall outside of the scope of the SPS agreement. All are incorrect.

21. The concern described in the EC brief is that the antibiotic resistance gene could be transferred from the plant to a human or animal pathogen in the digestive tract of a human or animal consuming food from the plant. For an animal infected with the pathogen that would ordinarily be treated with the antibiotic to which the pathogen had become resistant, the transfer of the resistance gene would contribute to the establishment and spread of disease--the disease caused by the now resistant pathogen—a risk that clearly falls within paragraph 1(a).

22. Additionally, the antibiotic resistance gene falls within the definition of an additive under the SPS Agreement. The SPS Agreement does not define the term "additive." Nor does the

[20] ISPM 11, Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Effects and Living Modified Organisms, at 19 (Ex. US-123).

[21] *Id. at 36.*

term, as used in this agreement, have an ordinary meaning. Reference to the Codex definition is consequently particularly helpful in this context. According to Codex, a food additive is:

> any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.[22]

Notwithstanding the EC's unsupported assertion, nothing in this definition *per se* excludes genetic inserts or constructs added to food crops. The gene is a component of the food from the biotech plant; is not normally consumed as a food by itself; is not normally used as a typical ingredient of the food, and is intentionally added to the plant (and thus the food from the plant), for a technological purpose in the manufacture of the food. As such, protection against any associated human or animal health risks, such as either the development of antibiotic resistance or the development of the disease the antibiotics would be used to treat, falls within paragraph 1(b). For the same reason, products of resistance genes are also covered by the SPS Agreement.

23. The EC bases its argument primarily on the assertion that "genes are not 'substances;' they are instructions for the creation of "substances." Contrary to the EC's argument, a gene falls within the ordinary meaning of the term "substance, " which is defined as "That of which a physical thing consists; the material of which a body is formed and in virtue of which it possess certain properties. Any particular kind of corporeal matter."[23]

24. In addition to the above arguments, the EC argues that plant DNA is not itself an organism, and it is therefore necessarily excluded from the scope of paragraph 1(b). The United States would agree that plant DNA is not itself an "organism," but disagrees that concerns related to effects on plant DNA are therefore necessarily excluded from the scope of the SPS Agreement.

25. It is not necessary for plant DNA to be an organism for measures taken to protect against any increased risk of antibiotic resistance to fall within the scope of the SPS Agreement. As the EC recognizes, plant DNA is part of the plant, which is undisputedly an organism within the scope of paragraph 1(a). Concerns relating to effects on plant DNA are essentially concerns about the potential effects of the altered plant. As discussed above, the antibiotic resistance gene falls within the SPS Agreement's definition of an additive, and protection against any associated human or animal health risks, such as either the development of antibiotic resistance or the development of the disease the antibiotics would be used to treat, falls within paragraph 1(b).

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[22] Codex Alimentarius Commission: Procedural Manual, p. 49 (Ex. US-124).
[23] The Compact Oxford English Dictionary, 1971, page 3128 (Ex. US-121).

26. The EC also argues that it is not the plant DNA, but a separate pathogen, that causes the disease; the plant DNA merely contributes to the development of antibiotic resistance, and therefore such effects fall outside of the scope of paragraph 1(a). This is based on a misreading of Annex, A, paragraph 1(a), which requires only that the measure be adopted to protect against the risks…arising from the establishment or spread of diseases ,…or disease-causing organisms." In seeking to limit the development of antibiotic resistance, the Member is essentially seeking to protect against the risks arising from the spread and establishment of the resistant pathogen and the diseases it causes. Antibiotic resistance is only of significance because of the disease the pathogen causes; it has no other inherent significance. Ultimately, the fact remains that if the altered plant contributes to the spread of the disease, a measure taken for the purposes of controlling such a plant is a measure taken to protect against the 'risks arising from the spread of...disease-causing organisms." The fact that the altered plant is not the sole cause of the disease does not change this conclusion.

Allergenicity

27. An allergen would generally fall within the definition of a toxin. A "toxin" is generally defined as "a poison."[24] A "poison," is in turn defined as "any substance which, when introduced into or absorbed by a living organism, destroys life or injures health,…."[25] Food allergens clearly fall within the description of a substance that "destroys life or injures health."[26]

28. There is, however, one exception to this general rule relevant to the products in this case. To the extent the allergen is itself or is a component of a pesticide residue, it would fall within the definition of a contaminant, pursuant to footnote 4 of Annex A. Footnote 4 provides that "[f]or the purposes of th[e] definitions [in Annex A],...'contaminants' include pesticide and veterinary drug residues and extraneous matter." Certainly any dietary risks the pesticide residues of the Bt crops present would be "risks arising from...contaminant in foods," including the risk of an allergic reaction from consuming the food.

29. Contrary to the EC's assertion, these interpretations are also consistent with Codex practice. As a preliminary matter, we note that Codex definitions, while informative, do not determine the meaning or scope of the terms under the SPS agreement. Rather, as noted previously, these terms are to be interpreted in accordance with their "ordinary meaning."

30. Nonetheless, Codex standards do not support restricting the term "toxin" to naturally occurring toxicants that are not intentionally added to food, as the EC has suggested. The Codex

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[24] The Compact Oxford English Dictionary, Oxford University Press, 1971, 24th Printing, page 2224 (Ex. US-121).

[25] *Id.* at 3367.

[26] Allergenicity concerns relating to the products at issue in this dispute would also meet the definition of a "toxin" under the EC's alternative definition. The concern raised with respect to the products at issue is that a protein produced in the plant could be allergenic. Or in other words, it is a substance that "destroys life or injures health," or a "poisonous substance," produced during the metabolism and growth of a plant.

Procedural Manual lists all of the definitions that have been adopted as generally applicable for the purposes of the Codex Alimentarius. No definition of "toxin" appears in these definitions.[27] Moreover, Codex Standard 193 does not purport to provide a comprehensive definition of "toxin," but merely establishes the types of toxins included in the scope of the Standard.[28]

31. Further, Codex generally treats pesticide residues as a special subset of "contaminants" in foods. Although Standard 193 generally excludes pesticides pesticide residues that are within the terms of reference of the Codex Committee on Pesticide Residues (CCPR), the Standard specifically provides that "Pesticide residues arising from pesticide uses not associated with food production may be considered for inclusion in the General Standard for Contaminants if not dealt with by the CCPR."[29]

32. A contaminant is defined by Codex as:

> any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include fragment, rodent hairs and other extraneous matter. [30]

Pesticides are typically applied to the plant, and there is neither the desire, nor the intention to add the residues to the food, as no benefit accrues from the presence of the residues on the food; it is merely an unavoidable consequence of pesticide application. Consequently, Codex does not treat such residues as "intentionally added to food." The same applies equally for the Bt plants at issue in this case.

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[27] Codex Alimentarius Commission: Procedural Manual, pp. 49-52 (Ex. US-124).

[28] Codex General Standard for Contaminants and Toxins in Foods, Codex Stan 193-1995 (rev.1-1997), at 2 (Ex. US-125).

[29] *Id.* at 1.

[30] Codex General Standard for Contaminants and Toxins in Foods, Codex Stan 193-1995 (rev.1-1997), at 1 (Ex. US-125); Codex Alimentarius Commission: Procedural Manual, at 49 (Ex. US-124).

ATTACHMENT III

COMMENTS OF THE UNITED STATES ON AMICUS SUBMISSIONS

1. Under DSU Article 13, panels have the right f the panel to seek information from any individual or body which it deems appropriate, including information from persons that have submitted unsolicited amicus briefs. The United States has reviewed the three amicus submissions filed to date in this dispute, and submits that – for the reasons explained below – the information provided in those briefs will not be of assistance to the Panel in resolving this dispute.

Submissions by FIELD and Five Scholars

2. In its Amicus brief, the Foundation for International Environmental Law and Development (FIELD) contends that the benefits of biotechnology are uncertain and risks are significant and site-specific (para. 30). As discussed above, however, the United States submits that the types of risks associated with agricultural biotech products are fundamentally similar to the types of risks associated with other agricultural products, and can be addressed on a case-by-case basis. Geographic variables can indeed be important in addressing risks of such products - which suggests that a case-by-case decision process, rather than a blanket moratorium, would be an appropriate regulatory approach.

3. FIELD also contends that the statements regarding a "moratorium" on approvals of agricultural biotech products were statements of political intent, not legislation and not of mandatory effect, and thus were not measures (para. 80). However, as the United States has explained at length, it is not just that officials announced the existence of a moratorium, its is also that EC officials have in fact applied a moratorium on biotech approvals.

4. In addition, FIELD argues that EC regulation of agricultural biotech products was evolving in response to increasing concerns about risks and concern that the regulatory system for GM approvals was not sufficiently rigorous to address these concerns (paras. 49 - 60). The amicus brief from the international group of five science, technology and society scholars makes this argument as well (p. 22 and p. 32). However, neither amicus submission explains why available scientific information was insufficient to assess the risks associated with the pending applications

5. FIELD further argues that there was no undue delay when one considers the complexity of the EC's decision-making procedures (paras. 94-95). However, FIELD was apparently not in possession of information concerning the EC's actual procedures, which show long periods of delay without any scientific consideration whatsoever. In fact, if the EC had followed the procedures in the relevant directives, it would have made decisions on the pending applications.

Submission by CIEL

6. The Center for International Environmental Law (CIEL) argues that there is so much uncertainty regarding the risks associated with agricultural biotech products that the scientific evidence is insufficient within the meaning of Article 5.7. (Para. 40). However, the mere existence of some uncertainty is not the same as the available scientific information being insufficient for a risk assessment to be performed. CIEL in fact recognizes in its amicus submission that "uncertainty is a given in any scientific endeavor." (Para. 37). To equate scientific uncertainty with inadequate scientific information would have the effect of nullifying the Article 5.1 requirement that an SPS measure be based on a risk assessment. Moreover, the EC has not even raised an Article 5.7 defense to its adoption of a general or product-specific moratoria.

ATTACHMENT IV

COMMENTS OF THE UNITED STATES ON
THE EC'S DESCRIPTION OF ITS BIOTECH APPROVAL PROCEDURES

1. In paragraph 149 of its First Written Submission, the EC notes that the competent authority that has received a notification must prepare an "assessment report," indicating whether the GMO should be placed on the market. The EC misleads, however, by stating that the authority is required to prepare this report "in principle within a delay of 90 days" after receiving the notification.[31] In fact, Article 12.2 of Directive 90/220 required that the competent authority prepare this report "[a]t the latest 90 days after receipt of the notification."[32] Similarly, Article 14.2 of Directive 2001/18 states that "[w]ithin 90 days after receipt of the notification the competent authority shall … prepare an assessment report … ."[33]

2. Second, in paragraph 150, the EC states that if the competent authority concludes that consent should be granted, "the procedure moves to the Community level: the competent authority submits the notification together with the report to the Commission, which forwards it to the competent authorities of all the other Member States." The EC fails to mention, however, that Article 13.1 of Directive 90/220 required the Commission to forward this report "immediately" to the competent authorities of all the other member States. Article 14.2 of Directive 2001/18 requires the Commission to do so "within 30 days of its receipt."

3. Third, the EC describes the procedure set out in Article 13 of Directive 90/220 and Article 5 of Decision 1999/468/EC concerning the review process of the regulatory committee and the Council.[34] However, the EC conveniently leaves out several deadlines included in the approval legislation and wrongly implies that the Commission has the legal authority not to act on a product notification. For example, the EC fails to mention that, in the event that the Regulatory Committee does not give a favorable opinion or fails to render an opinion, the Commission must submit a proposal to the Council "without delay."[35]

4. Moreover, if the Council fails to adopt the Commission decision, the EC implies that the Commission has discretion whether to adopt the decision. In particular, the EC states, "[i]f the Council does not act within 3 months, the Commission can adopt the decision."[36] In fact, Article

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[31] EC First Written Submission, para. 149 (emphasis added).

[32] Emphasis added. Article 12(5) provides that "[f]or the purpose of calculating the 90-day period … any period of time during the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account."

[33] Emphasis added. Article 14(4) provides that, "[f]or the purpose of calculating the 90 day period … any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account."

[34] EC First Written Submission, para. 153.

[35] Directive 90/220, art. 21; Decision 1999/468/EC, art. 5(4).

[36] EC First Written Submission, para. 153 (emphasis added).

12 of Directive 90/220 states, "[i]f, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures **shall** be adopted by the Commission."[37] Likewise, Article 5.6 of Decision 1999/468/EC reads: "[i]f on the expiry of that [three month] period the Council has neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures, the proposed implementing act **shall** be adopted by the Commission."[38]

5. The EC describes its safeguard procedure in a similarly misleading manner, leaving out crucial deadlines and procedural steps. For example, the EC states that a member State invoking the safeguard procedure must inform the Commission and the other member States, "giving reasons for its action."[39] In fact, the obligation of the member State is not merely to give reasons for its action but to provide "justifiable reasons"[40] or "detailed grounds"[41] to consider the product in question to "constitute[] a risk to human health or the environment."[42] In addition, the EC fails to mention that the Community decision procedure for safeguard measures must be completed "within three months" under Article 16(2) of Directive 90/220 and "within 60 days" under Article 23(2) of Directive 2001/18. [43]

6. Further, as with the initial regulatory procedure above, the EC implies that the safeguard procedure confers discretion on the Commission that is not found in the legislation. In particular, the EC states, "[i]f the Council does not act within 3 months, the Commission can adopt the decision."[44] As noted above, however, Article 12 of Directive 90/220 and Article 5(6) of Decision 1999/468 provide that if the Council has not acted within three months then the measures proposed by the Commission "shall be adopted."

7. Similar omissions and misleading statements are found in the EC's description of the approval procedures set forth in Regulation 258/97. For example, the EC fails to mention that the Commission, after it receives a notification from a member State, must forward that notification to the other member States "without delay," as required by Article 6(2) of Regulation 258/97.[45] The EC also omits the requirement that, once the sponsoring member State submits its initial assessment report, the Commission must forward that report to the member States "without delay," pursuant to Article 6(4).[46]

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[37] Emphasis added.
[38] Emphasis added.
[39] EC First Written Submission, para. 154.
[40] Directive 90/220, art. 16(1).
[41] Directive 2001/18, art. 23(1).
[42] Directive 2001/18, art. 23(1); Directive 90/200, art. 16(1).
[43] EC First Written Submission, para. 154.
[44] EC First Written Submission, para. 154.
[45] EC First Written Submission, para. 173.
[46] EC First Written Submission, para. 175.

8. The EC also fails to note that, in the event that the Regulatory Committee delivers an unfavorable opinion of the Commission's draft measure or if it fails to render an opinion, the Commission must submit the measure to the Council "without delay," as required by Article 13(4)(b).[47] Further, the EC again implies that the Commission has discretion whether to adopt the if the Council does not act within three months when in fact Article 13(4)(b) provides that, in such circumstances, the measure "shall be adopted by the Commission."[48] Finally, the EC does not mention that the Commission must inform the applicant of the decision "without delay," as required by Article 7(3).

[47] EC First Written Submission, para. 177.
[48] EC First Written Submission, para. 177.

EXHIBIT LIST

US-110 OECD, *Recombinant DNA Safety Considerations*, Paris 1986 (excerpt).

US-111 National Academy of Sciences, *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues*. National Academy Press. Washington, D.C. 1987.

US-112 OECD, *Traditional Crop Breeding Practices: An Historical Review To Serve As A Baseline For Assessing The Role Of Modertn Biotechnology*. Paris 1993 (excerpts).

US-113 EC, Scientific Steering Committee, Opinion of the Scientific Steering Committee Accompanying the Guidance Document for the risk Assessment of Genetically Modified Plants and Derived Food and Feed, March 2003.

US-114 International Council for Science. *New Genetics, food and Agriculture: Scientific discoveries-Societal Dilemmas*. Paris. 2003 (excerpts).

US-115 Excerpts of websites of regulatory authorities of the United States, Canada, Japan, Australia, and South Africa listing approved biotech products.

US-116 Ian Brownlie, *Principles of Public International Law* (5th ed.) (1998) (excerpts).

US-117 John O. McGinnis, "The Appropriate Hierarchy of Global Multilateralism and Customary International Law: The Example of the WTO", 44 Va. J. Int'l L. 229 (Fall 2003) (excerpts).

US-118 David VanderZwaag, "The Precautionary Principle in Environmental Law and Policy: Elusive Rhetoric and First Embraces", 8 J. Envtl. L. & Prac. 355 (1999).

US-119 European Parliament, Committee on Industry, External Trade, Research and Energy, Report on the Future of the Biotechnology Industry (2000/2100(INI)), 28 February 2001.

US-120 European Parliament, Motion for a European Parliament resolution on the impact of genetically modified organisms (GMOs) on organic/conventional farming, 18 March 2003 (B5 0190/2003).

US-121 The Compact Oxford English Dictionary, Oxford University Press, 24th Printing, 1971 (excerpts).

US-122 International Plant Protection Convention (1999) (excerpts).

US-123 ISPM No. 11, *Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Effects and Living Modified Organisms* (excerpts).

US-124 *Codex Alimentarius Commission: Procedural Manual* (excerpts).

US-125 Codex General Standard for Contaminants and Toxins in Foods, Codex Stan 193-1995 (rev.1-1997).

US-126 FAO/WHO, Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety, Rome, Italy, 30 September to 4 October 1996.

US-127 ISPM No. 5, *Glossary of Phytosanitary Terms* (2002) (excerpts).

US-128 Letter from the Danish Ministry of Environment and Energy (2001).