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

(WT/DS291, 292, and 293)

Responses of the United States to the Additional Questions Posed by the Panel on March 4, 2005

March 11, 2005

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.

1. As the United States has previously noted,[1] it not necessary for the Panel to determine that every potential risk evaluated under Directive 2001/18 falls within the scope of the SPS Agreement. The Agreement makes clear that "any measure" applied to protect against one of the enumerated risks falls within the scope of the SPS agreement. Moreover, the EC has acknowledged that at least some of the potential risks that Directive 2001/18 was intended to address fall within the scope of the Agreement.[2]

2. Nonetheless, in the context of the products at issue in this dispute, the majority, if not all, of the endpoints referenced in Annex II C.2.1 would fall within the scope of the risks enumerated in Annex A(1) of the SPS Agreement. [3]

_____*-disease to humans including allergenic or toxic effects (see e.g. items IIA(11) and IIC(2)(i) in Annex IIIA, and B(7) in Annex IIIB);*

3. While the United States would not typically consider toxic and allergenic effects to be diseases, measures taken to address concerns that a biotech plant might cause disease to humans would appear to fall squarely within the scope of paragraph 1(c)–"to protect human life or health...from risks arising from diseases carried by...plants or products thereof."

4. To the extent allergenic and toxic effects are not considered to be diseases, such concerns would still fall within paragraph 1(c). Because the Directive does not address the safety from the human consumption of biotech food, the United States assumes that this relates to any toxic or allergic effects arising from occupational or residential exposures. These would be "risks to human health arising from the entry, establishment or spread of pests." As the United States has previously explained, the ordinary meaning of the term "pest" is "any thing or person that is noxious, destructive, or troublesome."[4] Any plant responsible for causing allergic or toxic effects in any person exposed to it would certainly qualify as "destructive" or "troublesome."

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[1]U.S. Answers to Questions Posed in the Context of the First Panel Meeting, Q. 49.

[2]EC First Written Submission, para. 433.

[3]Because the Directive is intended to encompass a much wider variety of products than are relevant to this dispute (e.g., genetically modified insects or microbes), the effects listed in these sections are extremely broad, and there is consequently, some degree of ambiguity. In general, the United States has attempted to address the effects in the context of the products at issue in this dispute, rather than speculate on all of the possible adverse effects that might be encompassed within the categories, and the degree to which they might fall within Annex A.

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

> *disease to animals and plants including toxic, and where appropriate, allergenic effects (see e.g. items IIA(11) and IIC(2)(i) in Annex IIIA, and B(7) and D(8) in Annex IIIB);*

5. This would appear to fall squarely within the scope of paragraph1(a), irrespective of whether toxic and allergenic effects are considered to be diseases. Whether one considers the biotech plants as "disease-carrying or disease-causing" or as pests, the risks would fall squarely within paragraph 1(a) as "risks arising from the entry, establishment, or spread of pests, diseases, disease-carrying organisms, or disease-causing organisms."

> *effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see e.g. items IVB(8), (9) and (12) in Annex IIIA);*

6. Any damage that a biotech plant could cause to population dynamics or genetic diversity 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 displacing wild flora thereby potentially altering the availability of resources such as food and shelter used by wild fauna. As the United States has previously noted, such plants would be a weed, and thus fall within the definition of a pest, pursuant to footnote 4. Accordingly, measures taken to address such concerns would fall within paragraph 1(a), as measures taken to protect animal or plant life or health from "risks arising from the entry, establishment, or spread of pests." The intended breadth of the covered 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."

> *altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;*

7. As a general matter, based solely on the general description, this endpoint would appear to fall squarely within either paragraphs 1(a) or (c). To the extent the measure was adopted to protect animal or plant life or health, the risk would appear to arise from "the establishment of disease-carrying organisms, or disease-causing organisms," and would fall within the scope of paragraph 1(a). If, however, the concern related to human health, the measure would appear to fall within paragraph 1(c).

8. Alternatively, in the context of the products at issue, the question of whether the plant has the potential to alter the susceptibility to pathogens or to create new vectors, is something that the IPPC typically considers in determining whether an organism could be considered a pest. For example, in ISPM 11, *Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Effects and Living Modified Organisms,* Annex 3 specifically include the following as potential phytosanitary risks for LMOs:

"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.

c. Adverse effects on non-target organisms including, for example:
-changes in the host range of the LMO, including the case where it is intended for use as a beneficial control agent or organism 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 an 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."[5]

Consequently, these risks fall within paragraph 1(a) as risks to plant health arising from pests.

> *compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, e.g. by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see e.g. items IIA(11) e) and IIC((2)(i)(iv) in Annex IIIA);*

9. The relevant risks described by the above paragraph would primarily relate to concerns to human and animal health arising from the presence of the antibiotic resistance marker genes in the plants.

10. As the United States has previously explained, the risks the EC has raised relating to antibiotic marker genes generally fall within paragraph 1(a). The concern described is that the antibiotic resistance gene could be transferred from the plant to a human or animal pathogen. 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.

11. Additionally, the antibiotic resistance gene falls within the definition of an additive under the SPS Agreement. As such, protection against any associated human or animal health risks, such as the transfer of antibiotic resistance to human or animal pathogens that the antibiotics would be used to treat, falls within paragraph 1(b).

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

12. The reference to "compromising plant protection treatments" also appears to indicate a concern that a biotech plant might compromise the use of various pesticide or herbicides. The most likely concern would relate to the development of pesticide resistance. As the United States has previously explained[6], such risks would generally fall within the scope of paragraph 1(a).

> *effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see e.g. items IIA(11) f) and IVB(15) in Annex IIIA, and D(11) in Annex IIIB).*

13. As Dr. Andow described, biogeochemical cycles relate to the environmental fate of individual chemical elements in the environment–how these chemicals, which are generally plant nutrients, cycle through the environment. These are of concern, and particularly the ones explicitly referenced above, primarily because they could affect the availability of nutrients to plants, which is relevant to plant health. In addition, changes in these cycles can indicate that there have been effects or changes in soil microorganisms. Although the experts' testimony confirmed that there is no evidence that biotech crops affect biogeochemical cycles, concerns that biotech plants might alter biogechemical cycles would generally fall within the scope of paragraph 1(a) as risks arising from pests.

14. The Panel also requested that the parties comment on the effects listed in Annex II, section D; section D.1 applies only to "GMOs other than higher plants," and as none of the products at issue in this dispute fall within this category, there is no need for the Panel to reach this question. Section D.2, relating to the effects of higher plants, lists nine potential endpoints to be addressed as part of an environmental safety assessment.

15. Section D.2, relating to the effects of higher plants, lists nine potential endpoints to be addressed as part of an environmental safety assessment.

> *1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.*
> *2. Any selective advantage or disadvantage conferred to the GMHP.*
> *3. Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species*

16. The first three points would primarily relate to the potential for the plant to become invasive or weedy. The Agreement explicitly provides that pests include weeds[7], and measures applied to address such concerns would generally fall within the scope of paragraph 1(a) as a

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[6]U.S. Answers to Questions Posed in the Context of the First Panel Meeting, Response to Q. 75, para 103-107.

[7]SPS Agreement, Annex A, note 4.

measure to protect plant life or health from risks arising from the entry, establishment or spread of pests. It is also theoretically possible that the risks would fall within the scope of paragraph 1(c), depending on whether the biotech plant presented a hazard to human or animal health.

> *4. Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable).*
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> *5. Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.*

17. These two concerns relate to direct and indirect effects on non-target organisms caused by the biotech plant. Measures taken to address such effects would generally fall within paragraph 1(a) as measures to protect animal life or health from the establishment of pests.

> *6. Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s).*

18. Measures taken to address any risks from occupational or residential exposure to the biotech plants would generally fall within paragraph 1(c), as measures "to protect human life or health...from risks arising from...the establishment or spread of pests." In addition, to the extent the concern relates to the presence of the *Bt* toxin/pesticidal substance in the plant, the measure would fall within para 1(b) as a "measure to protect human life from a risk arising from...a contaminant in foods."

> *7. Possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it if it is intended to be used as animal feed.*

19. Concerns relating to effects on animal health resulting from the consumption of feed derived from a biotech plant would generally fall within the scope of paragraph 1(b). This would also include any effects on the feed/food chain, which could relate to concerns that the biotech feed would contain contaminants or toxins that would pass through the animal and remain in the meat or milk.

> *8. Possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s).*

20. As discussed in other responses, measures taken to address concerns that a biotech plant may adversely affect biogeochemical processes or non-target organisms, either directly or indirectly, would generally fall within paragraph 1(a).

> *9. Possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.*

21. These are specific examples of potential indirect effects of biotech crops, and as such, would generally fall within the scope of paragraphs 1(a) or (c), relating to risks arising from pests.

> **171. In Japan - Apples, the Appellate Body interpreted Article 5.7 of the SPS Agreement and notably the phrase "in cases where relevant scientific evidence is insufficient". It stated at para. 179 that:**
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> > **Article 5.1 [...] informs the other provisions of Article 5, including Article 5.7. We note, as well, that the second sentence of Article 5.7 refers to a "more objective assessment of risks". These contextual elements militate in favour of a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1: "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence 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. [...] The question is whether the relevant evidence [...] is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.**
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> **In this regard, please answer the following questions:**
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> **(a) Is there a reason to believe that a lack of relevant scientific evidence could prevent a Member from performing a risk assessment "as required under Article 5.1 and as defined in Annex A to the SPS Agreement"? Or is it rather a question of that Member perhaps being unable, due to the insufficiency of scientific evidence, to conduct a fully objective risk assessment, such that any measure based on that assessment might be maintained without sufficient scientific evidence?**

(b) Does the phrase "more objective assessment of risks" in Article 5.7 support the view that a provisional measure adopted in accordance with Article 5.7 must be based on risk assessment, as required by Article 5.1? (Canada may wish to elaborate further on what it has already said in its supplementary rebuttal in relation to this point.)

22. This question pertains to the relationship between the following phrases used in the SPS Agreement:

(1) "assessment of . . . risks" (Article 5.1) and "risk assessment" Annex A(4);

(2) "cases where relevant scientific evidence is insufficient" (Article 5.7); and

(3) "more objective assessment of risk" (Article 5.7).

23. The Appellate Body in the above quote from *Japan-Apples* explicates the relationship between (1) assessment of risk/risk assessment, as those phrases are used in Article 5.1 and Annex A; and (2) "insufficient" scientific evidence as used in Article 5.7. The key statement is as follows:

> These contextual elements militate in favour of a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1: "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence 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.[8]

24. The first sentence in Question 171(a) above – "*Is there a reason to believe that a lack of relevant scientific evidence could prevent a Member from performing a risk assessment "as required under Article 5.1 and as defined in Annex A to the SPS Agreement"?* – is largely consistent with the Appellate Body's explication as set out above. It is important, however, to clarify that the question is not whether the evidence is sufficient to perform a risk assessment in the abstract. Rather, the pertinent question is whether the evidence is sufficient for a Member to meet its obligation of performing a risk assessment in relation to the specific risk at issue. Or, as the Appellate Body summarized the issue above, was the evidence sufficient to perform an "adequate" risk assessment, as required under Article 5.1 and as defined in Annex A. So, for example, in light of the fact that the measure at issue in the *Apples* case was intended to stop the spread in Japan of fire blight (a plant disease), the Appellate Body explained that:

[8] *Japan-Apples*, para. 179.

> Thus, the question is not whether there is sufficient evidence of a general nature or whether there is sufficient evidence related to a specific aspect of a phytosanitary problem, or a specific risk. The question is whether the relevant evidence, be it "general" or "specific", in the Panel's parlance, is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.[9]

25. The second sentence in Question 171(a) above – "*Or is it rather a question of that Member perhaps being unable, due to the insufficiency of scientific evidence, to conduct a fully objective risk assessment, such that any measure based on that assessment might be maintained without sufficient scientific evidence?"* – is somewhat inconsistent with the Appellate Body's explication as set out above. As noted, the question is whether the evidence is sufficient for the Member to perform an adequate risk assessment, as required under Article 5.1 and as defined in Annex A. The term "fully objective risk assessment" is not used in the SPS Agreement, and the meaning of this phrase is uncertain. In addition, the second part of the above question – *such that any measure based on that assessment might be maintained without sufficient scientific evidence* – is incomplete. Article 5.7 applies where the scientific evidence is not sufficient for the Member to complete an adequate risk assessment, as required under Article 5.1 and as defined in Annex A. However, the measure must still be based on "available pertinent information," and the Member must also meet the additional requirements in the second sentence of Article 5.7.

26. With regard to Question 171(b), the United States does not agree that "*the phrase 'more objective assessment of risks' in Article 5.7 support[s] the view that a provisional measure adopted in accordance with Article 5.7 must be based on risk assessment, as required by Article 5.1*". As noted above, the Appellate Body explained that "insufficient" scientific evidence, as used in Article 5.7, means "insufficient" scientific evidence for a Member to perform an adequate risk assessment, as required under Article 5.1 and as defined in Annex A. Since a precondition for the application of Article 5.7 is the insufficiency of evidence for an adequate risk assessment, it would not make sense to conclude that a provisional measure under Article 5.7 must nonetheless be based on a risk assessment (as required under Article 5.1 and as defined in Annex A to the SPS Agreement). However, a measure under 5.7 cannot be adopted on an arbitrary basis. To the contrary, Article 5.7 explicitly provides that a provisional measure must be adopted on the basis of "available pertinent information."

27. In *Japan-Agricultural Products*, the Appellate Body addressed the interpretation of "more objective assessment of risk," as used in Article 5.7:

> Neither Article 5.7 nor any other provision of the SPS Agreement sets out explicit prerequisites regarding the additional information to be collected or a specific collection procedure. Furthermore, Article 5.7 does not specify what

[9] *Id.*

> actual results must be achieved; the obligation is to "seek to obtain" additional information. However, Article 5.7 states that the additional information is to be sought in order to allow the Member to conduct "a more objective assessment of risk". Therefore, the information sought must be germane to conducting such a risk assessment, i.e., the evaluation of the likelihood of entry, establishment or spread of, *in casu*, a pest, according to the SPS measures which might be applied. We note that the Panel found that the information collected by Japan does not "examine the appropriateness" of the SPS measure at issue and does not address the core issue as to whether "varietal characteristics cause a divergency in quarantine efficacy". In the light of this finding, we agree with the Panel that Japan did not seek to obtain the additional information necessary for a more objective risk assessment.[10]

As confirmed by the above interpretation, Article 5.7 does not call for a "fully objective" risk assessment. Rather, Article 5.7 uses the term "more objective assessment" to highlight that a Member applying an Article 5.7 provisional measure has an ongoing obligation to seek to obtain more and better information that is germane to performing an adequate risk assessment, as required under Article 5.1 and as defined in Annex A.

> **172. Annex A(1) of the SPS Agreement suggests that "approval procedures" are SPS measures. When a Member decides to delay the completion of such an approval procedure for a number of days, would such action be another SPS measure within the meaning of Annex A(1), or would such action rather need to be characterized as an application of an SPS measure (the application of the approval procedure)?**

28. This question addresses the analysis to be used under the SPS Agreement of a Member's decision "to delay the completion of an approval procedure." The United States submits that in the context of the facts and circumstances of this dispute, such a decision to delay completion of approval procedures should be analyzed both:

(1) under the provisions of Annex C, including the "undue delay" provision of Annex C(1)(A); and

(2) as a distinct SPS measure that must be consistent both with the obligations in Annex C of the SPS Agreement and with the obligations outside of Annex C, including the obligations in SPS articles 2.2, 2.3, 5.1, 5.5 and 7.

29. Annex C Obligations: Article 8 of the SPS Agreement provides that "Members shall observe the provisions of Annex C in the operation of control, inspection and approval

[10] *Japan-Agricultural Products*, AB-1998-9, para. 92 (emphasis added).

procedures . . . ."[11] A decision to delay the completion of an approval procedure fits squarely within Article 8's disciplines on the "operation of . . . approval procedures," including the "undue delay" discipline in Annex C(1)(a).

30. SPS Obligations Outside of Annex C, including Articles 2.2 and 5.1: The United States has not contended that a decision to delay the completion of an approval procedure for a particular product for a day, or a week, would amount to a distinct SPS measure that requires analysis of SPS obligations outside of Annex C.[12] Rather, the United States submits that a decision to delay completion of approval procedures for biotech products for an indefinite period of time – in this case from late 1998 up through at least August 2003 – and which consequently has the effect of preventing the sale or marketing of new biotech products – amounts to both a single distinct SPS measure (the general moratorium) and separate distinct SPS measures for each covered product (the product-specific moratoria) and that these measures must meet obligations outside of Annex C.[13] The reasoning is straightforward: a decision to delay approval procedures for an indefinite period is effectively equivalent to decision to adopt bans on the import and marketing of all products subject to the approval procedure. The requirement that product bans must, for example, not be "maintained without sufficient scientific evidence"[14] lies at the core of the object and purpose of the SPS Agreement.

173. May the fact that existing approval legislation does not permit a Member to adopt certain risk management measures which that Member considers appropriate serve as a justification, for purposes of an analysis under Annex C(1)(a) of the SPS Agreement, for delaying approval procedures conducted pursuant to the existing legislation? Are the provisions of Article 27 of the Vienna Convention on the Law of Treaties relevant to such a situation?

31. As an initial matter, the United States notes that it does not accept the premise that any delays in the EC's processing of biotech applications were due to any need by the EC to adopt additional legislation authorizing new or different risk management measures. In fact, this premise is directly contrary to the EC's own contention that it adopted an "interim approach" in 2000, under which products could be considered and approved under the legal authority of Directive 90/220 while applying the (allegedly different) standards of Directive 2001/18 (which

[11] Question 172 uses the phrase "application of an approval procedure." Given the text of SPS Agreement Article 8, perhaps a more precise phrasing would be "operation of an approval procedure."

[12] Such delays in the operation of approval procedures would, of course, have to be consistent with the "undue delay" obligation in Annex C(1)(A).

[13] See First U.S. Submission, sections IV(b)(1)(f), (g), (h), and (i) (discussion of general moratorium) and IV(b)(2)(e),(f), and (g) (discussion of product-specific moratoria).

[14] SPS Agreement, Article 2.

did not enter into force until 2003).[15] Furthermore, the EC has denied that the EC delayed all final decisions on biotech approvals until the April 2004 entry into force of the GM Food and Feed and Traceability and Labelling legislation.

32. As the United States has explained previously, questions of "undue delay" must be determined on the basis of the facts and circumstances of any particular delay. In this case, the EC has not shown that the moratorium lasting from October 1998 through at least August 2003 was justified by any purported need for additional legislation (nor has the EC shown that the moratorium was justified for any other reason). Likewise, the EC has not shown that any particular delays in processing applications were delayed by any purported need to await new legislation.

33. Although questions of "undue delay" must be addressed on a case-by-case basis, there is an important legal principle that is implicated by the Panel's question: the United States submits that a Member's supposedly inadequate legislation cannot *excuse* a member from its obligation under Annex C(1)(A) to undertake and complete approval procedures without "undue delay." A finding to the contrary would render the "undue delay" obligation a nullity: a Member could avoid the obligation to undertake and complete approval procedures without "undue delay" simply by failing to take the steps necessary under its domestic law to adopt the necessary legislation.

34. An analogy to provisional measures under Article 5.7 is also instructive.[16] A decision by a Member to suspend approval procedures until the Member adopts new legislation has an effect equivalent to the adoption of a provisional ban on all new products covered by those procedures. When the drafters of the SPS Agreement considered provisional bans, the only circumstance included in Article 5.7 for the adoption of provisional measures is "in cases where relevant scientific evidence is insufficient." If inadequate legislation were also considered to be a justification for the adoption of provisional measures, Article 5.7 could have stated "in cases where relevant scientific evidence or domestic legislation is insufficient." But, of course, Article 5.7 includes no such statement.

35. With regard to Article 27 of the Vienna Convention on the Law of Treaties, the United States agrees that the *principle* set out in Article 27 – namely, that "A party may not invoke the provisions of its internal law as justification for its failure to perform a treaty" – is relevant for a consideration of whether inadequate domestic legislation excuses a Member from its WTO obligations. The United States submits, however, that the principle in Article 27 is already fully reflected in the text of the WTO Agreement and is confirmed in Appellate Body reports.

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[15] EC Answers to First Set of Questions, para. 35. Furthermore, as Canada explained in Part II.B.1 of its Second Written Submission, the EC has entirely failed to show that Directive 2001/18 was adopted for the purpose of authorizing additional risk management measures.

[16] As noted in response to the Panel's Question No. 125, the United States considers that Article 5.7 can serve as relevant context to be examined in deciding how to apply the "undue delay" provision of Annex C.

Accordingly, there is no need to turn to general principles of international law in order to support a finding that inadequate domestic legislation does not excuse a WTO Member from its WTO obligations.

36. The text of the SPS Agreement explicitly states that SPS measures include "all relevant laws,"[17] and the Agreement sets out specific obligations with regard to those measures (including a Member's domestic laws). By imposing obligations on "all relevant laws" of a Member, the Agreement is clear that inadequate laws cannot serve as an excuse for nonperformance of SPS obligations.

37. In addition, in one of its first reports – *U.S.-Reformulated Gasoline* – the Appellate Body confirmed that a WTO Member is responsible for the actions of its legislative branch. In that case, the United States explained that it had adopted the measure at issue (a measure found to be inconsistent with GATT Article III) because of "difficulties of verification and enforcement." The Appellate Body agreed with the Panel that cooperative, nondiscriminatory measures were available to overcome those difficulties. The Appellate Body acknowledged that such cooperative measures required the U.S. Congress to provide funding, but explained that "of course" this fact did not excuse the United States from compliance with its GATT obligations:

> The fact that the United States Congress might have intervened, as it did later intervene, in the process by denying funding [for the cooperative verification and enforcement measures], is beside the point: the United States, of course, carries responsibility for actions of both the executive and legislative departments of government.[18]

38. In sum, even if the EC could show that it adopted the moratorium and delayed product applications in order to await the legislative enactment of revised SPS legislation, this showing could not justify a five-year moratorium and resulting delays, or otherwise bring the measure into compliance with the EC's obligations under the SPS Agreement. The principle that inadequate legislation does not justify a Member's noncompliance with WTO obligations is plainly reflected in the text of the WTO Agreement and is confirmed in Appellate Body reports.

174. With regard to Article 2.2 of the TBT Agreement:

(a) Please explain the phrase "the risks non-fulfilment [of a legitimate objective] would create" and illustrate using an example.

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[17] SPS Agreement, Annex C(1).

[18] *United States - Standards for Reformulated and Conventional Gasoline*, AB-1996-1, at 27.

(b) Article 2.2 refers to "scientific information" which must be taken into account in assessing risks. Article 5.2 of the SPS Agreement, on the other hand, refers to "scientific evidence". Are these different concepts? Why?

39. As the United States has previously shown, and as the EC does not contest, each measure at issue in this dispute was adopted for at least some reasons covered within the scope of the SPS Agreement. This fact brings the measures within the scope of the SPS Agreement, and – pursuant to Article 1.5 of the TBT Agreement[19] – the TBT Agreement does not apply to the measures at issue. Accordingly, the United States respectfully submits that the Panel need not engage in an analysis under the TBT Agreement of the measures at issue.

175. Are measures applied to ensure co-existence of biotech crops and non-biotech crops covered by Annex A(1) of the SPS Agreement or do they fall, in whole or in part, outside of the scope of Annex A(1)?

40. As an initial matter, the United States notes that the EC has not shown or even claimed that any measures at issue in this dispute are applied solely to ensure "co-existence" of biotech and non-biotech crops. The EC has denied even the existence of the general and product-specific moratoria, and the EC has conceded that each of the member State measures was adopted for at least some reasons that the EC agrees are covered within the scope of the SPS Agreement.

41. Also, the United States notes that the concept of "co-existence" is not well-defined. Accordingly, the analysis of whether any particular "co-existence" measure would fall within the scope of the SPS Agreement would turn on the details of the particular measure.

42. However, the United States would make the following two points on the application of the Annex A definition of an SPS measure to a hypothetical EC measure addressed only to "co-existence." In the event that the entry, establishment or spread of a biotech crop created a risk of damage to other crops (be they other biotech or non-biotech crops) – by, for example, reducing the quality of such other crops – such risks would be covered by either Annex A(1)(a) (covering risks to plant life or health) or A(1)(d) (covering other damage within the territory of a Member). It should be noted that the United States is not aware of any evidence that the entry, establishment, or spread of a biotech crop poses the risk of causing such damage.

43. The United States has serious concerns, however, with the notion that merely mixing biotech crops with non-biotech crops could amount to a "risk to plant life or health" or to "other damage" – either as a matter of fact, or for purposes of applying Annex A(1) of the SPS Agreement. Every time any new crop variety is introduced into a Member, there are possibilities that the new varieties will mix with existing varieties by mechanisms such as cross-pollination,

[19] "The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures." TBT Agreement, art. 1.5.

delayed germination of the new seeds in fields subsequently used for existing varieties, and mixing in handling and transportation facilities. The United States understands that such mixing normally would not cause "damage" to either the new varieties or to the existing varieties. The United States would need to evaluate carefully any EC argument to the contrary.

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?**

44. The Austrian reference to insufficient labeling requirements is unclear. Since Regulation 258/97 already included a labeling requirement for biotech foods,[20] Austria's concern is particularly puzzling.

45. Based on Austria's statement in the cover note, Austria's rationale for labeling may relate solely to the provision of information about the method used to produce BT-176 maize, and may not have any purported rationale based in food safety. On the other hand, the accompanying memorandum also refers to a concern that biotech corn seed will be bred, and that subsequent progeny will not be labeled, even though they contain antibiotic resistance marker genes.[21] To the extent this was intended to express a concern that the products should be labeled to communicate a potential risk from the presence of the antibiotic marker, the concern would fall within the scope of the SPS Agreement–either pursuant to subparagraph 1(a) or (c), depending on the precise nature of the concern.

46. But ultimately, the reference to concerns regarding the adequacy of labeling does not affect the conclusion that Austria's safeguard measure falls within the scope of the SPS agreement. As outlined in the accompanying eight-page memorandum, the Austrian safeguard measure was adopted to address concerns relating to human and animal health risks arising from the presence of the antibiotic resistance marker gene in the plant, and concerns relating to the development of insect resistance to the Bt toxin. As previously discussed, these concerns fall within the scope of the SPS Agreement–under Annex 1(a) or (b) and under subparagraph (c). .

For the United States and the European Communities:

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[20] Regulation 258/97, Article 8(d).

[21] EC Exhibit 158, att. 7, p. 8.

177. At para. 336 of Canada's first written submission and paras. 570 and 544-545 of Argentina's first written submission, the allegation is made that certain member State safeguard measures are inconsistent with Article 2.1 of the TBT Agreement because imported biotech products subject to the safeguard measures are treated less favourably than like domestic non-biotech product varieties which may be sold freely in the relevant member States. Do the United States and the European Communities share the interpretation of the concept of less favourable treatment underlying Argentina's and Canada's claims? In answering this question, please discuss the relevance of para. 100 of the Appellate Body report on EC - Asbestos. If it is relevant, could the United States and the European Communities (a) indicate whether they agree with the interpretation offered at para. 100, and (b) explain in detail how this interpretation could be applied in practice?

47. The United States respectfully refers the Panel to the U.S. response to Question 174 above.

For all complaining parties:

178. Please indicate whether the following alleged effects of biotech products fall within any of the subparagraphs of Annex A(1) of the SPS Agreement:

(a) Environmental components of biodiversity "outside human, animal or plant life or health, such as the ecological complexes referred to in the Convention on Biodiversity" (EC rebuttal, para. 266).

48. It is unclear what effects the above phrase would encompass that would be relevant to the products at issue in this dispute. 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. And as the United States has previously explained, such effects are generally covered by paragraph 1(a), as risks to animal or plant life or health "arising from the entry, establishment, or spread of pests."

49. To the extent this phrase is intended to address the health of the entire web of life in a particular environment--such as the ecological relationship among plants and animals, apart from the life or health of individual plants and animals--this ultimately does relate to life and health of the members of the individual species within that web, such that a particular species or subtype within a species in a particular environment would not survive.

50. Moreover, the pertinent question is not whether the SPS agreement covers every conceivable environmental risk, but whether the risks that the EC has raised with respect to the products at issue in this dispute, either in whole or in part, fall within the scope of the SPS

Agreement. And as the United States has previously explained, the text of Annex A clearly encompasses the full range of adverse environmental effects that a biotech plant might present.

51. Any damage that a biotech plant might cause 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 displacing wild flora thereby potentially altering the availability of resources such as food and shelter used by wild fauna. Further, to the extent the issue relates to concerns regarding direct or indirect effects on non-target organisms, the measure would generally fall within the scope of paragraph 1(a).

(b) "A predator insect eating another insect because it is itself growing better on a diet of Bt maize" (EC rebuttal, para. 266).

52. This hypothetical effect is simply a specific example of a possible indirect effect of a *Bt* crop. To the extent the crop is either directly or indirectly responsible for an adverse ecological effect, it would fall within the definition of a pest. Measures taken to address risks arising from pests fall squarely within Annex A.

(c) Human health risks arising from occupational exposure to a substance in a biotech product that is a toxin for insects (e.g., the Bt toxin) as opposed to risks arising from the consumption of the biotech product (EC rebuttal, para. 316). (The United States may elaborate on its response to Panel Question 73 or comment on the European Communities' response).

53. As the United States originally noted in its response to Panel Question 73, given that footnote 4 clearly identifies pesticide residues as contaminants, such a measure would fall within the scope of paragraph A(1)(b). In this regard, it should be noted that paragraph A(1)(b) is not limited to the risks from the "consumption" of contaminants in foodstuffs.

54. In addition, as the United States has noted above in response to these questions, measures taken to address risks from occupational or residential exposure to the biotech plants would generally fall within paragraph 1(c), as measures "to protect human life or health...from risks arising from...the establishment or spread of pests."

179. Please comment on the European Communities' statement that "for the purposes specifically of proving a 'moratorium' that applies across the board, it does not suffice to address only a limited selection of product applications" (EC rebuttal, footnote 212).

55. The EC's argument is without merit, and based on two false premises.

56. The first false premise is that the complainants have defined the general moratorium as a decision to suspend all processing of all applications, regardless of where those applications stand in the EC's complex approval process. However, as the complainants have explained repeatedly, the general moratorium was a political decision to prevent any products from reaching the final stage of approval. Thus, nothing in the theory of the U.S. case requires an examination of each and every delay for each and every product. Moreover, the fact that some applications made some progress in the EC's complex approval procedures is entirely consistent with the adoption of a general moratorium on final approvals.

57. The second false premise is that the complainants "address only a limited selection of product applications." This is untrue: the United States has shown that no biotech product application under consideration in the period October 1998 to August 2003 completed the EC's community-level approval procedures.[22] (Indeed, the EC does not even contest this fundamental fact.) Because the complainants assert that the general moratorium was a decision not to allow any product to reach the final stage of the approval process, a showing that indeed no product reached a final decision is precisely the evidence the complainants needed to support complainants' contention that the EC adopted a general moratorium.

For Canada and the United States:

> **182. Could Canada and the United States provide examples of why and how allergens in food can be said to "destroy[] life or injure[] health" (US rebuttal, attachment II, para. 27)or "destroy[] life or impair[] seriously the functions of organs or tissues" (Canada's supplementary rebuttal, para. 51)?**

58. An allergen present in food can cause a variety of symptoms in individuals allergic to that allergen. Some examples of food allergic reactions include angioedema (swelling and redness of the skin), urticaria (itchy hives), allergic rhinitis (runny nose), asthma, and anaphylaxis (a sudden and severe reaction characterized by a sudden drop in blood pressure and breathing difficulties that may be fatal).[23]

For the United States:

> **191. In relation to antibiotic marker genes, please answer the following questions:**
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> **(a) With reference to para. 22 of attachment II of the US rebuttal and Codex standard 192, (i) what is the "technological purpose" for which**

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[22] First U.S. Submission, Part III.C.1.

[23] Additional information on food allergy and its impacts on human health can be found in HA Sampson. Food allergy Part 1: Immunopathogenesis and Clinical Disorders, J Allergy Clin Immunol 1999; 103:717-28, attached to these responses as Exhibit US-149.

antibiotic marker genes are added to food and (ii) in what way does the antibiotic marker gene become a "component" or "otherwise affect the characteristics" of the food to which it is added?

59. *(Question 191(a)(i)):* Antibiotic resistance marker genes are used in the development of biotech food crops. They aid the developer in isolating and amplifying the gene of interest, so that the gene of interest can be introduced into the plant. In some cases, it may also be used to isolate plant cells that have incorporated the newly introduced gene of interest. Those plant cells are then used to generate the bioengineered plant. Thus, the technological purpose of antibiotic resistance marker genes is to aid in the manufacture of the food from the biotech plant.

60. *(Question 191(a)(ii)):* The marker gene becomes a part of the DNA of the plant, and of food from the plant. Thus, it is a component of the food from the plant, the 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.

(b) Please comment on the European Communities' assertion that "there is concern about the development of antibiotic resistance in connection with 'plants' as such" (EC rebuttal, para. 64) and on whether a measure applied to address this concern would fall within the scope of Annex A(1).

61. As noted in answer to 191 (a)(i) above, an antibiotic resistance marker gene can be considered an additive in foods and feedstuffs, under Annex A(1)(b), and as such, measures applied to address risks in foods and feedstuffs from such marker genes is covered under Annex A(1). Whether the European Communities believes that antibiotic resistance marker genes pose additional risks in "plants as such," and whether those risks are or are not covered by the SPS Agreement, in no way alters the fact that risks posed by antibiotic resistance marker genes include risks covered by the SPS Agreement.

62. However, we would note that the main (if not only) risk that can be posed by "the persistence of plant-derived DNA in the environment during crop cultivation and harvesting, and in soil residues," (EC rebuttal, para. 64) such that there could be "concern about the development of antibiotic resistance in connection with "plants" as such" (EC rebuttal, para. 64) is that resistance will pass to microbial pathogens that would otherwise be treatable by the antibiotic at issue if the pathogens should infect and cause disease in humans or animals. As noted by the food safety expert to the panel, there is no evidence that such transfer occurs at a biologically significant rate so as to pose a real risk to life or health of plants or animals. However, whatever risk is posed would be posed similarly from food on the plant and from parts of the plant that are not used as food. We would further note that animals eat almost all parts of the crops at issue in this dispute. Therefore, there is little real distinction for the purposes of this discussion between "plants as such" and “food from plants.”

192. With reference to paras. 16 and 17 of the US supplementary rebuttal, please clarify whether a measure applied to protect against risks to wild fauna from increased use of the herbicide associated with a biotech crop or another herbicide, due to the development of herbicide resistance, falls within the scope of Annex A(1) of the SPS Agreement. If so, please indicate the relevant subparagraph.

63. A measure applied to protect against risks to wild fauna from increased use of an herbicide in the circumstances described above would fall within the scope of Annex A(1), subparagraph (a)–a measure to protect "animal...life or health...from risks arising from the entry, establishment, or spread of pests."

64. In the circumstances described in paragraphs 16 and 17 of the U.S. rebuttal, the pest against which the measure was directed would be the herbicide resistant crop. As previously explained, the phrase, "arising from" does not require that the risk be direct or immediate. The critical question is whether the risk results from the presence of the organism, and in the scenarios described in paragraphs 16 and 17, the risks "arise from" the organism in that it is the presence of the organism that triggers the necessary sequence of events. Here, the herbicide resistant crop would ultimately be responsible for any increased potential for risks to animal life or health that resulted from either the increased use of an herbicide, or the application of a more toxic alternative, because the herbicide-resistant crop would have been responsible for the need to apply the additional herbicide.

193. With reference to paras. 62 and 63 of the US supplementary rebuttal, did the United States submit evidence that the UK supported the alleged moratorium at the time it completed its initial assessment of GA21? If not, what is the basis for the assertion that the alleged inaction by the UK was "politically motivated"?

194. With reference to paras. 52 and 59, 102-103, 159, 168 and 195-196 of the US supplementary rebuttal, did the United States submit evidence that the Netherlands supported the alleged moratorium at the time at issue in the aforementioned paragraphs?

195. With reference to paras. 72, 95, 150-151 and 190 of the US supplementary rebuttal, did the United States submit evidence that Spain supported the alleged moratorium at the time at issue in the aforementioned paragraphs?

65. *(Combined response to questions 193, 194, and 195)*: In its prior submissions, the United States has submitted overwhelming evidence of the existence of the de facto moratorium. Such evidence consisted of, inter alia, statements from EC member States and EC officials that openly acknowledged a general moratorium on the approval of biotech products. And, as the United

States has detailed in its prior answer to Panel's question 151, the EC's own evidence provide numerous additional examples of EC member States confirming the existence of the moratorium. That evidence includes numerous examples of countries other than the above five "moratorium countries" acknowledging the moratorium and even stating their support for the moratorium. For example, EC Exhibit 92, attachment 24_trans, provides:

> In the German Government's view, the effective moratorium on approval for genetically modified organisms will be lifted by the Commission once the regulations on the approval and traceability/labelling of genetically modified foods and feeding stuffs have entered into force.

66. Spain likewise recognized the moratorium. For example, in EC Exhibit 73, attachment 12, the Spanish authority stated: "Sin embargo, en el año 1999 se votaron ambos expedientes y no se alcanzó la mayoría cualificada, quedando pendientes y paralizados durante la moratoria de facto."

67. Such statements against interest are particularly compelling evidence. In this regard, at least Austria, France, Belgium, Germany, Spain, Italy, Luxembourg, Denmark, Sweden, and the Commission have all made statements or made reference to the fact that a moratorium existed. As the United States said in its oral statement at the second substantive meeting of the panel, it is only in the context of this case that the EC denies the existence of a moratorium.

68. In its supplementary rebuttal, the United States has complemented this core evidence with further examples, culled from the information submitted by the EC during the course of this proceeding, of various actions by member States that resulted in undue delay, were wholly consistent with the moratorium, and reflected the impact of the moratorium. When assessed within the context of all the prior evidence Complainants have already provided, these numerous examples of unexplained delays and gaps across the spectrum of biotech applications, and of unjustified requests for additional data, serve to further confirm the moratorium's existence and to confirm that biotech applications were unduly delayed. As the United States stated in its supplementary rebuttal, once the EC had made a political-level decision to adopt a moratorium on biotech approvals, EC and member State regulators understandably were in no hurry to process pending biotech applications.

69. Thus, for example, in paragraphs 62 and 63 of its supplementary rebuttal, the United States pointed out a *7 month* delay by the UK competent authority in forwarding the application on to the Commission after the UK authority had reached a positive safety assessment on the product at issue. Many EC member States, including the UK, are divided internally on their position related to biotechnology. On the one hand, elements of the UK government have been supportive of agricultural biotechnology. On the other hand, certain political figures are not supportive. In particular, the UK Environment Minister at the time of the delay in question was Michael Meacher, and Mr. Meacher was and is strongly opposed to the introduction of

genetically modified foods in the UK.[24] Thus, such examples show that countries other than the "moratorium countries" allowed the moratorium to continue, recognized its political reality, and that this reality at times affected the manner in which they conducted their assessments of biotech applications.

196. With reference to para. 38 of the European Communities' second oral statement, does the United States agree that the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open, such that a competent authority would be justified in awaiting the outcome of the missing assessment?

70. No, the United States does not agree.[25] The general approach to assessing the safety of a new plant variety developed through biotechnology is to perform a molecular characterization, a safety assessment of any newly expressed substances, and compositional analysis. The compositional analysis consists of a comparison of the levels of key compositional components (e.g., key nutrients, key anti-nutrients, and key toxicants) of the new variety with those of conventional varieties of the same crop. One way that is often done is to compare the composition of the new variety with that of its parents. However, if the safety of one or both of the parental varieties has not been established for use as a comparator, one might use other closely related lines. For example, para. 44 of the Codex Plant Guideline (CAC/GL 45-2003) states: "The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen."

197. For the purposes of demonstrating the existence of the European Communities' alleged failure to consider specific biotech products for approval ("product-specific moratoria"), is the United States seeking to rely on the evidence and argument adduced in support of the existence of a general moratorium? In other words, is the United States arguing that the existence of a general moratorium necessarily implies the existence of product-specific moratoria? Please clarify.

71. The United States submits that the EC has adopted a general moratorium on biotech approvals, under which no biotech application was allowed to reach final decision up through August 2003 (the time of the establishment of the Panel). Since the general moratorium applied to all products, a necessary corollary is that the EC also adopted product-specific moratoria on

[24] See attached Exhibit US-150 (article by Mr. Meacher comparing his anti-biotech stance with the more pro-biotech stance of "the Prime Minister, ministers on the relevant cabinet sub-committee, Defra officials, and the Government's chief scientific advisers.")

[25] The United States also notes that the above assertion by the EC appears to be inconsistent with the EC's positions as stated during the meeting with the experts. In particular, at the experts' meeting, the United States understood the EC to be asserting that a *de novo* safety evaluation of hybrids was necessary even if the parental lines had been favorably assessed.

each of the product applications covered in the U.S. panel request.[26] Thus, the evidence and arguments that the United States adduced in support of the existence of a general moratorium also establish the existence of the product-specific moratoria, and that the EC did not undertake and complete its approval procedures for each individual product without "undue delay."

72. In addition, the evidence and arguments adduced by the United States include examples of unwarranted delays in the processing of particular applications,[27] as well as delays specifically arising from scientific questions posed by member States that were not required for completion of the EC's approval procedures.[28] Such evidence and arguments, like the non-product-specific evidence and arguments adduced by the United States, serves two purposes. First, the showing of particular, product-specific delays is further confirmation of the existence of the general moratorium, and rebuts the EC's contention that all applications subject to the moratorium were processed normally and without undue delays. Second, the showing of particular, product-specific delays provides further confirmation of the existence of the product-specific moratoria, and establishes specific instances of "undue delay" for those particular products.

[26] As the United States noted previously, the United States is not requesting findings on the product-specific moratoria for applications that were withdrawn prior to the establishment of the Panel in August 2003.

[27] *See, e.g.*, U.S. Rebuttal Submission, Part V.A; U.S. Supplementary Rebuttal, Part III.

[28] *See* U.S. Supplementary Rebuttal, Part IV.