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

(WT/DS291, 292, and 293)

Comments of the United States on the EC's Responses to the Questions Posed by the Panel after the Second Substantive Meeting

March 18, 2005

1. The United States appreciates this opportunity to comment on the EC's responses to the questions posed by the Panel in connection with the second substantive meeting. Many of the points raised by the EC have already been addressed by the United States in prior oral and written submissions, or are not relevant to the resolution of this dispute. In the responses below, the United States will focus on new points raised by the EC that are pertinent to the resolution of this dispute and which have not been addressed in prior U.S. submissions.

For all parties:

> **119. With reference to exhibit US-123 (reproduced at para. 9 of attachment II of the US rebuttal), do the references in ISPM 11 to "indirectly affect plants … by other processes such as competition" (page 34) and "significant reduction, displacement, or elimination of other plant species" (page 19) support the view that the term "injurious" in the IPPC definition of "pest" ("any species, strain or biotype of plant, animal, or pathogenic agent, injurious to plants or plant products") should be given a broad interpretation?**

2. Generally, the EC responses that concern the scope of the SPS agreement present few issues that have not already been fully addressed in previous filings. Of these, the United States will focus primarily on two overarching points, before addressing some of the individual arguments.

3. First, the EC acknowledges that many of the risks alleged to be relevant to this dispute fall within the SPS agreement.[1] Consequently, the Panel does not need to engage in a sweeping examination of whether every risk the EC has raised falls within the scope of the SPS Agreement. The SPS Agreement explicitly provides that "any measure" applied to protect against one of the enumerated risks falls within its scope. The Agreement does not require that an SPS measure be exclusively applied to protect against enumerated risks.

4. The second point relates to the EC's repeated attempts to confuse the question before the Panel by arguing that "biodiversity and environmental issues do not fall within the scope of the SPS agreement."[2] This argument attempts to create an artificial distinction between effects on the environment and biodiversity in the abstract, and the specific effects on biodiversity and the environment that the EC has alleged are relevant to the products at issue in this dispute.

5. While it is clear that, as a general matter, the text of the Agreement does not support the EC's categorical exclusions of "risks to biodiversity and the environment," the Panel need not reach the question of whether the SPS Agreement covers all environmental risks to resolve this dispute. Even assuming some need to examine whether individual risks fall within the scope of Annex A, the pertinent question is whether the risks the EC has identified as relevant to this dispute, based on the characteristics of the products at issue, fall within the risks in Annex A, not whether the SPS Agreement generally covers every conceivable environmental risk. Thus, for example, the Panel need not find that all risks to non-target organisms are necessarily covered

[1] EC Answers of March 11, 2005, paras 1-52.

[2] EC Answers of March 8, 2005, para 8.

under the SPS Agreement in order to conclude that any risks to soil microorganisms from a biotech plant falls within the ordinary meaning of a risk to animal or plant life or health from a pest, pursuant to Annex A.1(a).

6. Accordingly, the Panel should only consider the facts presented in this dispute, not the hypothetical facts the EC has presented. As the United States has previously explained, the specific environmental effects that the EC has raised fall within the scope of Annex A.[3] And as discussed more specifically below, none of the EC's responses effectively rebuts this conclusion.

7. A central flaw in the EC categorization of risks is the EC's inconsistent and illogical treatment of IPPC and Codex definitions. As the United States has explained, the Panel is to interpret the Agreement "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."[4] The United States has also explained that definitions in Codex and IPPC documents may be used as additional factual evidence of the ordinary meaning of terms contained in Annex A of the SPS Agreement, but that IPPC and Codex definitions cannot control the interpretation of the Agreement. Thus, the point is not that environmental issues fall within the SPS Agreement because ISPM 11 addresses environmental risks. Rather, the point is that the ordinary meaning of the SPS Agreement encompasses the specific risks that the EC has alleged to be relevant–for example, because the term "pest" encompasses organisms that pose both direct and indirect risks. Consequently, for example, measures adopted to address risks to animal or plant health arising from changes in the biogeochemical cycles, as a result of the biotech plant, would fall squarely within Annex A.1(a).

8. With respect to the EC's use of IPPC and Codex definitions, however, no logical, consistent underlying principle can be discerned from the EC's responses. For example, the responses simultaneously argue that the Panel is, in some cases, bound by a subset of the IPPC definition: "If a GMO crop adversely affects the biogeochemical cycle, for example, it is simply not behaving as a "pest" within the meaning of the IPPC–and in this respect the European Communities also refers to its answer to question 119. These matters therefore fall outside the scope of the SPS Agreement."[5] Yet in other cases, the EC argues it would be "legal error to simply transpose [the IPPC] definition [of a pest] into Annex A.1 of the SPS Agreement."[6]

9. In yet other responses, the EC argues that the Panel may consider "parts of [Codex and IPPC standards as] relevant context."[7] However, the sole basis the EC articulates for how the Panel is to determine the "parts" that provide relevant context appears to be whether the EC has any "particular difficulty" with the standards.[8]

[3] US Rebuttal Submission, Attachment II; Responses of the United States to the Questions by the Panel Posed During and After the Second Substantive Meeting with the Parties; Responses of the United States to the Additional Questions Posed by the Panel on March 4, 2005.

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

[5] EC Answers of March 8, 2005, para 57.

[6] EC Answers of March 8, 2005, para 5.

[7] EC Answers of March 8, 2005, para 91 (emphasis added); see also para 5.

[8] EC Answers of March 8, 2005, para 5, 91.

10. In its most recent submission, the EC raises several objections to consideration of ISPM 11, attempting to discount the fact that the IPPC's interpretation of the term "pest" contradicts the EC's attempts to rely on the IPPC definition of a pest to support its categorical exclusions. These include the arguments that ISPM 11 (rev. 2) should be rejected because (1) it post-dates the Panel's establishment, and (2) that the environmental risks described in ISPM 11 were merely "designed to reflect the Biosafety Protocol." The EC is wrong on both counts.

11. First, with regard to the timing of the IPPC document, the IPPC also articulated the interpretation that the term "pest" applies to organisms that have indirect effects on plants in ISPM 11, Rev 1, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risk* in April 2003, prior to the date the Panel was established. Annex 1 of that document reads:

> **"COMMENTS ON THE SCOPE OF THE IPPC IN REGARD TO ENVIRONMENTAL RISKS**
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> "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:
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> - *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*
>
> 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."[9]

[9] ISPM 11, Rev 1, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risk* (2003), p. 29 (Ex. US-151).

12. Similarly, the IPPC document elsewhere makes clear that part of the evaluation of whether an organism is a quarantine pest includes consideration of both an organism's direct and indirect effects.[10] For example, section 2.3.1.1 "Direct pest effects," provides:

> "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:
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> - reduction of keystone plant species
>
> - reduction of plant species that are major components of ecosystems (in terms or 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
>
> The estimation of the area potentially endangered should relate to these effects."

13. The EC also has no basis for its second argument – that the environmental risks described in ISPM 11 were merely "designed to reflect the Biosafety Protocol." In fact, the earlier, 2003 version of ISPM 11 (rev. 1) did not even specifically address biotech organisms. Accordingly, there is no reason to believe that ISPM 11's inclusion of an organism's direct and indirect effects on the environment related to the adoption of the Protocol.

> **120. With reference to Annex A(1)(d) of the SPS Agreement, please answer the following questions:**
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> **(a) What is the meaning of the term "other damage"?**
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> **(b) Does the term "other" imply that Annex A(1)(a) through (c) are also about "damage"? If so, does the term "other damage" cover damage sustained by plants, animals or humans other than damage to their "life or health"? Please provide examples.**
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> **(c) Is "other damage" limited to damage sustained by plants, animals or humans? If not, please provide examples.**

14. In it answer to Question 120, the EC again makes the unsupported – and unsupportable – assertion that "environmental damage is not covered by the SPS Agreement."[11] As the United States previously explained, the SPS Agreement contains no such exclusion of environmental damage. To the contrary, SPS Agreement specifically provides that for purposes of the

[10] ISPM 11, Rev 1, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risk* (2003), pp. 18-20 (Ex. US-151).

[11] EC Answers of March 8, 2005, para. 21.

definitions in Annex A, "'animal' includes fish and *wild fauna*; [and] 'plant' includes forests and *wild flora*."[12]

15. In its answer, the EC for the first time cites to a late 1990 draft text of the SPS Agreement, and argues that the changes from that draft to the final SPS text supports the EC's view regarding a purported exclusion of environmental damage. As an initial matter, the United States notes that where, as here, the text of the agreement explicitly covers damage to wild flora and fauna, there is no ambiguity and thus no need to examine negotiating history on whether damage to wild flora and fauna is covered within the scope of the SPS Agreement.[13] That said, the EC's citation to the negotiating history is incomplete and misleading, and in no way supports the EC's contention.

16. The EC's citation to the late 1990 draft text includes no footnotes, document numbers, or exhibits.[14] However, based on the quotations in the EC submission, the EC is apparently referring to "Negotiating Group on Agriculture: Working Group on Sanitary and Phytosanitary Regulations and Barriers; Draft Text on Sanitary and Phytosanitary Measures," MTN.GNG/NG5/WGSP/7 (20 November 1990). The cover note to this document does include the following language quoted by the EC: "the brackets in the note to definition 1 and in definition 4 (Annex A) are all linked to the question of whether or not this agreement should apply to measures taken for the protection of animal welfare and of the environment, as well as of consumer interests and concerns".

17. The EC then goes on to assert "The bracketed text (which included a reference to the environment) disappeared in the final text of the agreement, as we all know. As a result, environmental damage per se does not fall under the scope of the SPS Agreement." What the EC fails to explain, however, is precisely what that "bracketed text" contained. As a result, and as explained below, the EC's assertions are completely baseless.

18. The "bracketed text" referred to above is actually two different bracketed phrases. Both of these phrases are contained in the concluding paragraph of the Annex A(1) definition of "SPS measure" (that is, in the paragraph following lettered paragraphs *a to d*) – a paragraph which (in its final form) describes types of measures – such as labelling and quarantines – as opposed to describing particular types of risks.[15] One of the bracketed phrases would have expressly

[12] U.S. Rebuttal Submission, Attachment II.

[13] See Vienna Convention on the Law of Treaties, Article 32 ("Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31: (a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable.").

[14] EC Answers of March 8, 2005, para. 22.

[15] That paragraph, in its final form, states "Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk

included animal welfare, environment, and consumer interests and concerns.[16] The second bracketed phrase would have expressly excluded those issues.[17]

19. The final text of the SPS Agreement drops both the proposal for an explicit inclusion and the proposal for an explicit exclusion of environmental and animal welfare concerns. Thus, contrary to the EC's assertions, this change is *not the least bit instructive* on whether the drafters of the agreement intended to include or exclude environmental issues. On the other hand, this change could support an interpretation that the drafters decided to leave the last paragraph of Annex A(1) to describe types of measures (such as labelling and quarantines) and to place the types of covered risks within the lettered paragraphs *a to d.*

20. Moreover, the EC does not make note of a more relevant and significant change between the late 1990 draft text and the final SPS Agreement. The late 1990 draft text did not include footnote 4, which defines "animal" to include "wild fauna" and "plant" to include "wild flora." The fact that these clarifications were added to the text means that the issue of environmental damage was in fact considered by the drafters, and that the drafters purposely and specifically decided to include damage to wild flora and fauna within the scope of the SPS Agreement. Thus, contrary to the EC's assertions, the negotiating history of the SPS Agreement provides no support for the EC's contention that the SPS Agreement was not intended to cover damage to the environment.[18]

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assessment; and packaging and labelling requirements directly related to food safety."

[16] The first bracketed phrase, which followed "packaging and labelling requirements directly related to food safety" in the concluding paragraph to Annex A(1), was "[measures for the protection of animal welfare and of the environment, as well as of consumer interests and concerns]." MTN.GNG/NG5/WGSP/7, Annex A (20 November 1990). This phrase would have explicitly included these issues within the scope of an SPS measure.

[17] The second bracketed phrase was in a new sentence at the end of the concluding paragraph to Annex A(1): "Requirements concerning quality, composition, grading, [consumer preferences, consumer information, animal welfare, the environment or ethical and moral considerations] are not included in the definition of sanitary or phytosanitary measures." MTN.GNG/NG5/WGSP/7, Annex A (20 November 1990).

[18] The EC also asserts that the "negotiating history of the SPS Agreement supports the European Communities view that Annex A.1 must be interpreted strictly and not in a broad manner." EC Answers of March 8, 2005, para. 20. The United States does not agree that the negotiating history supports any such view. The United States also notes that the EC statement is inconsistent with the EC's own position elsewhere in the same submission, where the EC states that: "In short, the European Communities does not consider that Annex A.1 of the SPS Agreement should be given either a narrow interpretation or a 'broad' interpretation." EC Answers of March 8, 2005, para. 12. The most instructive factor in interpreting Annex A(1) is of course the text itself. In this regard, the United States notes that the text uses *inclusive* language. In particular, footnote 4 is drafted to make clear that the definitions in the footnote are inclusive and not limiting:

> "animal" *includes* fish and wild fauna; "plant" *includes* forests and wild flora; "pests" *include* weeds; and "contaminants" *include* pesticide and veterinary drug residues and extraneous matter.

Also, paragraph (d), covering "other damage", is plainly a catch-all provision, and undermines any EC contention that Annex A(1) is to be construed "strictly" or "narrowly."

For the European Communities:

> **135. In paragraph 52 of the EC Responses to the Questions from the Panel (16 June 2004) that "Since the late '80s, the EC institutions are required to provide an explanation of the reasons for not following the opinion of the specific scientific committee relevant to the matter under consideration". Are these explanations made public or provided to the notifier concerned?**

21. The United States notes that the EC answer to this question – "yes" – needs more of an elaboration than the EC gave in order not to leave a misimpression. In the context of this dispute, the situation referred to in this question arises when member States continue to oppose approvals of biotech applications after those applications have received positive assessments by EC-level scientific committees. As the EC's product histories show, in many cases member States requested more information without providing any explanations (public or otherwise) for why that member State did not accept the scientific committee's positive assessment.

22. Perhaps the EC's answer was intended to mean that had the EC actually made a final decision on a biotech application during the period October 1998 through August 2003 – instead of imposing a moratorium on final decisions – then the EC institution involved would have had to issue a reasoned decision if that decision departed from the view of the EC scientific committee.

> **136. In the context of paragraph 195 of the EC Responses to the Questions from the Panel (16 June 2004), does the EC maintain that the appropriate level of protection that might be relevant to a definitive action is different from the ALOP that would be relevant to a provisional measure taken in the face of insufficient scientific evidence?**

23. The United States has two comments on the EC's response to this question. First, the EC answer assumes that EC member States and the EC itself have adopted different levels of protection. However, there is no basis in the record for this assertion by the EC. In fact, when the Panel in Question 162 asked the EC to elaborate on any supposed differences in levels of protection, the EC did not provide a specific response, and did not explain how the EC member States might have a different level of protection than that adopted by the EC itself. Instead, the EC asserted only that:

> "It is not possible to describe an 'appropriate level of protection' in general terms. It is clear from the terms of the above measures that they seek to secure a high level of protection."[19]

24. Second, the EC seems to be stating that the appropriate level of protection for provisional measures may differ from the level of protection for other (non-provisional) measures. The

[19] EC Answers of March 8, 2005, para. 121.

United States fails to see any basis in logic or in the text of the SPS Agreement for this assertion. Members must select an appropriate level of protection, and then must ensure that any measures adopted to meet that level "are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection."[20]

For all parties:

140. With reference to (1) Codex standards 192 and 193, (2) IPPC and (3) ISPM 11:

(a) Are they "rules of international law applicable in the relations between the parties to this dispute " within the meaning of Article 31(3) of the Vienna Convention on the Law of Treaties?

(b) May they be used as additional factual evidence of the ordinary meaning of terms contained in Annex A of the SPS Agreement, as the United States appears to suggest in its rebuttal at para. 6 of attachment II? (The United States is invited to provide elaboration on its statement at para. 6.)

25. Please see the above U.S. comments in relation to Question 119.

141. With reference to Annex (B)(1) of the SPS Agreement, please answer the following questions:

(a) Does the term "sanitary and phytosanitary regulations" cover administrative decisions which relate to the operation of approval procedures and which are generally applicable?

(b) May the phrase "sanitary and phytosanitary regulations which have been adopted" be interpreted to encompass also sanitary and phytosanitary regulations which have been adopted de facto (e.g., generally applicable decisions which have been reached informally and which are unrecorded)?

26. The EC's answer to this question – that a measure like the moratorium on biotech approvals cannot be "adopted de facto" (as the term "de facto" is used in the question) – is completely without merit. The EC's entire argument is based on the EC's unsupported assertion that the word "adopted" connotes some sort of "formal context."[21] The EC has no basis for this assertion. The normal meanings of the verb "adopt" are to "choose for one's own practice, take up"; or "approve, accept."[22] Nothing in the normal usage of the verb "adopt" entails a "formal context." Thus, the EC has presented no reason why a measure like the moratorium – which was

[20] SPS Agreement, para. 5.6.

[21] EC Answers of March 8, 2005, para. 95.

[22] New Shorter Oxford English Dictionary (1993), p. 29.

adopted and applied to all pending biotech product applications – cannot be "adopted," as that phrase is used in Annex B of the SPS Agreement.

27. The United States also makes note of the EC's statement that "the European Communities can only repeat that it is not possible, in the Community jurisdiction, to adopt an act with legal effects that is 'unrecorded'."[23] This assertion, however, is directly contradicted by the EC's own claim that it adopted an "interim approach." As the EC described it, under that approach the EC would not approve products unless those products met standards of new, yet to be enacted legislation (and changing approval standards is certainly an act with a "legal effect"). Yet, this approach apparently went "unrecorded" – it certainly was never published in the EC's official journal nor notified to the WTO.

> **144. The Panel notes that a number of products containing the same transgenic modifications as products at issue in this dispute were previously approved by the European Communities prior to July 1998 (eg, swede rape tolerant to glufosinate ammonium (MS1, RF1) and (MS1, RF2); swede rape tolerant to glufosinate ammonium (Topas 19/2); maize tolerant to glufosinate ammonium (T25); maize expressing the Bt cry1A(b) gene (MON 810); maize tolerant to glufosinate ammonium and expressing the Bt cry1A(b) gene (Bt-11); soybean tolerant to glyphosate; chicory tolerant to glufosinate ammonium; maize Roundup Ready NK603). To what extent and how were the previous assessments of potential risks to human, animal or plant health and/or the environment associated with these transgenic modifications taken into consideration in the evaluation of potential risks arising from the products at issue before the Panel?**

28. The United States notes that it does not agree with the EC's claim that "as explained in previous EC submissions and confirmed by Dr. Nutti at the hearing, the understanding of the concept of substantial equivalence has greatly evolved since 1998."[24] The EC has not established, as it implies, that "substantial equivalence [was] recognised to constitute a risk assessment in itself." Likewise, the United States did not understand Dr. Nutti to be supportive of this claim, nor did the United States understand that Dr. Nutti agreed with the EC's more general claim that "the understanding of the concept of substantial equivalence has greatly evolved since 1998."

> **154. At paras. 27 and 30 of the European Communities' second oral statement, reference is made to concerns regarding "regulatory requirements outside the scope of this dispute (traceability and labelling)". Is it the European Communities' view that any delays that may have occurred as a**

[23] EC Answers of March 8, 2005, para. 97.
[24] EC Answers of March 8, 2005, para. 104.

result of member States invoking the need for legislation on traceability, labelling or coexistence were justified? Why?

29. The EC's response to this question is illogical, and lacking in any legal or factual basis. The EC's entire response is as follows:

> "When referring to 'regulatory requirements outside the scope of this dispute (traceability and labelling)' the European Communities was referring to the fact that the Complainants have not claimed that the requirements relating to traceability and labelling set out in its GMO legislation were unjustified. Accordingly, delays resulting from the need to satisfy these requirements cannot be considered to be "undue" or contrary to the WTO Agreements."[25]

30. First, the EC is correct that the United States in this dispute has not taken issue with the specific requirements contained in the traceability and labelling legislation. However, the EC has not explained what the relevance of the particular requirements of such legislation might be to the present dispute. The traceability and labelling legislation did not even enter into force until April 2004 – which is eight months after the terms of reference of this Panel were established. Moreover, the EC has denied that it delayed any final decisions on product approvals until such legislation entered into force.

31. Second, to the extent that the EC is arguing that it would be entitled to adopt a moratorium until traceability and labelling legislation entered into force in April 2004, the United States submits that such a delay would indeed be "undue" under Annex C of the SPS Agreement. As explained in the U.S. answer to Question 173, a Member's supposedly inadequate legislation cannot excuse a member from its SPS obligations, including the obligation under Annex C(1)(A) to undertake and complete approval procedures without "undue delay."

158. In paragraph 313 of the EC Responses to the Questions from the Panel (16 June 2004) the European Communities states that the absence of final consent from the lead CA does not mean that the applicant is not entitled to place the product on the market. Has the product at issue (canola/oilseed rape MS1/RF1 and MS1/RF2) been sold in all of the European Community, including in France, and if not, why not?

32. It is remarkable that the EC asserts that canola/oilseed rape MS1/RF1 and MS1/RF2 have been approved for sale in the EC. As the complainants have explained, the EC deliberate release legislation clearly provides that the lead competent authority must take the final step of placing the product on the market.[26] The United States would also note that the Commission's own

[25] EC Answers of March 8, 2005, para. 110.

[26] Directive 90/220, art 13.4 "(Where the Commission has taken a favourable decision, the competent authority shall give consent in writing to the notification so that the product shall be placed on the market . . . .); *Id.* art. 13.5 (Once a product has received a written consent, it may be used without further notification throughout the

official status document on biotech approvals shows that France has failed to take the final step of placing the product on the market.[27]

160. What is the current status of Italy's safeguard measures on maize Bt11, MON 809, MON 810 and T-25? If these products are now permitted to be marketed in Italy, as of when was this marketing permitted?

33. The United States does not understand the EC's contention that this safeguard measure adopted by Italy was repealed in July 2004.[28] To the contrary, the United States understands that the safeguard remained in force at least through November 2004, because at that time the measure was subject to a ruling by the Regional Administrative Tribunal.[29] The United States further notes that although the Tribunal ordered that the safeguard measure be annulled, the United States has no information indicating that the Government of Italy has actually implemented the tribunal's order by annulling the safeguard.

34. In any event, however, the central fact remains that the Italian safeguard was in force at the time the Panel was established in August 2003. The United States, as explained previously, submits that the Panel should make findings on the EC measures as of August 2003. The DSU contemplates separate proceedings for determining whether a measure found to be inconsistent with a Member's WTO obligations remains in existence or has been made consistent with a covered agreement.

For Argentina, European Communities and the United States:

169. With respect to the safeguard measures invoked for Maize Bt-176, please list the scientific evidence on which the concerns raised by Austria and Germany on potential adverse effects on non-target organisms were based (August 2003).

35. The United States has three comments on the EC's response to Question 169.

36. First, the EC response states that the EC "again summarises" the reasons given by Austria and Germany for adopting these safeguards. The EC's March 8, 2005 answer to question 169,

Community"). Directive 2001/18 includes comparable provisions. 2001/18, art. 18.2 ("Where a favourable decision has been taken, the competent authority which prepared the report shall give consent in writing to the placing on the market . . . ."); *Id.* art. 19.1 ("only if a written consent has been given for placing on the market of a GMO as or in a product may that product be used without further notification throughout the Community . . . .").

[27] Questions and Answers on the Regulation of GMOs in the EU, MEMO/02/160 Rev., Brussels 4 March 2003 (Ex. US-107), at page 14 (MS1/RF1 "not finally approved by F"); page 15 (MS1/RF2 "not finally approved by F").

[28] The EC's supporting exhibit (EC-166) contains a copy of a letter from the Government of Italy to the Commission, but the exhibit does not include an official document from the Italian health ministry repealing the safeguard measure.

[29] The ruling, which appears to be included in the Ex. EC-166, resulted from a legal proceeding brought by seed companies and a biotech association.

however, is the first time in this dispute that the EC has described in any detail the purported rationales for any of the member State safeguard measures.

37. Second, the EC does not assert that any of the rationales put forth by Austria or Germany are in fact correct,[30] nor that such rationales provide the basis for a product ban (as would be required for such a measure under the obligations set out in the SPS Agreement). The reluctance of the EC to make such claims is understandable, in light of the fact that the Commission itself disagrees with the member States' decisions to adopt safeguards. Furthermore, the EC does not dispute that the EC's own scientific committees examined and rejected all of the rationales put forward by the member States. The EC also does not discuss whether, or how, the analysis of the EC's own scientific committees was in any way inadequate.

38. Third, the EC does not address whether the member States sought "to obtain the additional information necessary for a more objective assessment of risk" or "review[ed] the sanitary or phytosanitary measure accordingly within a reasonable period of time," as required under Article 5.7. Nor does the EC discuss whether there may have been less trade-restrictive measures (such as measures other than complete product bans) that would have met the concerns expressed by the member States. For example, the member State concerns are addressed to purported risks associated with planting, but the safeguards ban all uses of the biotech products, including import and processing.

39. Thus, although the EC for the first time has described purported rationales for certain member State safeguards, the EC has not begun to develop the information and arguments that would be needed for the Panel to consider a claim that these safeguards met all the requirements of Article 5.7. Rather, the most pertinent information on the record remains that the EC's own scientific committees found that the available evidence was sufficient for the completion of risk assessments, that those committees made positive assessments, and those committees reviewed and rejected the rationales put forth by the member States in relation to the safeguard measures.

For all parties:

> **170. With reference to EC Directive 2001/18, Annex II, Section C.2.1, please indicate for each of the listed potential adverse effects of GMOs whether measures applied to prevent or minimise such effects fall within the scope of Annex A(1) of the SPS Agreement, and if so, why. The parties are also invited to address Section D with the same question in mind.**

40. Please see the above U.S. comments in relation to Question 119.

[30] To the contrary, the EC's language – by using phrases such as "Austria and Germany consider" and "According to Austria and Germany," – is carefully qualified so as not to indicate whether the EC even agrees with the rationales put forth by the member States.

For Argentina, the United States and the European Communities:

> **176. With reference to Austria's safeguard measure on Bt-176 maize, please comment on the reference in exhibit EC-158 att. 7 to insufficient labelling requirements laid down in the Commission Decision relating to the relevant product. In particular, what is the basis for the concern expressed about insufficient labelling (e.g., food safety, consumer information, etc.), and how does the labelling issue affect the analysis of whether the Austrian safeguard measure falls within the scope of the SPS Agreement and/or the TBT Agreement?**

41. The EC response on Austria's purpose for requiring food labelling is not supported by the exhibits. The EC reasoning is as follows:

> "The second concern (the insufficient labelling for the purpose of effective and fair consumer information) is also an issue that is independent and not related to any component of the risk analysis process to tackle any of the risks to human, animal or plant life or health, which may be at stake in the Austrian provisional measure."
>
> "Indeed, the Commission Decision for this product states (fifth recital, 6th indent) that 'there are no safety grounds for mentioning on the label that the product has been obtained by genetic modification techniques'."[31]

42. To be sure , the Commission found that there were no food safety grounds for labelling the product. But the question posed by the Panel is why Austria wanted additional labelling. And Austria, of course, disagreed with the Commission on many issues – that is why it adopted the safeguard. And, as the United States noted in its prior answer to this question, the Austrian memorandum does indicate an Austrian concern with purported risks to human health from antibiotic resistance marker genes. Thus, the EC has no basis for asserting that Austria's concerns regarding labelling were unrelated to purported risks to human health.

> **200. With reference to para. 20 of the European Communities' second oral statement (concerning Bt cotton 531), is the European Communities asserting that the applicant was formally required or requested to submit the information in question? If so, please provide support.**

43. The issue with Bt cotton 531 is that the Regulatory Committee voted on the application in February 1999 and failed to reach a qualified majority to approve or disapprove; that the EC did not follow its own procedures by then sending the application on to the Council and if necessary, the Commission, for final decision; and that the application then languished for over 3 years, without any activity other than purported *"interservice consultations,"* until the application was

[31] EC Answers of March 11, 2005.

updated in early 2003 to meet the requirements of Directive 2001/18.[32] This delay, as the United States has explained, is a clear example of the EC applying its moratorium to a product that under EC law, should have proceeded promptly to a final decision.

44. At the second substantive meeting, the EC tried to justify this lengthy delay by claiming that in fact there were outstanding requests for information that justified the delay of more than 3 years, and that those requests for information were reflected in the comments of the member States during the vote of the Regulatory Committee.

45. In its response to Question 200, the EC now retreats from this assertion. In particular, the EC claims that in its oral statement, it only meant to make the point that member State objections before "February 1999" – that is, prior to the Regulatory Committee vote – were transmitted to the applicant. The United states appreciates that the EC is no longer contending that a non-decision in the Regulatory Committee is equivalent to a request for information. In fact, elsewhere in its answers, the EC states that the Regulatory Committee voting procedure cannot serve as a request for information:

> "The role of a Regulatory Committee is to vote on a proposal for a decision presented by the Commission. It cannot itself propose any decision nor amend the one proposed by the Commission. Equally, it does not itself have any power to seek further information from the applicant. If the Regulatory Committee does not endorse the Commission's proposal, the procedure moves up to the next level."[33]

Having dropped its argument that the Regulatory Committee vote served as a request for additional information, the EC simply has no rationale for claiming that the delay of more than three years in the consideration of Bt cotton 531 was justified. The only explanation for this delay is that it reflected the EC's decision to adopt a moratorium on making final decisions on biotech product applications.

[32] See EC Exhibit 65, Chronology. As the United States explained in its Supplementary Rebuttal (paras. 40-51), the applicant took the initiative to provide some updated information in 2002, although this information was not requested by the EC.

[33] EC Answers of March 8, 2005, para. 125 (emphasis added).