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

(WT/DS291, 292, and 293)

Responses of the United States to the Questions by the Panel and the European Communities Posed in the Context of the First Substantive Meeting with the Parties

June 16, 2004

FIRST SET OF QUESTIONS FROM THE PANEL

For all parties:

1. Are the parties of the view that the Panel must base its findings and conclusions on the facts as they existed on the date of establishment of this Panel?

1. Under the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU"), a panel's terms of reference are to "examine . . . the matter referred to the DSB by [the complaining Member] in" the panel request. Accordingly, the United States submits that the measure to be examined by the Panel is the measure as it existed at a time no later than the date of the establishment of the panel. With regard to facts concerning events occurring after the date of panel establishment, the United States understands that panels have the discretion to consider such facts if to do so it would assist the panel in making "an objective assessment of the matter before it," for example, in order to understand better the measure as it existed at the time of panel establishment. The Panel, however, is not authorized to make findings with respect to measures, or any alleged changes to measures, in existence after the date of the establishment of the panel.

2. Annex A of the SPS Agreement contains two apparently alternative definitions of risk assessment. Which of these definitions would be appropriate to evaluate the purported risks of biotech products? Or would both definitions be appropriate?

2. Both definitions could be appropriate, depending on the type of risk addressed by the particular SPS measure. Annex A defines "risk assessment" as follows:

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

The first clause covers SPS measures addressed to risks arising from the "entry, establishment or spread of a pest or disease". The second clause covers SPS measures addressed to risk arising from "the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

3. Do the parties consider that food allergens can be considered to be "toxins" or "disease-causing organisms" in a food, beverage or feedstuff?

3. The WTO Agreement is to be interpreted "in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."[1] A "toxin" is generally defined as "a poison." E.g., *The Compact Oxford English Dictionary*, Oxford University Press, 1971, 24th Printing, page 2224. A "poison," is in turn defined as "any substance which, when introduced into or absorbed by a living organism, destroys life or injures health,…." *The Compact Oxford English Dictionary*, page 3367. Food allergens clearly fall within the description of a substance that "destroys life or injures health."

4. In this regard, the United States disagrees with the EC's suggestion that the SPS term "toxin" should be limited to naturally occurring toxicants that are not intentionally added to food, based on Codex Standard 193. As a preliminary matter, we note that Codex definitions, while informative, do not determine the meaning or scope of the terms under the SPS agreement. Rather, as noted above, these terms are to be interpreted in accordance with their "ordinary meaning." Moreover, Codex Standard 193 does not purport to provide a comprehensive definition of "toxin," but merely establishes the types of toxins included in the scope of the Standard.

4. Which (if any) are the other binding international law instruments which are relevant to this case? Could the parties please identify the specific provisions which they believe to be of relevance, and explain specifically how these provisions could be applied in this case?

5. There are no binding international law instruments of relevance to this dispute, other than the WTO Agreement.

For all complaining parties:

5. With reference to paras. 285 to 297 of the EC first written submission, how do the complaining parties account for the fact that the companies withdrawing notifications apparently did not cite undue delays in the processing of notifications as reasons for the withdrawal (except in the case of the notification concerning Monsanto Roundup Ready oilseed rape (GT73))?

6. The United States understands that companies did not cite undue delays in all of their withdrawal letters for the following reasons. First, there was no need to explicitly mention the delays – all applicants plainly sought EC approvals at the time that the applications were

[1] Vienna Convention on the Law of Treaties, Article 31.1.

submitted. But over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. For example, in some cases, a company sought approval for both an initial version of a product and then for an improved, later-developed product. Once the moratorium had caused the application for the initial version to stall in the approval process, in light of the application for the later-developed product, the company no longer had a reason to pursue the application for the earlier product. Second, the companies have a strong incentive to maintain cordial relations with EC regulators, and saw no advantage of complaining to EC regulators about the length of the delays resulting from the moratorium.

6. With reference to pp. 27-36 of the EC first written submission, could the complaining parties please indicate whether the European Communities' description of their own regulatory systems is accurate?

The EC's Characterization is Inaccurate and Misleading

7. The EC has not accurately described the U.S. regulatory systems in pages 27-36. As a preliminary matter, the United States notes that this dispute is not about the U.S. regulatory system. It is about how the EC has applied its system in a manner that violates a number of provisions of the SPS Agreement. The EC's description of the U.S. system is not relevant to this dispute.

8. The United States notes that the only description of the U.S. regulatory system in pages 27-36 of the EC's submission occurs in paragraphs 75 and 86, and this characterization is inaccurate. The U.S. system is most certainly not "laissez-faire." To the extent that this characterization is intended to imply that biotech products on the U.S. market have not undergone a thorough case-by-case risk assessment of the product in question, it is also misleading. All biotech products in the United States, including all biotech foods, have successfully completed a safety evaluation by the relevant competent authorities.

9. Furthermore, the EC presents only one aspect of the overall U.S. regulatory system. Regulation of biotech products in the United States is divided between several regulatory agencies–primarily the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA)--and in general, products are reviewed by multiple agencies. Focusing on only one aspect of that system is inherently misleading.

FDA's Regulatory Role

10. The discussion in paragraph 75 omits any description of the oversight provided by USDA and EPA on environmental and food safety issues. Rather, the description focuses only on the role of FDA and even then is misleading in describing that role. Foods from bio-engineered plants must meet the same strict safety and regulatory standards in the United States as do all

other foods. Similarly, food additives present in biotech foods are subject to the same stringent safety standard and pre-market approval regime that applies to food additives in processed foods.

11. Additionally, all the biotech foods on the market in the United States have gone through a food safety evaluation by FDA, and there is no evidence, and indeed no credible allegations, that any such foods are any less safe than their counterpart non-biotech foods.

12. Contrary to the EC's characterization of the FDA policy statement of 1992 in paragraph 75 as establishing that food from bio-engineered varieties "was generally considered to be as safe as conventional food," FDA said the following: "In regulating foods and their byproducts derived from new plant varieties, FDA intends to use its food additive authority to the extent necessary to protect public health. Specifically, consistent with the statutory definition of "food additive" and the overall design of FDA's current food safety regulatory program, FDA will use section 409 of the act [the Federal Food, Drug and Cosmetic Act] to require food additive petitions in cases where safety questions exist sufficient to warrant formal premarket review by FDA to ensure public health protection." 57 F.R. 22990.

13. FDA did state that it did not "anticipate that transferred genetic material would itself be subject to food additive regulation," noting that "nucleic acids are present in the cells of every living organism, including every plant and animal used for food by humans and animals, and do not raise a safety concern as a component of food." (That is, even though the DNA is added to food, it does not pose a risk warranting a premarket approval measure.) FDA also provided descriptions of the kinds of substances that would, and that would not, likely require premarket approval as a food additive. The policy statement also pointed out that "producers remain legally responsible for satisfying section 402(a)(1) of the act [which prohibits added substances in food at a level that may be injurious to health, including substances present unexpectedly or inadvertently in food], and they will continue to be held accountable by FDA through application of the agency's enforcement powers."

USDA's Regulatory Role

14. With respect to paragraph 86, to the extent the EC's statement that the United States is discussing the "introduction of appropriate monitoring policies" implies that there is no monitoring of biotech products in the United States, that characterization is incorrect and misleading. The United States currently monitors transgenic crops after commercialization and has done so since the mid-1990s.

15. The EC cites in a footnote to paragraph 86 a Federal Register notice by USDA's Animal and Plant Health Inspection Service (APHIS). USDA has the authority to regulate the importation, interstate movement, and release into the environment of plant pests and other articles to prevent direct or indirect injury, disease, or damage to plants or plant products, including genetically engineered organisms. All field testing, planting, and/or release of such genetically engineered organisms in an open environment is subject to authorization by USDA.

For plants, that authorization means that the release does not pose any danger of creating a plant disease or pest problem. USDA reviews information from the field tests and other information gathered from the scientific literature and agricultural experience to determine whether a new plant variety poses a plant pest risk and whether it is as safe to grow as any other traditionally bred plant variety. This decision is based on the finding that the new plant variety:

(1) exhibits no plant pathogenic properties;
(2) is no more likely to become a weed than the non-engineered plant;
(3) is not likely to increase the weediness of any other plant with which it is sexually compatible;
(4) will not cause damage to processed agricultural commodities; and
(5) is not likely to harm other organisms that are beneficial to agriculture.

16. As part of its review, USDA also considers a broad range of environmental issues. When considering such possible impacts, USDA's expertise overlaps with that of other federal agencies, namely EPA and FDA.

17. As explained in the Federal Register notice, USDA is in the process of reviewing its regulations under the authority of the Plant Protection Act of 2000. One area USDA is reviewing is its regulatory role in post-commercialization monitoring of biotech organisms. USDA is considering changes that would increase the flexibility of its biotechnology regulatory system to respond to new types of products. Possible examples of such products are biotech trees and other plants that are likely to establish and persist outside of managed environments, or crops that have been engineered to make products that are not intended for food or feed use.

18. USDA has removed certain biotech organisms from regulation and, hence, there are no regulatory requirements for monitoring those organisms based merely on the fact that a variety is biotech. Currently, for all products that USDA has deregulated, USDA has determined that the biotech varieties do not pose a plant pest risk and are not expected to have a significant impact on the environment. In other words, USDA has found that unconfined release of these products is just as safe for purposes of "plant pest risk" as that of their non-biotech counterparts. However, if evidence became available that a deregulated product actually posed a plant pest risk, USDA could bring such a product back under USDA's oversight. Furthermore, if USDA determined that monitoring of a product was required to mitigate a plant pest risk, it could refuse to deregulate the product and allow commercialization only under USDA oversight with conditions for monitoring.

EPA's Regulatory Role

19. EPA is responsible for regulating the distribution, sale, use and testing of pesticides, including those genetically engineered into plants or other organisms, in order to protect humans and the environment. EPA must issue a registration for a plant-pesticide before the plant-pesticide can be sold or distributed. In evaluating whether any pesticide may be registered, EPA

conducts a comprehensive assessment of all potential risks posed to humans and the environment by the pesticide, including potential hazards to non-target organisms, potential for ground- or surface-water contamination, worker impacts, and any potential impacts from consumer or residential exposures. EPA also evaluates the safety of any pesticide residues in or on food crops, establishing the maximum safe levels that may be present. In conducting this review, EPA evaluates all aspects of human dietary exposure to those pesticide residues, including, for example, the potential contribution from other sources of exposure and the potential for varying susceptibilities of different sub-populations, such as infants and children.

7. In the light of the European Communities' answer to Question 1 above in which it touched upon the concept of "mootness", do the complaining parties consider that this concept is of relevance in the present case?

20. The United States submits that the concept of "mootness" that the EC has articulated is not of relevance to this dispute. Panels have declined to issue findings on measures that expired *before* the establishment of the panel (and before the fixing of the panel's terms of reference). However, the United States is not aware of any panel that has done so for a measure that was in force when its terms of reference were set. To the contrary, past GATT and WTO panels have examined and made findings on measures even if they were discontinued during the panel's work. As the panel wrote in the India-Autos dispute:[2]

> A WTO panel is generally competent to consider measures in existence at the time of its establishment. This power is not necessarily adversely affected simply because a measure under review may have been subsequently removed or rendered less effective. Panels in the past have examined discontinued measures where there was no agreement of the parties to discontinue the proceedings.{FN}
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> > "[Footnote] See for instance the Panel Report on *US – Wool Shirts and Blouses*, WT/DS33/R, adopted on 23 May 1997, as upheld by the Appellate Body Report, para. 6.2 (DSR 1997:I, 343), where the measure was withdrawn following the issuance of the interim report, and the panel nonetheless issued a complete report. See also the Panel Report on *Indonesia – Autos* where the panel proceeded with its examination of the claims despite a notification in the course of the proceedings by the respondent that the programme in issue had expired: "(…) In any event, taking into account our terms of reference, and noting that any revocation of a challenged measure could be relevant to the implementation stage of the dispute settlement process, we consider that is appropriate for us to make

[2] *India – Measures Affecting the Automotive Sector*, WT/DS146/R, WT/DS175/R, para. 7.26.

> findings in respect of the National Car Programme. In this connection, we note that in previous GATT/WTO cases, where a measure included in the terms of reference was otherwise terminated or amended after the commencement of the panel proceedings, panels have nevertheless made findings in respect of such a measures" (WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R, para. 14.9, DSR 1998:VI, 2201). As mentioned by that panel, there have also been such instances of continued proceedings despite expiry or partial disappearance of the measures at issue under the GATT: see for instance *EEC –Apples I (Chile)* (BISD 27S/98) paras 2.2 and 2.4; *United States – Prohibition of Imports of Tuna and Tuna Products from Canada* (BISD 29S/91), paras. 2.8, 4.2 and 4.3, where despite some evolution in the measures in the course of the proceedings and encouragement from the Panel to reach a mutually agreed solution, there was no agreement among the parties that such a solution had been found and the panel issued a complete report.

21. Thus, consistent with the requirements of the DSU, the practice has been for panels to make findings and conclusions with respect to the measures that the complainant identified in its request for establishment of a panel.

For all parties:

22. How many products have been approved under the simplified procedure for foods produced from but not containing GMOs since October 1998?

22. As an initial matter, the United States notes that the simplified procedure is not an "approval" as that term is used in the EC legislation for the regular, non-simplified procedure. In particular, the key characteristic of the simplified procedure is that there is no approval at the Community level, but rather that there only needs to be a notification by a member State to the Commission (Article 5, 258/97), and no further decision by the Commission is required for the product to be legally on the market.

23. According to the Commission's April 15 2004 Memo "Qs&As on the regulation of GMOs in the EU", foods derived from a total of 13 traits have been notified altogether, six of which have been notified since October 1998:

-- RR Soybean and Bt176 Maize on market prior to entry into force of 258/97

-- MS1/RF2, MS1/RF1, GT73, MON810, T25, Bt11 all notified before October 1998

-- (1) MON809, (2) FalconGS40/90, (3) LiberatorL62, (4) MS8/RF3, (5) Cotton1445, (6) Cotton531 notified since 1998

-- pRF69/pRF93 is not a plant trait but Riboflavin in Bacillus Subtilis

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

24. With bioengineering, developers can introduce into a plant the specific DNA segments that encode the desired traits. However, the techniques of bioengineering do not generally control where the introduced DNA segment will insert in the recipient cell's genome. Depending on where in the recipient cell's genome the introduced DNA inserts, it can potentially cause undesirable characteristics in the plant (referred to as "insertional mutagenesis"). In order to ensure that the plants and foods have only the desired traits, developers conduct extensive field tests of new plant varieties. Because of the potential for undesirable traits resulting from the site of DNA insertion, regulatory authorities in both the EC and the United States typically evaluate each plant line derived from a separate bioengineering experiment, even when the safety of the foreign gene itself is not at issue.

25. In contrast, the techniques of conventional cross hybridization do not provide developers with control over the specific genes and traits from the two parents that will end up in the progeny. Although insertional mutagenesis would not be expected to occur commonly in conventional breeding, any such occurrences would likely be unnoticed given the much larger percentage of progeny whose undesirable characteristics result from an inopportune combination of genes from the two parents. Thus, with conventional breeding, developers also have to do extensive field testing of new varieties to ensure that the new plants have the desired traits and do not have undesirable properties.

26. Conventional breeding, particularly when using a wild variety as a parent in a conventional cross hybridization, can also result in genetic translocations and disruptions analogous to what is described in the EC submission in paras 26-28. Many plants contain mobile genetic elements that can "jump" around the genome during and after conventional selective breeding techniques.

27. There is little dispute that bioengineering enables much greater control over breeding than can be exerted through conventional methods. There is also little dispute that, irrespective of the breeding method used, developers can inadvertently generate plant varieties that can pose food safety or environmental risks. As the EC itself notes, the nature of these risks will depend on the individual nature of the plant, the genetic modification (irrespective of the method by which the

genetic modification was introduced), and the environment. There is no basis to conclude that the use of bioengineering in developing new plant varieties creates new types of risks that across-the-board are inherently difficult to assess.

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

28. With bioengineering, one can introduce a much greater range of new proteins into a particular food plant than can be introduced through conventional breeding. Because virtually all allergens are proteins (although, we would point out, few proteins actually are allergens) it is appropriate to evaluate the potential allergenicity of all new proteins introduced into a food plant. With conventional breeding, if one is crossing two varieties that are both commonly used for food, it is unlikely that one would be introducing a new protein into the plant or its food. On the other hand, when doing wide crosses with wild relatives that are not commonly used for food, it is quite possible that new proteins will be introduced that have not been in foods from that plant variety before. However, because developers cannot identify the new proteins introduced into food via conventional breeding, they can not assess the potential allergenicity of those proteins.

25. How do concerns regarding potential problems of invasiveness or persistence of biotech crops in the environment (e.g., as described by the European Communities at para. 55 of its first written submission) compare with the development of herbicide/pesticide resistance in conventional crops which may then become invasive or persistent in the environment?

29. Herbicide/pesticide resistant biotech crops pose no greater or different risk of invasiveness or persistence than conventional herbicide/pesticide resistant crops pose. Moreover, for both biotech and conventionally bred crops, the potential problems of invasiveness or persistence is minimal.

30. In its 2001 report on genetically engineered plants, the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology (available at http://www.rsc.ca/foodbiotechnology/indexEN.html) stated that the likelihood that existing genetically engineered plants will become invasive and constitute serious weed problems is remote. This is because most of today's major crop species have been subjected to intense artificial selection over centuries for traits (phenotypes) with low survival value under most natural conditions. Traits such as nonshattering of grain in cereals, lack of seed dormancy, and requirement of high fertilizer inputs restrict the ability of most domesticated species to thrive outside the agroecosystem. Although crops are grown over vast areas of the world today and they are generally alien introduction in those environments, there are relatively few cases in which they persist without deliberate human intervention for more than a few growing seasons. Such volunteer plants are usually confined to agroecosytems and rarely if ever invade

undisturbed natural communities. Domesticated crop plants are not represented among the worlds serious plant invaders. This is because persistence in wild communities results from the combined effects of many genes working in cooperation to produce a functioning phenotype adapted to local ecological conditions. Therefore, in most cases insertion of highly specific transgenes into a crops species possessing a plethora of domesticated traits is unlikely to alter its natural ecology so that it comes converted into an aggressive invading species. Such targeted genetic modifications are unlikely to nullify many generations of human selection involving countless loci.

31. Most engineered plants that have been commercialized to date have few weedy characteristics and would not be considered invasive plants by any reasonable standard. We realize that the certain plants that have been commercialized, e.g., canola, have been domesticated relatively recently as compared to maize and posses two fitness traits of its parent plant: weak seed dormancy and some seed shattering. However, those traits have not translated into any increased invasiveness in natural settings to date.

32. To date, there are no reports of increased invasiveness from any of the engineered plants grown on millions of hectares worldwide as compared to conventionally bred plants.

26. For what, if any, crops is Europe considered to be the center of origin? What relevance does this have to the approval of biotech crops?

33. Europe is not generally considered the center of origin for agricultural and horticultural crops. See, Hammer, K., and M. Spahillari, M., Crops of European Origin, IN: IPGRI (editor) (2000), pages 35-43 (report of a network coordinating group on minor crops. Ad hoc meeting - June 16, 1999, Turku, Finland) Of the crop plants under the moratorium, only sugar beet (Beta vulgaris) has its origin in greater Europe. Canola (Brassica napus) is sexually compatible with two species from Europe: B. oleracea and B. rapa.

34. In the view of the United States, any potential effects of engineered crops, whether created through conventional breeding or recombinant DNA techniques, on native plants for which a Member is the center of origin must be considered on a case-by-case basis, taking into account the particular circumstances of each situation. However, as a general matter, the significance of the concept of the "center of origin" relates to the concern that genetic diversity would be decreased, and ultimately, the ecosystem could be more susceptible. For example, if a particular plant species share a single genetic makeup, they are more susceptible to being completely wiped out by an epidemic/ new fungus or virus; part of the value of biological diversity is that the species is less vulnerable. A measure taken in consideration of such potential effects, however, would, depending on the exact effects at issue, generally fall under paragraph 1(a) of Annex A of the SPS Agreement as measures applied "to protect . . . plant life or health . . . from . . . pests, diseases, disease-carrying organisms or disease-causing organisms" or paragraph 1(d) as measures applied "to prevent or limit other damage within the territory of the Member from . . . pests."

27. In the context of the Codex working definition of a contaminant, do you consider that the modification or reaction created by gene transfers, or the resulting protein, could be considered a "contaminant"? (see, e.g., EC first written submission, para. 403)

35. No. The United States would note, however, that if the premise of this question is that Codex definitions necessarily govern the interpretation of the terms of the SPS Agreement, the United States does not agree with such premise. The terms of the SPS Agreement, like the terms throughout the rest of the WTO Agreement, must be interpreted in accordance with the customary rules of interpretation of public international law.

28. Is one of the food-safety related concerns regarding biotech products that genetic modification might unintentionally result in the production of a toxin in the modified food product? Would this be a toxin in the context of the Codex working definition of a toxin? (see, e.g., EC first written submission, para. 405.) Would this be a toxin in the context of the SPS Agreement, Annex A?

36. Yes, a food safety-related concern regarding all new plant varieties, developed through biotech or otherwise, is the unintentional production of a toxin in the food. As we noted in response to question 3, such toxins would not be those that are addressed in the Codex standard cited by the EC. That standard is for contaminants, and encompasses toxins that are present in food as a result of fungal contamination. That Codex standard thus is not relevant to the issue being discussed relative to biotech crops, in which a toxin is potentially introduced into the plant through breeding and thereby becomes an integral part of the plant. However, toxins introduced into foods by way of biotech or conventional breeding are clearly encompassed by the term "toxins" in the context of the SPS Agreement, Annex A. Annex A 1(b) explicitly treats contaminants and toxins as separate entities, as shown by the fact that they are listed individually. And there is nothing in the Agreement to indicate that "risks arising from … toxins … in foods, beverages or feedstuffs" should not apply to risks arising from toxins that are in food as a result of breeding changes introduced into the food plant.

29. With reference to para. 420 of the EC first written submission, is there any way in which a GMO can damage biodiversity or the ecological balance of an area other than through negatively affecting the wild flora and/or fauna of the area? Please explain.

37. A biotech plant can only damage biodiversity or the ecological balance of an area through its ability to adversely affect, directly or indirectly, the wild flora or fauna of the area. Any damage to biodiversity or the ecological balance of an area would 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) 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 noted in our response to question 77, such damage would fall within the scope of paragraph 1(a) of the SPS Agreement.

30. With reference to para. 421 of the EC first written submission, what sort of negative impact on human or animal life or health may be caused by the increased use of specific herbicides or the use of novel biotech-specific herbicides? Should these potential negative effects be addressed differently than those which could occur from any other use of herbicides? Please explain.

38. No biotech-specific herbicides exist on the market. The herbicide-tolerant crops that have been developed and that are the subject of this dispute were created to be used with herbicides that are already commonly deployed in agriculture and already approved for use by the appropriate regulatory bodies.

39. Increased use of herbicides associated with biotech crops, to the extent it occurs, could potentially have a negative impact on human or animal life or health due to increased exposure, with particular effects varying depending on the herbicide in question. For example, the increased use of herbicides increases exposure to workers and non-target flora and fauna, thereby increasing any risks that the chemicals may directly present (e.g., acute toxicity to aquatic organisms). Another example would be that, with the increased use of herbicides, the consequent reduction in the non-target flora surrounding the fields could have an indirect impact on the insects and animals in the ecosystem, due to loss of a food source (e.g., weed seeds or berries) or protective cover.

40. However, the potential negative effects would be identical in nature to those associated with traditional use patterns of these herbicides and should be addressed in the same way for both cases. Any herbicide, whether it is used on biotech crops or non-biotech crops, should undergo a rigorous risk assessment to determine potential impacts on human and health and determine safe levels and conditions for use.

31. With reference to para. 422 of the EC first written submission, how does herbicide resistance negatively affect flora and fauna? How is this potential effect different for biotech crops compared to the development of herbicide resistance in non-biotech crops?

41. To answer the second question first, the potential effect on flora and fauna of herbicide-resistant biotech crops is no different compared to the effect on flora and fauna of non-biotech herbicide-resistant crops.

42. There are two parts to the first question. First, does the herbicide tolerant plant itself negatively affect flora/fauna, and second, does the use of the herbicide on herbicide tolerant plants negatively affect flora/fauna.

43. Herbicides have been used in agricultural since 1940s. Plants that survive herbicide treatment inherently have herbicide tolerance genes in their DNA. With the advent of modern technologies, new herbicide tolerance genes have been selected (somaclonal variation or mutation) or engineered into plants. Such plants, irrespective of how they have been produced, have not been reported to be more invasive of natural areas; in most studies to date, the plants containing these herbicide tolerance genes do not have increased fitness characteristics that would lead to increased invasiveness (e.g. seed dormancy, increased seed numbers).

44. The potential impacts on flora and fauna are mainly due to the use of herbicides. Herbicide tolerant plants, irrespective of how they are produced, have not been reported to be more invasive of natural areas since the introduction of the first herbicide 2,4-D was introduced in the 1940's. However, it should be noted that agricultural practices in general, including mechanical cultivation, inter-cropping (growing two or more crops simultaneously on the same field), or no-till versus conventional cropping measures all alter flora, thereby altering fauna.

45. Since the 1970s, long before biotech plants were available, herbicide-resistant weeds were found because of repeated use of a single herbicide. Weed scientists have responded to this by educating growers to rotate the types of herbicides they use in a particular field to reduce the chance of selecting weeds that can tolerate or resist the toxic effects of a particular type of herbicides. Herbicide-resistant weeds are an issue any time herbicides are used irrespective of whether the plant is engineered or not.

32. With reference to para. 423 of the EC first written submission, could any undesirable cross-breed of plant be considered to be a "pest"? Is the IPPC definition of "pest" relevant in this context?

46. The United States believes that any undesirable cross-breeding of a plant (e.g., increased invasiveness) would render the plant a "pest" in that context. Moreover, such a plant would be considered a pest under the IPPC definition of "pest," which the United States does consider relevant in this context.

47. The official IPPC definition of pest is: "any species, strain or biotype of plant, animal, or pathogenic agent, injurious to plants or plant products." 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: (1) directly affect uncultivated/unmanaged plants; (2) indirectly affect plants; or (3) indirectly affect plants through effects on other organisms.

33. With reference to para. 425 of the EC first written submission, could the development of resistant target insects be of concern if such pests cannot become established or spread?

48. No, the only possible concern about the potential development of resistant target insects would be if those individuals carrying the resistance trait were to become established or spread throughout the population, and that as insect populations become resistant to the less toxic pesticide Bt, more toxic chemical pesticides might be applied to control the Bt-resistant insect.

34. With reference to para. 46 of the EC first oral statement, do the parties consider that any potential negative impact on soil micro-organisms from the use of biotech crops could be considered to be "other damage to the territory of a Member arising from the entry, establishment or spread of a pest"? Please explain.

49. Yes, potential negative impact on soil micro-organisms can be considered to be "other damage to the territory of a Member arising from the entry, establishment or spread of a pest." A pest is defined as "any thing or person that is noxious, destructive, or troublesome." *The Compact Oxford English Dictionary*, 1971, page 2145. Thus, a biotech crop, or indeed, any plant, that injured beneficial soil microbes could be considered to be a "pest" within the meaning of the SPS Agreement.

50. In this regard, it is also worth noting that the IPPC's recently adopted revisions to ISPM 11, Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks, specifically tailoring the existing standard to address biotech crops ["living modified organisms"] includes the following:

> Annex 3, "DETERMINING THE POTENTIAL FOR A LIVING MODIFIED ORGANISM TO BE A PEST"
>
> Potential phytosanitary risks for LMOs may include: …
>
> c. Adverse effects on non-target organisms including, for example:
>
> - changes in host range of the LMO, including the cases where it is intended for use as a biological control agent or organism otherwise claimed to be beneficial
> - <u>effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)</u>
> - capacity to vector other pests
> - <u>negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants</u>.

(Emphasis added.)

51. While not dispositive of the scope of the term "pest" under the SPS agreement, the specific inclusion of such damage in ISPM 11, by the body explicitly recognized by the SPS Agreement as responsible for international standards for plant health, is additional evidence that the ordinary meaning of the term "pest" can include a biotech product that might affect soil micro-organisms.

35. With regard to the requirement to undertake and complete procedures without undue delay (Annex C(1)(a) of the SPS Agreement):

(a) What is the object and purpose of this requirement?

52. As noted in paragraph 3 above, the WTO Agreement is to be interpreted in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of the treaty's object and purpose. Thus, as an initial matter, the United States would note that the pertinent issue is the object and purpose of the SPS Agreement or WTO Agreement, and not the object and purpose of the particular requirement in Annex C(1)(A). The Preamble to the SPS Agreement provides that one object and purpose of the Agreement is that Members "Desir[e] the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade." The term "undue delay" should be interpreted in accordance with its ordinary meaning, in context, and in light of the object and purpose of the SPS Agreement of minimizing the negative effects of SPS measures on trade.

(b) Is it correct that a delay in the completion of procedures would not result, ipso facto, in a breach of Annex C(1)(a)? If so, how is a panel to determine when a delay rises to the level of being "undue"?

53. The United States agrees that any delay is not, ipso facto, a breach of Annex C(1)(a). Rather, Annex C(1)(a) is concerned with delays that are "undue." A determination of whether a delay is "undue" in any particular dispute must turn on the specific facts and circumstances of that dispute. In this particular dispute, the United States submits that the adoption of an indefinite delay on all approvals, without justification, must be considered an "undue"delay in a Member's approval procedures. Otherwise, the "undue delay" obligation would have no meaning.

36. With respect to those applications originally submitted under EC Directive 90/220 and subsequently "re-submitted" under EC Directive 2001/18, did the re-submission of these applications mark the beginning/opening of a new procedure for the purposes of Annex C(1)(a) of the SPS Agreement, or is/was there only one single procedure? What are the implications of your reply for the calculation of the length/duration of the

relevant approval procedure(s)? Specifically, from what time/event should the length be calculated (e.g., when the original procedure was initiated under EC Directive 90/220; when the second procedure was initiated under EC Directive 2001/18)?

54. In this dispute, the EC seems to agree that the adoption of 2001/18 did not restart the clock. To the contrary, the EC has explained that under its "interim approach," the EC in fact began to apply the 2001/18 requirements to 90/220 approvals well before the entry into force of Directive 2001/18. In addition, the United States submits that the adoption of EC Directive 2001/18 cannot restart the clock for purposes of determining whether approvals procedures are completed without "undue" delay. A finding to the contrary would undermine the obligation to complete approval procedures without "undue delay." In particular, since it is not uncommon to consider and adopt revisions to SPS approval procedures, finding that a revised procedure restarts the clock would permit a WTO Member to indefinitely postpone approvals by making frequent changes to its approval procedures.

37. With reference to Annex A(1) of the SPS Agreement, are the parties of the view that "procedures" and, more specifically, "approval procedures" are SPS measures? If so, are (approval) procedures as such subject to the requirements of Articles 2.2, 5.1, 5.5 and 5.6 of the SPS Agreement? Why? Why not? In answering this question, please include a discussion of the second clause of Article 8 ("otherwise ensure that […]") of the SPS Agreement and indicate which are the relevant "provisions of this Agreement".

55. The United States wants to make clear that this dispute is not about the EU's right to adopt an approval system. In this dispute, the United States is claiming that (1) the moratorium is inconsistent with the specific obligations in Annex C governing a Member's approval procedures, and (2) that the moratorium, in so far as it is a measure that has the result of barring the marketing and sale of all new biotech products, is a measure that is inconsistent with Articles 2.2, 5.1, and 5.5 of the SPS Agreement. The additional elements of the above question raise broad systemic issues that are not necessary to address in order to resolve this dispute.

38. With particular reference to the complaining parties' challenge to various member State safeguard measures under Article 5.5 of the SPS Agreement, please answer the following questions:

(a) Which is the relevant "Member" for the purposes of the Panel's analysis of the complaining parties' challenges? Is it: (i) the member State

applying the safeguard measure or (ii) the European Communities as a whole?

56. The United States considers the relevant Members to be both the European Communities as a whole and the individual member States applying the safeguards.

(b) Would it be permissible under Article 5.5 for an EC member State to apply within its territory, either permanently or provisionally, a higher level of protection than that which is applied in the rest of the European Communities?

57. The United States does not assert that an EC member State must apply the same level of protection as the EC as a whole. However, the mere fact that an EC member State has adopted a more restrictive SPS measure does not indicate that the member State has in fact applied a higher level of protection. To the contrary, as the United States understands the facts in this dispute and the operation of the EC "safeguard" provisions, the member States in this case are applying the same level of protection as the EC as a whole, and that the member State measures are not based on a risk assessment.

For all complaining parties:

39. Do the complaining parties agree with the statement at para. 17 of Norway's written submission that "modern biotechnology" refers to more than just "recombinant DNA" technology? Please explain what relevance, if any, this difference may have for the issues in this dispute.

58. The phrase "modern biotechnology" might be used to refer to more than just "recombinant DNA" technology. The measures addressed in this dispute, however, are applied with respect to agricultural products of recombinant DNA technology. Thus, as the United States indicated in footnote 2 of its first written submission, the United States used the phrase "modern biotechnology" to refer only to "recombinant DNA" technology. In any event, however, the term "modern biotechnology" is not a treaty term, and no issue in this dispute turns on the definition of this phrase.

40. Do the complaining parties agree with Norway arguments at paras. 130-131 of its written submission that risks associated with the use of antibiotic resistant marker genes do not fall within the scope of the SPS Agreement?

59. The United States believes that the risks Norway has identified with the use of antibiotic resistant marker genes are covered by the SPS Agreement.

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

61. Additionally, the antibiotic resistance gene falls within the definition of an additive under the SPS Agreement. The gene is a component of the food from the biotech plant; is not normally consumed as a food by itself; is not normally used as a typical ingredient of the food, and is intentionally added to the plant (and thus the food from the plant), for a technological purpose in the manufacture of the food. As such, protection against any associated human or animal health risks, such as either the development of antibiotic resistance or the development of the disease the antibiotics would be used to treat, falls within paragraph 1(b). For the same reason, products of resistance genes are also covered by the SPS Agreement.

41. Do the complaining parties agree with Norway's statement at para. 130 of its written submission that plant DNA is not an "organism" and that concerns related to effects on plant DNA do not fall within the scope of the SPS Agreement?

62. The United States would agree with Norway that plant DNA is not itself an "organism," but disagrees that concerns related to effects on plant DNA are therefore necessarily excluded from the scope of the SPS Agreement.

63. First, it is not necessary for plant DNA to be an organism for measures taken to protect against any increased risk of antibiotic resistance to fall within the scope of the SPS Agreement. As the Norwegian submission recognizes, plant DNA is part of the plant, which is undisputedly an organism within the scope of paragraph 1(a). Concerns relating to effects on plant DNA are essentially concerns about the potential effects of the altered plant. As discussed in the response to question 40, the antibiotic resistance gene falls within the SPS Agreement's definition of an additive, and protection against any associated human or animal health risks, such as either the development of antibiotic resistance or the development of the disease the antibiotics would be used to treat, falls within paragraph 1(b).

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

42. Do the complaining parties agree with Norway's assertion at para. 141 of its written submission that "[t]he situation which characterises the present dispute is therefore one where a lot of scientific research has been carried out on a particular issue without yielding reliable evidence"? (emphasis in the original) Please explain your views.

65. No. Norway's assertion is essentially that, because biotechnology is a relatively new technology, so much scientific uncertainty necessarily exists about the technology as a whole, that it is consequently impossible to reach defensible scientific conclusions or decisions about individual products. The United States strongly disagrees with this. As discussed in paragraphs 27-28 of the First U.S. Submission, several highly-regarded scientific bodies have considered the weight of the evidence in evaluating the considerable body of literature that exists with respect to the health and environmental safety aspects of biotech products, and have deemed it reliable enough to draw conclusions about the general health and environmental safety of existing biotech products and the methods that would be appropriate for evaluating future.

43. According to the European Communities, the processing of some applications was delayed due to exchanges deriving from the requests for voluntary commitments or amendments of the notifications so that the notifications would be in line with the requirements provided for by new legislation. For example, in respect of release into the environment, in the summer of 1999 a Common Position on the proposed modification of the Directive was adopted by the Council, and since then notifiers appear to have tried to address additional concerns contained in it. The European Communities cites similar cases in respect of the novel food legislation as well. However, there is no reference to these cases in the complaining parties' submissions. Do the complaining parties agree with the European Communities' account? If so, could they please explain their understanding

of these cases? Please explain the relevance of these cases to your belief that a de facto moratorium existed.

66. The United States has not claimed and does not claim that every single request for information by EC authorities amounts to "undue delay" under the SPS Agreement. Rather, the United States initiated this dispute because the EC adopted a nontransparent, unpublished moratorium on all biotech approvals, and proceeded to apply that moratorium up through the August 2003, when the terms of reference for this Panel were established. Thus, regardless of whether a particular product dossier includes exchanges between the applicant and EC authorities, under the EC moratorium no product was allowed to proceed to final approval.

67. The United States also notes that the EC, in making this argument, is trying to gain advantage in this dispute by relying on yet another breach of its WTO obligations. In particular, the EC has informed the Panel that under its "interim approach," the predicted requirements of unenacted EC legislation were imposed prospectively on all pending product applications. This change in the EC's approval procedures was not, as required under Article 7 and Annex B, notified and published. Having failed to meet its basic transparency obligations under the SPS Agreement, the EC cannot then argue that the complainants should have made note in their submissions of this unpublished measure making changes in the EC approval procedures.

44. Are the complaining parties making any claims in respect of a "failure to consider" applications (as opposed to a "failure to grant final approval" or a "failure to allow products to move to final approval")? If so, could they please indicate which, if any, of the applications referred to in their first written submissions and/or first oral statements in their view constitute instances of "failure to consider" and why?

68. The United States is not aware of a substantive distinction between a failure to consider and a failure to allow a product to move to final approval. In any event, Annex C(1)(A) requires that approval procedures be "undertaken and completed" without undue delay. And, in this case, the EC has not "undertaken and completed" its procedures without undue delay. To the contrary, the EC's adoption of a moratorium in which it has decided, without justification, not to make final decisions for an product for an indefinite period of time must amount to "undue delay" under Annex C(1)(A).

45. With reference to paras. 2 and 24 of the US first oral statement ("failure to allow products to move to final approval"), paras. 16 and 40 of Canada's first oral statement ("stalling and blocking of applications at key decision-making stages") and paras. 21 and 26 of Argentina's first oral statement ("un movimiento de tipo circular que nunca concluye en una aprobación"), can it be said that the complaining parties view the alleged moratorium essentially as a "decision not to decide", for an unspecified

period of time, with respect to any applications for approval, rather than as a "decision to decide negatively" with respect to any and all such applications?

69. The moratorium could be accurately described either as a "decision not to decide" or as a "decision not to grant final approval" for an indefinite period, lasting at least through the establishment of the panel and its terms of reference in August 2003. The EC both (1) did not reject any applications during this period, and (2) did not grant final approval during this period. The United States would like to emphasize, however, that the effect of the EC's decision "not to decide" was to keep all new biotech products off the EC market. Thus, although the EC did not formally reject any applications, the effect of the moratorium *vis-à-vis* market access during the period covered by this dispute was equivalent to the rejection of all applications for approval of new biotech products.

46. Are the complaining parties asserting that the alleged across-the-board moratorium led to "undue delays" with respect to all applications pending as of the date of establishment of this Panel, regardless of when these applications were submitted to the relevant member State authority?

70. Yes, the specific obligation under the SPS Agreement is for a Member to ensure that SPS procedures are "undertaken and completed without undue delay." By adopting an across-the-board moratorium on all approvals, no applications pending as of the date of panel establishment could be processed without "undue delay." An indefinite delay without justification cannot be considered anything other than "undue."

47. Using the analytical framework presented by Canada at paras. 19 to 26 of Canada's first oral statement, could the complaining parties indicate briefly how the European Communities has given effect to the alleged moratorium in respect of each of the relevant individual product applications? (see EC first written submission, p. 70 et seq)

71. The United States intends to address this issue, which entails a review of the voluminous EC exhibits containing the product application dossiers, in its rebuttal submission. Nonetheless, the United States has provided a preliminary response in Annex I to these answers.

48. With reference, inter alia, to paras. 285 to 297 of the EC first written submission, do the complaining parties consider that procedural delays would be justified in situations:

72. Before addressing each subpart of this question, the United States would like to reemphasize that the EC's moratorium – that is, its decision not to decide with respect to all pending applications – was adopted without any justification and must necessarily amount to "undue delay" under Annex C(1)(A). Thus, regardless of whether any particular product

application was delayed in part by any reason listed below (or for any other reason), each product application suffered "undue delay" because the EC had decided not to allow any application to proceed to a final decision.

(a) where they are caused by risk considerations which do not fall within the scope of Annex A of the SPS Agreement;

73. The EC has not shown that the moratorium and its resulting delays were justified by risks outside the scope of the SPS Agreement. Moreover, we are uncertain of the meaning of the term "risk considerations." As long as the approval procedure is within the scope of the SPS Agreement (and the EC apparently agrees that its Novel Foods regulation and Deliberate Release directive are within the scope of the SPS Agreement), the Member has an obligation to undertake and complete that procedure without undue delay, regardless of whether the Member also considers risks outside the scope of the SPS agreement.

(b) where they have been voluntarily accepted by the applicant;

74. The EC has not shown that the moratorium and its resulting delays were voluntarily accepted by any applicant. In fact, it is very difficult to conceive of an applicant "accepting" a delay in product approvals – the very reason that an applicant seeks approval is to be able to market its product in the EC, and any delay is prejudicial to an applicant.

75. The United States would also point out that the EC is incorrect in stating that information submitted by applicants in order to meet requirements of unenacted legislation was "voluntary." If, as the EC states, no application would be approved without such additional information, the submission of such information can hardly be called "voluntary." What the EC really means, perhaps, is that EC officials had no legal authority to request the information.

(c) where the entry into force of new legislation is imminent and the applications that are pending under the old legislation on the date of entry into force of the new legislation become subject to the stricter requirements of the new legislation;

76. The EC has not shown that the moratorium and its resulting delays were due to stricter requirements of the new legislation. Moreover, even if the EC adopted new approval procedures with new substantive requirements, it still had the obligation to undertake and complete those new procedures without "undue delay."

(d) where they are not attributable to a Member (e.g., where they have been caused by the applicant);

77. The EC has not shown that the moratorium and its resulting delays were not attributable to a Member, nor were caused by an applicant. To the contrary, the moratorium was adopted by

the EC. That said, the United States is not claiming that a WTO Member is in violation of Annex C(1)(a) where an applicant itself delays in providing information in response to a reasonable request for information issued by the Member's competent authority.

> **(e) where they are necessary in order to ensure compliance with existing legislation and relevant international standards (e.g., Codex Principles; see Exhibit EC-44);**

78. The EC has not shown that the moratorium and its resulting delays were necessary in order to ensure compliance with existing legislation and relevant international standards. In addition, the question of "ensuring compliance with existing legislation" is not dispositive of whether any delay is "undue." For example, if existing legislation required that a competent authority would not submit an application for final approval for five years, then the United States submits that such delay would be "undue." On the other hand, if the competent authority legitimately needed time to complete a risk assessment as required by existing legislation, the time needed for such a procedure probably would not amount to "undue delay."

79. With regard to "relevant international standards," the United States is not aware of any international standards that would result in any delays in approval procedures.

> **(f) where they result from efforts to elaborate monitoring requirements, adequate agricultural practices and similar efforts to manage SPS risks?**

80. The EC has not shown that the moratorium and its resulting delays were necessary in order to elaborate monitoring requirements, adequate agricultural practices and similar efforts to manage SPS risks.

> **Would any of the above situations justify (i) the alleged across-the-board moratorium and (ii) the alleged product-specific delays referred to in the complaining parties' submissions?**

81. As the United States explained in its first submission, and as it will further elaborate in its rebuttal submission, it does not consider that the EC has put forth any justifications for the delay in its approval procedures resulting from the moratorium.

> **49. With reference to paras. 440 and 441 of the EC first written submission, it appears that the European Communities is arguing, in effect, that the SPS Agreement would apply to a measure (a legal provision, etc.) to the extent that measure pursues SPS objectives as defined in Annex A(1) of the SPS Agreement, and that the TBT Agreement would simultaneously apply to that same measure (legal provision, etc.) to the extent that measure is a technical regulation which does not pursue SPS objectives. Do the**

complaining parties agree with this argument? In answering this question, please address the provisions of Article 1.5 of the TBT Agreement.

82. The United States does not understand or agree with the EC argument that, in the context of this dispute, the SPS Agreement applies to certain "aspects of a measure", and that the TBT Agreement applies to other "aspects of a measure." Nor does the EC explain how in this dispute a panel is to define or analyze an "aspect of a measure."

83. As the Panel notes in the above question, Article 1.5 of the TBT Agreement is quite clear in stating that the provisions of the TBT Agreement "do not apply" to SPS measures as defined in Annex A of the SPS Agreement. Annex A makes clear that "any measure" applied to protect against one of the enumerated risks falls within the scope the SPS Agreement. It does not state that the measure needs to be exclusively applied to protect against only the enumerated risks. Furthermore, the SPS Agreement does not say that an SPS measure -- meaning a measure addressed to a risk enumerated in Annex A -- somehow loses its status as an SPS measure if the adoption of the measure is also supported by other rationales. Thus, for example, even if the EC's Deliberate Release directive could be construed to cover some risks outside the scope of the SPS Agreement, the Deliberate Release legislation would still be an SPS measure**.**

50. With reference to Article 5.7 of the SPS Agreement, do the complaining parties agree with the European Communities that:

(a) Article 5.7 excludes the applicability of Article 5.1 and is not an exception (affirmative defence) to Article 5.1 (EC first written submission, para. 575)? In answering this question, please address the relevance of the Appellate Body Reports on Japan – Apples (footnote 316), EC – Hormones (para. 104) and EC – Sardines (para. 275) and Japan – Agricultural Products II (paras. 86 et seq)?

84. The United States does not agree that Article 5.7 "excludes the applicability" of Article 5.1. To the contrary, these two provisions must be read together. In *Japan Apples*, the Appellate Body elaborated on this connection between Article 5.1 and Article 5.7.

> The first requirement of Article 5.7 is that there must be insufficient scientific evidence. When a panel reviews a measure claimed by a Member to be provisional, that panel must assess whether "relevant scientific evidence is insufficient". This evaluation must be carried out, not in the abstract, but in the light of a particular inquiry. The notions of "relevance" and "insufficiency" in the introductory phrase of Article 5.7 imply a relationship between the scientific evidence and something else. Reading this introductory phrase in the broader context of Article 5 of the SPS Agreement, which is entitled "Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection", is instructive in ascertaining the nature of the relationship to be established. Article 5.1 sets out a key

> discipline under Article 5, namely that "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment . . . of the risks to human, animal or plant life or health". This discipline 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.[3]

Thus, the first inquiry in applying Article 5.7 must be to determine whether there is sufficient scientific evidence to perform a risk assessment as required under Article 5.1 and as defined in Annex A.

85. With regard to the issue of burden of proof, the United States is not arguing in this dispute that the defending Member has the burden of proof to show that Article 5.7 applies to a particular SPS measure. However, by showing that each of the products subject to a member State measure were subject to positive risk assessments by the EC's own scientists, the United States has met any burden of proof to show that scientific evidence was not "insufficient" and that Article 5.7 does not apply.

(b) Article 5.6 is not "relevant" where Article 5.7 applies (EC first written submission, para. 612)?

86. The United States does not agree that Article 5.6 is not relevant where Article 5.7 applies. The EC provides no basis for arguing that even a provisional measure should not be more trade restrictive than required to achieve the appropriate level of SPS protection.

(c) Article 5.7 "effectively" excludes Article 5.5 (EC first written submission, para. 618)?

87. The United States does not agree that Article 5.7 "effectively excludes" Article 5.5. Article 5.5 is addressed to arbitrary or unjustifiable discrimination in appropriate levels of SPS protection, while Article 5.7 does not even address the level of protection. The EC provides no basis for arguing that the adoption of a provisional measure excuses a WTO Member from its obligation not to engage in such arbitrary or unjustifiable discrimination.

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[3] *Japan-Measures Affecting the Importation of Apples,* WT/DS245/AB/R, para. 179.

(d) the sufficiency of relevant scientific evidence depends, inter alia, on a country's level of protection and the nature of the risks (e.g., reversibility of damage)? (see EC first written submission, paras. 605-606).

88. The United States does not agree that the "sufficiency of relevant scientific evidence" depends on the level of protection or the nature of the risks. In the *Japan-Apples* dispute, the Appellate Body rejected the idea that the application of 5.7 turns on the nature of the risk under examination:

> "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. 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.[4]

51. Concerning the complaining parties' claims in respect of the various member State safeguard measures, are those measures "cases where relevant scientific evidence is insufficient" within the meaning of Article 5.7 of the SPS Agreement?

89. No, the scientific evidence was not "insufficient." To the contrary, each of the products subject to a member State measure were subject to positive risk assessments by the EC's own scientists.

52. Do the complainants agree with the definition of "an adequate risk assessment" as put forward by the European Communities in the last sentence of para. 604 of its first written submission?

90. No, the United States does not agree with the EC's conception of an "adequate risk assessment." For example, there is no basis in the SPS Agreement for finding that a risk assessment must be "unequivocal," that it has "withstood the passage of time," or that it is "unlikely to be revised." In fact, in the *EC-Hormones* dispute, the Appellate Body rejected the idea that a risk assessment must resolve all possible uncertainties:

> In one part of its Reports, the Panel opposes a requirement of an "identifiable risk" to the uncertainty that theoretically always remains since science can *never* provide

[4] *Japan-Measures Affecting the Importation of Apples,* WT/DS245/AB/R, para. 179.

> *absolute* certainty that a given substance will not *ever* have adverse health effects. We agree with the panel that this theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed.[5]

Contrary to the EC's suggestion, the SPS Agreement already sets forth the requirements and definition of a risk assessment in Article 5.1 and Annex A.

For the United States:

> **73. The United States states at para. 163 of its first written submission that one of the justifications put forward by Italy for its suspension of the sale and use of four corn products relates to concerns about "occupational allergies to Bt bacterium spores in farmers using Bt pesticides". Does the United States consider that measures taken to protect farmers from "occupational allergies" are subject to the SPS Agreement? Please explain.**

91. The U.S. conclusion that the Italian decree is an SPS measure is in part based on the stated concern that the products could have adverse effects on consuming animals. A measure to protect against such a risk would clearly constitute a measure "to protect . . . animal life or health" from "toxins" and thus would fall within the scope of Section1(a) of the SPS Agreement Annex A definition of SPS measure.

92. The purpose for which the other report, suggesting the possibility of "occupational allerg[ies] to Bt bacterium spores in farmers using Bt pesticides," was cited by the Italian government is less clear. In the absence of any explanation, one possibility is that the Italian government was relying on this report of allergic reactions in farmers applying Bt microbial pesticides as an indication of a possible risk of allergic reactions from consumption of the engineered corn. An action to protect humans or animals who consume the corn from suffering allergic reactions constitutes a measure to "protect human life or health" from "toxins" in "foods" and thus would fall within the scope Annex A, paragraph 1(b) of the SPS Agreement. Additionally, to the extent the basis for the Italian decree was to protect farmers from occupational allergies in a plant used for food or feed, such a measure would also fall within the scope of paragraph 1(b). Paragraph 1(b) is not restricted to dietary risks, but includes any measure taken to protect human or animal life or health from "risks arising from...toxins...in foods...or feedstuffs." Measures taken to protect against occupational exposures from the Bt toxin in the corn would clearly fall within this description.

> **74. At para. 24 of the US first oral statement, the United States argues that "the EC has decided not to submit final decisions for a majority vote by**

[5] *EC – Hormones*, para. 186 (emphasis in original, footnote omitted).

the Commission". Please explain who in the European Communities made that decision (i.e., the Commission, certain member States, the Council, etc.?).

93. The decision not to submit final decisions for a majority vote by the Council (and failing a qualified majority, on to the Commission) appears to have been made by the unit within the Commission responsible for biotechnology matters. From statements made by relevant Commission officials, it appears that they well understood that the moratorium was not consistent with the WTO obligations of the Communities, but with a "blocking minority" of member States preventing approval under defined EC procedures, the Commission unit decided not to submit final decisions for a majority vote, knowing that a negative vote would have also been unsupported by risk assessment or sound science and, thus, by the Communities' WTO obligations.

75. With reference to paras. 138 and 139 of the US first written submission:

(a) Please explain for each individual application (those referred to in letters (a) through (d) of para. 138) why, in the United States' view, there has been an undue delay.

(b) In answering sub-question (a) above, please also indicate, based on the provisions of EC Directives 90/220 and 2001/18 and Regulation 258/97 what you consider to be the processing period that should have applied to the applications in question.

94. The EC's moratorium – that is, its decision not to decide with respect to all pending applications – was adopted without any justification and must necessarily amount to "undue delay" under Annex C(1)(A). Thus, regardless of whether any particular product application exhibited some progress or whether some delays might have been justifiable under Annex C(1)(A), each product listed in paragraphs 138 and 139 of the U.S. first submission was subject to the moratorium and thus subject to "undue delay" because the EC had decided not to allow any application to proceed to final decision.

95. In addition, as noted in the answer to Question 47 above, the United States plans to address the EC's product histories more fully in its rebuttal submission.

(c) Please provide support for the assertion that prior to the adoption of the alleged moratorium all approval procedures undertaken under EC Directive 90/220 were completed in less than three years.

96. Please see Annex II attached to these answers.

(d) With reference to sub-question (c) above, were all those procedures completed within the timelines provided for in EC Directive 90/220?

97. Directive 90/220 does not precisely specify the time of each step, but appears to contemplate a time-frame from application to decision of no more than 1 year.

76. Have there been instances in which applicants requested to be informed of the stage of the procedure and/or requested an explanation for any delays, but where these requests were denied or no response was provided?

98. As explained in paragraphs 96-97 of the U.S. First Submission, the EC's adoption of an unpublished, nontransparent moratorium on all biotech approvals is fundamentally inconsistent with the EC's transparency obligations under Annex C(1)(B).

77. With reference to paras. 157 to 159, 161 and 163 to 164, could the United States be more specific regarding which of the concerns/justifications cited by the various EC member States relate to risks or damage arising from the spread of "pests", from "disease-causing organisms", from "toxins", from "contaminants", and why? (E.g, under what heading(s) would the concern about insect resistance fall, and why? What is the relevant pest, disease-causing organism, etc.?)

99. The member State measures cite the following concerns: (1) the effects of Bt toxin on non-target organisms; (2) a concern that the ingestion of antibiotic resistant genes by humans and animals would cause the recipients to also develop resistance; (3) the potential for insects to develop resistance to the Bt toxin, and thus, become more difficult to manage and control; (4) concern over the impact on agriculture, the environment, and consumer health, from the genetic escape and the spread of herbicide tolerance to other plants. These risks all fall within the scope of the SPS Agreement.

(1) Effects of the Bt toxin on non-target animals.

100. As noted in the response to Question 34, a pest is defined as "any thing or person that is noxious, destructive, or troublesome." *The Compact Oxford English Dictionary*, 1971, page 2145. Thus, any Bt crop presenting a risk to non-target organisms could be considered to be a "pest" within the meaning of the SPS Agreement, pursuant to Annex A, paragraph 1(a).

(2) Ingestion of antibiotic resistant genes would lead to the spread of antibiotic resistance.

101. As noted in the response to questions 40 and 41, the stated concern is that the antibiotic resistance gene would be transferred from the plant to a human or animal pathogen in the digestive tract of a human or animal consuming food from the plant. For an animal infected with

the pathogen that would ordinarily be treated with the antibiotic to which the pathogen had become resistant, the transfer of the resistance gene would "contribute to the establishment and spread of disease"--the disease caused by the now resistant pathogen—a risk that clearly falls within paragraph 1(a). Similarly, for the human infected with the antibiotic-resistant pathogen, the transfer of the resistance gene would be a risk "arising from a…disease-causing organism in foods," which would fall under paragraph 1(b).

102. Alternatively/additionally, the antibiotic resistance gene falls within the definition of an additive. The gene is a component of the food from the biotech plant; is not normally consumed as a food by itself; is not normally used as a typical ingredient of the food, and it intentionally added to the plant (and thus the food from the plant), for a technological purpose in the manufacture of the food. As such, protection against any associated health risks falls within paragraph 1(b).

(3) Potential for insects to develop resistance to Bt

103. The articulated concern here is that, as insect populations become resistant to the less toxic pesticide Bt, more toxic pesticides would need to be applied to control the pest, causing greater environmental damage. In this instance, the pest would be the Bt crop, which indirectly causes an increased potential for risks to animal or plant life or health. Such risks are clearly covered by the SPS Agreement.

104. In this regard, it is worth noting two IPPC standards that address this point. Section 2.3.1.2 of ISPM 11, Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks, describes some of the potential "indirect pest effects" that can be considered in determining whether an organism is a quarantine pest: "environmental and other undesired effects of control measures feasibility and cost of eradication or containment" (page 19).

105. In addition, the recent IPPC revisions to ISPM 11, tailoring the existing standard to address biotech crops ["living modified organisms"] includes the following:

> Annex 3, "DETERMINING THE POTENTIAL FOR A LIVING MODIFIED ORGANISM TO BE A PEST"
>
> Potential phytosanitary risks for LMOs may include:
>
> a. Changes in adaptive characteristics which may increase the potential for introduction or spread, for example alterations in:
>
> - tolerance to adverse environmental conditions (e.g. drought, freezing, salinity etc.)
> - reproductive biology

- dispersal ability of pests
- growth rate or vigour
- host range
- pest resistance
- pesticide (including herbicide) resistance or tolerance.

(Emphasis added.)

(4) Effects on agriculture, the environment, and consumer health from the spread of herbicide tolerant genes to other plants.

106. There are essentially two SPS-related concerns at issue here. First, the stated concern is that, assuming the two species are growing in proximity, herbicide tolerance genes from a crop plant might cross-breed with wild relatives or other sexually-compatible plants and transfer the herbicide-tolerant gene. While most studies to date indicated that the plants containing these herbicide tolerance genes do not have increased fitness characteristics that would lead to increased invasiveness, the concern has been raised that the herbicide tolerant gene would confer a selective advantage on the off-spring. One resulting risk, should that occur, would be that the herbicide-tolerant offspring would eventually eliminate the existing flora, or otherwise result in a loss of biological or genetic diversity, either in the plant species, or by affecting the larger ecosystem. In the event of such a circumstance, the herbicide-tolerant plant would present a risk of "invasiveness," or "weediness," and thereby meets the definition of a pest under the SPS agreement. A second category of risks would be that, if the resulting herbicide tolerant offspring results in an increased use of herbicides, it would thereby increase the risks to flora, fauna, and consumer health. The risks to flora and fauna fall within Annex A paragraph 1(a)--risks to "animal or plant life or health arising from the…establishment or spread of pests," while the risks to consumer health would fall within paragraph 1(d)—"other damage within the territory of the Member from the…establishment or spread of pests."

107. Here as well, it is worth noting two IPPC standards that address this point. Sections 2.3.1.1 and 2.3.1.2 of ISPM 11, describes some of the potential effects that can be considered in determining whether an organism is a quarantine pest:

> In the case of the analysis of environmental risks, examples of direct pest effects on plants and/or their environmental consequences that could be considered include:
>
> - reduction of keystone plant species
> - reduction of plant species that are major components of ecosystems (in terms of abundance or size), and endangered native plant species (including effects below species level where there is evidence of such effects being significant)

- significant reduction, displacement, or elimination of other plant species.

Specified examples of indirect pest effects on plants and/or their environmental consequences to be considered include:

- significant changes in ecological processes and the structure, stability or processes of an ecosystem (including further effects on plant species, erosion, water table changes, increased fire hazard, nutrient cycling, etc.)

(Page 19.) In addition, the recent IPPC revisions to ISPM 11, tailoring the existing standard to address biotech crops ["living modified organisms"] include the following:

> Annex 3, "DETERMINING THE POTENTIAL FOR A LIVING MODIFIED ORGANISM TO BE A PEST"
>
> Potential phytosanitary risks for LMOs may include:…
>
> 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.

SECOND SET OF QUESTIONS FROM THE PANEL

For all complaining parties:

4. Is there any scientific disagreement on the part of the co-complainants with the scientific arguments and facts submitted by the EC (including the member States)?

108. The United States will answer the panel's question in two ways – first, quite literally, and then in a more focused manner, based on the intent of the question.

109. First, on whether the United States has any scientific disagreements with the EC, there may well be some. The United States is in the process of preparing its rebuttal submission, and had planned in that time frame to decide whether to take issue with some of the scientific statements of the EC. Given the length of the EC submission, the United States cannot compress that time frame and give a definitive answer at this time. However, as the Panel will note, in the U.S. oral statements and interventions to date, the United States has not taken issue with any scientific statements of the EC. This is because, to the knowledge of the United States, no dispositive issue in this dispute turns on a scientific issue.

110. Second, the United States would like to answer the Panel's question based on what we understand to be the intent of the question. Namely, are there dispositive scientific issues with respect to which the advice of scientific experts would be of assistance to the panel? As of this time, the United States has not been able to identify any such issues. As the United States has explained, in our view, the central issue in this dispute is that the EC announced and applied an across-the-board moratorium on biotech approvals. The adoption of this nontransparent measure results in "undue delay" under Annex C; is inconsistent with its obligations to publish measures promptly and to keep applicants informed of the progress of applications; is not based on a risk assessment as required under Article 5.1; and results in arbitrary or unjustifiable distinctions in the EC's chosen levels of protection.

– With regard to the general moratorium and product-specific moratoria, the EC's only defense is that the moratoria in fact never existed and that with respect to individual applications, the lengthy delays are not "unjustified." But, whether the EC's moratorium is a "measure" and thus subject to the disciplines of the SPS agreement is a legal, not a scientific question.

– Similarly, the question of whether delays are "unjustified" under the SPS Agreement also is a legal, not scientific question. The EC seems to be arguing that scientific concerns justified certain delays. But whether or not this is true for particular applications is not dispositive, because under the EC moratorium no products were allowed to reach final decision, regardless of the underlying science. This is clearly shown by, among other things, the fact that product

applications were stalled for over two years by nothing more than "interservice consultations."

– Even aside from this fundamental problem with the EC argument, the United States has not identified any scientific issues that would be pertinent to the question of undue delay. In particular, science may identify and analyze risks. Indeed, the EC completed risk assessments on many of the pending applications. But once the risks have been identified, it is up to the decisionmaker, not the scientist, to decide when to take a decision on the application.

– As the Panel is aware, in past disputes involving the SPS Agreement experts have been consulted to advise on issues related to the scientific basis for a Member's identification of risks and how this has been reflected in the Member's risk assessments. But in this dispute, the EC has put forward no risk assessment in an attempt to justify its moratorium.

– With respect to the member State measures, again the United States does not see any question that would call for scientific advice. The EC has claimed that risk assessments may support the member State measures, but it has not yet identified those assessments.

FURTHER COMMENTS ON TERMS OF REFERENCE FOR POSSIBLE SCIENTIFIC AND TECHNICAL ADVICE

111. The United States appreciates that the Panel has provided the complaining parties with an additional opportunity to comment on terms of reference for scientific and technical advice, in the event that the Panel should decide to seek such advice. At this time, however, the United States has little to add to its comments filed on June 8, 2004. As stated in those comments, the United States has not identified as of this time any dispositive scientific issues with respect to which the advice of scientific experts would be of assistance to the panel. The United States also agrees with the EC that if scientific questions should develop that are pertinent to the resolution of this dispute, it is not possible to identify precisely at this stage of the proceedings what those questions might be. The United States also notes that the EC apparently intends to submit a large volume of information on June 18, 2004, and that the content of that information may be relevant with respect to the terms of reference for possible scientific and technical advice.

QUESTIONS BY THE EUROPEAN COMMUNITIES TO THE COMPLAINANTS

A. To All

Question 1

Is it the position of the Complainants that new scientific information which emerges after a scientific committee opinion should be disregarded? How should a regulator react to a situation where sources of information other than appointed scientific committees report the existence of a risk in connection with a given product? Could you indicate the basis for your position in the relevant WTO agreements?

112. In all the cases described above, the regulator of the WTO Member must undertake and complete its approval procedures without "undue delay." See SPS Agreement, Annex C(1)(A). The EC has not shown that any of the scenarios in the above question justified the delays resulting from its moratorium on biotech approvals.

Question 2

Once a WTO Member has adopted an appropriate level of protection, is it allowed to change its mind and adopt a higher one?

113. Yes. The United States would note, however, that a change in the level of protection would not justify the adoption of a general moratorium on all biotech approvals.

Question 3

In a federal entity, have sub-entities the right to have different appropriate levels of protection? If you do not agree, could you indicate the basis for your position in the SPS Agreement?

114. Please see answer to Question 38(b) of the Panel**.**

Question 3 [second question so numbered in this section]

What would it take in your opinion for the alleged moratorium to be removed? Would the European Communities have to grant one more approval, ten more approval, or how many? Would the European Communities have to stop asking for more information under the approval procedures? Would all MS have to vote in favour of proposals to grant

authorisations for the products at issues in the Regulatory Committees and in the Council? (see paras. 24 and 27 of the oral statement of Canada)

115. As the United States explained during the first substantive meeting of the Panel, questions of compliance are not within the Panel's terms of reference. Moreover, once the Dispute Settlement Body has adopted a finding that a WTO Member is in breach of its WTO obligations, it is up to the defending Member to decide how it wishes to come into compliance with its obligations. That said, the United States would expect that in order for the EC to bring its measures into compliance with its obligations under the SPS Agreement, the EC would have to make decisions on agricultural biotech applications without undue delay.

C. Questions to Canada and the United States

Question 1

Please explain why you notified the following measures under both the SPS Agreement and the TBT Agreement:

for Canada: Living Modified Organisms Regulations, document G/TBT/N/CAN/46 of 14 October 2002 and document G/SPS/N/CAN/144 of 4 October 2002;

for the United States: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, document G/TBT/N/USA/32 of 13 February 2003 and document G/SPS/N/USA/691 of 6 February 2003.

116. The United States notified its Prior Notice of Imported Food, Administrative Detention, and Records proposed rules only under the SPS Agreement, because the rule is designed to address SPS risks, such as risks arising from contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs. FDA notified its Registration of Food Facilities proposed rule under both the TBT and SPS agreements, because registration would be used to address both SPS issues, such as food safety, and TBT issues, such as many food labeling requirements.

E. Question to the United States:

Question 1

If a declaration of political intent by five EU ministers constitutes a measure that may constitute a violation of the WTO Agreement on the part of the European Communities, would the same be true of a declaration by 60 Members of the US Congress that they would block any attempt to not repeal

the Byrd amendment also constitute a violation by the US of its obligation to implement the Panel report in that case?

117. The premise of the question is false. The United States did not argue that the "declaration of political intent," standing alone, constitutes a measure. Rather, the United States submits that the EC in fact adopted a moratorium on biotech approvals, and that the declaration of the five EU ministers is compelling evidence of the existence of that measure. Other compelling evidence, as the United States has explained, includes the fact that the EC followed through on this declaration and failed to allow any biotech product application to move to final approval for over five years.