ANNEX D

REPLIES BY THE PARTIES TO QUESTIONS POSED BY THE PANEL IN THE CONTEXT OF THE FIRST SUBSTANTIVE MEETING

ANNEX D-1

REPLIES BY THE UNITED STATES TO QUESTIONS POSED BY THE PANEL IN THE CONTEXT OF THE FIRST SUBSTANTIVE MEETING

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*

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

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 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 US regulatory systems in pages 27-36. As a preliminary matter, the United States notes that this dispute is not about the US 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 US system is not relevant to this dispute.

8. The United States notes that the only description of the US regulatory system in pages 27-36 of the EC's submission occurs in paragraphs 75 and 86, and this characterization is inaccurate. The

US system is most certainly not "laissez-faire." To the extent that this characterization is intended to imply that biotech products on the US 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 US regulatory system. Regulation of biotech products in the United States is divided between several regulatory agencies– primarily the US Department of Agriculture (USDA), the US 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}
>
> > "[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 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;

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

> *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

– effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)

– capacity to vector other pests

– negative direct or indirect effects of plant-produced pesticides on non-targetorganisms beneficial to plants.

(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 US 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.

(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

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

> "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 *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.

<u>For the United States</u>:

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 US 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

[4] *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, para. 179.
[5] *EC – Hormones*, para. 186 (emphasis in original, footnote omitted).

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 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 US 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 US 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:
>
> – <u>transfer of pesticide or pest resistance genes to compatible species</u>

– 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.

ANNEX I

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)

Paragraph No. in EC Written Submission	*Product*	*Applicable Legislation*	*Stages 1 & 2 Competent Authority Review*	*Stage 3 Circulation to Member States*	*Stage 4 Regulatory Committee Vote*	*Stage 5 Council Decision*	*Stage 6 Consent to placing on the market*
202	**C/DE/96/05 Bayer OSR Falcon**	**90/220**		**Circulation to MS Nov.96**	**No vote in Reg.Cttee**		
209	**C/BE/96/01 Bayer OSR MS8**	**90/220**		**Circulation to MS Jan 97**	**No vote in Reg. Cttee**		
216	C/DK/97/01 Monsanto RR Fodder Beet	90/220			Despite ... - positive MS opinion (7 Oct.1997), and - positive SCP opinion (23 June 1998), and - Applicant responds to all MS questions (27 Apr.1998): Commission failed to submit measure for vote by Regulatory Committee		
222	C/ES/96/02 Monsanto Bt Cotton (531)	90/220			Regulatory Committee vote held on 11 Feb. 1999. No qualified majority necessary for adoption of Commission's proposed measure approving product.	Despite... - positive MS opinion (19 Nov.1997), and - positive Scientific Committee opinion (14 July 1998), and - 11 Feb.1999 vote in Regulatory Committee with no outcome: AND legal obligation to forward to Council "without delay" under Art.21 of 90/220 Commission failed to submit to Council	

Paragraph No. in EC Written Submission	*Product*	*Applicable Legislation*	*Stages 1 & 2 Competent Authority Review*	*Stage 3 Circulation to Member States*	*Stage 4 Regulatory Committee Vote*	*Stage 5 Council Decision*	*Stage 6 Consent to placing on the market*
229	C/ES/97/01 Monsanto RR cotton (RRC1445)	90/220			Regulatory Committee vote held on 11 Feb. 1999. No qualified majority necessary for adoption of Commission's proposed measure approving product.	Despite... - positive MS opinion (19 Nov.1997), and - positive Science Committee opinion (14 July 1998), and - 11 Feb.1999 vote in Regulatory Committee with no outcome: AND legal obligation to forward to Council "without delay" under Art.21 of 90/220 Commission failed to submit to Council	
235	C/SE/96/3501 Amylogene Starch Potato	90/220		Circulation to MS June 98	**No vote in Reg. Cttee**		
239	C/D/98/06 Bayer OSR Liberator	90/220		Circulation to MS 98/99	**No vote in Reg. Cttee**		
244	C/F/96/05-10 Syngenta HT/Bt11 stack	90/220		Circulation to MS May.99	**No vote in Reg. Cttee**		
254	C/NL/98/11 Monsanto RR OSR (GT73)	90/220	Total time for CA review: 54 months (7.Jul 1998 to 22.Jan.2003) Time taken by Applicant to respond to questions: 12 months **Difference: 32 months instead of 90 days (Art. 12 of 90/220)** (note that 10 were taken to resolve confidentiality issues in relation to detection methods)	MS review was completed on 6 Oct.2003	EFSA scientific review completed 11 Feb.2004 Regulatory Committee vote expected 16 June 2004		
258	C/BE/98/01 Bayer LL Soybeans	90/220	still at MS level				
264	C/GB/99/M5/2 Bayer LL OSR	90/220	still at MS level				
266	C/ES/99/01 Stoneville BXN Cotton	90/220	still at MS level				

Paragraph No. in EC Written Submission	*Product*	*Applicable Legislation*	*Stages 1 & 2 Competent Authority Review*	*Stage 3 Circulation to Member States*	*Stage 4 Regulatory Committee Vote*	*Stage 5 Council Decision*	*Stage 6 Consent to placing on the market*
270	C/NL/00/10 Pioneer/Dow BtCorn Cry1F	90/220		Circulation to MS after Aug. 03	**No vote in Reg. Cttee**		
275	C/ES/01/01 Pioneer Dow BtCorn Cry1F	90/220		Circulation to MS after Aug. 03	**No vote in Reg. Cttee**		
279	C/ES/00/01 Monsanto RR corn (NK603)	90/220	Total time for CA review: 25 months Time taken by Applicant to respond to questions: 13 months **Difference: 12 months instead of 90 days (Art. 12 of 90/220)**		Regulatory Committee vote held on 18 Feb. 2004. No qualified majority necessary for adoption of Commission's proposed measure approving product.	Proposed measure has been submitted to Council –expected vote at 28 June 2004 ENV Council	
285	C/NL/94/25/A Bejo Zaden withdrawn	90/220					
286	C/ES/98/01 Monsanto RR corn (GA21) Withdrawn: 15 Sept. 2003	90/220			*Despite ...* - positive MS opinion (27 May 1998) - applicant answers all MS questions (21Oct.1999) - positive SCP opinion (22. Sep. 2000), - completed MS consultation - reduction of scope by applicant to exclude cultivation and progress less controversial import only (21 Mar.2001): Commission failed to submit measure for vote by Regulatory Committee		
287	C/F/95/06/01 Monsanto RR OSR (GT73) Withdrawn: 15 Jan.2003	90/220	Competent Authority refused to consider or respond since Feb.1996 (date of last request for information to applicant **Total Time: more than 100 months**				
288	C/ES/98/02 Syngenta Bt11 withdrawn	90/22ß	MS review not completed				
289	C/PT/99/01 Bayer LL Soya withdrawn	90/220	MS review not completed				

Paragraph No. in EC Written Submission	*Product*	*Applicable Legislation*	*Stages 1 & 2 Competent Authority Review*	*Stage 3 Circulation to Member States*	*Stage 4 Regulatory Committee Vote*	*Stage 5 Council Decision*	*Stage 6 Consent to placing on the market*
290	C/ES/99/02 Monsanto MaisGard x RR corn (MON810 x GA21) stack Submitted: 3 Sept. 1999 Withdrawn: 15 Sept. 2003	90/220	In the light of legal uncertainty caused by the moratorium, the applicant was unable to devote resources to respond to the questions posed by the MS CA in a timely fashion.				
291	C/F/95/12-01/B Pioneer MON809 withdrawn	90/220	MS review done	Circulation to MS	no vote		
292	C/ES/96/01 Zeneca Tomato	90/220	MS review done	Circualtion to MS	no vote		
293	C/GB/97/M3/2 Monsanto RR corn (GA21) Submitted: 6 Nov. 1997 Withdrawn: 29 March 2001	90/220	Total time for CA review: 15.5 months (6 Nov1997 – 23 Mar. 1999) CA ready to forward dossier to Commission with positive opinion (16.Feb.1999); requests updated dossier, which was submitted by applicant on 23. Mar.1999) MS failed to forward dossier to Commission for another 7.5 months (2 Nov.1999)		Commission fails to submit measure to Regulatory Committee after completion of MS consultation on 18 Feb.2000		
294	C/NL/98/08 Pioneer T25 x MON809 withdrawn	90/220	MS review done	Circulation to MS	no vote		
295	C/NL/98/09 Pioneer HighOleic Soy	90/22ß	MS review not completed				

Paragraph No. in EC Written Submission	*Product*	*Applicable Legislation*	*Stages 1 & 2 Competent Authority Review*	*Stage 3 Circulation to Member States*	*Stage 4 Regulatory Committee Vote*	*Stage 5 Council Decision*	*Stage 6 Consent to placing on the market*
296	C/BE/99/01 Monsanto /Syngenta RR sugar beet Submitted: 22 Dec.1998 Withdrawn: April 2004	90/220	MS CA fails to complete review, thereby exceeding 90 day limit by several years. April 1999, Nov.2000 and Jan.2001 MS CA requests applicant to "voluntarily" comply with 2001/18 (despite fact that 2001/18 would not be in force until Oct.2002), saying that Commission and Member States would otherwise oppose dossier.				
297	AgrEvo T14 withdrawn	90/220	MA review not completed				
298	C/F/95/01A Bayer Crop Science Ms1xRf1 Canola/Oilseed Rape	90/220					Commission Decision 97/392/EC consents to placing on the market. MS refuses to issue consent letter
298	C/F/95/01B Bayer Crop Science Ms1xRf2 Canola/Oilseed Rape	90/220					Commission Decision 97/393/EC consenting to placing on the market. MS refuses to issue consent letter
301	Monsanto RR corn (GA21) Submitted 24 July 1998	258/97	Total time for CA review: 18 months (24 July 1998 to 17 Jan. 2000) Time taken by applicant to respond to questions: 8 months **Difference: 10 months instead of 90 days (Art. 6(3) 258/97)**		SCF review takes 17 months out of which one month can be attributed to applicant – considered to be excessive Commission fails to submit measure to Regulatory Committee after completion of MS consultation on 18 Feb.2000		
305	Syngenta Bt11 Sweet Corn	258/97					approved 2004
310	Bayer LL Soybeans	258/97	MS review not completed				

Paragraph No. in EC Written Submission	*Product*	*Applicable Legislation*	*Stages 1 & 2 Competent Authority Review*	*Stage 3 Circulation to Member States*	*Stage 4 Regulatory Committee Vote*	*Stage 5 Council Decision*	*Stage 6 Consent to placing on the market*
314	Monsanto MaisGard & RR corn (MON810 x GA21) stack Submitted: 16 Mar.2000	258/97	In the light of legal uncertainty caused by the moratorium, the applicant was unable to devote resources to respond to the questions posed by the MS CA in a timely fashion.				
317	Pioneer BtCorn Cry1F	258/97	MS review completed	Circulation to MS	no vote		
322	Monsanto RR corn (NK603) Submitted: 24 Apr. 2001	258/97	Total time for CA review: 18 months (24 Apr. 2001 to 5 Nov. 2002) Time taken by applicant to respond to question: 3.5 months (13 Dec.2001 to 28 Mar.2002) **Difference: 14.5 months instead of 90 days (Art. 6(3))**		Regulatory Committee vote held on 30 April 2004. No qualified majority necessary for adoption of Commission's proposed measure.		
328	Bejo-Zaden Radicchio withdrawn	258/97					
329	Bejo-Zaden Chicory withdrawn	258/97					
330	Pioneer High Oleic Soya withdrawn	258/97					
331	Zeneca Tomato	258/97					
332	Pioneer T25 x MON810	258/97					
333	Monsanto/ Syngenta RR sugar beet (77) Submitted: 3 Nov.1999 Withdrawn: 16 April 2004	258/97	In the light of legal uncertainty caused by the moratorium, the applicant was unable to devote resources to respond to the questions posed by the MS CA in a timely fashion.				

Paragraph No. in EC Written Submission	*Product*	*Applicable Legislation*	*Stages 1 & 2 Competent Authority Review*	*Stage 3 Circulation to Member States*	*Stage 4 Regulatory Committee Vote*	*Stage 5 Council Decision*	*Stage 6 Consent to placing on the market*
337	Monsanto MON863 X MON810 Submitted : 13 Aug 2002	258/97	Product is moving according to the rules.				

ANNEX II

Approvals under 90/220 prior to the Moratorium

Note: Unless indicated otherwise, the application number for each product indicates the year that the application was submitted. E.g., Application C/D/92/I-1 was submitted in 1992.

1. Vaccine against Aujeszky's disease
C/D/92/I-1 approved 18.12.92 completed in less than 3 years

2. Vaccine against rabies Rhône-Mêrieux
C/B/92/B28 & C/F/93/03-02 approved 19.10.93 completed in less than 3 years

3. Tobacco tolerant to bromoxynil
C/F/93/08-02 approved 08.06.94 completed in less than 3 years

4. Vaccine against Aujeszky's disease (further uses)6
C/D/92/I-1 approved 18.07.94 completed in less than 3 years

5. Male sterile swede rape resistant to glufosinate ammonium (MS1, RF1)
C/UK/94/M1/1 approved 06.02.96 completed in less than 3 years

6. Soybeans tolerant to glyphosate Monsanto
C/UK/94/M3/1 approved 03.04.96 completed in less than 3 years

7. Male sterile chicory tolerant to glufosinate ammonium
C/NL/94/25 approved 20.05.96 completed in less than 3 years

8. Bt-maize tolerant to glufosinate ammonium (Bt-176) Ciba-Geigy
C/F/94/11-03 approved 23.01.97 completed in less than 3 years

9. Test kit to detect antibiotic residues in milk Valio Oy
C/F1/96-1NA approved 14.07.97 completed in less than 3 years

10. Carnation lines with modified flower colour Florigene
C/NL/96/14 approved 01.12.97 completed in less than 3 years
(MS consent)

11. Swede rape tolerant to glufosinate ammonium (Topas 19/2)
C/UK/95/M5/1 approved 22.04.98 completed in less than 3 years

12. Maize tolerant to glufosinate ammonium (T25) AgrEvo
C/F/95/12/07 submitted June 96, approved 22.04.98 completed in less than 3 years

13. Maize expressing the Bt cryIA(b) gene (MON 810) Monsanto
C/F/95/12-02 submitted June 96, approved 22.04.98 completed in less than 3 years

14. Maize tolerant to glufosinate ammonium and expressing the Bt cryIA(b) gene (Bt-11)
C/UK/96/M4/1 approved 22.04.98 completed in less than 3 years

15. Carnation lines with improved vase life Florigene
C/NL/97/12 approved 20.10.98 completed in less than 3 years

16. Carnation lines with modified flower colour Florigene
C/NL/97/13 approved 20.10.98 completed in less than 3 years

ANNEX D-2

REPLIES BY CANADA TO QUESTIONS POSED BY THE PANEL IN THE CONTEXT OF THE FIRST SUBSTANTIVE MEETING

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. The Panel must make its findings and conclusions regarding whether the EC was in violation of its WTO obligations as of the date of establishment of the Panel, August 29, 2003.

2. To the extent that facts that occurred after the date of establishment of the Panel are relevant to the determination of whether the EC was in violation of its WTO obligations as of August 29, 2003, the Panel should consider those facts. For instance, if after the date of establishment of the panel, an EC official stated that the "moratorium has been lifted" in 2004, the fact that the statement was made could serve as evidence of the existence of the moratorium as of 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?

3. Both definitions could be appropriate. The first definition of risk assessment in Annex A, paragraph 4, applies to assessments of risks posed by pests or diseases. The second definition applies to risks to human or animal health of the sort identified in sub-paragraph 1(a) of Annex A. The definition of risk assessment in Annex A that would be appropriate to evaluate the risks of biotech products therefore would depend on the nature of the risk being assessed. To the extent that the EC approval procedures are applied to protect human or animal life or health from risks falling within paragraph 1(b) of Annex A, these approval procedures would fall within the second category of risk assessments. For example, as Regulation 258/97 is applied to protect human life or health from risks arising from contaminants and toxins in food, an assessment of these risks would fall within the second category.

4. To the extent that the EC approval procedures are applied to protect against risk falling within paragraphs 1(a), (b) and (d) of Annex A, the first definition of risk assessment in Annex A, paragraph 4 would apply. For example, Directive 2001/18 is applied, in part, to protect animal or plant life or health from risks arising from the entry, establishment or spread of pests. A risk assessment respecting these risks would be covered by the first definition of risk assessment in Annex A, paragraph 4. However, to the extent that Directive 2001/18 is applied to protect animal life or health from risks arising from contaminants or toxins in feedstuff, a risk assessment respecting these risks would be covered by the second definition in Annex A.

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

5. Canada does not consider food allergens to be "toxins" or "disease-causing organisms". However, a food allergen could be considered a "contaminant" under the *SPS Agreement* where the presence of the food allergen in a food is unintentional. This would be the case, for example, where

the genetic modification results in the unintended presence or creation of a substance with allergenic properties. Canada elaborates on this in its answer to Question 27.

6. The *SPS Agreement* sets out obligations in respect of sanitary measures related to food safety. The presence of allergens in foods is squarely a food safety issue. It could not have been the intention of the drafters of the *SPS Agreement* to exclude such an important aspect of food safety assessment from the scope of the *SPS Agreement*. Excluding allergens would lead to the irrational result that food safety measures applied to protect human life or health from risks of certain substances that affect the population as a whole (i.e. toxins) would fall within the *SPS Agreement* while food safety measures applied to protect human life or health from risks of certain substances that affect only a sub-set of the population (i.e. food allergens) would not.

7. International organizations, such as the FAO and WHO, have recognized the assessment of possible allergenicity as one element of the recommended food safety assessment for biotech products.[1] The EC includes the assessment of allergenicity potential in its food safety procedures under Regulation 258/97 as set out in Commission Recommendation 97/618/EC.[2]

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?

8. With the possible exception of the *International Plant Protection Convention, 1979* ("IPPC 1979"), there are no binding internationally law instruments relevant to this case.

9. In accordance with Article 11 of the *Dispute Settlement Understanding*, a panel must assess the applicability of the covered agreements and the conformity with those agreements of the measures of the Member complained against. Pursuant to Article 3.2 of the DSU, a panel is to interpret the covered agreements "in accordance with the customary rules of interpretation of public international law." These customary rules of interpretation are codified in the Vienna Convention on the Law of Treaties (VCLT). The Panel in this case is bound to apply these rules, as codified in the VCLT for the purposes of interpreting the relevant covered agreements.

10. For other binding international law instruments to be relevant to the assessment of a WTO Member's conformity with its obligations under the covered agreements, it would have to be shown that these other instruments: (a) are relevant to the interpretation of those obligations in accordance with Articles 31 or 32 of the VCLT; (b) are successive treaties relating to the same subject matter consistent with Article 30 of the VCLT; (c) amend or modify the covered agreements in accordance with Part IV of the VCLT; or (d) are deemed relevant by the covered agreements themselves. With the exception of the IPPC, no other binding international law instruments qualify as relevant under any of these four categories.

11. Canada notes that the *International Plant Protection Convention, 1997* ("IPPC 1997"), cited by the EC at paragraph 410 of its written submission, is not currently in force. The IPPC 1997 embodies amendments to the IPPC 1979. While Canada, Argentina and the United States, as well as several EC Member States, have deposited instruments of acceptance of the amendments, the requisite two-thirds of contracting parties of the IPPC 1979 has not yet been reached in order for IPPC 1997 to take effect.

[1] Exhibit EC-44, p. 53.
[2] Exhibit CDA-24, Article 3.10 ("Allergenic Potential").

12. The IPPC 1979, which is in force, is a "binding international legal instrument". Canada, Argentina and the United States, together with most of the EC Member States, have either ratified or adhered to the IPPC 1979.

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))?

13. It is understandable in the circumstances that companies withdrawing notifications did not cite undue delays in the processing of applications as reasons for the withdrawal. As companies have an interest in maintaining a good working relationship with the regulatory authorities responsible for approving their products, it is reasonable to expect companies to act with circumspection. The absence of specific reference to undue delay does not imply that undue delay was not the cause of the withdrawal. Many companies have cited "commercial reasons" for withdrawing their applications. Given rapid advancements in the field of biotechnology, protracted delays in an approval process may cause products submitted for approval in 1998 to become obsolete. Also, given the considerable time and financial resources necessary to support an application, it may not be commercially justified to proceed with the application in the face of the legal uncertainty created by the moratorium. The sheer number of withdrawals (thirteen under Directives 90/220 and 2001/18 and six under Regulation 258/97) is evidence of the dramatic impact the moratorium has had on the trade in biotech products in the EC.

14. Nor can the silence of the applicants be taken as evidence of satisfaction with the process; they are just as likely to be concerned about maintaining good relations with the regulators, and may feel constrained in voicing complaints for fear, whether legitimate or not, that future applications will be unfairly treated.

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?

15. The EC does not describe the Canadian regulatory system anywhere in its submission. The only paragraph that might be seen to depict the Canadian regulatory system is paragraph 78. However, not only does paragraph 78 fail to accurately depict the Canadian regulatory system, it is misleading.

16. The premise of the paragraph is that in many countries the details of specific risk assessments are reviewed continuously. The EC cites Canada as an example. Even if the premise was accurate, and Canada doubts that it is, Canada is certainly not an example. Referring to a Royal Society of Canada Report, the paragraph states that the report criticized the use of the principle of substantial equivalence as a decision threshold to exempt new GM products from rigorous safety assessments. The EC insinuates that Canada regulates biotech products in this manner. The Royal Society's Expert Panel stated in its report that the concept of substantial equivalence represents an effective safety standard and not a decision threshold. More specifically, the Royal Society noted in recommendation 8.5, which the EC does not mention, that "when substantial equivalence is invoked as an unambiguous safety standard (and not as a decision threshold for risk assessment), it stipulates a

reasonably conservative standard of safety consistent with a precautionary approach to the regulation of risks associated with GM food."

17. This latter interpretation is in line with the way Canada has applied, and continues to apply, the concept of substantial equivalence in assessing the safety of foods derived from biotechnology, as well as with the interpretation of the application of substantial equivalence noted by recent Joint FAO/WHO Expert Consultations on Foods Derived from Biotechnology and the Codex Guidelines for the Conduct of Safety Assessment of Foods derived from Recombinant DNA Plants and Microorganisms. The FAO/WHO and Codex documents clearly articulate that the concept of substantial equivalence is a comparative approach focusing on the determination of similarities and differences between the genetically modified food and its conventional counterpart, which permits the identification of potential safety and nutritional issues. In any event, this case is not about substantial equivalence.

18. As for the assertion that Canada is reviewing its food safety and environmental safety guidelines for plants with novel traits, be they products of modern biotech or products of other breeding techniques, Canada does review these guidelines from time to time. Canada is completing the update of its Guidelines for the Safety Assessment of Novel Foods. The revised guidelines build upon the original guidelines published in 1994. Revisions proposed are to reflect:

- the promulgation, in 1999, of the regulations on Novel Foods which introduced changes to the definition of novel foods (which includes but is not limited to foods derived from genetically modified organisms) and made the pre-market notification process mandatory in Canada;
- the experience gained over the past ten years of conducting safety assessments of novel foods derived from microorganisms and plants in Canada; and,
- relevant national and international developments in the area of safety assessment of novel foods (including the recent Codex guidelines).

19. Overall, the revised guidelines provide more clarity and explanation with regard to substantial equivalence and offer more detailed requirements for the chemical, nutritional, microbiological, molecular biological and toxicological assessment of genetically modified and other novel foods. Canada has accomplished these revisions while continuing to assess and to regulate novel foods.

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. Generally, a legal proceeding is considered "moot" when it no longer presents a justiciable controversy because the issues involved have become academic or have ceased to exist.[3] To the extent that the EC is implying that the issues in this dispute have become academic or have ceased to exist, Canada vigorously disagrees.

21. The concept of "mootness" has arisen in previous WTO cases where a defending Member asserts that the measure in dispute is no longer in existence. Even in cases where the measure has been unambiguously withdrawn, panels have found that it is within their jurisdiction to make findings in

[3] Black's Law Dictionary, p. 1008. (Exhibit CDA-111)

relation to the measure as at the time of the establishment of the panel.[4] The WTO dispute settlement bodies have based these decisions on the over-arching objective of the DSU of securing a "satisfactory settlement of the matter" or "positive resolution to the dispute".[5]

22. Canada does not agree that the measure in question, the moratorium, has been withdrawn. It is therefore, necessary for the Panel to make findings in relation to the moratorium as it existed as of the date of the establishment of the Panel in order to secure a "positive resolution to the dispute".[6]

To Canada:

9. At page 200 of its written submission, under the heading "Request for findings and recommendations", Canada claims that the EC member State safeguard measures are contrary to the TBT Agreement and in particular, to Articles 5.1.2 and 5.2.1. However, Canada provides no arguments in support of such claims in its submission, nor does it indicate, at page 75 of its submission, that it is not pursuing claims under these Articles. Does Canada wish to raise claims under Articles 5.1.2 or 5.2.1 in relation to the EC member States safeguard measures?

23. As Canada indicated during the first substantive meeting of the parties, it will not be raising claims under Articles 5.1.2 and 5.2.1 of the *TBT Agreement* in relation to the EC Member State national measures. Canada has submitted a corrigendum to the Panel with respect to the relevant paragraphs in its First Written Submission.

10. With reference to paras. 326 to 331 of Canada's first written submission, the Panel would be grateful if Canada could provide clarification with regard to the following point. In paragraph 327, Canada asserts that the "product-specific marketing bans" are technical regulations, as they meet the three criteria applied by the Appellate Body. However in the paragraph concluding the sub-section in question (para. 331), Canada states that the EC legislation (rather than the "product-specific marketing bans") meets the definition of a "technical regulation". What is the point Canada is trying to make at paras. 326 to 331? That the "product-specific marketing bans" are "technical regulations", or that relevant EC legislation should be considered a "technical regulation"?

24. Canada apologizes to the Panel if the thrust of its arguments with respect to the product-specific marketing bans and the *TBT Agreement* is less than completely clear.

25. In the alternative to its arguments with respect to the *SPS Agreement*, Canada is arguing, at paragraphs 326 to 331 of its First Written Submission that the EC's relevant legislative instruments – that is, Directives 90/220 and 2001/18, and Regulation 258/97 – contain both technical regulations and conformity assessment procedures. Canada is also arguing that the product-specific marketing bans are technical regulations in so far as they amount to the application – or, more accurately, the mis- or non-application – of these legislative instruments.

---

[4] See *Chile – Price Band System*, Report of the Panel, para. 7.125. See also *Indonesia – Autos*, Report of the Panel, para. 14.9 and *India – Autos*, Report of the Panel, para 7.26. In the latter case India claimed that because the law requiring MOUs to be signed with manufacturers was no longer in effect, the measures was revoked and therefore the existing MOUs fell outside the panel's jurisdiction. The panel found that the original measures were within its' jurisdiction and made findings on the MOUs.

[5] DSU, Article 3.4, 3.7. See also, *Chile – Price Band System*, Report of the Appellate Body, paras. 140-144.

[6] DSU, Article 3.7.

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?

26. It is important to note that no product has been "approved" under the simplified procedure. The process does not involve an approval, but simply a notification to the Commission based on a favourable opinion by a competent authority as to the "substantial equivalence" of the product in question to existing foods.

27. Exhibit CDA-25 contains copies of the "Summary of notifications received [] by the Commission pursuant to Article 5 of Regulation 258/97 of the European Parliament and of the Council" for the years 1997, 1998, 1999, 2000, 2002 and 2003 published in the Official Journal of the EC. It does not appear that a summary was published for the year 2001.

28. According to these summaries, seven food or food ingredients produced from GMOs were notified to the Commission pursuant to Article 5 of Regulation 258/97 from October 1998 to the end of 2003.

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?

29. By failing to refer to conventional selective breeding techniques and other forms of genetic modification, such as mutagenesis, the EC appears to imply that the "potentially adverse consequences for human health and the environment" identified in paragraph 26 are exclusive to rDNA techniques. This is simply not true.

30. The ability to precisely control the resulting new genome is greater with rDNA techniques than with conventional selective breeding techniques and other forms of genetic manipulation, such as mutagenesis. While conventional selective breeding techniques and mutagenesis may result in random rearrangements of the genome, rDNA techniques permit a more precise modification of the genome, resulting is less disruption to other non-targeted areas of the genome. Thus, rDNA techniques enable plant breeders to develop a greater understanding of what has occurred at the molecular level the genome than do conventional selective breeding techniques and mutagenesis.

31. Regardless of the method used, the resulting organism must be screened for the desired traits (i.e. the desired phenotypic characteristic). This may involve screening several generations of the organism to ensure stability of the genetic modification. Regulators can then evaluate the end product to determine its safety.

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?

32. In paragraph 45, the EC does not provide any supporting scientific evidence for its assertion that rDNA techniques can produce novel proteins with allergenic properties. Nonetheless, Canada recognizes that it is theoretically possible, although highly unlikely, that rDNA techniques could produce novel proteins with previously unknown allergenic properties. However, there is no reason to

conclude that this possibility is any greater for biotech foods as compared with non-GM novel foods. As far as Canada is aware, no approved product in the EC or elsewhere produced from rDNA technology has ever been found to possess new allergenic properties.

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?

33. Canada agrees that the risks identified by the EC at para. 55 are theoretically possible. The risk of out-crossing is routinely assessed as a part of the approval procedures for biotech products in the EC and in Canada. However, if the EC is implying that the risks identified at para. 55 are limited only to biotech products, Canada disagrees. The risks of invasiveness and persistence are comparable as between biotech and non-biotech products.

34. "Conventional crops" can and do develop herbicide/pesticide resistance. Moreover, using traditional breeding methods or mutagenesis, "conventional crops" have been specifically developed for herbicide/pesticide resistance traits. In Canada, the potential risks of invasiveness or persistence arising from plants with herbicide-tolerant traits are assessed and managed regardless of the production method for developing the herbicide/pesticide resistance trait.

35. It is important to note that the potential for out-crossing has more to do with the species of the crop in question than the genetic modification. The invasiveness of a plant is dependant on multiple genes and is unlikely to be altered by the addition of one or a few transgenes. In assessing the risk of invasiveness or persistence, the following factors are considered: the quantity and viability of seeds produced by the crop, the pollen flow rate of the crop, and the viability of the seeds in various soil types and under various weather conditions. These factors should be taken into consideration regardless of whether the herbicide-tolerance was developed through rDNA techniques, conventional breeding or mutagenesis.

36. It is also important to note that herbicide management systems are a common feature of agronomic practice. This applies to conventional and biotech products alike. Resistance to one herbicide, regardless of whether the crop is biotech or not, does not imply that risks cannot be controlled. It may simply mean that another herbicide must be used to control any resulting volunteers (i.e. re-growth of a previously grown crop in a subsequent crop).

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?

37. As far as Canada is aware, the EC's community level scientific assessments of biotech product applications have never cited the fact that Europe is the centre of origin for a particular crop as a concern relevant to the assessment of the risks of those products.

38. In general, centres of origin are important for plant breeding purposes because they are typically the "centre of genetic diversity" for a particular crop. It is important for plant breeders to know the centre of diversity of the plant of interest because this is where there is the greatest diversity of plant germplasms. Centres of origins may be relevant to the approval of biotech crops because as a centre of genetic diversity there may be a greater range of plant species related to the biotech product under review and, thus, concerns relating to out-crossing may be greater. However, the EC's scientific bodies consider, as a matter of course, the potential for out-crossing to related wild species, regardless of whether or not Europe is a centre of origin. The reference to "centres of origin" is

another example of the EC raising abstract, hypothetical concerns that have never been raised in the context of specific applications because they are not relevant or that have been rejected as unsubstantiated.

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)

39. Canada considers that the modification or reaction created by gene transfer, or the expressed protein, could be considered a "contaminant" as that term is defined in Codex General Standard for Contaminants and Toxins in Food (Codex Stan 193-1995 (Rev.1-1997) ("Codex Stan 193").

40. First, Codex Stan 193 defines contaminant as "any substance not intentionally added to food …". While the insertion of the transgene is intentional, that insertion may have unintended effects, one of which could be the creation or expression of an unintended substance. Second, the Codex definition requires that the substance must be "present in food as a result of production". One of the examples of production cited is "operations carried out in crop husbandry." As the development of seeds is an example of production linked closely to crop husbandry, it logically follows that an unintended substance arising from the genetic modification or reaction by gene transfers is "present in food as a result of production". Therefore, such an unintended substance could be considered a "contaminant" for the purposes of Codex Stan 193.

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?

41. Yes. A food-safety related concern regarding biotech products is that the genetic modification might unintentionally result in the production of a toxin. The same is true of products from traditionally-bred plants. As stated in the OECD Report of the Task Force for the Safety of Novel Foods and Feeds (Exhibit CDA-7) at page 15:

> Increases in the level of natural toxicants can occur in plant varieties bred using traditional techniques. It is possible, therefore, that GM varieties could also have altered expression of natural toxicants and antinutrients…
>
> A related safety concern is that expression of the transgenic protein could result in the plant producing a toxicant not observed in the parent species.

42. Toxins that are unintentional by-products of genetic modification would likely not be considered a "toxin" in the context of Codex Stan 193. Codex Stan 193 does not provide an exhaustive definition of toxin but only sets out the types of "toxins" that fall within the scope of that standard. These include toxins that are not intentionally added to food (i.e. mycotoxins and phycotoxins). This is not surprising given that the primary focus of Codex Stan 193 is on "contaminants".

43. Codex Stan 193 further notes that "inherent natural toxicants that are implicit constituents of foods resulting from a genus, species or strain ordinarily producing hazardous levels of a toxic metabolite(s), i.e. phytotoxins are not generally considered within the scope of this standard." Moreover, the standard further states "[inherent natural toxicants] are, however, within the terms of

reference of the CCFAC [Codex Committee on Food Additives and Contaminants] and will be dealt with on a case-by-case basis."

44. Codex Stan 193 does not support the EC assertion that toxins arising from genetic modification do not fall within the definition of "toxin" in the *SPS Agreement*. To the contrary, the standard expressly recognizes the existence of "inherent natural toxicants" that fall outside the scope of Codex Stan 193, but are nonetheless a food safety concern.

45. There is no question that internationally accepted food safety assessment procedures for biotech products provide for the assessment of the toxicity of both the intentional and unintentional consequences of the genetic modification. The EC approval procedures for biotech foods without question assess for potential toxicity and as such are squarely measures applied to protect against risks arising from toxins in foods.

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.

46. The EC's assertion in paragraph 420 is far too vague to provide a detailed response. In Canada's view, the most likely way in which biotech products can damage biodiversity or the ecological balance of an area is by negatively affecting wild flora and/or fauna. This risk squarely falls within sub-paragraph 1(d) of Annex A.

30. With reference to para. 421 [422?] 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.

47. First, Canada is not aware of the existence of "novel biotech-specific herbicides". The herbicides associated with most, if not all, of the herbicide-tolerant biotech products with pending applications in the EC (glufosinate-ammonium and glyphosate) are commonly available herbicides. They have not been developed for specific biotech products; to the contrary, the biotech products were developed specifically for the herbicides, which have long been used on non-biotech crops.

48. Second, the type of negative impact on human, or animal life or health, caused by the use of herbicides is specific to individual herbicides. These impacts are routinely assessed at the time the herbicide is approved for marketing and may involve the imposition of conditions on the use of the herbicide. Any negative impact on human or animal life or health, if one exists, is related to the agronomic practices associated with herbicide use, not the biotech product *per se*. In fact, certain herbicide-tolerant biotech crops permit more environmentally sustainable agronomic practices. For example, the use of herbicide-tolerant Roundup Ready canola (tolerant to the herbicide glyphosate) enables farmers to practice zero-till agriculture resulting in less adverse impacts on the environmental than the traditional practice, common in the EC, of using pre-emergent herbicides.

31. With reference to para. 422 [423?] 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?

49. Canada understands the question to be referring to the "negative impact on wild flora and fauna" in paragraph 423 not 422.

50. The EC claims that "[t]his specific use of herbicide" could have a "negative impact on wild flora and fauna". If the EC is suggesting that herbicide use could have a "negative impact on wild flora and fauna", Canada agrees. However, whether herbicide use or misuse negatively impacts wild flora and fauna is a general issue not limited to biotech products.

51. One possible effect of herbicide use is that it may lead to the development of herbicide-tolerance in surrounding wild flora. For example, some broad-spectrum herbicides, such as imidazolone, may give a selective advantage to weeds that are tolerant of that herbicide due to the fact that the herbicide remains effective in the soil longer than other herbicides. By contrast, glyphosate (marketed under the tradename Roundup), is less likely to give the same advantage because glyphosate rapidly degrades in the soil. Imidazolone is typically applied to traditionally-bred herbicide-tolerant crops, while Roundup is typically applied to biotech herbicide-tolerant crops. Whether wild flora develops herbicide-tolerance is related to the characteristics of the herbicide used, including its accumulation and residual soil activity, not the presence of the herbicide-tolerant crop.

52. One possible effect of herbicide-tolerant crops on wild flora and fauna is that the herbicide-tolerant trait may be transferred to wild flora through out-crossing. Consequently, the wild flora may be able to withstand an application of the herbicide to which it is now tolerant. The presence of the herbicide-tolerant gene in the wild flora, however, will not provide a selective advantage in the absence of herbicide use.

53. In any event, these concerns are not limited to biotech products. The herbicides associated with the majority of biotech products with pending applications in the EC, glufosinate-ammonium and glyphosate, are not specific to biotech products at all. Moreover, there are many types of herbicides used primarily with conventionally bred herbicide-tolerant plants, such as imidazolinone, imazamox imazethapyr and sethoxydim. The EC's statements in paras. 422 and 423 apply equally to these other herbicides. If the EC is suggesting that it is legitimate to stall the approval of biotech products because of concerns about the negative impact of herbicide use, Canada disagrees. Concerns about the negative impact of herbicides should be dealt with on their own merits and apply to the use of herbicides in relation to all crops, conventional and biotech alike.

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?

54. It is Canada's view that any undesirable cross-breed of plant could be considered to be a "pest" under the *SPS Agreement* to the extent that the undesirable cross-breed of the plant harms "animal or plant life or health" or "human life or health" or cause "other damage".

55. To the extent that the "pest" in question is a pest to plants or plant products, the definition of "pest" in the IPPC, 1979 may inform the interpretation of the term "pest" as used in the *SPS Agreement*. That definition is:

> any form of plant or animal life, or any pathogenic agent, injurious or potentially injurious to plants or plant products.

56. Therefore, if the "undesirable cross-breed of plant" is "injurious or potentially injurious to plants or plant products" then it should be considered a "pest" for the purposes of the *SPS Agreement*. However, this does not define the full extent of what may be considered a "pest" under the *SPS Agreement*.

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?

57. At paragraph 425, the EC seems to suggest that if a pest management strategy is no longer effective because the target pest has developed resistance, an alternative pest management strategy to combat the resistant target pest would no longer be an SPS measure. This argument is without merit. If a pest management strategy is no longer effective because the target pest has developed resistance, the risks that then arise are those relating to the establishment or spread of the resistant pests.

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.

58. Yes. To the extent that a plant could cause "damage to the territory of a Member" by negatively impacting on soil-micro-organisms, the plant could be considered a pest.

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?

59. In Canada's view, the object and purpose of the requirement for WTO Members to undertake and complete procedures "without undue delay" is similar in purpose to the substantive requirement in Articles 2.2 and 5.6 of the *SPS Agreement* not to create unnecessary barriers to trade. In other words, there is an obligation on the Members to ensure that their procedures are not only designed, but also implemented and applied as efficiently and expeditiously as possible in the circumstances, without at the same time compromising the substantive objective of ensuring that SPS measures are fulfilled.

(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"?

60. Canada agrees that a delay in the completion of procedures would not result, *ipso facto*, in a breach of Annex C(1)(a). The delay must be "undue". What constitutes "undue delay" must be assessed in light of all the relevant circumstances.

61. In paragraphs 237 to 244 of its First Written Submission, Canada set out some relevant considerations for determining whether a delay rises to the level of being "undue." The ordinary meaning of "undue delay" suggests that both the justification for and the duration of the delay are relevant considerations in determining whether a delay is undue.[7]

62. In terms of duration of the delay, Canada disagrees with the EC's assertion at paragraph 480 of its First Written Submission that time constraints set forth in the relevant approval procedure are not relevant to a determination as to whether the delay has been excessive. Under Annex C(1)(a), a Member is obligated to publish the standard processing time for an approval procedure. There is no reason, in law or logic, that such standard processing time should not be considered in determining the excessiveness of the duration of the delay. Whether a product has been previously approved in other

[7] The EC agrees with this proposition. EC's First written Submission, para. 479.

jurisdictions and the processing time for those approvals in other jurisdictions are also relevant considerations, although not dispositive, in determining whether the delay is undue.

63. There is, of course, a distinction to be drawn between delays attributable to a Member and those outside a Member's control. *Force majeure*, such as the example cited by the EC of an earthquake destroying the building of a competent authority[8] would fall into the latter category. A state is not legally responsible for acts of *force majeure* and should not be held legally responsible for delays caused by *force majeure*. However, to Canada's knowledge, *force majeure* is one excuse that the EC has not yet raised for the suspension of its approval procedures.

64. Canada also rejects the EC's contention that delays due to scientific considerations of the kind that fall outside the *SPS Agreement* cannot be taken into account in determining a whether a delay is "undue" under Annex C. This proposition is based on the misguided premise that the reason for the delay should determine whether the obligations of Annex C apply. It is not the reason for the delay but the nature of the approval procedure that determines whether Annex C applies.

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)?

65. The approval procedures under Directives 90/220 and 2001/18 constitute a single, continuous approval procedure for the purposes of paragraph 1(a) of Annex C. The length of time/duration of the approval procedure should be calculated from the time the notification was first submitted to the relevant competent authority. In those cases where a notification was initially submitted under Directive 90/220 and then re-submitted under Directive 2001/18, the date of submission under Directive 90/220 should be considered the date on which the procedure commenced.

66. The conclusion that the approval procedure for biotech products is one single procedure is supported by the text of Directive 2001/18. First, Directive 2001/18 simultaneously repealed and replaced Directive 90/220. There was no overlap. Second, Article 35 of Directive 2001/18 provides that "pending notifications" under Directive 90/220 shall be subject to the new Directive and that notifiers shall "complement" their notifications by submitting additional information. Third, to find otherwise would be to allow Members to avoid "undue" delay simply by changing or replacing regulatory instruments and starting the process anew.

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".

67. To determine whether the procedures described in the chapeau to paragraph 1 of Annex C are SPS measures, one must first look to the definition of an "SPS measure" that is found in paragraph 1

[8] EC's First Written Submission, para. 481.

of Annex A. That definition quite clearly includes approval procedures, provided that such procedures are measures applied to protect against the types of risks outlined in subparagraphs 1(a) through (d). Articles 2.2, 5.1, 5.5 and 5.6 refer generally to "sanitary and phytosanitary measures", without in any way distinguishing between "procedures" and other types of SPS measures.

68. This is also consistent with the wording of Article 8, which requires the Members to "observe the provisions of Annex C in the operation of control, inspection and approval procedures", as well as "otherwise ensur[ing] that their procedures are not inconsistent with the provisions of this Agreement". The use of the term "otherwise" indicates that the procedures are subject, not only to the "provisions of Annex C" but also "the provisions of this Agreement". Logically, the "provisions of this Agreement" must be taken to refer to provisions other than those found in Annex C.

69. Hence, Canada concludes that the types of procedures referred to in paragraph 1 of Annex C of the *SPS Agreement* are subject to, not only the obligations found in Articles 2.2, 5.1, 5.5, and 5.6, but also the other obligations of the *SPS Agreement*, including, for example, the obligations in Article 3.

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?

70. Although the "measures" in question were taken by individual EC Member States, these "measures" were taken pursuant to EC-wide legislation (Article 16 of Directive 90/220; Article 23 of Directive 2001/18; and Article 12 of Regulation 258/97). That legislation establishes the appropriate level of protection for "safeguard" measures taken by the EC Member States.

71. Furthermore, the EC has taken legal responsibility for the conduct of its Member States and for the defence of their measures, as reflected, for example, in its defence of France's measure in *EC – Asbestos*. For these reasons, the relevant "Member", for the purposes of Article 5.5, is the EC as a whole, rather than to the individual Member States, notwithstanding the fact that they are also WTO Members.

(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?

72. There is nothing per se in Article 5.5 that prevents an individual EC Member State from applying an appropriate level of protection that is higher (or lower) than that which is applied in the rest of the EC. Whether such action is permitted can only be determined with reference to the three elements necessary for a violation of Article 5.5.

<u>For all complaining parties</u>:

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.

73. In its first submission, Canada used the term "modern biotechnology" to refer to recombinant DNA techniques. However, the term "modern biotechnology" could be applied to other techniques of agricultural biotechnology. In any event, this dispute does not turn on the definition of this term.

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?

74. Canada does not agree with Norway's assertion. Potential risks arising from the use of antibiotic resistance marker genes include reduced clinical efficacy of antibiotics used to protect livestock from diseases, disease-carrying organisms or disease-causing organisms. This falls squarely within the scope of paragraph 1(a) of Annex A of 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?

75. The answer to this question is related to the answer to Question 74. The issue is not whether plant DNA is an organism or plant DNA causes disease, but that the risks arising from the use of antibiotic resistant marker genes are risks that fall within paragraph 1(a) of Annex A.

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 <u>reliable</u> evidence"? (emphasis in the original) Please explain your views.

76. No. Norway's assertion ignores the considerable body of scientific evidence complied with the EC's own scientific committees. The EC's own committees have not indicated that there is insufficient scientific evidence upon which to make scientific justified conclusions in relation to particular applications. To the contrary, the EC's own scientific committees have determined that there is sufficient and reliable evidence upon which to base their conclusions regarding the safety of the biotech products in question. Norway's assertion is tantamount to alleging negligence on the part of the EC's scientific committees.

77. Moreover, Norway's assertion ignores the considerable body of peer-reviewed scientific research that has been conducted both within the EC and internationally, including the EC's own decade long biosafety research project, involving 400 research teams in 81 projects. In the Foreword to the publication reviewing that research, "EC-Sponsored Research on the Safety of Genetically Modified Organisms", Sir John Beringer, former Chair of the UK Advisory Committee on Releases into the Environment, stated:

> Is it all doom and gloom? It most certainly is not, as this compilation of results from 81 EC-supported projects on GM safety research demonstrates. One of the "best kept secrets" during the last few years of acrimonious discussion about GMOs has been the enormous body of research being conducted in Europe and elsewhere that is directly relevant to risk assessments. For those of us who have been involved in running GM safety committees in Member States there has been a steady stream of

> research results that have enabled our committees to improve their ability to make risk assessments and recommend safe conditions for the release of GMOs.[9]

78. Norway's assertion is self-serving and without merit.

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.

79. However the EC may now wish to characterize the evolution of its regulatory regimes, the fact remains that the EC's highest officials, as well as numerous EC documents, referred, and continue to refer, to the fact that applications for approval of biotech products were subject to a "moratorium", a "suspension" or a "standstill", and to the need to "relaunch" the process. Canada has already documented this in its written submission and oral statement. These are not terms invented by Canada to describe this state of affairs; they are terms that originate with the EC itself. Canada's assertion that a *de facto* moratorium exists is thus, in part, guided by those who are intimately familiar with, and in charge of, the EC's approvals processes, and who evidently consider these terms to be an accurate reflection of the state of affairs in the EC.

80. As to the specifics of the cases cited by the EC, first, Canada finds it curious that the EC claims that it is entitled, under the WTO Agreement, to withhold indefinitely approval of products for multiple risk assessments had been done, and for which no scientific evidence of adverse effects on human health or the environment exists, on the basis of "requirements" that did not even exist in its own laws at the time the approvals were withheld.

81. Second, even if the companies were complying with these extra-legal requirements, their willingness to do so can hardly be characterized as "voluntary", given their evident desire to move their products through the approval process. In fact, GATT and WTO jurisprudence has recognized, albeit in a different context, that "voluntary" actions on the part of private sector enterprises can amount to legal "requirements" where the enterprise in question is effectively left with no choice in the face of government demands, even where those demands do not arise from formal legal instruments.[10] Canada is not making this point to support a claim that the "voluntary" requirements imposed on the product applicants are "measures" that are being challenged; rather, Canada is merely noting the elastic qualities of the term "voluntary" and how its true meaning can only be discerned through an appreciation of the context in which it is used.

82. The more plausible characterization of the "voluntary commitments" is that the applicants were told that these were the requirements that they would have to meet if they wanted their products considered and approved. Put differently, it is at least questionable whether the applications would

[9] Exhibit CDA-13, pp. 11-12.

[10] *Japan – Semi-Conductors*, Report of the Panel, paras. 106-111; *Japan – Film*, Report of the Panel, para. 10.374.

have been approved – regardless of whether they met the legal requirements in place at the time – if the applicants had not agreed to comply with the additional or extra-legal requirements. In effect, there was little practical choice for the applicants in the matter, with the exception of simply withdrawing the product applications.

83. Third, to accept that the EC is entitled to impose ever-changing requirements on applicants in order to have their product applications processed and approved, is to accept that WTO Members can prevent products from ever being approved, regardless of whether the products actually pose any risks, simply by continuing to alter the process requirements indefinitely on the basis of vague concerns about "scientific uncertainty", or the on-going and never-ending need to "update" or "modernize" or "streamline" the existing regulatory regime. This would defeat the very object and purpose of the disciplines put in place through the WTO Agreement with respect to non-tariff barriers to trade, and could not therefore have been the intention of the drafters.

84. Finally, the simple fact is that even the applicants' efforts to meet the extralegal requirements imposed by the EC seem to have had little effect. With the very recent exception of Bt-11, all of these applications have yet to be approved, and there is no indication that they will be approved at any time in the near future, despite the fact that Directive 2001/18 has now been in effect for almost two years, and the EC apparently began to impose its requirements long before that time.

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?

85. Juxtaposing the phrases "failure to consider applications" and "failure to allow products to move to final approval" creates a false dichotomy. The EC's *de facto* moratorium has as its ultimate intent the prevention of products from being approved. This is reflected, for example, in the Declaration of the five EC Member States, and is given effect through a variety of means, at various stages in the approvals process. The concept of "failure to consider" does not simply refer to applications being completely ignored; it also refers to the timely and efficient completion of all necessary steps at a particular stage in the process. Thus, in some cases, at some stages, there is a "failure to consider applications" in the sense that they are not assessed or evaluated on their merits and allowed to move on to the next stage. While they have not been formally rejected, the fact that they are held up at that stage amounts to a "failure to consider" them. Of course, this "failure to consider" contributes to or forms a part of the "failure to allow products to move to final approval".

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?

86. Whether the EC has made a "decision not to decide" or a "decision to decide negatively", in either case, the effect is that products for which the EC's scientific experts have explicitly identified no evidence of risks of adverse effects to human health or the environment are being prevented from being marketed. Given the limited commercial "shelf-life" for many of these products, due to the on-

going development of new varieties, a prolonged delay – particularly an indefinite delay of many years – can be equated with a complete denial to approve because of the lost and irretrievable market opportunities. The reality is that many of these products may never be marketed in the EC because by the time they receive approval – if they ever receive approval – the market will have passed them by. Thus, whether the product applications are formally rejected, or are simply held up in the system, will in all likelihood, and certainly for many of these products, amount to the same thing, practically speaking.

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?

87. The across-the-board moratorium leads to "undue delays" with respect to all applications that reach critical decision-making junctures in the approval procedures. The fact that certain applications have not yet reached one of these critical decision-making junctures does not mean that such applications will avoid the effect of the moratorium.

88. Furthermore, Canada recognizes that certain EC Member State competent authorities have conducted risk assessments and prepared their initial reports on the basis of sound science (e.g. Bt cotton (531) application C/ES/96/02). Thus, for any particular application, there may not have been undue delay at each stage of the approval process. This does not mean, however, that these applications have not, or will not, eventually experience undue delay.

89. Canada notes, however, that, with respect to the moratorium, the violation of the EC's WTO obligations does not depend on product applications actually experiencing undue delay. The existence of the moratorium does not depend on whether there are any product applications or whether pending product applications have faced undue delay if those product applications have not yet reached a critical decision-making juncture.

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)

90. Please refer to the Annex to this submission for a table outlining how the EC has given effect to the moratorium in respect of each relevant individual product application.

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:

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

91. This depends on the justification for and the duration of the delay. If the "risk considerations" in question are justified on the basis of scientific evidence and the length of delay caused by the assessment of those risks is reasonable in the circumstances, the procedural delays may be justified.

92. Canada disagrees that the justification for delay to an approval procedure falling within the scope of the *SPS Agreement* cannot be examined by a Panel under Annex C, if the defending Member asserts that the delay is caused by "risk considerations" that do not fall within the scope of Annex A.

The implication of the EC's argument is that if a delay to an approval procedure that qualifies as an SPS measure is related to non-SPS considerations, then Annex C would cease to apply to the approval procedure. This would effectively nullify the obligations of Annex C, as a Member could simply assert that the delay was caused by non-SPS considerations, precluding a determination as to whether the approval procedure has been "undertaken and completed without undue delay." The delay being examined is the delay to the SPS measure, the approval procedures. The obligations in respect of those approval procedures do not cease to apply merely because those measures are also applied to protect against non-SPS risks.

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

93. Again, this depends on the circumstances. As set out in Canada's answer to Question 43, it is doubtful in this case that the applicants had much choice but to comply with the "voluntary" commitments imposed by the EC in anticipation of revisions to its legislation if they hoped to secure approve for their products. The "voluntary" commitments should be viewed as an effective change in the requirements of the legislation. Any delay arising from such "voluntary" commitments should be assessed in the same manner as one would assess a delay caused by a legislative or regulatory amendment.

(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;

94. In principle, where the entry into force of new legislation is truly imminent, it may be justified to delay the completion of the approval procedure pending the entry into force of the new legislation. However, this must be subject to reasonable limits. Several factors should be considered, including, the length of time before which the new legislation enters into force; the purpose of the "stricter requirement" (i.e. if the stricter requirement is a measure applied to protect human, animal or plant life or health, then such a delay may be considered reasonable; however, if the stricter requirement was not necessary to protect human, animal or plant life or health, then the delay may not be reasonable); whether or not compliance with the "stricter requirement" could have been achieved under the existing legislation; and the amount of time the application has been pending under the old legislation.

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

95. Where the applicant has caused the delay, a delay in the completion of the approval procedure would be justified.

(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);

96. It depends on the nature of the "existing legislation". If the existing legislation was the SPS measure containing the approval procedure, and that existing legislation was consistent with the *SPS Agreement*, then procedural delays that were "necessary in order to ensure compliance" with the existing legislation would be justified. However, if the existing legislation was unrelated to the approval procedure, then the delay may not be justified.

97. To the extent that the Member has incorporated the relevant international standard into its domestic law, the same considerations as with "existing legislation" apply. Where a relevant international standard has not been adopted, Canada fails to see how the standard is relevant to an approval procedure under Annex C.

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

98. To the extent that risks that need to be managed are identified based on relevant scientific evidence, the elaboration of risk management tools for such risks is a legitimate component of the approval procedure. However, the risk management tools must be tailored to the actual risks of the product in question, developed in a manner consistent with Annex C, including the stipulation that "any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary" and must not be arbitrary and result in discrimination or a disguised restriction on international trade. For instance, the need for a monitoring plan for biotech products for which an application has been submitted for import and processing only, but not cultivation, may not be "reasonable and necessary". Such risk management measures must also comply with all other relevant provisions of the *SPS Agreement*. To the extent that risk management tools are legitimate, they should be developed in an open and transparent fashion within a reasonable timeframe.

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?

(i) No. (ii) No.

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.

99. The EC appears to be trying to engage in a very complicated metaphysical exercise when it states in paragraph 441 of its First Written Submission that "a measure that pursues multiple objectives must be considered to be a series of measures". This raises the very difficult question of what constitutes a discrete "measure". For example, can or must a single provision (e.g., an Article, or a paragraph or a subparagraph, whatever the case may be) in a legislative or regulatory instrument, which sets out a singular and discrete legal requirement or burden, be considered as a single or indivisible "measure" even if the objective or purpose underlying that provision is multifaceted? The EC seems to believe not only that it can, but also that it must, be divided on the basis of those objectives, at least in the case of the *SPS Agreement* and *TBT Agreement*.

100. The text of Article 1.5 of the *TBT Agreement* states that it does not apply to SPS measures as defined in Annex A of the *SPS Agreement*. This does not assist in resolving the more discrete question of whether a single or "indivisible" measure taken for both SPS and non-SPS reasons can be considered as both an SPS measure and a non-SPS measure, or whether, as the EC contends, it "must be considered to be a series of measures. On balance, Canada is of the view that a hermetic approach to the *SPS Agreement* and the *TBT Agreement*, respectively, is probably neither valid from an interpretive standpoint, nor useful from a practical perspective. A Member's measure is an SPS

measure to the extent that it addresses SPS risks; to the extent that it addresses other risks or policy objectives, it is another type of measure, including, possibly, a TBT measure. Whether a measure that addresses both SPS risks and other types of risks or policy objectives should be considered a single measure or a "series of measures" is purely semantic.

101. In any event, it is not necessary to resolve this issue in order to answer the questions that are before this Panel. It seems clear that all the Parties agree that a measure taken for reasons having to do with the definition of an SPS measure in Annex A must be examined in the light of the requirements of the *SPS Agreement.* As a consequence, if that measure does not meet those requirements, it gives rise to a violation of one or more of the provisions of the *SPS Agreement*. The fact that the measure might also have a TBT dimension and may even be TBT-consistent would be entirely beside the point because consistency with one Agreement cannot operate to excuse or remedy a violation under another Agreement.

102. More to the point, the EC has not identified any risks – whether TBT or SPS – that would justify delaying the approval of the specific products that are the subject of Canada's complaint. To the extent that risks have been identified, they have been addressed in the EC's own risk assessments, which found no evidence that these products are likely to cause adverse effects to human health or the environment.

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);

103. Canada fails to see how the simple invocation of Article 5.7 – even as a "threshold" argument – can act to exclude the applicability of Article 5.1. As Canada noted in its oral statement, the issue is not the provisional nature of the measure – a claim, by the way, that the EC has asserted but, in Canada's view, not demonstrated – but whether the "relevant scientific evidence is insufficient" to allow for an objective assessment of risk.

104. In *Japan – Apples*, Japan argued that sufficient scientific evidence existed to maintain the measure under Article 2.2. The United States argued the opposite. Importantly, the United States did not, in its initial claims and arguments, assert that Article 5.7 did not apply to the measure at issue in that dispute. Japan invoked Article 5.7 as an alternative argument that, if the panel found that sufficient scientific evidence did not exist, then the measure was captured by Article 5.7 and therefore exempted from the primary requirement in Article 2.2 not to maintain measures without sufficient scientific evidence. The same approach was used by both the United States and Japan in *Japan – Agricultural Products II*. In neither case did the United States argue the inapplicability of Article 5.7 as part of establishing its *prima facie* case of a violation of Article 2.2. Evidently, neither the United States, nor Japan, nor the panels, considered that making out a *prima facie* case under Article 2.2 required also the explicit demonstration that the requirements of Article 5.7 had not been met. Had that been the case, then presumably the United States would have failed to establish its *prima facie* case and a violation of Article 2.2 would not have been made out. Clearly, that is not what happened.

105. Establishing a *prima facie* case under Article 2.2 that a measure is being maintained without sufficient scientific evidence can be demonstrated in at least two ways. One way is to demonstrate

that no risk assessment exists that meets the requirements of a "risk assessment" as defined in the *SPS Agreement*. Another way is to demonstrate the absence of any risk assessment on which the measure in question can reasonably said to be based.

106. To the extent that there is a relationship between Article 5.1 and Article 5.7, that relationship stems from the requirement in Article 2.2 not to maintain a measure without sufficient scientific evidence. In the case of Articles 5.1 and 2.2, the central issue is whether there is sufficient scientific evidence to support the measure at issue. In contrast, in Article 5.7, the central issue is whether there sufficient scientific evidence to conduct an objective assessment of the risk. Where there is sufficient scientific evidence for an objective assessment of the risk, in accordance with Article 5.1 that assessment must serve as the basis for the measure, that is, it must sufficiently support or reasonably warrant that measure.

107. As Canada has already demonstrated, the products subject to the EC Member State national measures have already been the subject of multiple risk assessments, and have already been approved for marketing throughout the EC. This proves, *prima facie*, that the relevant scientific evidence was sufficient, not only to conduct an objective assessment of the risk, but to come to the conclusion that there was no evidence that these products were likely to give rise to any adverse effects to human health or the environment. To put it slightly differently, the risk assessments conducted by the EC's own experts must have demonstrated to the satisfaction of the EC itself that no scientific evidence existed to justify denying these products approval for marketing within the EC. Otherwise, the EC would presumably not have approved the products in the first place, and equally presumably would not now be asking the EC Member States to withdraw the national bans.

108. With respect to the current Appellate Body jurisprudence on Article 5.7, Canada is of the view that none of the passages referred to by the Panel in the four reports provide only limited guidance in addressing the question of the allocation of the burden of proof.

109. The relevant paragraphs in *Japan – Agricultural Products II* do not address the basic issue of burden of proof at all. In that case, Japan had invoked Article 5.7 as a defence in the face of a finding that the United States had discharged its burden of proof in demonstrating a violation of Article 2.2. The issue addressed in the relevant paragraphs was whether Japan had met the requirements of the four elements set out in Article 5.7. The reference to the burden of proof in footnote 316 of the Appellate Body report in *Japan – Apples* provides no information other than the Appellate Body's confirmation that the assignment of the burden of proof was not being appealed. In *EC – Sardines*, the Appellate Body expressly noted the "conceptual similarities between, on the one hand, Articles 3.1 and 3.3 of the *SPS Agreement* and, on the other hand, Article 2.4 of the *TBT Agreement*" in finding "no reason why the Panel should not have relied on the principle [the Appellate Body] articulated in *EC – Hormones* to determine the allocation of the burden of proof under Article 2.4 of the *TBT Agreement*". The conceptual similarity in that case was the fact that Articles 3.1 and 3.3 of the *SPS Agreement*, and Article 2.4 of the *TBT Agreement* all deal with the obligation to base measures on international standard unless a valid reason exists to depart from those standards. As described in more detail below, no such "conceptual similarity" exists between Article 5.7 and Articles 3.1 and 3.3.

110. Finally, and perhaps most tellingly, in *EC – Hormones*, the Appellate Body found that the "general rule – exception" relationship did not apply to Articles 3.1 and 3.3 of the *SPS Agreement* in the manner that it does in the case of, for example, Articles III and XX of the GATT 1994. The Appellate Body noted that the panel had misconceived the relationship because:

> Article 3.1 of the *SPS Agreement* simply excludes from its scope of application the kinds of situations covered by Article 3.3 of that Agreement, that is, where a Member has projected for itself a higher level of sanitary protection than would be achieved by a measure on an international standard.[11]

111. This is not the case with respect to Articles 2.2 and 5.1, and 5.7. In effect, Article 5.7 operates as an exception to Articles 2.2 and 5.1. It is an exception because it allows a Member to maintain a measure without sufficient scientific evidence, on the specific grounds that sufficient scientific evidence to complete on objective assessment of risk does not exist. Thus, the application of Article 5.7 logically only arises where it has been determined that a measure is maintained without sufficient scientific evidence, which, unless justified under Article 5.7, would amount to a violation of Article 2.2. Unlike Articles 3.1 and 3.3, which allow the Members to choose which track to follow in the light of the appropriate level of protection sought to be achieved, Article 5.7 does not operate as an option for the Members to choose in place of Article 2.2. If sufficient scientific evidence exists to conduct an objective risk assessment, then Article 5.7 is simply not available.

112. In this context, the relationships between Articles 3.1 and 3.3 of the *SPS Agreement*, and the first and second parts of Article 2.4 of the *TBT Agreement*, as compared to the relationship between Article 5.7 on the one hand, and Articles 2.2 and 5.1 on the other hand, are irrelevant.

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

113. Canada disagrees with the EC's assertion that Article 5.6 is irrelevant where Article 5.7 applies. Moreover, the EC makes this assertion without any supporting textual analysis or jurisprudential support. There is nothing in the text of Article 2.2, Article 5.6 or Article 5.7 to support such an interpretation. Furthermore, in *Japan – Agricultural Products II*, the Appellate Body noted that Article 5.7 operates as "a qualified exemption from the obligation under Article 2.2 not to maintain SPS measure without sufficient scientific evidence".[12] It did not state that the exemption extended to Article 2.2 as a whole. Given the relationship between Article 5.6 and the first element of Article 2.2, it is therefore logical to conclude that the exemption also does not extend to Article 5.6.

(c) Article 5.7 "effectively" excludes Article 5.5 (EC first written submission, para. 618)?No, there needs to be consistency, the acceptable level of protection must still be taken into account.

114. The EC makes the bare assertion that Article 5.7 of the *SPS Agreement* contains an express rule that effectively excludes Article 5.5 but fails to indicate what that rule is or where exactly it may be found. It then asserts, once again without any supporting evidence or textual analysis, that the operation of Article 5.7 necessarily excludes the remainder of Article 5 as a whole.

115. Neither assertion can withstand scrutiny. There is no language in Article 5.7 that reasonably lends itself to a finding that the application of Article 5.5 is effectively excluded if Article 5.7 applies – and, in any event, as has already been made clear, Canada in no way concedes that Article 5.7 does apply in this case. In fact, there is no logical or textual connection to be made between these two provisions.

---

[11] *EC – Hormones*, Report of the Appellate Body, para. 104.
[12] Para. 80 (emphasis added).

116. Article 5.7 is connected to Article 2.2. Furthermore, based on the Appellate Body's statement in *Japan – Agricultural Products II*, quoted in Canada's answer to part (b) of Question 50, that connection appears to be limited to the third element of Article 2.2, that is, the requirement not to maintain a measure without sufficient scientific evidence.

117. In contrast, the obligation in Article 5.5 does not find its general expression in Article 2.2 at all. It is found in Article 2.3. Article 2.3 does not mention Article 5.7. In fact, Article 2.3 -- and therefore Article 5.5 – concerns itself with issues that are very different as compared to the issues addressed in Article 2.2. These issues have to do with discrimination and disguised restrictions on trade, and consistency of application in the concept of appropriate levels of sanitary and phytosanitary protection. Setting or applying appropriate levels of protection is essentially a policy matter.

118. In short, there is no reason – whether based on their respective texts or on the internal logic of Articles 2.2, 2.3, 5.5 and 5.7 – for concluding that Article 5.7 can result in the exclusion of the application of Article 5.5.

(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).

119. Canada does not agree with the EC's characterization of what constitutes "sufficient scientific evidence".

120. First of all, it is not clear whether the EC is referring to the term as used in Article 2.2, or as used in Article 5.7. The term as used in Article 2.2 is relevant to an interpretation of Article 5.1.

121. In the context of Article 2.2, the sufficiency of the scientific evidence relates to whether it adequately supports the measure taken. As has been noted in the jurisprudence, the ordinary meaning of "sufficient" is "of a quantity, extent, or scope adequate to a certain purpose or object".[13] With respect to the requirements of Article 2.2 and Article 5.1, this means that there must exist a rational or objective relationship between the SPS measure and the scientific evidence. This is to be determined on a case-by-case basis and will depend on the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence.

122. In the context of Article 5.7, the reference to insufficient scientific evidence goes to the determination as to whether that provision is available to exempt the measure in question from the requirement under Article 2.2 not to maintain a measure without sufficient scientific evidence. In other words, the sufficiency of the scientific evidence goes to the question of whether there is adequate scientific evidence to make an objective assessment of risk. If there is sufficient scientific evidence to make an objective assessment, then Article 5.7 would not be available, and the measure would have to conform to the requirements of Articles 5.1 and 2.2, third element. There would be no need, and therefore no justification, for a provisional measure taken pursuant to Article 5.7.

123. Furthermore, the appropriate level of protection is a matter that goes, not to whether there is sufficient scientific evidence to make an objective assessment of risk, but the selection of the measure to address any risks disclosed by the scientific evidence. This is also true for the nature of the risks.

[13] *EC – Hormones*, Report of the Appellate Body, para. 187.

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?

124. According to the EC's own scientific committee opinions, which considered the information provided by the EC Member States in support of their national bans, these were not cases where there was "insufficient scientific evidence". These committees found that sufficient scientific evidence was available to them to complete their assessments, and to come to a favourable opinion with respect to the biotech products in question. The EC has not provided any scientific rationale to demonstrate the absence of sufficient scientific evidence or, more generally, to support the continued maintenance of these measures. To the contrary, it has officially requested the Member States in question to lift their national bans.

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?

125. Canada agrees with the EC's earlier statement in paragraph 604 of its First Written Submission, in which it quotes the Appellate Body to the effect that a risk assessment is a "process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions,…". It is Canada's understanding that this is exactly what is supposed to be done by the Competent Authority of the Member State where a product application originates, and the independent scientific committees (such as the Scientific Committee on Plants).

126. By contrast, the definition put forward by the EC in the last sentence of paragraph 604 has several problematic elements. First, it states that an adequate risk assessment is one prepared by a "reputable source". It is unclear what the EC means by this term. If the EC intends it to be synonymous with "qualified and respected", as used by the Appellate Body in *EC – Hormones*,[14] Canada would agree. In any event, Canada has to assume that the scientific experts chosen by the EC and its Member States to conduct their risk assessments are "reputable".

127. Of equal importance are the standards of scientific methodology applied to the collection and analysis of the data. The quality of a risk assessment must rest on the reliability of the data and the professionalism and independence that the risk assessor brings to the task of analysing that data.

128. The second problematic element in the EC's definition is its assertion that an adequate risk assessment "unequivocally informs the legislator" about the risk. Again, the meaning of this phrase is unclear. In any event, the vast majority, if not all, of the risk assessments produced by the EC scientific community for individual product applications are unequivocal in their conclusions, and state clearly their findings, without expressing any significant concerns about ambiguity or absence of key data. It seems, however, that there is no relationship between how the EC "legislators" have treated the applications, and the unequivocal and precise risk assessments provided to them by the independent scientific experts. No matter what the scientific experts have said, the legislators have found themselves unable to act – that is, to decide – on the product applications.

129. The third problematic element in the EC's definition is its assertion that an adequate risk assessment is one that "has withstood the passage of time". Certainly there is nothing in the definition of "risk assessment" in paragraph 4 of Annex A of the *SPS Agreement* to indicate that the adequacy of a risk assessment is dependent on any passage of time. On the contrary, it is only if there is

[14] *EC – Hormones*, Report of the Appellate Body, para. 194.

insufficient scientific evidence for an objective assessment of the risks, in accordance with Article 5.7 of the *SPS Agreement*, that the passage of time becomes relevant. In those circumstances, time becomes a factor in so far as the Member maintaining the provisional measure must review that measure within a reasonable period of time. In contrast, where there is sufficient scientific evidence for an objective risk assessment to be carried out – and all indicators in the present case support the proposition that the scientific evidence available to the EC's risk assessors was sufficient for their purposes – it is impossible to understand how the objectives of the *SPS Agreement* could be served if a Member could fail to act on the basis of a favourable risk assessment of a product while awaiting the passage of some unspecified period of time.

130. In the circumstances of this case, when most, if not all, of the product applications in issue have languished despite receiving favourable risk assessments, it is not surprising that the EC would advance such an obviously self-serving criterion to determine the adequacy of a risk assessment. However, Canada doubts very much that the EC would advocate that product applications by EC companies in other WTO Member jurisdictions should also be held up for many years while regulators in those Member jurisdictions wait for the completed risk assessments to "withstand the passage of time".

131. In any event, in the instant case, Canada has demonstrated that there are no risk assessments that support a complete moratorium on approvals. Likewise, there are also no risk assessments that support the refusal of the EC to approve the four product applications listed in Annex II of Canada's Request for the establishment of a panel in this dispute.

To Canada:

59. Could Canada please submit a copy of Commission Recommendation 97/618?

132. Commission Recommendation 97/618 has already been submitted as Exhibit CDA-24. Please advise if additional copies are required.

60. With reference to para. 86 of Canada's first written submission, does Canada agree with the European Communities that the application concerning GT73 which was submitted to France in 1995 was not later re-submitted under EC Directive 2001/18? (see EC first written submission, para. 287) If so, what is the relevance of this application to Canada's claim in respect of what it calls "product-specific marketing bans"?

133. Canada agrees that the application concerning GT73 submitted to France in 1995 (C/F/95/06/01) was not re-submitted under Directive 2001/18. In a letter dated January 15, 2003 to the French competent authority, Monsanto wrote "As a consequence of the prolonged inaction on this notification from the French Competent Authority, Monsanto is focusing its commercial and regulatory activity on supporting the cultivation of GT-73 oilseed rape outsider the EU and, as a consequence, we have elected not to longer puruse the notification C/F/95/06/01 under Directive 2001/18/EC." (Exhibit EC-79).

134. This is relevant to Canada's claim because it demonstrates that if the delay is long enough, it has the effect of discouraging applicants from continuing with their applications. A lengthy delay causing an applicant to discontinue an application in frustration may be less overt and direct than a marketing ban, but it is no less effective.

61. With reference to para. 42 of the US oral statement, is the United States correct in stating that "the co-complainants here are not saying that a pattern of decisions itself *constitutes*

a measure. Instead, the co-complainants have pointed to an unbroken pattern of [non-] decisions as the inevitable *result* of the moratorium, which is itself an independent measure"?

135. Yes, the United States is correct. While the moratorium consists of concerted acts and omissions by the EC and its Member States, it is more than "an unbroken pattern of [non-]decisions". The ultimate intention behind the moratorium is the prevention of biotech products from being approved. The "unbroken pattern of [non-] decisions" is the manner in which the EC and its Member States have given effect to the moratorium, or, using the US terminology, the "result of the moratorium."

62. With reference to para. 207 of Canada's first written submission, is it Canada's position that if the European Communities wished to apply a higher level of protection, it would have to apply that higher level of protection also to biotech products that have already been approved, such that, for some products, the approval might have to be revoked?

136. Article 5.5 requires that each Member avoid arbitrary or unjustifiable distinctions in the level of protection that it considers appropriate in comparable situations if they result in discrimination or a disguised restriction in international trade. Biotech products for which applications for approval were made to the EC after the imposition of the moratorium are in a comparable situation to biotech products approved for marketing in the EC prior to the imposition of the moratorium. Canada has shown that the apparent distinction in the appropriate levels of protection the EC has applied to these two categories of products is arbitrary and unjustifiable, and results in discrimination or a disguised restriction on international trade. As there is no basis for holding product applications affected by the moratorium to a higher appropriate level of protection than that applied to products approved prior to the imposition of the moratorium, to avoid a violation of Article 5.5 the EC must apply the same appropriate level of protection to the pre-moratorium biotech products and biotech products subject to the moratorium, whatever that level of protection is. If the EC therefore wants to impose a higher level of protection on more recent biotech products, it would also have to do so in respect of the products approved prior to the imposition of the moratorium.

63. With reference to paras. 293 to 295 of Canada's first written submission:

(a) Please address in more detail at what stage in the relevant procedure "delays" arose, and why they are considered "undue".

137. Please see Canada's response to Question 47.

(b) Is it correct that some of the alleged delays occurred prior to October 1998, i.e., before the alleged across-the-board moratorium was applied? If so, are these delays relevant in the light of Canada's statement that the "product-specific marketing bans are a direct consequence of the moratorium"? (Canada's first written submission, para. 255)

138. It is correct that some of the alleged delays occurred prior to October 1998 (e.g. Ms1/Rf1 and Ms1/Rf2 were approved by the Commission in June 1997; the first notification for GT73 was submitted to the competent authority of France in May 1995). Whatever the motivation of France prior to October 1998, these products were the victims of the moratorium after October 1998 as much as any products. For the period of the moratorium, the product-specific marketing bans were a direct consequence of the moratorium as applied to individual product applications.

64. With reference to paras. 301 to 303 of Canada's first written submission, could Canada please clarify whether it is challenging the alleged "product-specific marketing bans" as "laws, regulations or requirements" in their own right (sub-heading a)) or as instances of application of "laws, regulations or requirements", specifically, of EC Directives 2001/18 and 90/220 and Regulation 258/97?

139. Under the GATT 1994, Canada is challenging the product-specific marketing bans as the application of "laws, regulations or requirements". The "laws, regulations or requirements" in question are Directives 90/220 and 2001/18, and Regulation 258/97. Paragraphs 301 to 303 are intended to demonstrate that the product-specific marketing bans are instances of the application (or, more accurately, the mis- or non-application) of the relevant legislation, including the prohibition on the marketing of unapproved biotech products.

65. With reference to paras. 326 to 331 and 335 to 336 of Canada's first written submission, could Canada please clarify whether it is challenging the alleged "product-specific marketing bans" as "technical regulations" in their own right (sub-heading a)) or as instances of application of "technical regulations", specifically, of EC Directives 2001/18 and 90/220 and Regulation 258/97?

140. As Canada has now explained in its answer to Question 10, in the alternative to its arguments with respect to the *SPS Agreement*, Canada is arguing, at paragraphs 326 to 331 of its First Written Submission that the EC's relevant legislative instruments – that is, Directives 90/220 and 2001/18, and Regulation 258/97 – contain both technical regulations and conformity assessment procedures. Canada is also arguing that the product-specific marketing bans are technical regulations in so far as they amount to the application (or, more accurately, the mis- or non-application) of these legislative instruments.

66. With reference to paras. 361 to 363 of Canada's first written submission, could Canada please confirm that it is challenging the alleged "product-specific marketing bans" as instances of application of conformity assessment procedures, specifically, of EC Directives 2001/18 and 90/220 and Regulation 258/97?

141. That is correct.

67. With reference to para. 381 of Canada's first written submission, please explain when / at what point a delay becomes a ban.

142. The EC's own pre-marketing approval requirement effectively imposes a prohibition on biotech products until those products are found to be safe and, accordingly, approved. The moratorium effectively extends that ban or prohibition indefinitely. To be clear, Canada is not challenging the pre-marketing approval requirement, as such. But it is challenging a measure – the moratorium – that converts that pre-marketing approval requirement into a complete, rather than conditional, ban.

143. There are other considerations that contribute to the characterization of the moratorium as a ban rather than a delay. For example, a measure that departs to such a significant degree from the approval procedure in question – that is, moving from approvals based on risk assessment to no approvals regardless of the scientific evidence -- can more properly be characterized as a mis- or non-application rather than a "slow" application of the relevant legislation. Furthermore, when there is clear evidence of concerted action on the part of the EC Member States to conspire to prevent the approval of biotech products, regardless of their merits in terms of actual risks to human health or to

the environment, and not a single biotech product is approved for more than five years, it is more appropriate to speak of a ban rather than a mere delay. Finally, it is especially telling that the EC's own most senior officials have not referred to a "delay" in approvals, but rather, to a "moratorium", a "suspension", and a "standstill". Under the circumstances, and in the light of all the evidence, a "ban" rather than a mere "delay" is the more accurate description of the situation.

144. Even if one were to speak of a "delay", Canada considers that, in this particular case, referring to "delay" rather than a "ban" is, practically speaking, a distinction without a difference. As was noted by Canada in its reply to Question 45, the limited commercial life – and therefore value – of these products means that any prolonged delay – particularly an indefinite delay that has already lasted many years – can be equated with a complete denial to approve because of lost and irretrievable market opportunities. Thus, whether these products are formally rejected, or are simply held up in the system, will, in all likelihood, amount to the same thing.

145. The WTO itself recognizes this problem, in a different context, in having special, expedited dispute settlement procedures for perishable goods. Of course, Canada is not seeking to imply that biotech products are "perishable goods" in the sense meant by that term as used in Article 4(8) and 4(9) of the DSU, but the idea is the same.

68. With reference to paras. 476 to 480 of Canada's first written submission, could Canada please confirm that it is challenging the relevant member State safeguard measures as "technical regulations" in their own right?

146. Canada confirms that it is challenging the EC Member State national measures as "technical regulations" in their own right.

69. With reference to para. 655 of the European Communities' first written submission, is the European Communities correct in arguing that Article 2.1 of the *TBT Agreement* only applies "to differences in treatment between products that are covered by the technical regulation in question"?

147. No. Canada does not agree with this interpretation.

148. First, the EC appears to be drawing an unwarranted distinction between the technical regulation itself, and the application of that technical regulation, and suggesting that only the application of the technical regulation is subject to the obligation in Article 2.1 of the *TBT Agreement*. There is no textual or jurisprudential basis for drawing such a distinction.

149. Second, the text of Article 2.1 does not specify that a comparison of "like products" can only be conducted with reference to products covered by the same technical regulation. Likewise, while it may be true that "there will always be a difference in treatment between products that fall within the technical regulation and those that do not", this has nothing to do with whether two products can be considered "like" or not. In any event, the rationale for such different treatment may be a reason to argue that such products are not "like", but it is not a reason to disqualify certain products from the analysis in the first place.

150. Third, the EC mischaracterizes the thrust of Article 2.1 when it states that "it makes no sense that a technical regulation must accord no less favourable treatment to products to which it does not apply as it does to products to which it does apply". Article 2.1 addresses the discriminatory use of technical regulations as non-tariff barriers. The purpose of Article 2.1 is to ensure that technical regulations are not used to favour or have the effect of favouring domestic products over their like

imported counterparts. The imposition of a requirement in the form of a technical regulation against imported products and not against like domestic products is precisely the sort of discriminatory treatment prohibited by Article 2.1. If this sort of discrimination were found not to fall within the scope of the obligation in Article 2.1, WTO Members could accord less favourable treatment to imported products by subjecting them to technical regulations to which they did not subject their own like products. This cannot have been the intention of the drafters of the *TBT Agreement*.

151. In this particular case, the issue is whether it is acceptable under Article 2.1 of the *TBT Agreement* to prohibit the marketing of corn/maize or canola/oilseed rape (colza) products with certain characteristics, while permitting the marketing of their domestically-grown non-biotech counterparts, when the available scientific evidence demonstrates clearly – and to the satisfaction of the EC's own scientific experts – that the biotech varieties are no more risky than the non-biotech varieties.

70. With reference to paras. 357 and 359 of Canada's first written submission, why is it necessary to consider the first two of the three factors referred to at para. 359? Why would it not be sufficient to determine whether the conformity assessment procedure, or its application, is more trade-restrictive than is necessary to fulfil "the objective of ensuring that products conform with" a requirement, as para. 357 appears to suggest?

152. The three elements set out in paragraph 359 of Canada's First Written Submission were enunciated in the context of the application of Article XX(d) of the GATT 1994 to a measure, and more specifically to the interpretation of the word "necessary". This word also appears in Article 5.1.2 of the *TBT Agreement*, albeit in the context of a provision addressing disciplines on procedural requirements. While there is no reason to believe that the ordinary meaning of the word "necessary" in the context of Article 5.1.2 of the *TBT Agreement* is any different than its meaning in Article XX(d) of the GATT 1994, the Appellate Body did indicate in *Korea – Beef* that the term was capable of a range of meanings, ranging from "indispensable" to "convenient" or "appropriate to the end sought".

153. Given that the term "necessary" as used in Article 5.1.2 is not linked to a measure, as such, but to the application of the conformity assessment procedure, the three elements set out in *Korea – Beef* necessarily will require some adjustments in terminology. Thus, where *Korea – Beef* refers to "the relative importance of the common interests or values that the *measure* is intended to protect", the word "measure" should be replaced by "the application of the conformity assessment procedure". The same adjustments apply to the other two elements.

154. Canada noted in paragraph 357 of its First Written Submission that the concept of necessity is relational. It focuses on the preservation of proportionality between the trade-restrictive effect arising from the application of the conformity assessment procedure and the underlying purpose of ensuring conformity.

155. In light of the foregoing, the first two elements set out in paragraph 359 effectively provide guidance to the interpreter for assessing the underlying purpose, and the extent to which that purpose is being fulfilled through the application of the conformity assessment procedure. The third element provides the counterbalance, that is, the relative restriction on trade that is caused by that application. Where the underlying purpose of the application of the conformity assessment procedure is highly important in the sense that non-conformity leads to serious consequences, such as threats to human health or safety, and the procedure makes a central contribution to the avoidance of such threats, then it may be justifiable to enforce the procedure in a manner that is highly restrictive to trade. Conversely, where the application of the procedure makes no demonstrable contribution to the

underlying policy objective that is reflected in the technical regulation against which conformity is being assessed, it is not justifiable for that mode of application to have a significant negative effect on trade.

156. In this particular case, the product-specific marketing bans have influenced or affected the application (or mis-application) of the conformity assessment procedure. The question that arises is to what extent this application (or mis-application) of the conformity assessment procedure can be said to be "necessary" in the sense described above and in paragraphs 357 to 363.

71. With reference to Article 5.2.1, first clause, of the TBT Agreement, is there a difference between a requirement to undertake and complete a procedure "as expeditiously as possible" and a requirement to undertake and complete a procedure "without undue delay" (see Annex C(1)(a) of the SPS Agreement)? For instance, is it possible that a procedure has not been completed as expeditiously as possible, but that this nevertheless did not entail any undue delay?

157. Canada considers that, in principle, these two phrases are intended to reflect the same concept. There is no reason in principle, logic, textual construction, or the negotiating history of the two provisions, to suggest that they were intended to give rise to different obligations. This view is also supported by the fact that, in each case, the provision that follows (paragraph 1(b) of Annex C, and Article 5.2.2 of the *TBT Agreement*) uses essentially the same language in elaborating on the requirements entailed by the concepts of "without undue delay" and "as expeditiously as possible".

158. At the same time, Canada notes that whether a procedure is completed "without undue delay" or "as expeditiously as possible" must be determined on a case-by-case basis, and with regard to the specific requirements of the *SPS Agreement* on the one hand, and the *TBT Agreement* on the other hand.

72. With reference to para. 478 of Canada's first written submission, could Canada please indicate how the text of each of the relevant member State safeguard measures supports its view that these measures specify which characteristics products must not exhibit in order to be placed on the market rather than identifying specific products which must not be marketed or imported?

159. In each case, the measure refers to the specific genetic characteristic as the basis for the prohibition, rather than the particular species in question. For example, the French measures refer to canola/oilseed rape (colza) containing the events Topas 19/2 and Ms1/Rf1. The effect is that, for canola/oilseed rape (colza) to be marketed legally in France, it must not contain these genetic characteristics. As long as the canola/oilseed rape (colza) complies with the requirement that it not contain the specific genetic event specified, it can be legally marketed. As the Appellate Body has noted,[15] product characteristics can be expressed in negative, as well as positive, terms. Furthermore, the products in question do not have to be expressly identified, only identifiable.[16]

[15] *EC – Asbestos*, Report of the Appellate Body, para. 69.
[16] *Ibid.*, para 70.

ANNEX

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)

Paragraph No. in EC Written Submission	Product	Applicable Legislation	Stages 1 & 2 Competent Authority Review	Stage 3 Circulation to Member States	Stage 4 Regulatory Committee Vote	Stage 5 Council Decision	Stage 6 Consent to placing on the market
216	C/DK/97/01 Monsanto RR Fodder Beet	90/220			Despite ... - positive MS opinion (7 Oct.1997), and - positive SCP opinion (23 June 1998), and - Applicant responds to all MS questions (27 Apr.1998): Commission failed to submit measure for vote by Regulatory Committee		
222	C/ES/96/02 Monsanto Bt Cotton (531)	90/220			Regulatory Committee vote held on 11 Feb. 1999. No qualified majority necessary for adoption of Commission's proposed measure approving product. Opposition by MS not based on scientific risk assessment.	Despite... - positive MS opinion (19 Nov.1997), and - positive Science Committee opinion (14 July 1998), and - 11 Feb.1999 vote in Regulatory Committee with no outcome: AND legal obligation to forward to Council "without delay" under Art.21 of 90/220 Commission failed to submit to Council	
229	C/ES/97/01 Monsanto RR cotton (RRC1445)	90/220			Regulatory Committee vote held on 11 Feb. 1999. No qualified majority necessary for adoption of Commission's proposed measure approving product. Opposition by MS not based on scientific risk assessment.	Despite... - positive MS opinion (19 Nov.1997), and - positive Science Committee opinion (14 July 1998), and - 11 Feb.1999 vote in Regulatory Committee with no outcome: AND legal obligation to forward to Council "without delay" under Art.21 of 90/220 Commission failed to submit to Council	

Paragraph No. in EC Written Submission	Product	Applicable Legislation	Stages 1 & 2 Competent Authority Review	Stage 3 Circulation to Member States	Stage 4 Regulatory Committee Vote	Stage 5 Council Decision	Stage 6 Consent to placing on the market
254	C/NL/98/11 Monsanto RR OSR (GT73)	90/220	Total time for CA review: 54 months (7.Jul 1998 to 22 Jan.2003) Time taken by Applicant to respond to questions: 12 months **Difference: 13 months instead of 90 days (Art. 12 of 90/220)** (note that over 20 months were taken to resolve confidentiality issues in relation to detection methods)	Total time for MS review: 8 months (22 Jan.2003 to 6 Oct.2003) instead of 105 days (Art.15) EFSA scientific review completed 11 Feb.2004 (total 3 months) Regulatory Committee vote expected 16 June 2004 (total 4 months)			
279	C/ES/00/01 Monsanto RR corn (NK603)	90/220	Total time for CA review: 25 months Time taken by Applicant to respond to questions: 13 months **Difference: 12 months instead of 90 days (Art. 12 of 90/220)**		Regulatory Committee vote held on 18 Feb. 2004. No qualified majority necessary for adoption of Commission's proposed measure approving product. Opposition by MS not based on scientific risk assessment.	Proposed measure has not yet been submitted to Council	
286	C/ES/98/01 Monsanto RR corn (GA21) Withdrawn: 15 Sept. 2003	90/220			*Despite ...* - positive MS opinion (27 May 1998) - applicant answers all MS questions (21Oct.1999) - positive SCP opinion (22. Sep. 2000), - completed MS consultation - reduction of scope by applicant to less controversial import only (21 Mar.2001): Commission failed to submit measure for vote by Regulatory Committee		
287	C/F/95/06/01 Monsanto RR OSR (GT73) Withdrawn: 15 Jan.2003	90/220	Competent Authority refused to consider or respond since Feb.1996 (date of last request for information to applicant **Total Time: more than 100 months**				

Paragraph No. in EC Written Submission	Product	Applicable Legislation	Stages 1 & 2 Competent Authority Review	Stage 3 Circulation to Member States	Stage 4 Regulatory Committee Vote	Stage 5 Council Decision	Stage 6 Consent to placing on the market
290	C/ES/99/02 Monsanto MaisGard x RR corn (MON810 x GA21) stack Submitted: 3 Sept. 1999 Withdrawn: 15 Sept. 2003	90/220	Application withdrawn.				
293	C/GB/97/M3/2 Monsanto RR corn (GA21) Submitted: 6 Nov. 1997 Withdrawn: 29 March 2001	90/220	Total time for CA review: 15.5 months (6 Nov1997 – 23 Mar. 1999) Applicant and UK CA reach agreement to forward dossier to Commission with positive opinion (16.Feb.1999) if certain amendments are made, which were made by applicant on 23. Mar.1999) MS failed to forward dossier to Commission for another 7.5 months (2 Nov.1999)		Commission fails to submit measure to Regulatory Committee after completion of MS consultation on 18 Feb.2000		
296	C/BE/99/01 Monsanto /Syngenta RR sugar beet Submitted: 22 Dec.1998 Withdrawn: April 2004	90/220	MS CA fails to complete review, thereby exceeding 90 day limit by several years. April 1999, Nov.2000 and Jan.2001 MS CA requests applicant to "voluntarily" comply with 2001/18 (despite fact that 2001/18 would not be in force until Oct.2002), saying that Commission and Member States would otherwise oppose dossier.				
298	C/F/95/01A Bayer Crop Science Ms1xRf1 Canola/Oilseed Rape	90/220					Commission Decision 97/392/EC consents to placing on the market. MS refuses to issue consent letter.

Paragraph No. in EC Written Submission	Product	Applicable Legislation	Stages 1 & 2 Competent Authority Review	Stage 3 Circulation to Member States	Stage 4 Regulatory Committee Vote	Stage 5 Council Decision	Stage 6 Consent to placing on the market
298	C/F/95/01B Bayer Crop Science Ms1xRf2 Canola/Oilseed Rape	90/220					Commission Decision 97/393/EC consenting to placing on the market. MS refuses to issue consent letter.
209	C/BE/96/01 Bayer Crop Science Ms8/Rf3 Canola/Oilseed Rape Submitted: 30 Sept 1996	90/220	CA renders positive assessment (20 Dec.1996)	MS objections take approx 12 months. Commission requests opinion of SCP, which renders opinion in May 1998. For the next 12 months, discussions ensue relating to fulfilling SCP recommendations (including monitoring plan). Summer 1999 application discussed at Regulatory Committee. Application not put to a vote. Imposition of "interim approach".	Despite… - positive MS opinion (20 Dec.1996) - positive SCP Opinion (19 May 1998) - one year addressing recommendations of SCP Commission failed to submit measure for vote by Regulatory Committee. **Application effectively returned to MS CA. 7.5 year delay in processing application.**		
301	Monsanto RR corn (GA21) Submitted 24 July 1998	258/97	Total time for CA review: 18 months (24 July 1998 to 17 Jan. 2000) Time taken by applicant to respond to questions: 8 months **Difference: 10 months instead of 90 days (Art. 6(3) 258/97)**		SCF review takes 17 months out of which one month can be attributed to applicant Commission fails to submit measure to Regulatory Committee after completion of MS consultation on 18 Feb.2000		
314	Monsanto MaisGard & RR corn (MON810 x GA21) stack Submitted: 16 Mar.2000	258/97	Application pending with the MS CA.				

Paragraph No. in EC Written Submission	Product	Applicable Legislation	Stages 1 & 2 Competent Authority Review	Stage 3 Circulation to Member States	Stage 4 Regulatory Committee Vote	Stage 5 Council Decision	Stage 6 Consent to placing on the market
322	Monsanto RR corn (NK603) Submitted: 24 Apr. 2001	258/97	Total time for CA review: 18 months (24 Apr. 2001 to 5 Nov. 2002) Time taken by applicant to respond to question: 3.5 months (13 Dec.2001 to 28 Mar.2002) **Difference: 14.5 months instead of 90 days (Art. 6(3))**		Regulatory Committee vote held on 30 April 2004. No qualified majority necessary for adoption of Commission's proposed measure. Opposition by MS not based on scientific risk assessment.		
333	Monsanto/ Syngenta RR sugar beet (77) Submitted: 3 Nov.1999 Withdrawn: 16 April 2004	258/97	Application withdrawn.				
337	Monsanto MON863 X MON810 Submitted : 13 Aug 2002	258/97	Product is moving according to the rules.				

ANNEX D-3

REPLIES BY ARGENTINA TO QUESTIONS POSED BY THE PANEL IN THE CONTEXT OF THE FIRST SUBSTANTIVE MEETING

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?

Yes.

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 risk of biotech products? Or would both definitions be appropriate?

Argentina considers that both definitions are appropriate. The applying definition will depend on the type of risk being assessed.

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

Considering the potential risk involved, the risk arising from a food allergens can be considered to be comparable with the risk arising from "toxins" or "disease causing organisms". Allergens and toxins or disease causing organisms relate with risks referred to health, even if in some cases allergens may affect just a sub-set of the population, instead of the population as a whole.

4. Which (if any) are the other binding international 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.

In connection with the specific question, there is no other binding international instrument.

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))?

On the one hand, the absence of a specific reference to "undue delay" in the applicants withdrawals does not imply that "undue delay" was not the case. On the other hand, the silence of the applicants cannot be taken as evidence of satisfaction with the process, but rather as the applicants concern with maintaining good relations with the approving authorities. Anyway, this situation is another expression of the effect of the "de facto" 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 has properly identified the Resolution 39/2003, which controls the liberation of agricultural biotech products. However, footnote 68 of the EC's First Written Submission quotes partially the content of the above mentioned regulation.

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?

No, because the «de facto» moratorium is still in force, and given the fact that it has not been imposed through any document or administrative act we cannot be certain neither on whether it will be effectively withdrawn or not nor on the possibilities of it being reintroduced -should it have been withdrawn -. Additionally, we have mentioned the case Chile – Price Band System in the Oral Hearing, in relation to the safeguard measures, which were subject to the Panel's finding on inconsistency[1].

Argentina strongly disagrees with the EC's argument in the sense that the moratorium has ceased to exist. Precisely, this EC attempt demonstrates the accuracy of the complainants argument about the existence of a "de facto" moratorium.

On the other hand, and assuming for the sake of the argument that the EC statement is correct, how could something cease to exist if it never existed in the first place?

For Argentina:

8. Please elaborate further on para. 71 (notion of appropriate balance) and para. 101 (notion of reasonable relationship) of Argentina's first written submission.

Paragraph 71 uses wording of WTO case law. Argentina referred to the necessary balance between rights of Members to adopt measures to protect life and health and the equally important right of other Members that these measures -if trade restricting- be adopted consistently with the SPS Agreement.

In paragraph 101 of its First Written Submission, Argentina mentions that a measure has to observe the central requirements of the SPS Agreement, namely to be based on scientific evidence and not to be maintained without sufficient scientific evidence. Argentina considers that these requirements have to be given particular importance, since they are established in the title "Basic rights and obligations" of the SPS Agreement. In the present WTO dispute, the measure, the"de facto" moratorium, has been established without this requirement -scientific evidence-, and it is being maintained for more than five years without scientific evidence supporting it.

In this sense, the Appellate Body determined that "sufficiency" implied a relationship between two elements: i) the sanitary or phytosanitary measure and ii) the scientific evidence. In the opinion of Argentina, its application to the present dispute implies that the relationship must be between the measure, the "de facto" moratorium, and the scientific evidence.

Since the EC has applied the measure, the "de facto" moratorium, with no support of any scientific evidence, Argentina considers that the EC has infringed its obligations under Article 2.2 of the SPS Agreement.

[1] Panel Report in *Chile – Price Band System and Safeguard Measures Relating Certain Agricultural Products*, WT/DS207/R, paragraph 7.125.

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?

It must be highlighted that these products did not receive any "approval", but did undergo a "notification" procedure instead. So, strictly said, the answer is none.

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?

Compared to conventional selective breeding techniques which frequently result in random rearrangements of the genome, rDNA techniques permit a more precise modification of the genome, resulting less disruptive to other non-targeted areas of the genome. These techniques enable plant breeders to develop a greater understanding of what has occurred to the genome at the molecular level.

Regardless of the method used, the resulting organism must be screened for the desired traits -i.e the desired phenotypic characteristic-. This may involve screening several generations of the organism to ensure stability of the genetic modification. Regulators can then evaluate the end product to determine its safety.

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?

While it is theoretically possible that rDNA techniques could produce novel proteins with previously unknown allergenic properties, there is no reason to conclude that this possibility is any greater for biotech foods as compared with non-GM novel foods.

The potential allergenicity for biotech foods compared to conventional food is the same, because it depends on the introduced gene and the donor, not on the method by which the gene is introduced.

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?

The concerns are comparable, which is why it is important to consider the final trait, regardless of the method of introducing the trait.

It is also important to note that herbicide management systems to combat invasiveness of crops are a common feature of agronomic practice. This applies to conventional and biotech products alike. Resistance to one herbicide, regardless of whether the crop is biotech or not, does not imply that risks cannot be controlled. It may simply mean that another herbicide must be used to control any resulting volunteers.

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?

As regards to the specific question, Europe is considered to be the center of origin of wheat, oats, barley and rye -none of which have currently any developed "biotech counterpart"-. Despite this, the EC has not mentioned the issue of Europe being the center of origin of any specific crops. EC's vague and general reference to "center of origin" is another attempt of raising abstract and hypothetical concerns which have never been raised referred to specific applications because they are not relevant or which have been rejected because they are unsubstantiated.

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)

Considering the possible risks arising from a developing agricultural biotech product -with no risk assessment- the gene transfers could generate effects similar to "contaminants".

The expression "reaction created by gene transfers" is less accurate. Despite that, considering the general sense of the question and the point related to potential risks of an agricultural biotech product, the gene transfer could generate effects assimilable to contaminants.

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?

Whenever the genetic modification raises a food-safety concern, this concern should fall within the SPS Agreement as a human health concern.

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.

In Argentina's view, the most likely way in which biotech products can damage biodiversity or the ecological balance of an area is through negatively affecting wild flora and/or fauna.

Nevertheless, Argentina considers that the scope of Annex A:1(d) is broad enough ("to prevent or limit other damage...") so as to encompass any further damage to biodiversity or the ecological balance.

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.

Related to the expression "novel biotech-specific herbicides", the herbicides have not been developed for specific biotech products; to the contrary, the biotech products were developed specifically for the herbicide.

The type of negative impact on human, or animal life or health, caused by the use of herbicides is specific to individual herbicides. These impacts are routinely assessed at the time the herbicide is approved for marketing and may involve the imposition of conditions on the use of the herbicide. Any negative impact on human or animal life or health, if any, is related to the agronomic practices associated with herbicide use, not the biotech product per se. In fact, certain herbicide-tolerant biotech crops permit more environmentally sustainable agronomic practices. For example, the use of herbicide-tolerant soybean (tolerant to the herbicide glyphosate) enables farmers to practice zero-till agriculture resulting in less adverse impacts on the environment than the traditional practice, common in the EC, of using pre-emergent herbicides.

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?

The EC's arguments appear to be related to herbicide use, not herbicide resistance.

In any event, the potential effect of herbicide resistance on flora and fauna is not dependent on whether the herbicide tolerance trait has been produced through rDNA techniques, but rather on the type of herbicide used. For example, some broad spectrum herbicides, such as imidazolone, may lead to greater selection of herbicide tolerant weeds due to the fact that the herbicide remains effective in the soil longer than with other herbicides. By contrast, glyphosate (marketed under the tradename Roundup), leads to lower selection pressure for herbicide tolerant weeds as glyphosate rapidly degrades in the soil. Imidazolone is typically applied to traditionally bred herbicide tolerant crops, while Roundup is typically applied to biotech herbicide tolerant crops. The potential negative effect is more a function of the accumulation and residual soil activity of the herbicide than the method by which the herbicide tolerant trait is produced.

The EC also fails to mention that one of the benefits of herbicide-tolerant crops is that they allow for greater efficiency and provide greater flexibility for managing and rotating crops. Herbicide-tolerant crops may result in a reduction in the use of herbicides, saving time, fuel and chemical costs, reducing farmer's exposure to herbicides, and reducing the impact on the environment.

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?

Yes, regarding the risks, any undesirable cross-bread of plant could be considered a "pest" -for instance, when a herbicide-tolerant gene is transferred to the crops' weeds.

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?

Controlling insects has been part of agricultural management practices for a long time. If a pest management strategy is no longer effective because the target pest has developed resistance, the "risks arising from the entry, establishment or spread" of that pest do not disappear. Regulators and farmers alike are still concerned about the risks of that pest becoming "established" or "spreading". This does apply no matter whether the resistance was acquired through pesticides within the genome of a crop or through conventional application of pesticides.

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.

Yes. For example, the modification of the balance of the complex micro-organism population in the RIZOSFERA of the plant.

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?

The object and purpose of this requirement is to provide predictability within the approval procedures.

(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"?

Yes, it is correct, because a delay needs to be "undue" in order to breach Annex C:1(a) of the SPS Agreement. Additionally, a delay is "undue" when it is not justified under a substantive provision of the SPS Agreement or under a specific provision of Annex C of the same Agreement.

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)?

We are dealing with a single procedure, and the length of the approval must be calculated from the original application. Otherwise, a Member would be entitled to delay indefinitely the approval just by changing its approval regulation.

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".

Yes, the "approval procedures" are SPS measures, as stated in Annex A:1 which explicitly includes "inter alia... approval procedures...". Consequently, these approval procedures are subject to the substantive provisions of the SPS Agreement as set forth in Article 8. If there is any infringement of the substantive provisions put forward by the complaining parties -i.e. Articles 5.1, 2.2, 5.5, 5.6 and 2.3 of the SPS Agreement-, this would lead to an infringement of Article 8 of the same Agreement. However, even without any infringement of the substantive provisions, Article 8 could be breached through infringement of any provision within Annex C.

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?

The EC is the relevant WTO Member. It is the EC the one which has been complained against in this proceedings and the one which is internationally responsible before the WTO. This has been acknowledged by the EC in these proceedings.

(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?

WTO Members do have the right to apply the level of protection they consider to be appropriate. Nevertheless, this does not imply that they can ignore the rest of the requirements within Article 5.5 of the SPS Agreement.

Consequently, it can be inferred that EC Members may apply –permanently or provisionally- different levels of protection than the one applied by the EC, as long as they respect the SPS Agreement.

In any case, we should bear in mind that the EC regulatory system -which Argentina is not questioning in this dispute- provides safeguard measures to be used.

In this case, it should be noted that the prohibitions by some Member States on certain biotech products -alleging safeguard measures- were rejected within the EC's own approving system based on scientific evidence.

The real problem about these issues, according to Argentina, does not point to the fact whether EC Member States are entitled to establish the level of protection they consider to be appropriate –which has never been questioned in these proceedings-, but to establish whether the Member States have infringed the SPS Agreement by exercising this right.

At any case, the EC did never raise the issue of right to a higher level of protection by its Member States, neither within the EC's First Written Submission nor within the Oral Intervention.

<u>For all complaining parties</u>:

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.

There appears to be no difference in substance between the position expressed by the complaining parties and that of Norway on this point. The phrase "modern biotechnology" might well 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.

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?

We do not agree. The mentioned risk falls within the scope of the SPS Agreement, because it refers to health and life.

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?

Argentina agrees that DNA is not an organism. However, the risk to be protected against is the risk arising from the modification of DNA within a living organism -a plant-, so it falls within the scope of the SPS Agreement.

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.

Argentina does not agree. There is reliable evidence at hand, namely the positive opinions of the scientific committees of the EC.

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.

The EC has stated that there was a "Common Position" taken on an uncertain date somewhere "in summer of 1999" -describing it as "a document adopted by the Council"[2] but with no submission of this document-. Through the reference to a document like the "Common Position", the EC continues acknowledging that the "de facto" moratorium is an intended measure, responding to a specific intention, and addressed to all biotech products. Through the "Inter-Service Consultation" from February 1999, the "Common Position" from summer 1999, and the following "interim approach", the EC continues stating that there are, in fact, EC political actions not regulated in its approval system, which did prevent the approval of biotech agricultural products, which did respond to a political intention of the EC, and which, added to all evidence submitted by the co-complainants, demonstrates the beginning of the "de facto" moratorium.

[2] First Written Submission of the EC, paragraph 206, footnote 140.

With the introduction of these concepts -"Inter-Service Consultation", "Common Position" and "Interim Approach", all of which took place in early 1999, the moment when the "de facto" moratorium was beginning to be applied after the last approval in 1998-, the EC is giving name to stages which were not set forth in the approval procedures and which had the effect of stalling these procedures, thus manifesting the beginning of a "de facto" measure.

In short, these concepts further demonstrate that from the beginning of 1999 the EC intervened on the approval procedures on the grounds of an alleged change of legislation. The EC thus admits that it applied a "de facto" measure. This "de facto" measure was supposed to last -at least as the EC first stated- until Directive 2001/18/EC would come into effect. As the co-complainants demonstrated and the EC did not refute, the "de facto" measure would still last longer. Argentina considers that the EC admitted that the "de facto" moratorium had a beginning and was maintained for years and request the Panel to make finding on this issue accordingly.

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?

Argentina considers that the phrases "failure to grant final approval" or "failure to allow products to move to final approval" used in the Panel's question are equal to the phrase "suspension of" -as used in the terms of reference of Argentina-

In the Argentinean claim, the phrase "suspension of..." refers to procedures with a positive scientific opinion which was led to no approval anyway, while the phrase "failure to consider..." refers to procedures which did not even obtain any scientific assessment at all within the proceeding.

Being so the case, Argentina claims against the "failure to consider" the application of A2704-12 and A5547-127 soy.

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?

No, the measure "de facto" moratorium cannot be exclusively described as a "decision not to decide", since it has been revealed sometimes as a "decision not to decide", while other times as a "decision" of not approving (i.e. through the blocking in some stage within the EC approval system).
In this sense, Argentina points out that the "de facto" moratorium implies both actions as well as omissions.

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?

The "de facto" moratorium had as an effect an "undue delay" in all the EC approval system. In this sense, the "de facto" moratorium has affected all applications.

Being the "de facto" moratorium a general measure as described in the First Written Submission of Argentina, it has affected all the applications regardless of the moment in which these applications were presented.

Argentina reminds that the "de facto" moratorium affects all applications of biotech products, while the claim of "undue delay" refers to specific products of interest of Argentina. Additionally, we remind the Panel that the "suspension of processing and failure to consider individual applications for approval of specific biotech agricultural products of particular interest to Argentina" refers to specific products of Argentina, too.

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)

For all the products of its interest, Argentina is referring to the latest stage in which the application was affected by the "de facto" moratorium. Further details will be submitted in the rebuttal.

In the first and second stage, Argentina considers that there is indeed a "decision not to decide". The measure, "de facto" moratorium, is indeed given effect through a "decision not to decide" when the "initial reports" are not prepared[3].

In the third stage, the "de facto" moratorium is given effect through a specific action, expressed by the objections of EC Member States. In this case, there is not a "decision not to decide", but a specific action.

In the fourth stage, the "de facto" moratorium is given effect when the Commission does not submit any draft decision to the Regulatory Committee -thus implying a "decision not to act"-[4].

In the cases in which the Commission did submit a draft decision to the Regulatory Committee, the "de facto" moratorium is given effect when the Committee has not been able to achieve the majority of votes to make a decision. In this case it is difficult to establish whether there was a "decision not to act", since there was indeed an action -the submission of the draft to the Regulatory Committee- with no majority at the end.

In the fifth stage, when there is no majority within the Regulatory Committee, the Commission must submit the matter to the Council of Ministers. When the Commission does not make the submission, the "de facto" moratorium is given effect. Hence, there is a "decision not to decide"[5].

---

[3] For Soybeans (A2704-12 and A5547-127) under Directive 90/220/EEC, see EC's First Written Submission, paragraph 261, and under Regulation (EC) 258/97, see paragraphs 310-313.

[4] For GA-21 maize under Directive 90/220/EEC, see EC's First Written Submission, paragraph 286 et seq, and under Regulation (EC) 258/97, in paragraphs 301-304.

[5] For Bt-531 cotton under Directive 90/220/EEC, see EC's First Written Submission, paragraphs 222-228.

For RRC 1445 cotton under Directive 90/220/EEC, see EC's First Written Submission, paragraphs 229-234.

In the sixth stage, once the decision has been made, the Member State in which the application was presented must notify the applicant that the product is to be put in the market (according to Directive 90/220/EEC and Directive 2001/18/EC). Here there is also a "decision not to act".

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:

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

No, since the relevant risk falls within the scope of Annex A of the SPS Agreement and does not have any justification in light of the SPS provisions.

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

No, applicants have no other choice but to accept any further requirements they are put. Accordingly, their behaviour cannot be deemed to be "voluntarily", thus it might not be inferred that the following procedural delays would be justified.

Besides that, the behaviour of the applicant is not relevant anyway, since individuals or firms are not in a position to wave rights or obligations under the covered Agreements.

(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;

Argentina highlights that whether a new legislation is "imminent" rather than "effective" has no legal value in order to consider any justification under the WTO. On the contrary, Argentina reminds of the fact that, regardless of whether the EC's new legislation was "imminent" or not, applicants had no other choice than complying with the new requirements set forth by the EC authorities.

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

Where the applicant has caused the delay, a delay in the completion of the approval procedure would be justified.

(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);

For NK-603 maize under Regulation (EC) 258/97, see EC's First Written Submission, paragraph 327. Nevertheless, with reference to the application under Directive 90/220/EEC and Directive 2001/18/EC – paragraph 284 – the Commission did indeed submit the matter to the Council; Argentina trusts that this is going to end in a final approval as the EC keeps stating.

If there was any existing legislation or other relevant rule, the obligation might be the rejection or the approval of the application, but never something like an "undue delay".

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

No, the delay is not justified, because the approval must be based on risk assessment. Where there is positive risk assessment, approval must be granted. Otherwise, the refusal to approve becomes "undue delay".

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?

No to both cases.

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.

No, Argentina does not agree. The SPS Agreement and the TBT Agreement are mutually exclusive, according to Article 1.5 of the TBT Agreement. Besides, and specifically related to paragraph 441, by definition a measure cannot be a "series of measures". Additionally, Argentina considers that the measure at issue does not comply with the TBT requirements related to the form of the measure as contemplated in Annex 1 of the TBT Agreement.

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)?

Without prejudice to Argentina's position on the nature of the relation between Articles 5.7 and 5.1 of the SPS Agreement, in order to exclude the applicability of Article 5.1 by virtue of Article 5.7, substantive requirements of the latter must be fulfilled. It is up to the EC to satisfy the burden of proof within the logic of its arguments[6] related to the four elements of Article 5.7. Argentina argued in its First Written Submission about the lack of fulfilment of Article 5.7 requirements by the "de facto" moratorium. The EC argued in its submission about the exclusion by Article 5.7 in the Member States bans. However, no proof has been advanced, even in relation to the first requirement of Article 5.7 -absence of scientific evidence- vis-à-vis scientific evidence supporting the approvals. The Panel formally requested the EC

[6] EC's First Written Submission, paragraph 575.

to table this evidence in order to satisfy its burden of proof, so the complainants are not in a position to argue further on the second, third and forth requirement of Article 5.7 of the SPS Agreement.

Additionally, Argentina endorses Canada's argument in paragraphs 67 and subsequent, highlighting that in the case of the Member State bans, risks assessments were performed at least two times for each product. It is clear that there is in fact sufficient scientific evidence in order to have the Member States bans lifted. Argentina will further develop this argument as necessary in the rebuttal.

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

Argentina does not agree with this attempt of the EC of turning Article 5.7 to a pivotal Article capable of disabling other provisions in the SPS Agreement, given that there is no textual relationship between them -unlike Articles 2.2 and 5.7 which are referred to as rule and exemption-.Besides, both provisions do not deal with the same matter: while Article 5.7 refers to the amount of information needed for applying a measure and to the provisional character of that measure, Article 5.6 refers to the degree of trade restriction resulting from that measure. Articles 5.7 and 5.6 deal with different obligations.

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

On the same grounds, Argentina rejects the EC's assertion on Article 5.7 as excluding Article 5.5. The latter refers to distinctions in levels of protection which entail discrimination or disguised trade restrictions.

(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)

In the context of Article 2.2, the sufficiency of the scientific evidence relates to whether it adequately supports the measure taken. As has been noted in the jurisprudence, the ordinary meaning of "sufficient" is "of a quantity, extent, or scope adequate to a certain purpose or object". With respect to the requirements of Article 2.2 and Article 5.1, this means that there must exist "a rational or objective relationship between the SPS measure and the scientific evidence". This is to be determined on a case-by-case basis and will depend on the particular circumstances of the case, including the characteristics of the measure at issue and the quality and quantity of the scientific evidence.

The sufficiency of the scientific evidence goes to the question of whether there is adequate scientific evidence to make an objective assessment of risk. If there is sufficient scientific evidence to make an objective assessment, then Article 5.7 would not be available. There would be no need for a provisional measure.

The EC has acknowledged that by requesting the Member States to lift their bans[7].

[7] Canada's Oral Intervention, paragraph 68.

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?

No, they are not. There was sufficient relevant scientific evidence at hand, opposed to the bans, which were declared groundless by the scientific Committees of the EC.

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?

The EC definition of "adequate risk assessment" is not the correct one. An adequate risk assessment must basically consider two aspects: the phenotypical expression and the genetic molecular characterization. The assessment criteria must be based in a case-by-case approach.

Consequently, the definition of "adequate risk assessment" in paragraph 604 is not correct, since it does not consider the aforementioned aspects and because it does not currently remain valid given the advances in scientific knowledge.

For Argentina:

53. With reference to para. 42 of the US oral statement, is the United States correct in stating that "the co-complainants here are not saying that a pattern of decisions itself *constitutes* a measure. Instead, the co-complainants have pointed to an unbroken pattern of [non-]decisions as the inevitable *result* of the moratorium, which is itself an independent measure"?

Argentina considers that the "de facto" moratorium is a "measure".

In this sense, Argentina is of the opinion that the "de facto" moratorium is a compound of actions and omissions by the EC which has lead to the failure of approval of biotech agricultural products from 1998 to the present (or to the establishment of the Panel).

For this reason, and as stated in its First Written Submission and Oral Statement within the First Meeting of the Panel with the parties, the "de facto" moratorium -given its characteristics- cannot be restrained to concepts like "patterns of decisions or non-decisions".

The "de facto" moratorium constitutes an EC measure which had the effect of not allowing approvals in the mentioned period.

This measure is given effect through changes in the EC legislation which implied stalling the approval procedures, through failure to consider the applications -in those products which did not obtain any scientific assessment-, through suspensions of the procedures -in those products which did obtain a positive scientific assessment-, through a constantly and systematically alleged necessity for more adequate legislation, in such a way that the new legislation -Directive 2001/18/EC- had no time to enter into effect while the EC already was talking about new necessities. In short, the approval requirements became a "moving target" for the applicants.

In other words, the "de facto" moratorium is a measure by the EC. This is inferred from the declarations of the EC's own officials which acknowledged its existence many times. These

declarations, as mentioned by Argentina, are not per se binding for the EC, but are crucial since they are capable of proving the existence of the "de facto" moratorium.

54. With reference to para. 314 of Argentina's first written submission, could Argentina explain why the "additional information that may have been required or delays in the technical reports by the respective scientific committees" do not justify the alleged delays in the processing of any of the products specified by Argentina?

The last sentence of paragraph 314 must be read in the broader context of the same paragraph and in the much broader context of paragraphs 296 to 315. Then, it appears clear that there is no other specific information supporting the breach of the timeframes of the EC procedures.

Given the lack of any other relevant scientific evidence, the conclusion contained in the last sentence of paragraph 314 flows naturally. There were no other elements at the time when the delays took place.

55. 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?

Argentina is not aware of any of those situations. However, given the nature of the "de facto" moratorium, it becomes irrelevant.

56. With reference to para. 469 of Argentina's first written submission, could Argentina provide further details regarding why the member State safeguard measures were established in accordance with Annex A(1) of the SPS Agreement?

Argentina considers that these measures were applied- within the pertinent EC legislation- with SPS purposes, namely the safeguard mechanism established by Directive 90/220/EEC and Regulation (EC) 258/97). Additionally, these measures were analysed by the EC Scientific Committees, which found them to be groundless.

Besides, not only the purpose was an SPS one, but the Member States themselves decided to apply the measures under that provision.

57. With reference to para. 655 of the European Communities' first written submission, is the European Communities correct in arguing that Article 2.1 of the TBT Agreement only applies "to differences in treatment between products that are covered by the technical regulation in question"?

No. Argentina considers that a determination of similarity has to be made according to GATT/WTO jurisprudence.

The EC argument is incorrect, since it leaves the determination of similarity based on whether any product be or be not included within a specific regulatory system.

Besides that, if one were to follow that idea, a WTO Member would be able to apply so many regulatory schemes as the amount of similarity determinations it is intended to avoid. Being that the case, it would be very easy for a Member to avoid its WTO obligations (as stated by New Zealand in its Submission as a Third Party).

58. With reference to Article 5.2.1, first clause, of the TBT Agreement, is there a difference between a requirement to undertake and complete a procedure "as expeditiously as possible" and a requirement to undertake and complete a procedure "without undue delay" (see Annex C(1)(a) of the SPS Agreement)? For instance, is it possible that a procedure has not been completed as expeditiously as possible, but that this nevertheless did not entail any undue delay?

First, Argentina recalls that the SPS Agreement and the TBT Agreement are mutually exclusive.

Second, Argentina considers the terms "undue delay" to be of a stricter nature than the terms "as expeditiously as possible". The former refers explicitly to the word "undue", which implies the existence of requirements in order to render the delay "due" or "undue". It is the opinion of Argentina that Article 8 of the SPS Agreement refers to both substantive requirements -those listed, for instance, in Articles 5.1, 2.2, 5.5, 5.6 and 2.3 of the SPS Agreement- and to other requirements, listed in Annex A of the same Agreement.

On the other hand, the wording "as expeditiously as possible" only refers to the obligation to act in a quick manner, regardless of any further requirements besides the proper speed.

Despite the distinction, and with reference to the last question, Argentina considers that the proper order of analysis should be the opposite. The SPS Agreement and the TBT Agreement are mutually exclusive. Besides, the former deals with the specific object and purpose of protecting life and health while the latter makes no specific reference. Since the SPS Agreement has more requirements addressing the issue of delay -see "undue delay" with its requirements vis-à-vis the "expeditiousness" of the TBT Agreement-, the analysis should be made beginning with the SPS Agreement. Should the SPS Agreement -and the "undue" delay- be disregarded for some reason, then one should consider the TBT Agreement and the acting "as expeditiously as possible".

Consequently, we do not believe that a procedure that has not been completed as expeditiously as possible -under the TBT Agreement- would nevertheless not entail any undue delay -under the SPS Agreement-.