ANNEX F-7

REPLIES BY ARGENTINA TO QUESTIONS POSED BY THE PANEL IN THE CONTEXT OF THE SECOND SUBSTANTIVE MEETING 7 MARCH 2005

For all parties:

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

We agree with the broad scope contained in S1, Annex "Comments on the scope of the IPPC in regard to environmental risk", in Exhibit US-123, page 34. However, the important issue is the interpretation of the term "pest" in the *SPS Agreement*, not the interpretation of the term "pest" in the IPPC.

However, Argentina agrees that the term "pest" in the *SPS Agreement* should be given a broad interpretation in the light of the broad interpretation given to the term "pest" in the IPPC and the ISPM No. 11. The text of the ISPM No. 11 suggests that "[t]he 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."[1] This suggests that the phrase "injurious to plants and plant products" should be interpreted broadly.

The broad interpretation of the term "pest" in ISPM No. 11 serves to confirm that the term "pests" in the SPS Agreement should be given a similarly broad interpretation. However, an organism is only a "pest" for the purposes of the SPS Agreement and the ISPM No. 11 if it is "injurious to plants or plant products" in the sense of causing damage to plant life or health.

120. With reference to Annex A(1)(d) of the SPS Agreement, please answer the following questions:

(a) What is the meaning of the term "other damage"?

The concept of "other damage" refers to the prevention of the situations not listed in paragraphs (a), (b) and (c), and related to pests.

(b) Does the term "other" imply that Annex A(1)(a) through (c) are also about "damage"? If so, does the term "other damage" cover damage sustained by plants, animals or humans other than damage to their "life or health"? Please provide examples.

Yes. One example is damage referred to fitness.

[1] Exhibit US-123, p. 34.

(c) Is "other damage" limited to damage sustained by plants, animals or humans? If not, please provide examples.

No, it is not limited to these damages. One example refers to microbiota.

121. With reference to Article 5.1 of the SPS Agreement, what were the relevant risk assessment techniques developed by the relevant international organizations that the European Communities had to take into account in the relevant period (October 1998 – August 2003)?

There were no "relevant risk assessment techniques" by relevant international organizations at that time (October 1998-August 2003).

122. Please explain your views as to the relationship between a Member's appropriate level of protection and the requirement in Article 5.1 to ensure a measure is based on a risk assessment, as appropriate to the circumstances. Is the appropriate level of protection relevant to the conduct of the risk assessment?

In principle, we believe that appropriate level of protection and risk assessment are related. However, this relationship must be qualified to avoid that the obligation contained in Article 5.1 becomes meaningless.

Besides, Argentina deems that nothing in the wording of the SPS Agreement suggest that a Member can establish an "appropriate level of protection" disregarding risk assessment.

In this case, the EC has carried out a risk assessment through its own scientific committees which found no risks in the products assessed. Hence, there is no justification for not approving or for asking for more information.

In any case, the risk assessment as such, has to remain objective, autonomous and science-based.

123. Please assume for the sake of argument that Article 5.7 of the SPS Agreement provides for an exception in the nature of an affirmative defence:

(a) Could the Panel assess the merits of any such defence without having previously found an inconsistency with Article 2.2 of the SPS Agreement?

No.

(b) If not, in a case such as this one where a claim of inconsistency with Article 2.2 of the SPS Agreement is based on a claim of inconsistency with Article 5.1 of the SPS Agreement, would it be correct for the Panel to begin its analysis with the Article 5.1 claim, then move to the consequential Article 2.2 claim and finally turn to the Article 5.7 defence?

Yes.

For all complaining parties:

124. With reference to para. 19 of the European Communities supplementary rebuttal, do the complaining parties agree that the Panel "is not asked to determine whether a prudent government, in the abstract, *should* have behaved or not in a certain manner thus causing delay. It merely needs to find whether, in the concrete case and in light of the factual information and the legal arguments before the relevant authorities, that behaviour which in the end caused a delay *could* justifiably have been adopted"?

We do not agree. The Panel is called to determine whether a government has observed its obligations under the SPS Agreement.

125. The European Communities' opening statement at the Panel's meeting with the experts includes the following statements:

- **"[T]he European Communities' approach is to seek more evidence to establish whether or not there is a risk […] in order to make a definitive decision on the basis of full information – even if that takes a little more time". (para. 19)**

- **"The European Communities reacts [to uncertainty as to the appropriate risk management strategies] by saying 'let's take our time and reduce the uncertainty". (para. 17)**

Do the complaining parties consider that it would be consistent with Annex C(1)(a) of the SPS Agreement to delay making a definitive decision based on the approach outlined by the European Communities? In answering this question, please take into account the provisions of Article 2.2 of the SPS Agreement[2] and Article 5.7 of the SPS Agreement (adoption of provisional measures based on available pertinent information).

As regards the first statement, Argentina does not agree because of the following reasons:

(a) In this specific WTO case, risk assessments have been carried out properly, taking into account the past experience when dealing with agricultural biotech products. The expected risks have been properly analysed, so there is "sufficient" information to make a decision. The EC approach is, as defined by Dr. Snow, referred to what is "nice to know". As regards the last part of the statement ("little more time") we do not agree either. The time taken has not been little. This situation began in 1998 and affected a whole group of products. Within this specific WTO case, the EC has had "sufficient" information to assess whether there was any risk. Therefore, it is Article 2.2 that should be applied , not Article 5.7;

(b) the expression "full information" is misleading. Argentina considers the information that enables a WTO Member to establish a sanitary or phytosanitary measure, apart from being scientific evidence, has to be "sufficient". If a WTO Member intends to obtain "full information", it has to amount to scientific evidence and it has to be relevant and "sufficient". This applies to the general obligations set forth in Article 2.2 of the SPS Agreement, that clearly establish the requirement of

[2] In *EC – Hormones*, the Appellate Body stated in relation to Article 2.2 that "a panel charged with determining [...] whether 'sufficient evidence' exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned" (para. 124).

"sufficiency". In this specific case, Argentina considers that the EC had sufficient scientific evidence at hand, namely the positive opinions by the EC Scientific Committees -which have not been refuted by any scientific evidence-.

As regards the second statement, Argentina believes that it is not a question of "uncertainty" but about "sufficiency". As correctly stated by the experts and by the WTO jurisprudence, science cannot provide a complete and definitive assurance regarding risks or uncertainties. If we were to accept the concept of uncertainty instead of "sufficiency", any WTO Member would be entitled to use it as an excuse for not making any decision within the SPS Agreement, thus, circumventing its obligations.

126. In paragraph 10 of the EC Responses to the Questions from the Panel (16 June 2004), the European Communities compares the definitions of risk assessment as used in the SPS Agreement and as used in Codex, and concludes that "It is clear that the SPS definition of risk assessment is equivalent to 'weighing policy alternatives in the light of the results of risk assessment' which is part of the Codex Definition to ¨'risk management'". Do you agree with this conclusion? Please explain your response.

Argentina does not agree.

The "risk assessment" in the SPS Agreement must be science-based. Even the EC seems to agree with this position since in its Responses to the Panel Questions (June 2004) cites a decision of the European Court to the effect that if the Regulatory Committee disregards the scientific opinion "it must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter. The statement of reasons must be of a scientific level at least commensurate with that of the opinion in question."[3]

Besides, there is no scientific evidence able to contradict the EC's scientific committee opinions.

Questions not Previously Provided to the Parties

For all parties:

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

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

The IPPC 1997 is not yet in force, as the required two-thirds of the IPPC contracting parties have not yet deposited their instruments of acceptance of the 1979 amendment of the IPPC. Therefore, although the IPPC 1979 could be considered "rules of international law", this is not the case with respect to the IPPC 1997 because it has not yet come into force.
Argentina does not consider Codex Standards 192 and 193 or ISPM No. 11 to be "rules of international law".

[3] EC Responses to Panel Question, para. 57.

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

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

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

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

Yes, as stated in our First Written Submission, paragraphs 57-63.

142. Please explain the meaning and rationale of the requirement in Article 2.2 that SPS measures be "based on scientific principles" and how this is different from the requirement that SPS measures not be maintained "without sufficient scientific evidence".

The reference in Article 2.2 to "scientific principles" relates to the methodological soundness and rigor of the scientific evidence relied upon to support the measure in question. "Scientific principles" are reflected in Articles 5.1 through 5.3 and in the definition of "risk assessment" found in paragraph 4 of Annex A in the sense that the risk assessment must be methodologically sound, sufficiently rigorous to meet the requirements of the definition, and must include consideration of the factors set out in Articles 5.2 and 5.3.

The foregoing suggests that "scientific principles" as used in Article 2.2 relates to the use of scientific methods of analysis, such as empiricism, objectivity, peer review and falsifiability (hypotheses can be tested and previous results verified or refuted). It is important that the data and other information put before the risk assessor is free from bias. In other words, it addresses the scientific rigor of the knowledge relied upon by the risk assessor. This can be distinguished from the term "scientific evidence", which focuses on the relationship between the conclusions of the risk assessment – rather than its conduct per se – and the risk management (SPS) measure selected.

To some degree, the notion of "scientific principles" is reflected in the requirements set out in Article 5.2 and 5.3 with respect to the conduct of the risk assessment, and in the definition of "risk assessment" found in Annex A. The two provisions specify, to a certain degree, the types of factors that must be included in the risk assessment, and the definition establishes the rigor that must be observed in its conduct.

143. The Panel notes a number of instances where the same or a related product was apparently submitted under separate applications for approval. This appears to be the case for Monsanto Roundup Ready oilseed rape GT73 (EC-70, EC-79); Syngenta Bt 11 maize (EC-80, EC-92, and related EC-69); Pioneer/Dow AgroSciences Bt corn Cry1F (1507) (EC-74, EC-75, EC-95); Monsanto Roundup Ready corn NK603 (EC-76, EC-96); Monsanto Roundup Ready corn GA 21 (EC-78, EC-85, EC-91); and the various "stacked" products. To what extent does the assessment by a lead CA, the relevant EC Scientific Committee and any information

provided by a notifier under one application serve as a basis for consideration of another application for the same or a related product?

Argentina observes that a product may have undergone different application procedures due to the EC legislation: Directive 90/220/EEC (later replaced by Directive 2001/18/EC) and Regulation (EC) 258/97. For example, NK 603 maize did undergo an assessment under the Directives (EC-76) and another under Regulation (EC) 258/97 (EC-96), legislation which has similar requirements. However, the risk assessment can entail different approaches. This makes it difficult to establish a general criteria. Notwithstanding, the assessment of a product by one scientific committee could have served as a basis for considering another application for the same or related product to the extent that the risks being assessed were the same or even similar. In any case, Argentina has relied on positive scientific opinions by the EC Scientific Committees in both proceedings (under the Directives and under the Regulation (EC) 258/97) when both proceedings applied.

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

Where the toxicology of the expressed protein had already been examined for one product (e.g. soybean tolerant to glyphosate), this would have simplified considerably the toxicological evaluation where the same protein was expressed by a second (e.g. NK603 maize), especially (as in this example) where the approval of the first product had created a history of safe consumption of the protein. Where there were minor differences in the DNA coding sequences for the given protein, or minor differences in the structure of the protein itself, this would require some examination.

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

145. With reference to para. 7 of the European Communities second oral statement, is it "for the Complainants to rebut this evidence [submitted by the European Communities] by putting forward arguments and evidence as to why reasons for delays put forward in the European Communities' submissions are unjustified"?

We do not agree with this statement, because it assumes that the EC has submitted evidence and that the complainants have the burden to refute it. This WTO case is to be seen the other way: the complainants have submitted scientific evidence and it was the EC, as a defendant, the party called to try to refute this evidence or to justify its measures.

In short, it is the EC the party being asked to justify its measures, given that the complainants already had put forward scientific evidence favouring approvals of agricultural biotech products.

For Argentina:

146. With reference to Argentina's contention in the first part of Argentina's Second Oral statement, 21-22 February 2005, that the European Communities' has not provided any scientific evidence (other than that produced by the EC scientific bodies), how would Argentina describe the studies and analysis undertaken, *inter alia*, by the Commission du Génie Biomoléculaire on Cotton RRC-1445 (EC-66/Att.54); and the French AFSSA (EC-76/Att.41) and the Commission du Génie Biomoléculaire on Maize GA-21 (EC-76/Att.43)?

Regardless the qualifications of the bodies that issued the mentioned documents, the documents themselves cannot be regarded as scientific evidence since they do not contain a technical analysis of scientific facts (like the EC scientific bodies). They do not constitute any risk assessment, they refuse to issue a decision or they deny approval just because there was (on their opinion) lack of some information (which apparently were not deemed necessary by the EC scientific bodies).

For instance in EC76-043, it is recognized that the application contains all the information required by the normative 2001/18 EC.

In EC76-041 it is explicitly concluded that the AFSSA is not able to issue any judgement based on scientific grounds, so it is evident that this is not intended to be a scientific/technical report at all.

Finally, in EC66-054, an unfavorable recommendation is based purely on alleged uncertainties.

These documents do not compare with the EC scientific bodies documents (for instance like exhibit EC76-attachment070), which contain a list of the people involved in the analysis (which can be recognized as competent experts), many pages of deep and thoughtfully review and evaluation of existing evidences (instead of a minimum description of the event), and a large list of references to the original scientific works that had been taken into account.

ANNEX F-8

REPLIES BY ARGENTINA TO ADDITIONAL QUESTIONS POSED BY THE PANEL IN THE CONTEXT OF THE SECOND SUBSTANTIVE MEETING 11 MARCH 2005

For all parties:

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

Measures applied to prevent or minimize each of the following "potential adverse effects of GMOs", as set forth in *Directive 2001/18,* Annex II, Section C.2.1, fall within the scope of Annex A(1) of the *SPS Agreement:*

- disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C.2(i) in Annex III A, and B 7 in Annex III B);

- disease to animal and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11 and II.C.2(i) in Annex II A, and B 7 and D 8 in Annex III B);

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

Measures to protect against these three types of adverse effects fall squarely within Annex A(1)(b) of the *SPS Agreement*, which refers to measures applied "to protect human or animal life or health … from risks arising from … toxins or disease-causing organisms in foods, beverages or feedstuffs." The "adverse effects" set forth above concern the potential that a GMO product could be toxic to or cause disease in (directly or by increasing susceptibility to disease) humans or animals, which are the same risks as those enumerated in Annex A(1)(b). This conclusion is confirmed by each of the following information requirements for GMO notifications referenced in the first two provisions above: (1) item II.A.11 in Annex III A, which relates to "pathological traits" of GMOs, including "infectivity, toxigencity, virulence [and] allergenicity," (2) item II.C.2(i) in Annex III A, which relates to "considerations for human health and animal health," including "toxic or allergenic effects" of GMOs, (3) item B 7 in Annex III B, which relates to "potential interactions, relevant to the GMO … including information on toxic effects on humans," and (4) item D 8 in Annex III B, which relates to "toxic, allergenic or other harmful effects" arising from GMO crops when used for "animal feedstuffs". For these reasons, measures to address these effects fall within the Annex A(1)(b) of the *SPS Agreement.*

Measures to prevent the second and third types of adverse effects above could also fall within Annex A(1)(a) of the *SPS Agreement*, which refers to measures applied "to protect animal or plant life or health … from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms". A measure would fall under this provision if the adverse effect to animal health that it seeks to protect against arises from exposure to a GMO product other than a feedstuff.

Annex II, Section C.2.1 also includes the following "adverse effects":

- effects on the dynamics of population species in the receiving environment and the genetic diversity of each of these populations (see for example items IV B 8, 9 and 12 in Annex III A);

- effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11(f) and IV.B.15 in Annex A, and D 11 in Annex III B).

Measures to prevent these two types of adverse effects fall within the scope of Annex A(1)(a) of the *SPS Agreement*, which refers to measures applied "to protect animal or plant life or health … from risks arising from the entry, establishment or spread of pests," or Annex A(1)(d) of the *SPS Agreement*, which refers to measures applied "to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests." Each of these adverse effects concerns the impact of a GMO product as a "pest," which the *SPS Agreement* defines to include "weed." More specifically, these adverse effects refer to the risk that a GMO product becomes a "weed," that is, a persistent and invasive plant that grows in environments where it is not wanted and overtakes other plant species, raising broader ecological concerns. The adverse effects, therefore, relate to "other damage" caused by the "entry, establishment or spread of pests." This conclusion is confirmed by the following information requirements for GMO notifications referenced in the two provisions above: (1) items IV B 8 in Annex III A, which relates to the "potential for excessive population increase in the environment," and (2) item IV B 9, which relates to the "competitive advantage of the GMOs in relation to the unmodified [organisms]." Accordingly, measures to prevent or minimize these adverse effects fall within the scope of Annex A(1)(d) of the *SPS Agreement*.

> "-compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A.11(e) and II.C.2(i)(iv) in Annex III A);"

Measures to prevent such adverse effects fall within the scope of Annex A(1)(a) of the *SPS Agreement*, which refers to measures applied "to protect animal or plant life or health … from risks arising from the entry, establishment or spread of…diseases, disease-carrying organisms or disease-causing organisms." If the antibiotic marker gene compromises the clinical efficacy of antibiotics used to protect animal life or health, then the measure would fall clearly within Annex A(1)(a).

171. In *Japan – Apples*, the Appellate Body interpreted Article 5.7 of the SPS Agreement and notably the phrase "in cases where relevant scientific evidence is insufficient". It stated at para. 179 that:

> **Article 5.1 [...] informs the other provisions of Article 5, including Article 5.7. We note, as well, that the second sentence of Article 5.7 refers to a "more objective assessment of risks". These contextual elements militate in favour of a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1: "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*. [...] The question is whether the relevant evidence [...] is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.**

In this regard, please answer the following questions:

(a) Is there a reason to believe that a lack of relevant scientific evidence could prevent a Member from performing a risk assessment "as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*"? Or is it rather a question of that Member perhaps being unable, due to the insufficiency of scientific evidence, to conduct a fully objective risk assessment, such that any measure based on that assessment might be maintained without sufficient scientific evidence?

The short answer to the first part of Question 171(a) is yes. It is possible that a lack of relevant scientific evidence could prevent a Member from performing a risk assessment as required under Article 5.1 and as defined in paragraph 4 of Annex A. In the quoted passage, Argentina understands the Appellate Body to be indicating that the threshold for a finding that the "relevant scientific evidence is insufficient" and therefore that Article 5.7 might be applicable, is linked to the obligation to perform a risk assessment found in Article 5.1. Thus, it is only when the relevant scientific evidence is insufficient to perform a risk assessment, as required by Article 5.1 and as defined in paragraph 4 of Annex A of the SPS Agreement, that Article 5.7 can be successfully invoked. Earlier in the paragraph, the Appellate Body refers to Article 5.1 as a "key discipline". The Appellate Body's reference to the phrase "a more objective assessment of risk" implies a connection between this phrase and a risk assessment as defined in paragraph 4 of Annex A.

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

The initial "measure adopted in accordance with Article 5.7" does not need to be based on a risk assessment conforming to the same standard as that required by Article 5.1. Article 5.7 refers to the adoption of a measure, at least initially, "on the basis of available pertinent information".

Besides, the reference in the second sentence of Article 5.7 to a "more objective" assessment of risk implies that "on the basis of available pertinent information" some form of risk assessment must be carried out, even if it does not meet the standard set out in paragraph 4 of Annex A, while the Member gathers the scientific evidence necessary to complete a risk assessment according to Article 5.1 and Annex A.4. It is also clear from the context that the "available pertinent information" refers to scientific information concerning risks to human, animal or plant life or health.

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

In a case when a Member decides to delay the completion of an approval procedure once and for a few days, it is possible to agree with the premise that we would be facing the application of the approval procedure. However, when a Member decides to systematically stall the approval procedure, as done by the EC in the case at hand, in such way that the procedure becomes meaningless, we are faced with the existence of another measure.

In other words, when a decision is taken with the aim of avoiding the completion of all applications submitted under an approval procedure, as in this particular case, we are not dealing with the application of the procedures but with the application of a separate measure. In this case that separate measure is the "de facto" moratorium.

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

The fact that existing approval legislation does not permit a Member to adopt certain risk management measures does not justify by itself a delay or suspension of that approval system, since that delay or suspension must be based on scientific evidence. However, the Member concerned is under an obligation to make the necessary legislative changes "without undue delay" in any case , so as to be in a position to make a final decision as quickly as possible under the circumstances.
Therefore, Article 27 of the Vienna Convention on the Law of Treaties becomes relevant only in case of a delay or suspension that is not based on scientific evidence (undue delay).

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

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

This phrase refers to the proportionality that must exist between the measure to be adopted (and the degree of restriction on trade it can produce) in order to fulfil a legitimate objective and the risk that is being addressed. In other words, the stricteness of a technical regulation must be proportionate to the risk being addressed.

A technical regulation is more restrictive than necessary if it does not fulfill a legitimate objective. It is also unnecessarily restrictive if the objective is legitimate but there is a less trade-restrictive alternative that is able to fulfill that objective.

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

It should be taken into account that the phrase "scientific information" in the TBT Agreement not only refers to issues such as health or the environment, but also to other issues such as national security and deceptive practices.

Thus, in this context, the use of the phrase "scientific information" is due the fact that the TBT Agreement covers a broader scope of issues than the SPS Agreement, where the scope is only focused on health and the environment.

The TBT should not be applied in a vacuum but to a particular situation. The situation in the present case is referred to an approval system aimed at protecting against risks to health and the environment. In that sense, "scientific information" must be interpreted as equal to "scientific evidence" in order to deal properly with an approval system of such characteristics.

Moreover, by using in the assessment of risk to health and the environment just "scientific information" instead of "scientific evidence" it would be difficult to scrutinize the existence of risks and to apply an adequate measure.

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

Whether the measure applied to ensure co-existence of biotech crops and non-biotech crops is covered by Annex A(1) of the SPS Agreement depends on the purpose of the measure. In that sense, a measure applied with the purpose of protecting plant life or health from risks arising from the admixture of biotech and non-biotech seeds or crops would fall within the scope of Annex A(1) of the SPS Agreement. On the other hand, a measure applied solely with the purpose of reducing or preventing the "potential economic impact" of the admixture of biotech and non-biotech products resulting from the imposition of labeling thresholds for GM products would not fall under the scope of SPS Agreement.

However, it has already been demonstrated in this dispute that the purposes of the "de facto" moratorium and the product-specific marketing bans are health and the environment. It must be inferred from the context in which they have been applied and from the declarations of high ranking EC officials. Therefore, the EC can not assert that this has taken place outside the scope of the SPS Agreement.

For Argentina, the United States and the European Communities:

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

It is not clear what was the basis for considering that labeling was insufficient.

For all complaining parties:

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

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

If humans, animals and plants comprise the universe of living things and biodiversity is concerned with the diversity of living things, then it is difficult to understand what component of biodiversity is "outside human, animal or plant life or health". A measure taken to protect the "environmental components of biodiversity" certainly could fall within Annex A(1), depending on the type of risks against which the measure seeks to protect.

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

It would seem that the EC is resorting to another hypothetical concern. In any case this hypothesis would fall within Annex A(1)(d) of the SPS Agreement.

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

Argentina agrees with the response of the United States to Panel Question 73. A measure to protect humans against occupational exposures from Bt toxins in corn, which is consumed as either a food or feedstuff, is subject to the SPS Agreement. Annex A(1)(b) does not specify or restrict the mode of exposure.

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

The EC assertion is flawed because, as a result of the moratorium, there have been neither approvals nor rejections. Besides, as already stated, the existence of some movement in one or more applications does not change the situation since the procedures were never completed.

In other words, the number of the selected product applications should not be relevant because this does not change the fact that there is a "de facto" moratorium.

For Argentina and Canada:

181. With reference to Argentina's and Canada's claims in respect of the member State safeguard measures under Article 2.1 of the TBT Agreement, do the relevant safeguard measures apply to the relevant biotech products when imported into the territory of the relevant member States and when produced in the relevant member States, or do they apply only when the products are imported?

In the case of the Austrian ban on maize T25, Bt-176 and MON-810 the ordinance banned commercialization. The Italian Ministerial Decree banning maize MON809, MON810, T25, and Bt11 specified that it was suspending the commercialization and utilization. In the case of Germany, the Amendment Notice applies a suspension against maize Bt-176. Luxembourg imposes a ban on the use and sale of maize Bt-176 through a ministerial order.

Given the broad language used, it must be assumed that the measure applies to the relevant biotech products when imported into the territory of the respective Member States and when they are produced in those Member States.

For Argentina:

183. With reference to para. 61 of Argentina's supplementary rebuttal, what is the basis for the assertion that Soy Lines A2704-12 and A5547-127 were affected by the alleged de facto moratorium?

In that context, the reference to that product was made in order to give an example of a product affected by the "de facto" moratorium, which has no scientific opinion from the scientific committees.

ANNEX F-9

**REPLIES BY THE EUROPEAN COMMUNITIES
TO QUESTIONS POSED BY THE PANEL
IN THE CONTEXT OF THE SECOND SUBSTANTIVE MEETING
7 MARCH 2005**

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

1. As the European Communities has previously explained, a distinction must be made between two different issues: first, the scope of the *SPS Agreement*, which is defined in Annex A.1 of the *SPS Agreement*; second, the definition of "International standards, guidelines and recommendations", referred to in Annex A.3 of the *SPS Agreement*. The "International standards, guidelines and recommendations" are relevant, for example, for the interpretation of Article 3.3 of the *SPS Agreement*.

2. The second issue may be summarised as follows. Annex A.3(c) of the *SPS Agreement* refers to the international standards, guidelines and recommendations "developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention". When the *SPS Agreement* was adopted what was in force (at least insofar as is relevant for these panel proceedings) was the International Plant Protection Convention approved by an FAO conference in November 1979. It entered into force on 4 April 1991, 13 days after acceptance by two-thirds of the contracting parties. There is a subsequent text – the International Plant Protection Convention 1997, which, at least at the date of establishment of this panel, had not yet been ratified by two thirds of the Members of the IPPC, and which therefore was not in force. The 1997 IPPC's principal organ would be the Commission on Phytosanitary Measures. Pending entry into force of the 1997 IPPC, an *Interim* Commission on Phytosanitary Measures published ISPM 11 (2004). With regard to declarations and reservations, the United States accepted the amended Convention (the 1997 IPPC) subject to the following understandings:

> (1) Relationship to other international agreements – The United States understands that nothing in the amended Convention is to be interpreted in a manner inconsistent with, or alters the terms or effect of, the World Trade Organization Agreement on the Application of Sanitary or Phytosanitary Measures (*SPS Agreement*) or other relevant international agreements.

3. There is thus an issue as regards timing. ISPM 11 (2004) was endorsed in April 2004. The Panel in this case was established on 29 August 2003. The Complainants cannot therefore rely on the text of ISPM 11 (2004) in order to support their claims relating to the scope of the *SPS Agreement*.

4. It is against this background that the European Communities would return to the first, distinct, issue referred to above – the scope of the *SPS Agreement*. On this question, it is necessary to distinguish between the general IPPC definition of "pest", and the further explanations in ISPM 11

(2004) concerning the scope of the IPPC with respect to environmental issues, to which the Complainants refer.

5. With regard to the general IPPC definition of "pest", it would be a legal error to simply transpose such definition into Annex A.1 of the *SPS Agreement*. All that it is possible to say is that the IPPC may provide relevant context for the purposes of the interpretation of the term of "pest" in Annex A.1 of the *SPS Agreement*. In this respect, in the context of this dispute, the European Communities has no particular difficulty with the general definition of pest in IPPC 1997 as being:

> Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.

6. In the context of the issues raised in these panel proceedings, this definition is not significantly different from that in Article II (2) of the 1979 IPPC:

> For the purposes of this Convention, the term "pest" means any form of animal or plant life, or any pathogenic agent, injurious or potentially injurious to plants or plant products.

7. Furthermore, the view of the European Communities is that, in certain circumstances, a GMO may indeed become a pest, just as any non-GMO might become a pest, as indicated in its first written submission.

8. **This does not mean**, however, that all negative or potentially negative effects of GMO's are automatically caught by the definition in Annex A of the *SPS Agreement*. In particular, the European Communities remains strongly of the view that biodiversity and environmental issues do not fall within the scope of the *SPS Agreement*. The scope of the *SPS Agreement* and the scope of IPPC, as elaborated by ISPM 11 (2004), are different things and should not be confused. Just because ISPM 11 (2004) tackles environmental issues does not bring environmental issues with the scope of the *SPS Agreement*. It simply reflects the fact that ISPM 11 (2004) takes into account the adoption of the Cartagena Protocol. In fact, the environmental provisions in ISPM 11 (2004) rather confirm that, absent any equivalent or similar provisions in the *SPS Agreement*, the scope of the *SPS Agreement* does not cover environmental issues – and this is definitely confirmed by the negotiating history of the *SPS Agreement*.

9. When it comes to specific issues, each case will have to be **considered on its merits**, in order to determine whether or not the issues fall within the scope of the *SPS Agreement*.

10. Turning to the first specific quotation in the question: "indirectly affect plants … by other processes such as competition." (ISPM 11 (2004) page 34) The European Communities would first note that this "quotation" in fact takes three words in italics and in the nature of a sub-title, and links them to other words in a different sentence. The phrase as presented in the question is not therefore actually a phrase that is used in ISPM 11 (2004). Second, and more importantly, this phrase is taken from Annex 1 of ISPM 11 (2004), which expressly relates to "environmental risks". If this is what the question has in mind when it refers to a "broad interpretation", then it is hardly surprising that the quotation suggests an environmental risk, since that is precisely what Annex 1 of ISPM 11 (2004) is concerned with. **This does not mean**, however, that the presence of the word "pest" in Annex A.1 of the *SPS Agreement* necessarily means that environmental risks are within the scope of the *SPS Agreement* – and it would be legally erroneous to proceed on that basis.

11. Similar comments apply with regard to the second quotation in the question, this being taken from page 23 of ISPM 11 (2004), from a paragraph which begins "In the case of the analysis of environmental risks …", and which is marked "S1" in the margin – which the endorsement on page 1 of ISPM 11 (2004) confirms means that it relates to "environmental risks".

12. In short, the European Communities does not consider that Annex A.1 of the *SPS Agreement* should be given either a narrow interpretation or a "broad" interpretation. It should simply be given an interpretation consistent with its text, context and purpose. The IPPC definition of "pest" provides context, but does not insert the word "injurious" into Annex A.1 of the *SPS Agreement*. Nor does the presence of the word "injurious" in the IPPC definition of pest, coupled with those parts of ISPM 11 (2004) that refer to environmental risks, have as a consequence that environmental risks are brought within the scope of the *SPS Agreement*. On the contrary, the text, context and purpose of the *SPS Agreement*, and its negotiating history, strongly support the view that environmental risks do not fall within the scope of the *SPS Agreement*.

120. With reference to Annex A(1)(d) of the SPS Agreement, please answer the following questions:

(a) What is the meaning of the term "other damage"?

(b) Does the term "other" imply that Annex A(1)(a) through (c) are also about "damage"? If so, does the term "other damage" cover damage sustained by plants, animals or humans other than damage to their "life or health"? Please provide examples.

(c) Is "other damage" limited to damage sustained by plants, animals or humans? If not, please provide examples.

13. (a) The words "other damage" must be interpreted in the light of their immediate context and in the light of the overall purpose of the *SPS Agreement*. "Other damage" is not an open ended formulation that may be used to include under the *SPS Agreement* any kind of negative effect arising from the entry, establishment or spread of pests. *Eiusdem generis* ("of the same type") is a basic rule of interpretation. The answer to the following two questions will serve to clarify what is the scope of letter (d) of point 1 of Annex A of the *SPS Agreement*.

14. (b) The European Communities considers that the term "other" implies that Annex A(1)(a) through (c) are also about damage. The terms "other damage" cover damages resulting from the entry or establishment or spread of pests and sustained by plants, animals or humans other than damage to their "life or health". To give a specific example: a pest may affect the quality of a plant product, which may be substandard, that is, of lower quality. For example, Citrus fruit quality is affected by the presence of pests such as the Mediterranean fruit fly *Ceratitis capitata*. Such pests do not threaten the life or the health of the plant, but rather affect the economic value of crops. The Mediterranean fruit fly may still qualify as a quarantine pest, as defined by the International Plant Protection Convention (i.e. "quarantine pests" means a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled). The economic damage resulting from the presence of the fruit fly, would in such a case fall under other damage as provided for in Annex A.1(d) of the *SPS Agreement*.

15. On fruits, any fruit flies or moths other than *C. capitata*, will equally create damage to fruit without compromising the health or development, etc. of plants. There are hundreds of fruit flies which would have the same effect as the Mediterranean fruit fly: for example, Anastrepha sp. fruit

flies, other Ceratitis fruit flies, Ragoletis, etc. All these pests affect the quality of the fruits they infect but in no case compromise the life or health of the plants.

16. Another example would be the apple codling moth (*Cydia pomonella*) which is largely present in some regions of Europe. This pest bores holes in fruits and generates harvest loss, without affecting the life of apple trees. This pest would still qualify as a quarantine organism as defined in the IPPC in regions, for example, where it is not present and if its introduction and establishment could result in economic damage to local production.

17. There are other pests such as scale insects, thrips, etc. whose presence may result in the development of black mould on fruits (or e.g. cut flowers). The presence of mould would not affect the plant health *per se*, however it would affect the economic value of the crop.

18. Another example would be potato ring rot (*Clavibacter michiganensis* sp. *Sepenocius*). This bacteria is considered to be a quarantine organism in many countries (including in the EU where it is subject to statutory control measures). In the EPPO book "Quarantine pests for Europe" (2nd edition) compiling data sheets on quarantine pests for the European Union and for the European and Mediterranean Plant Protection Organisation (ISBN 0 85199 154 8), it is noted that (p. 989) "*while the direct economic impact of the ring rot may only be moderate, especially with modern production system, it would constitute a major constraint on seed potato production where it does not occur, with considerable indirect effects on trade"*. The effect on trade would in fact qualify as "other damage" under the *SPS Agreement*.

19. (c) Yes: "other damage" is limited to damage sustained by plants, animals or humans, due to the entry, establishment or spread of pests. It does not extend to environmental damage *per se*. Environmental damage *per se* is not contemplated by the other terms used in Annex A or the rest of the *SPS Agreement.* It is, by contrast, expressly contemplated by the *TBT Agreement.*

20. With regard to this latter point, the European Communities would like to recall that the negotiating history of the *SPS Agreement* supports the European Communities view that Annex A.1 must be interpreted strictly and not in a broad manner (see paras. 57-59 of the European Communities Second Written Submission).

21. In particular, the European Communities is well placed to argue that environmental damage is not covered by the *SPS Agreement* since it was the European Communities itself that for some time supported the broadening of the scope of the Agreement. Its views were resisted by the majority of other Members and, by the time of the conclusion of the Uruguay Round, the European Communities had also come to the view that the SPS did not constitute the proper legal framework to address environmental issues. As further supporting evidence, the European Communities would mention the GATT Secretariat's Note summarising the main points raised at the 18th meeting of the SPS WG, 5-7 June 1990 (MTN.GNG/NG5/WGSP/W/24):

> "With regard to the measure coverage, [one participant], and some other participants, could not at this stage agree with the exclusion of consumer preferences, environment, animal welfare and ethical and world considerations and considered it a probable mistake to exclude them from a reinforced discipline"
>
> "Other participants agreed that there was a need to deal with other issues such as consumer preferences, environment, etc., which were already used for trade protection, but objected that they should not be covered by an SPS discipline. Other ways would have to be found to deal with them. It was noted that Article XX(b)

covered more than SPS measures and that it could be used for these types of measures"

22. The issue of the scope of the *SPS Agreement*, in particular as far as the environment is concerned, remained open until the end of the negotiations. Indeed, the Cover note to the SPS Decision circulated on 20 December 1990 (also known as the "Dunkel text") read as follows: "The brackets in the note to definition 1 and in definition 4 (Annex A) are all linked to the question of whether or not this agreement should apply to measures taken for the protection of animal welfare and of the environment, as well as of consumer interests and concerns". The bracketed text (which included a reference to the environment) disappeared in the final text of the agreement, as we all know. As a result, environmental damage per se does not fall under the scope of the *SPS Agreement*.

23. The European Communities stands ready to provide further details on the negotiating history of the *SPS Agreement* should the Panel so request.

121. With reference to Article 5.1 of the SPS Agreement, what were the relevant risk assessment techniques developed by the relevant international organizations that the European Communities had to take into account in the relevant period (October 1998 – August 2003)?

24. The requirement in Article 5.1 of the *SPS Agreement* to take into account the risk assessment techniques developed by the relevant international organizations relates only to the assessment of the risks to human, animal or plant life or health.

25. The European Communities has discussed at length the issue of the limited scope of sanitary or phytosanitary measures within the context of the *SPS Agreement*, as defined by its Annex A 1, and in particular to the extent that it does not cover environmental risks *per se* (see for instance the answer to the Question 120). Again in the context of Article 5.1 of the *SPS Agreement*, the same argument applies, namely that the "risk assessment techniques" to be taken into account need not to include those which address risks areas falling outside the risks to human, animal or plant life or health and outside the scope of its Annex A 1.

26. However, in developing and conducting its GMO approval procedures, the European Communities takes account of all relevant risk assessment techniques, including those aspects that do not relate to risks covered by the *SPS Agreement*. Accordingly, in order to fully inform the Panel, the European Communities, in responding to this question, will list these techniques without distinguishing between techniques relevant to risks coming within the scope of the *SPS Agreement* and other risks.

27. The "risk assessment techniques" developed by the relevant international organizations in the relevant time period are of two types: general "risk assessment techniques", and specialized ones for genetically modified (or living modified) products.

28. All the available guidance from relevant international organisations on "risk assessment techniques" which specifically address GM products, has been developed in an endeavour to cover the relevant risks areas that need to be specifically assessed for GM products. It is however noteworthy that not all areas are yet covered by international guidance specifically designed to cover GM products. This is the case, for instance, with GM feed safety "risk assessment techniques" and other animal health risk assessment techniques" for GM products.

29. The available guidance documents from relevant international organisations on "risk assessment techniques" which specifically address GM products are generally consistent with each

other: they are all based explicitly or implicitly on the Risk Analysis paradigm (which corresponds, as discussed earlier by the European Communities, to the "risk assessment techniques" referred to in the *SPS Agreement*, and which includes the three components of risk analysis, i.e. the science based assessment of the potential risks, risk management measures and risk communication).

30. Between October 1998 and August 2003, there was a lot of international activities aimed at developing specialized "risk assessment techniques" guidance for GM products; hence several if not most of the specialised "risk assessment techniques" developed by the relevant international organisations were developed within that period of time.

31. As regards **general** "risk assessment techniques", several standards had been developed within or before the relevant time period by relevant international organisations, in particular by the *Codex Alimentarius Commission*, by the IPPC, and by the OIE. These include for instance, as far as they address in part risks to human, animal or plant life or health:

32. As regards "risk assessment techniques" covering plant life or health, the following IPPC general ISPM are particularly relevant (ISPM # 06, 09, 13, and 14 are important in particular for general risk management components of the risk analysis):

- ISPM # 02: Guidelines for pest risk analysis
- ISPM # 06: Guidelines for surveillance
- ISPM # 09: Guidelines for pest eradication programmes
- ISPM # 11 (as adopted in April 2001, which does not include environmental risks, nor risks derived specifically from Living Modified Organisms): Pest risk analysis for quarantine pests
- ISPM # 13: Guidelines for the notification of non-compliance and emergency action
- ISPM # 14: The use of integrated measures in a systems approach for pest risk management
- ISPM # 16: Regulated non-quarantine pests: concept and application

33. As regards "risk assessment techniques" covering animal life or health, the following OIE general standards are particularly relevant:

- the Terrestrial Animal Health Code
- the Aquatic Animal Health Code

34. As regards "risk assessment techniques" covering human life or health and food safety, the following *Codex Alimentarius Commission* general guidance is particularly relevant:

- The conduct of risk analysis is guided by general decisions of the Codex Alimentarius Commission (CAC). These decisions include the Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account and the

Statements of principle relating to the role of food safety risk assessment (Codex Alimentarius Commission Procedural Manual; Thirteenth edition)., as well as the Codex Working Principles for Risk Analysis.[1]

– Codex Standard 193: General Standard for Contaminants and Toxins in Foods

– CAC/RCP 1: General Principles of Food Hygiene

– CAC/RCP 54: Recommended Code of Practice on Good Animal Feeding

– CAC/GL 20: Principles for Food Import and Export Certification and Inspection

– CAC/GL 26: Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems

– CAC/GL 30: Principles and Guidelines for the Conduct of Microbiological Risk Assessment

35. As regards **specialised** "risk assessment techniques", aimed at specifically addressing risks arising from GM products, several standards have been *developed* by relevant international organisations before, within or after the relevant time period, in particular by the *Codex Alimentarius Commission*, by the IPPC, by the OECD and by the Convention of Biological Diversity. These include for instance, as far as they address in part risks to human, animal or plant life or health:

36. As regards human life and health, the Codex principles for the risk assessment of foods derived from modern biotechnology (CAC/GL 44) and the Codex guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45) and for the conduct of food safety assessment of foods produced using recombinant-DNA Microorganisms (CAC/GL 46) were adopted in July 2003.

37. With respect to feed safety assessment specifically addressing GM products (and more generally to animal life and health "risk assessment techniques" specifically addressing GM products), no international guidance have been developed yet.

38. In addition, concerning plant life and health, the updated ISPM n° 11 (International Standard for Phytosanitary Measures on Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms) now includes the pest risk analysis of Living Modified Organisms, as adopted in April 2004. However, it should be noted that ISPM 11, as discussed earlier, also covers the environmental risks that fall outside of the scope of the *SPS Agreement*, as part of the pests risk analysis. Furthermore, Annex 2 of ISMP 11, specifies that "*PRA*[2] *may constitute only a portion of the overall risk analysis for import and release of a LMO. For example, countries may require the assessment of risks to human or animal health or the environment, beyond that covered by the IPPC …*"

39. Furthermore, as far as risks to human, animal or plant life or health are singular components (but components only) of the more global risks to the conservation and sustainable use of biological

[1] Adopted by the 26th Session of the Codex Alimentarius Commission, 2003.
[2] Pest Risk Analysis, as defined in the IPPC.

diversity, and the environment at large, relevant "risk assessment techniques" are also to be found in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted on 29 January 2000.

40. It constitutes the first international binding standard on GM products. It includes specific provisions as regards the science based assessment of risks derived from Living Modified organisms, as well as relevant risk management provisions. These are in particular its article 15 on the assessment of risks and its related Annex III, which provides minimum requirements for carrying out the assessment of risk under the Protocol, and its Article 16 provides a framework for risk management measures as part of risk analysis. More detailed international guidance for risk analysis of LMOs under the Protocol, including on risk assessment and risk management, still needs to be further developed. Indeed, at the first Meeting of the Parties (COP/MOP1), Decision BS-I/12 adopted a medium term programme which includes for possible consideration the development of guidance and of a framework for common approach in risk assessment and risk management.

41. It is also to be noted that the OECD has developed since the beginning of the 1980'ies a significant number of guidance documents on "risk assessment techniques" for recombinant DNA technologies and products. It formulated in particular general principles of the assessment of the risks of recombinant DNA in 1986, and an initial concept of "substantial equivalence" in 1993 as a guiding tool for the assessment of genetically modified foods. However, the concept further evolved and is still under current debate, as the European Communities has discussed in its comments on expert advice. This concept is only a part of the safety evaluation framework as already explained.

42. The OECD Working group on the harmonisation of regulatory oversight of biotechnology and the Task Force for the Safety of Novel Foods and Feeds have both decided, in the 1990s, to focus their work on the development of science-based consensus documents, which are mutually acceptable among member countries. These consensus documents address the relevant biological information of the recipient organisms or of the introduced traits, and contain information for use during the assessment of the risks of particular GM products or food/feed products, respectively.

43. Although the OECD may not qualify as an international organisation within the meaning of Article 5.1, the European Communities nevertheless takes its consensus documents into account. However, as the Panel will note from the list of OECD documents below, none of these documents provide for unique general principles for the risk assessment of GMOs.

44. At the present time, several consensus documents have been published and are available on the OECD web site (www.oecd.org). These relate both to food safety[3] and also environmental risks.[4]

[3] These include: Consensus Document on Compositional Considerations for New Varieties of Barley (Hordeum vulgare L.): Key Food and Feed Nutrients and Anti-Nutrients - No. 12, 2004, ENV/JM/MONO(2004)20; Consensus Document on Compositional Considerations for New Varieties of Cotton (Gossypium hirsutum and Gossypium barbadense): Key Food and Feed Nutrients and Anti-Nutrients - No. 11, 2004, ENV/JM/MONO(2004)16; Consensus Document on Compositional Considerations for New Varieties of Rice (Oryza sativa): Key Food and Feed Nutrients and Anti-Nutrients - No. 10, 2004, ENV/JM/MONO(2004)15; Considerations for the Safety Assessment of Animal Feedstuffs derived from Genetically Modified Plants - No. 9, 2003, ENV/JM/MONO(2003)10; Consensus Document on Compositional Considerations for New Varieties of Bread Wheat (*Triticum aestivum*): Key Food and Feed Nutrients, Anti-Nutrients and Toxicants - No. 7, 2003, ENV/JM/MONO(2003)7; Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea Mays*): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites - No. 6, 2002, ENV/JM/MONO(2002)25; Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants - No. 4, 2002, ENV/JM/MONO(2002)5; Consensus Document on Compositional Considerations for New Varieties of

45. In sum, it is clear that during the period 1998-2003, there was tremendous international activity to develop specific "risk assessment techniques" for GM products, and that this guidance was constantly evolving, incorporating as work progresses increasing numbers of relevant criteria and risk analysis elements, even within the limited scope of risks to human, animal or plant life or health. However, the Codex principles on the risk assessment of food derived from modern biotechnology was not adopted until July 2003 and the revised ISPM 11 was not adopted until April 2004.

122. Please explain your views as to the relationship between a Member's appropriate level of protection and the requirement in Article 5.1 to ensure a measure is based on a risk assessment, as appropriate to the circumstances. Is the appropriate level of protection relevant to the conduct of the risk assessment?

46. The European Communities considers that the "level of protection" is indeed relevant to the conduct of a "risk assessment" within the meaning of the *SPS Agreement*. As a matter of fact, the concepts of "risk assessment" and "level of protection" are interrelated. This is already clear from the definition of risk assessment in Annex A to the *SPS Agreement* which calls for an evaluation of the risks in the light of the SPS measures that might be applied.

47. In order to provide the Panel with a useful and comprehensive reply, the European Communities would like to discuss in some detail the reasons that may lead different WTO Members to evaluate differently a given set of scientific data. For the sake of simplicity, the European Communities would refer to three main reasons.

Sugar Beet: Key Food and Feed Nutrients and Antinutrients - No. 3, 2002, ENV/JM/MONO(2002)4; Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-Nutrients - No. 2, 2001, ENV/JM/MONO(2001)15; Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola) - No. 1, 2001, ENV/JM/MONO(2001)13;

[4] These include: An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology - No. 32, 2005, ENV/JM/MONO(2005)5; Consensus Document on the Biology of Helianthus Annuus L. (Sunflower) - No. 31, 2004, ENV/JM/MONO(2004)30; Consensus Document on the Biology of European White Birch (Betula pendula Roth) - No. 28, 2003, ENV/JM/MONO(2003)12; Consensus Document on the Biology of Zea mays (Maize) - No. 27, 2003, ENV/JM/MONO(2003)11; Module II: Herbicide Biochemistry, Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants - No. 25, 2002, ENV/JM/MONO(2002)14; Consensus Document on the Biology of Prunus Sp. (Stone Fruits) No. 24, 2002, EN/JM/MONO(2002)13; Consensus Document on the Biology of Pinus Strobus L. (Eastern White Pine) - No. 22, 2002, ENV/JM/MONO(2002)3; Consensus Document on the Biology of Picea Sitchensis (Bong.) Carr. (Sitka Spruce) - No. 21, 2002, ENV/JM/MONO(2002)2; Consensus Document on Information Used in the Assessment of Environmental Applications Involving Baculoviruses - No. 20, 2002, ENV/JM/MONO(2002)1; Consensus Document on the Biology of Beta vulgaris L. (Sugar Beet) - No. 18, 2001, ENV/JM/MONO(2001)11; Consensus Document on the Biology of Populus L.. (Poplars) - No. 16, 2000, ENV/JM/MONO(2000)10; Consensus Document on the Biology of Glycine max (L.) Merr. (Soybean) - No. 15, 2000, ENV/JM/MONO(2000)9; Consensus Document on the Biology of Oryza sativa (Rice) - No. 14, 1999, ENV/JM/MONO(99)26; Consensus Document on the Biology of Picea glauca (Moench) Voss (White Spruce) - No. 13, 1999, ENV/JM/MONO(99)25; Consensus Document on the Biology of Picea abies (L) Karst (Noway Spruce) - No. 12, 1999, ENV/JM/MONO(99)14 http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)14; Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Phosphinothricin Herbicid - No. 11, 1999, ENV/JM/MONO(99)13; Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Glyphosate Herbicide - No. 10, 1999, ENV/JM/MONO(99)9; Consensus Document on the Biology of Triticum Aestivum (Bread Wheat) - No. 9, 1999, ENV/JM/MONO(99)8 http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)8; Consensus Document on the Biology of Solanum tuberosum subsp. tuberosum (Potato) - No. 8, 1997, OCDE/GD(97)143; Consensus Document on the Biology of Brassica napus L. (Oilseed rape) - No. 7, 1997, OCDE/GD(97)63.

48. ***Different "objective" conditions***. It is often the case that the geographical, climatic or environmental conditions prevailing in two WTO Members are so different as to affect decisively the conduct of a risk assessment. A given product may, when imported, have negative sanitary or phytosanitary consequences for one WTO Member, while it may have no adverse consequences whatsoever for another WTO Member. For instance, if a fruit carrying Mediterranean flies (an insect that is deleterious for citrus fruit production) is imported into another Member, where the climate is cold and there is no citrus fruit production, there is simply no risk of spread of a pest. But if the same fruit is imported into California, that may be a reason for concern. In the case of the Member with a cold climate, there is no need for a specific risk assessment with regard to Mediterranean flies. In the case of California, there may be a need to conduct a risk assessment.

49. In the context of the present case, it is undisputed that there are objective differences between the territories of each of the Complaining parties and the territory of the European Communities that partly explain the differences in their respective assessments of the risks posed by GM products.

50. ***Different types of values and concerns***. A second reason that may lead two WTO Members to react differently to a given factual situation relates to the values or concerns prevailing in their respective societies. Indeed, two countries where the same "objective" conditions prevail may however react differently to a given risk factor.

51. Consider for instance the case of non target effects of Bt crops. If country A is not at all concerned about such effects, it will certainly not explore a wide range of issues when assessing Bt crops for approval (e.g. whether or not Bt crops may negatively affect microfauna). However, neighbouring country B may be concerned about non target effects, and it will therefore address the issue under the relevant authorisation procedures. It goes without saying that country B will need more information to complete its assessment of the risks of a given Bt crop. It also goes without saying that country B will need more time to complete its authorisation procedure.

52. ***Different levels of protection.*** Two WTO Members where the same "objective" conditions prevail, and which share the same type of values and concerns, may still react differently to a given situation depending on the level of protection that they deem appropriate. This will surely affect the conduct of a risk assessment.

53. For example, let's say that countries A and B are both concerned about the preservation of farmland biodiversity. For that reason, both countries want to ensure that the introduction of GM crops does not result in a significant reduction of plant diversity in arable lands. However, country A considers that a 25% reduction is reasonable (if balanced against the expected economic benefits), while country B would consider a 10% reduction as the maximum admissible impact on the environment. Available scientific evidence shows an expected reduction of plant diversity of between 5% and 20%. Clearly, country A can consider that information as sufficient for the purposes of its risk assessment because the extent of the losses remains in any event below its tolerance threshold. However, it is also clear that country B will consider the information to be insufficient and hence it will ask for a more detailed study before it can approve the product. In that way, the chosen level of protection of country B directly affects the conduct of the risk assessment.

54. The Panel should therefore be careful not to curtail the freedom of WTO Members to choose their appropriate level of protection and, accordingly, to establish the threshold of evidence for regulatory approval that is necessary to the achievement of their goals. The judgement on how much scientific information is needed to make a given decision is mostly a matter to be determined by reference to the specific situation of each WTO Member, the amount and quality of information

available, the novelty of the products concerned, and the degree of the remaining scientific uncertainties and, as explained above, its chosen level of protection.

123. Please assume for the sake of argument that Article 5.7 of the SPS Agreement provides for an exception in the nature of an affirmative defence:

(a) Could the Panel assess the merits of any such defence without having previously found an inconsistency with Article 2.2 of the SPS Agreement?

(b) If not, in a case such as this one where a claim of inconsistency with Article 2.2 of the SPS Agreement is based on a claim of inconsistency with Article 5.1 of the SPS Agreement, would it be correct for the Panel to begin its analysis with the Article 5.1 claim, then move to the consequential Article 2.2 claim and finally turn to the Article 5.7 defence?

55. The European Communities considers that the assumption referred to in this question is legally erroneous, as it has explained in its submissions. Consequently, for the European Communities, it is not possible to answer the following parts of the question in a legally meaningful way. The relationship between Article 5.7 and Article 2.2 of the *SPS Agreement* being one of exclusion, the question of whether or not there is an inconsistency with any particular obligation found in one of those provisions is entirely independent of the question of whether or not there is an inconsistency with an obligation contained in the other provision. The same is true with regard to Article 5.1 of the *SPS Agreement*.

128. With reference to para. 17 and footnote 2 of attachment II of the US rebuttal, does the European Communities agree that "risks arising from" biotech plants include "risks arising indirectly or secondarily from" biotech plants? If not, why not?

56. Whether or not the United States is correct to argue that "risks arising from" biotech plants include "risks arising indirectly or secondarily from" biotech plants misses the point made by the European Communities. As the European Communities stated at paragraph 396 of its First Written Submission: "The words 'arising from' indicate a degree of causality" ("découlant" "resultantes"). But the point which the Communities made in its First Written Submission - and which it strongly maintains - is that the measure which is adopted must be applied for the purpose of meeting one of the objectives identified in paragraph 1 of Annex A of the *SPS Agreement*. To the extent that a measure was not adopted for one of those purposes – e.g. because it was not applied "to protect animal life or health … from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs" – it cannot be an SPS measure.[5] In such a case it is wholly irrelevant whether the effects of the additive, contaminant or toxin are direct or indirect, or primary or secondary. The broad reading suggested by the United States cannot of itself transform a non-SPS measure into an SPS measure. What matters is the nature of the measure and the nature of the risk.

57. Paragraph 17 and footnote 2 of attachment II of the US rebuttal, to which the question refers, nicely illustrate the vacuum at the heart of the Complainants' submissions: the conveniently loose manner in which they read Annex A.1 of the *SPS Agreement*. The issues that are discussed in those parts of the US rebuttal clearly relate to, or at the very least include, environmental or biodiversity issues. And yet nowhere in these parts of its submission does the United States take the trouble to inform the reader of which specific provision of Annex A.1 of the *SPS Agreement* it is supposed to be

[5] Each of sub-paragraphs (a) to (d) of paragraph 1 of Annex A is self-contained, each identifies one or more objectives to be protected from a number of specified and limited risks.

referring to. The only clue that is given is in the second sentence of paragraph 5 of attachment II of the US rebuttal, which refers to sub-paragraph (d) of Annex A.1 of the *SPS Agreement*. And that is the point at which the US case simply collapses, because the risks with which the European Communities is concerned, at least in part, are not "pest" risks. The US just assumes that if A "injures" B, A is a "pest" *vis à vis* B, which neither scientifically nor legally makes sense. If a GMO crop adversely effects the biogeochemical cycle, for example, it is simply not behaving as a "pest" within the meaning of the IPPC – and in this respect the European Communities also refers to its answer to question 119. These matters therefore fall outside the scope of the *SPS Agreement*.

129. With reference to para. 61 of Canada's rebuttal, could the Regulatory Committee procedure have been used to establish harmonized risk assessment objectives and methodology pending the entry into force of a revised EC Directive 90/220?

58. The answer to this question is No.

59. The Regulatory Committee Procedure is a procedure of delegated decision-making.[6] It can only be used where the law so provides.

60. Under Directive 90/220, the use of the Regulatory Committee procedure was provided for in:

- Article 6(5) (simplified procedure for Part B authorisations),
- Article 9(1) (Part B authorisations, format for summary of notification),
- Article 10(3) (Part C authorisations, list of Community legislation providing for specific environmental risk assessment similar to that laid down in Directive),
- Article 12(3) (Part C authorisations, format of summary of notifications
- Article 13(3) (Part C authorisations, objections from Member States)
- Article 16(2) (Part C authorisations, safeguard measures), and
- Article 20 (Amendments to Annexes II and III).

61. None of the above allowed for the adoption of harmonised objectives and methodologies of a risk assessment. In particular, Article 20, which was the only provision allowing for formal amendments to the legislation through the Regulatory Committee procedure, was limited to "adaptations" of Annexes II and III. These annexes list information requirements for the notification. They do not contain any harmonised objectives or a harmonised methodology for a risk assessment.

[6] The decision-making power is delegated from the legislative body(ies) to the Commission who acts under the supervision of a Committee consisting of Member States representatives. There are different forms/degrees of supervision (Comitology), the "strictest" being that of the Regulatory Committee.

130. With reference to para. 48 of Canada's supplementary rebuttal, does the European Communities agree that it could not have been the intention to exclude from the scope of the SPS Agreement risks arising from allergens in food? If not, can the European Communities indicate a rationale for not subjecting risks arising from allergens to the disciplines of the SPS Agreement?

62. As the European Communities has explained in its written submissions, it considers that the scope of the *SPS Agreement* is the result of a carefully crafted compromise, reflected in the precise text of Annex A.1. It should not be "broadly" interpreted, but simply interpreted in a manner that gives proper weight to the text.

63. Canada's argument is essentially that all food safety issues were intended to be covered by the *SPS Agreement* and that allergenicity is a food safety issue. This is an unconvincing argument. First, food safety is not a term used in the *SPS Agreement.* Second, there is a continuum between food quality and food safety issues. For example, nutritional composition is clearly a food quality issue which may have implications for health and therefore food safety. The line between food quality and food safety has to be drawn somewhere and this has been done through the careful drafting of Annex A.1

64. Furthermore, the European Communities would point out that potential allergenic effects arising from GM plants may occur as a result of exposure other than through food. For example, it is well known that pollen inhalation, or contact between part of a plant and the skin of a human, may give rise to allergic reactions. Consequently, the issue of allergenicity is not confined to food safety. Rather, the potential presence of allergens in the environment as a result of the release of GM plants may be considered a broader environmental issue, not specifically included in the text of Annex A.1 of the *SPS Agreement.*

131. To what extent did/do Directives 90/220 and 2001/18 and Regulation (EC) No 258/97 permit for the establishment of conditions on the granting of approval for product applications?

65. As regards release into the environment, both Directive 90/220 and Directive 2001/18 provide for the possibility to make the consent for placing on the market subject to conditions. This can be inferred from Articles 12(3) and 13(5) of Directive 90/220 and from Articles 19(1), 19(3)(a), 20(3) of Directive 2001/18.

66. With respect to the extent to which such conditions (could) can be established, it is important to understand that it is the applicant who defines the *conditions of use and handling* in the notification (see Article 11(1) of Directive 90/220 and 13(2)(b) of Directive 2001/18). Indeed, it is within the limits of these conditions of use and handling only, that the authorisation can establish (additional) conditions to address concerns that have arisen in the risk assessment. Thus, it would not be possible for the authorities, for example, to set as a condition of the consent, the modification of the scope of the application from cultivation to import, if the applicant didn't agree to such condition, since this is a question of *conditions of use* which the applicant has to propose.

67. An example for a condition other than relating to use and handling established in market authorisations adopted in previous years is specific labelling requirements.

68. As regards food use, Art 7.2 of Regulation 258/97 states that:

> the decision shall define the scope of the authorisation and shall establish, where appropriate:

The conditions of use of the food or food ingredient. […]

69. This provision has in fact been implemented in all food product applications at stake, for instance by setting as a condition for approval, that the requirement to provide detection methods and reference material be provided.

132. Please explain the approval procedure applicable for a product for which approval was requested for feed use only. Which was the relevant EC scientific body requested to provide an opinion for such an application?

70. Feed use was not covered by Regulation 258/97 which applied exclusively to food use for human consumption (see Article 1). Feed use to the extent it concerned GMOs (i.e. living organisms), therefore, came under Directive 90/220, and later Directive 2001/18. Today, feed use is covered by Regulation 1829/2003.

71. Feed use, under Directive 90/220 was often included in applications for either cultivation or import and processing of GMOs. The lead Competent Authority was responsible for carrying out the relevant feed risk assessment, which it would usually do with the help of national scientific advisory bodies. At Community level, the Scientific Committee on Plants was supported by experts from the Scientific Committee on Animal Nutrition, as the relevant scientific body to provide advice on animal nutritional safety. The SCP's advisory opinion, therefore, would also cover feed safety aspects.

72. As has been made clear by the Panel's expert advice, the risk assessment of food uses and feed uses are notably different. Target animal physiology is different from human physiology and there are differences in what is consumed (which part of the plant, processed or unprocessed) and in what quantities. The results of a food safety assessment, therefore, cannot be extrapolated to feed safety.

133. Please explain the approval procedure applicable for a product for which approval was requested for both food and feed use, but not for cultivation. Which was the relevant EC scientific body requested to provide an opinion for such an application during the period 1998 through 2003?

73. Approval for both, food and feed use of a GMO, during the relevant period, necessitated two separate applications, namely one for food use under Regulation 258/97 and one for feed use (as part of the uses covered by an application for cultivation or import) under Directive 90/220 (until 17 October 2002) or Directive 2001/18 (after that date).

74. At Community level, for the application for food use under Regulation 258/97, the Scientific Committee for Food was requested to provide an opinion according to Article 11. Under Directive 90/220, although there was no obligation in the legislation, the Scientific Committee for Plants (SCP) was routinely consulted. As seen above under Question 132, for the purposes of assessing feed safety risks the SCP was supported by the Scientific Committee on Animal Nutrition. Under Directive 2001/18 the consultation became mandatory under Article 28 explicitly providing for the possibility of consulting several ("relevant") Committees.

134. With respect to the EC statement in paragraph 36 of its Responses to the Questions from the Panel (16 June 2004), is the Panel to understand that should an unintended adverse effect be identified for a product which had been approved prior to the entry into force of Directive 2001/18, it would be "legally impossible or at least questionable" to terminate that authorization?

75. The European Communities would like to point out that there is a difference between having identified an unintended adverse effect in a product and subjecting a product to new risk assessment and risk management requirements. The Panel's question is about the former, the European Communities' reply in para. 36 of its Responses to the Questions (16 June 2004) was about the latter.

76. As regards the former, even though this was less explicit than in Directive 2001/18 (see Article 20(3) of Directive 2001/18), there would have been no legal obstacle, under Directive 90/220, to terminating an authorisation in a situation where an unintended adverse effect had been identified for a product. Indeed, as can be inferred from Article 11(6) of Directive 90/220, there was an obligation on the notifier "to take measures necessary to protect human health and the environment." This can be read to encompass the obligation of ending the use of the product altogether if that is what would be necessary to protect human health and the environment. Furthermore, the possibility for Member States to adopt safeguard measures and for the Community to react to such safeguard measures with a Community level decision (Article 16 of Directive 90/220) implies that a product can be prohibited if unintended adverse effects have been identified.

77. As regards the latter, on the other hand, the European Communities reiterates its statement made in para. 36 of its Responses to the panel's questions (16 June 2004) that it would have been "legally impossible or at least questionable" to terminate existing authorisations just because new legislation was envisaged that would put in place stricter requirements as regards risk assessment and risk management issues.

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

78. The answer to this question is Yes. The explanations are made part of the decision.

79. It should be pointed out that it is a legal principle in Community law that a decision needs to be reasoned, i.e. sufficiently motivated (see Article 253 EC Treaty).

80. This principle has been put into more concrete terms for decisions requiring technical or scientific evaluations in the case law and in legislation towards the end of the eighties, early nineties. Thus, in the case *Technische Universität München v. Hauptzollamt München-Mitte* the Court struck down a decision which did not contain "a sufficient statement of the scientific reasons capable of justifying the conclusion […]."[7] Legislation in the field of risk regulation adopted around the same time specifically required that where a draft decision was not in accordance with the opinion of the

[7] Case C-269/90 *Technische Universität München v. Hauptzollamt München-Mitte*, Judgment of the 21 November 1991, 1991 ECR 5469, para. 27.

relevant scientific committee, the Commission was to annex a detailed explanation of the reasons for the differences.[8]

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

81. The principal point that the European Communities is making in para 195 of its replies to the Panel's questions following the first substantive meeting is that one cannot, in the context of Article 5.5 of the *SPS Agreement*, meaningfully compare the actions of the European Communities with those of the Member States, given the different ALOPs. The European Communities further noted that such a comparison between definitive and provisional measures might also, in principle, be questionable. That is at least the position in the case of provisional approvals. In this respect, it should not be forgotten that the ALOP and the risk assessment and the type of measure adopted are intimately connected. Thus, if the measure envisaged is an unconditional definitive approval, then the authorising authority may seek a particularly high degree of certainty – and one might say, in other terms, that it has a relatively high ALOP. If, on the other hand, the measure envisaged is a provisional and conditional approval, revocable in the light, for example, of the results of monitoring, then the authority might be satisfied, for the time being, with a lower degree of certainty – and one might say, in other words, that the ALOP is different.

137. Please explain the statement in paragraph 195 of the EC Responses to the Questions from the Panel (16 June 2004), that SPS 5.5 is not concerned with the consistency of the behaviour of regional authorities within a Member's territory within a provisional temporal frame of reference. Is this with respect to the consistency of different decisions by a single regional authority, or with respect to the consistency of decisions taken by different regional authorities with regard to the same potential risk?

82. The comment relates to the consistency of different decisions by a single regional authority. The point is that, over time, the available pertinent information may well be changing, so one cannot simply compare different provisional measures taken by the same authority at different times, and make the bare assertion that there is an inconsistency. Furthermore, under the *SPS Agreement*, authorities are entitled to change their ALOPs over time, even in the absence of "new information", simply because they reassess what objective they are trying to achieve, and that in itself would not disclose any inconsistency with the *SPS Agreement*. Otherwise, once an ALOP had been chosen, it would forever be "frozen" – which is clearly not something foreseen by the *SPS Agreement*. Finally, every product is different, and every product needs to be considered on its merits, so it is even possible that the same issue (such as Bt resistance) justifies a measure in one case, but not in another.

138. Please explain how the process identified in paragraphs 244-245 of the EC Responses to the Questions from the Panel (16 June 2004) functions. In particular, is the Panel to understand that if a request for further information concerns an issue which the lead CA considers has already been fully addressed by the SCP, the lead CA may decide not to forward this request to the notifier – but the other EC member State which submitted the request may continue to claim that is it not satisfied due to lack of information?

[8] See Article 32(1) of Regulation 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary se and establishing a European Agency for the Evaluation of Medicinal Products, (OJ N° L 214 of 24.8.1993, p.1)

83. The EC considers that the Panel's understanding is correct, as far as the part of the procedure involved is the one where the lead CA is in charge of the processing of the application. Such decision of the lead CA is however without prejudice to a possible different action by the Commission or another CA, at a later stage of the procedure, for the same application. In particular, if the MS that had initially filed the request remains unsatisfied due to the lack of the information after the lead CA's explanation of its decision not to forward the request to the applicant, it may ensue that its request is forwarded to the applicant at a later stage in the procedure or that that Member State will maintain a reserve or express a negative opinion when the authorization for the product under question is scrutinized by the Regulatory Committee. Two further qualifications appear, however, opportune.

84. First, this role of the lead CA may not hold true when a Member State request is directly before a scientific Committee, which may itself directly seek the relevant information from the applicant, without the involvement of the lead CA.

85. Second, this does of course not preclude a Member State that has requested further information, where such request has indeed been submitted to the applicant, from considering that the information provided in response by the applicant is not sufficient or appropriate for the purposes of completing a risk assessment in accordance with the provisions of the relevant legislation. Therefore, even in this case, that Member State could maintain a reserve or express a negative opinion when the authorization for the product under question is scrutinized by the Regulatory Committee in the so-called "Comitology" procedure.

139. With regard to paragraphs 293-294 of the EC Responses to the Questions from the Panel (16 June 2004) regarding the submission of draft measures to the Regulatory Committee, what is the purpose of submitting such draft measures to the Regulatory Committee when the Commission considers that they are not in a state to be considered for a final decision?

86. The Regulatory Committee of Directive 90/220 (the one addressed in the relevant paragraphs 293-294 of the EC Responses to the Questions from the Panel of 16 June 2004), had not only a regulatory but also an advisory role within the Comitology procedure of this Directive. Therefore, it was important for the Commission to submit draft measures to the Regulatory Committee to identify whether Member States had any outstanding concerns as regard the Commission's draft measure in view of final adoption, and if so, what were the relevant issues that the Member States considered to be inappropriately covered by the draft decision.

87. In the latter instance, if the Commission considered that the Member States were raising valid concerns, that might or might not necessitate further assessment of risks or development of risk management measures, or if any other relevant scientific information would have made it necessary, the Commission may have decided to postpone the vote and revise its draft measure, pending further assessment or the resolution of the valid concerns.

88. In more general terms, the Panel should be aware that in the Regulatory Committees the Commission and the Members States discuss the applications at length, e.g. present questions and answers. Before voting takes place, each application might be discussed several times. The agenda of the respective meetings indicates this also as 'discussion or exchange of views'.

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

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

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

89. No. The European Communities refers to its reply to Question 4 from the Panel (following the first substantive meeting with the parties). The European Communities there explained that Codex Standards and other equivalent standards are highly relevant to these proceedings. They may be considered as *inter alia* "international standards, guidelines and recommendations". However, the European Communities proceeds on the basis that the Panel does not consider these instruments to be binding international law instruments.

90. Furthermore, the IPPC revision on the basis of which ISPM 11 (2004) was published had not, at least at the date of establishment of this Panel, been ratified by the European Communities.

91. Annex A.1 of the *SPS Agreement* defines the scope of the *SPS Agreement*. It does not refer to "International standards, guidelines and recommendations". The provisions referred to in the question are not therefore dispositive of the meaning of words or phrases in Annex A.1 of the *SPS Agreement*. However, parts of those provisions may provide relevant context. This is not a question of "factual evidence", but a question of context relevant for the purposes of interpretation. For example, the European Communities has indicated (see the response to question 119 from the Panel) that it has no particular difficulty with the IPPC definition of the word "pest". That does not mean that the environmental risks described in ISPM 11 (2004), specifically designed to reflect the Biosafety Protocol, automatically fall within the scope of the *SPS Agreement*. The text of Annex A.1 of the *SPS Agreement* and its negotiating history make it clear that environmental and biodiversity risks fall outside the defined scope of the *SPS Agreement*.

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

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

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

92. (a) It is clear from footnote 5 that what matters is not the formal label attached to the measure, but the fact that it is "generally applicable" or normative in nature. A "sanitary and phytosanitary regulation" is a type of measure that would be attacked in WTO panel proceedings "as such", rather than "as applied". As the Appellate Body has recently observed, that is a measure "setting forth rules or norms that are intended to have general and prospective application" (Appellate

Body Report, US-Carbon Steel from Japan, para 82).[9] General normative rules of prospective application setting forth approval procedures in abstract terms are thus "sanitary and phytosanitary regulations" within the meaning of Annex B of the *SPS Agreement*. On the other hand, a single approval procedure, leading to an administrative decision in a specific case – such as would be attacked "as applied" in panel proceedings, is not a "sanitary and phytosanitary regulation" within the meaning of Annex B of the *SPS Agreement*.

93. Thus, the words "which relate to" in the question are ambiguous. If a measure is labelled an "administrative decision" but in fact sets out in abstract terms "approval procedures" intended to have general and prospective application, it is a "sanitary and phytosanitary regulation" within the meaning of Annex B of the *SPS Agreement*, and its formal label will not change that conclusion. If, on the other hand, the measure is adopted at the end of a specific administrative procedure and represents the outcome of a specific approval procedure in relation to a specific product, it is not a "sanitary and phytosanitary regulation" within the meaning of Annex B.

94. (b) The word "adopted" has a legal connotation. It indicates (1) someone or something that does the adopting (2) something, such as an act or document, that is adopted and (3) some kind of minimum procedure by which the "adoption" takes place. A thought or wish that may or may not have formed for a moment in the mind of one or more individuals with some potential role to play in a potential adoption procedure is not a measure; no more so if one or more such individuals articulate such thought or wish; no more so if one or more of them write it down or if their utterances are reported.

95. Thus, the phrase "de facto" "adoption" has no meaning, because the words "de facto" indicate a complete absence of any formal context; whilst the word "adoption" requires it. Indeed, in this case, the Complainants have not even plausibly alleged any one of the three constituent elements outlined above: whatever certain individuals may or may not have said, no authority has acted; the Complainants cannot point to any act or document; and the Complainants have not specified any procedure.

96. The word "informally" is equally vitiated. A measure cannot be "informally" "adopted". Either a measure is adopted or it is not.

97. Finally, with regard to the word "unrecorded" the European Communities can only repeat that it is not possible, in the Community jurisdiction, to adopt an act with legal effects that is "unrecorded". Such a thing simply does not exist. It is a chimera – an Orwellian "thought crime" - that persists only in the fertile imaginations of the Complainants, because they perceive it as convenient for their cause.

142. Please explain the meaning and rationale of the requirement in Article 2.2 that SPS measures be "based on scientific principles" and how this is different from the requirement that SPS measures not be maintained "without sufficient scientific evidence".

98. Viewing this provision from the point of view of definitive measures, one could consider there to be a degree of overlap, insofar as if it were demonstrated that a particular piece of evidence were not "scientific", it would presumably also be possible to argue that it was not based on scientific principles. And if the principles underlying an experiment were shown to be not "scientific", then presumably the "evidence" resulting from the experiment would equally be considered not to be "scientific". The concepts of "principle" and "evidence" are, however, clearly different. The testing

[9] See also Appellate Body Report, *Japan-Agricultural Products*, paras 103 to 108.

of hypothesis by controlled experiment, observation and reasoned conclusion are scientific principles. The relative mortality rates of butterflies fed on GM and non-GM plants is scientific evidence.

99. Viewing this provision from the point of view of provisional measures, the question is in fact very revealing and highly supportive of the position of the European Communities in this case. The core of the parties' disagreement often turns around the same point: how is one entitled to proceed if nothing or very little is known about certain issues; and who decides what are the issues that might require further investigation ? The European Communities considers that, at the frontiers of science, and taking its ALOP into account, it is entitled to be prudent. And this position is perfectly confirmed by the language of Article 5.7 of the *SPS Agreement*. The pertinent requirement here is that a Member acts "on the basis of available pertinent information". Understandably, there is no reference to "scientific evidence" because it might be that there is very little or even no scientific evidence in relation to the matter of concern. Equally, there is no reference to "scientific principles", because in the absence of any evidence, it is hard to see what role the principles would have to play. The "undue delay" provision of Annex C of the *SPS Agreement* must be read in the same light. That brings us to the following point. The European Communities was concerned, for example, about the possible effects of a GM crop on European biogeochemical cycles. We thought there was very little scientific evidence on this issue; we wanted to know more; and in the meantime, given our ALOP, we preferred to be cautious. By attacking us under Article 2.2 of the *SPS Agreement*, instead of the relevant provisions (Annex C and Article 5.7), the Complainants simply miss the point entirely – probably intentionally.

143. The Panel notes a number of instances where the same or a related product was apparently submitted under separate applications for approval. This appears to be the case for Monsanto Roundup Ready oilseed rape GT73 (EC-70, EC-79); Syngenta Bt 11 maize (EC-80, EC-92, and related EC-69); Pioneer/Dow AgroSciences Bt corn Cry1F (1507) (EC-74, EC-75, EC-95); Monsanto Roundup Ready corn NK603 (EC-76, EC-96); Monsanto Roundup Ready corn GA 21 (EC-78, EC-85, EC-91); and the various "stacked" products. To what extent does the assessment by a lead CA, the relevant EC Scientific Committee and any information provided by a notifier under one application serve as a basis for consideration of another application for the same or a related product?

100. The assessment of products under the environmental release directive (Directive 2001/18/EC and its predecessor Directive 90/220/EEC) aims at assessing the environmental impact of the release of the GMO as well as the possible impact of such release on human health or animal health (e.g. in case of incidental consumption). The assessment of products under Regulation 258/97 on novel food aims at assessing the safety of the GM food or GM food ingredients in question which are in general not consumed as GMO (i.e. living organisms) but as processed products. Therefore, the data set to be reviewed during the risk assessments are not identical. For example in the case of a novel food application, the nutritional impact of a regular intake of the GM food should be assessed, but this environmental impact (e.g. the issue of Bt resistance monitoring in case of food derived from a Bt crops) does not need to be assessed under Regulation 258/97.

101. Because of the existence of two different pieces of legislation, the assessment of applications filed under Directive 2001/18/EC (or Directive 90/220/EEC) and the assessment of applications filed under Regulation 258/97 were carried out separately and often by different scientific bodies encompassing different set of expertise: e.g. at EC level, such assessments were the responsibility of respectively the Scientific Committee on Plants (SCP) for application for environmental release and of the Scientific Committee for Food (SCF) for novel food applications. The European Community became rapidly aware of possible overlaps as well as possible gaps between the assessments carried out under different sets of legislation. This has been addressed by the creation of the European Food

Safety Authority in 2003 and the creation of one single scientific panel responsible for the risk assessment of GMOs and derived products. Pending the establishment of the European Food Safety Authority, an informal joint working group on GMOs and derived products including experts from the SCP, the SCF and the Scientific Committee on animal nutrition (SCAN) was established in 2001 to carry out the risk assessment of GMO and derived products in order to avoid duplication and gaps in the risks assessment process.

102. In addition, it should also be noted that in order to address these possible overlaps and gaps between the various regulatory regimes, the European Communities has recently developed a new legislation, on GM food and feed which entered into force in April 2004 (Regulation 1829/2203 on genetically modified food and feed) which streamlines the authorisation procedure for GMOs and derived food and feed. This regulation has established the one-door-one-key principle where applicants can request a complete authorisation in one single application, including food and feed use as well as cultivation. Such applications are assessed by the European Food Safety Authority.

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

103. As explained in the response to question 143, the data set for the risk assessment of an application filed under the environmental release directive and the one for a novel food application are not identical. Products approved under Regulation 258/97 were all processed products (and therefore were not GMOs) and have been approved under the simplified procedure laid down in Article 5 of the Regulation pertaining to products which have been recognised as substantially equivalent to conventional foods. As explained in previous EC submissions[10] and confirmed by Dr. Nutti at the hearing, the understanding of the concept of substantial equivalence has greatly evolved since 1998. The establishment of substantial equivalence is no longer recognised to constitute a risk assessment in itself; it is considered now to be a step of the risk assessment process as explained in Codex guidelines for the conduct of food safety assessment of food derived from recombinant-DNA plants (paragraph 13).

104. Applications filed under Directive 2001/18/EC (or its predecessor Directive 90/220/EEC), concern the environmental release of GMOs; in the EU definition, GMOs are living organisms. So, the establishment of substantial equivalence for food or food ingredients derived from these GMOs does not constitute a risk assessment for the release of the living organism itself. For example, oil produced from GT73 has been approved under the simplified procedure of Regulation 258/97. However, the establishment of substantial equivalence of oil produced from GT 73 does not provide information on the molecular characterisation of GT73, the possible presence or not of anti-biotic marker gene, or the fate of the GMO it-self in the environment.

[10] See Comments by the European Communities on the Scientific and Technical Advice to the Panel, paras. 51ff.

152. With reference to para. 211 of Canada's rebuttal, is it correct that the "Rapporteur had merely re-requested information that had previously been received from the applicant"?

105. No, it is not correct.

106. The entries in the chronology for the period referred to by paragraph 211 of Canada's rebuttal refer to four 'exchanges' between the lead CA[11] and the notifier which follow the lead CA's communication to the notifier of what still needed to be done with regard to the application. It is in the light of this communication dated 22 March 2000 (EC-70/Att. 018) that the notifier writes to the lead CA on 28 April 2000 (EC-70/Att. 019 and 020) sending "blots from three reports" (and, indeed, these had been already transmitted to the lead CA) as well as "the exact name of Monsanto in Europe". This second item addresses the remark by the lead CA in its email of 22 March 2000 that "the legal name and the registration of Monsanto need to be confirmed" and it is certainly a new element, not of a scientific nature, but still necessary to complete the requirements of the application process.

107. More importantly, the second entry for this period, "Clarifications from Monsanto", dated 17 May 2000 and contained in Att. 021, is an email with which the notifier forwards to the lead CA a "working document describing the modifications/addendum" it intends to do in the original application and on which it requires the opinion of the lead CA. Such an update of the application, although it may have contained information submitted over the past two years, is indeed a new element in the authorisation process because it changes the terms of the application. This can also be understood from the fact that the notifier sends it in draft format and requires the comment of the lead CA. Lead CA that, on 19 May 2000 (third entry for this period - Att. 022), informs Monsanto that it "will communicate its findings as soon as possible".

108. The European Communities has not been able to come in possession of the documents related to the phone and e-mail exchanges of November 2000 on this issue. However, it can be inferred from the letter of 12 March 2001 (Att.023) that during this period the lead CA had indeed analysed the update. It is, in fact, on that basis that it could conclude that "to confirm the unique molecular identity of line GT73 a PCR detection method of GT73 should be provided to complete dossier C/NL/98/11".

153. With reference to para. 298 of Canada's rebuttal, is it correct that the document provided in exhibit EC C-UK-94-M1-1-att.04 refers to the document provided in exhibit EC C-UK-94-M1-1-att.03? Also, what are the dates of these two documents?

109. The European Communities reads paragraph 298 of Canada's rebuttal as meaning that it is exhibit EC C-UK-94-M1-1-att.05 (now exhibit EC-161/Att.06) and not exhibit EC C-UK-94-M1-1-att.04 (now exhibit EC-161/Att.05) that it is referred to by exhibit EC C-UK-94-M1-1-att.03 (now exhibit EC-161/Att.04). In any case:

- exhibit EC C-UK-94-M1-1-att.03 (now exhibit EC-161/Att.04) is a note of the French Delegation for the attention of the Commission of the Autumn 2003, which sets out the arguments relating to the suspension of the commercialisation of genetically modified, herbicide resistant oilseed rape;

- exhibit EC C-UK-94-M1-1-att.04 (now exhibit EC-161/Att.05) is a note of the French authorities, dated 8 January 2004 (see the fax which forwards it,

[11] The European Communities responds to this question on the basis of the assumption that, when Canada refers to the "rapporteur", it intends the lead CA, in this case the Netherlands.

exhibit EC-161/Att.03), in response to a letter of the Commission dated 20 October 2003. With this note the French Authorities notify to the Commission the decree by which France had prolonged the suspension of the commercialisation of genetically modified, herbicide resistant oilseed rape. They also attach the opinion of the French Commission de Génie Biomoléculaire of 15 July 2003 (pages 3-5) on which such prolongation is based;

– exhibit EC C-UK-94-M1-1-att.05 (now exhibit EC-161/Att.06) is dated 16 February 2001 (its translation is contained in exhibit EC-161/Att.07 and 008) and consist of an opinion of the French Commission de Génie Biomoléculaire in which, indeed, a number of further scientific studies on oilseed rape were identified as necessary before its commercialisation.

154. At paras. 27 and 30 of the European Communities' second oral statement, reference is made to concerns regarding "regulatory requirements outside the scope of this dispute (traceability and labelling)". Is it the European Communities' view that any delays that may have occurred as a result of member States invoking the need for legislation on traceability, labelling or coexistence were justified? Why?

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

155. With reference to para. 211 of Canada's rebuttal, is it correct that the "Rapporteur had merely re-requested information that had previously been received from the applicant"?

111. The European Communities has already provided an answer to this very same issue under question 152.

156. With reference to para. 298 of Canada's rebuttal, is it correct that the document provided in exhibit EC C-UK-94-M1-1-att.04 refers to the document provided in exhibit EC C-UK-94-M1-1-att.03? Also, what are the dates of these two documents?

112. The European Communities has already provided an answer to this very same issue under question 153.

157. In its comments on the replies from experts with respect to EC-70, the European Communities notes that other data was provided by the notifier without separate appendices – was this information provided to the Panel, and if so, where is it to be found?

113. In paragraph 423 of its Comments on the Scientific and Technical Advice to the Panel of 28 January 2005, the European Communities was continuing to analyse the documents which were the object of Panel's question 28, i.e. the information provided by Monsanto to the Commission and contained in Exhibit EC-70/Att.84-97. The answer is, therefore, yes, this information was provided to the panel and it can be found in Exhibit EC-70/Att.84-97.

158. In paragraph 313 of the EC Responses to the Questions from the Panel (16 June 2004) the European Communities states that the absence of final consent from the lead CA does not

mean that the applicant is not entitled to place the product on the market. Has the product at issue (canola/oilseed rape MS1/RF1 and MS1/RF2) been sold in all of the European Community, including in France, and if not, why not?

114. Hybrid GM oilseed rape Ms1xRf1 and Ms1xRf2 have been approved for import, processing and cultivation in 1996 and 1997. The approvals did not provide for any reporting or monitoring of marketing in the European Communities. Accordingly, the European Communities is unable to say whether these products have been sold in the European Communities. The applicants may be able to provide the Panel with this information.

115. With respect to seed production, Ms1xRf1 had already been approved earlier under Directive 90/220. Again, the lack of appropriate tools (detection and identification, or traceability and labelling) at the time did not allow for proper monitoring of such seed production.

116. With respect to commercial cultivation, no oilseed rape varieties derived from Ms1xRf1 or Ms1xRf2 have been registered in Member States national Catalogues or in the Common Catalogue of varieties of agricultural plant species – which is a prerequisite for allowing their commercial cultivation – because there has been no application from companies to do so. The Panel should however note that GMO events such as Ms1xRf1 and Ms1xRf2, once approved, should be introduced in breeding programmes for introgression into commercial varieties which may require several years of breeding activities.

159. With respect to the products subject to safeguard measures, can the European Communities confirm that these products are currently permitted to be marketed, and are being marketed, in EC member States other than those maintaining the safeguard measure?

117. Yes. They are permitted to be marketed for all uses, provided that the varieties derived from these products and destined for commercial cultivation had been registered in the relevant national catalogue of varieties of the Member State where they were aimed to be cultivated, or in the Common Catalogue of varieties at Community level. Whether they were or are actually being marketed in all Member States is a factual issue that cannot be answered in the time available. Again, the applicants should be able to provide the Panel with this information.

118. What is however known is that many of these genetically modified events (Ms1xRf1; Bt176; …) have ceased to be commercialised in other countries, such as Canada or the United States, because of the lack of commercial interests of these particular lines and their replacement with newer transformation events.

161. With reference to paragraph 12 of the EC statement on 22 February 2005, as of when is MS8 x Rf3 under evaluation by the EFSA for all uses originally identified in the application?

119. As of 10 January 2005.

162. With reference to the EC response in paragraphs 345 of its responses to the questions from the Panel (16 June 2004), please describe the appropriate level of protection sought by the EC and its member States with respect to the products at issue in this dispute.

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

163. In paragraph 239 of its Third Written Submission, Canada maintains that for herbicide-tolerant seed varieties developed through conventional breeding or mutagenesis, an environmental risk assessment (including on farmland biodiversity) of either the seed variety of the associated herbicide is not required. Could the EC confirm the accuracy of this statement.

121. Under Community law, any new variety of plant (and therefore of seed) is submitted to Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species.[12] This prescribes that "a variety is accepted only if it is distinct, stable and sufficiently uniform. The variety must be of satisfactory value for cultivation and use" (Article 4, paragraph 1). In the case of a genetically modified variety, however, paragraph 4 of the same Article provides that "the deliberate release into the environment of the variety shall be accepted only if all appropriate measures have been taken to avoid adverse effects on human health and the environment."

122. This said the European Communities respectfully submits that it fails to see what the relevance of this piece of information is. Even if one were to follow the approach suggested by Canada at the second meeting with the Panel that this could be relevant for a consistency assessment under Article 5.5 of the *SPS Agreement*, the European Communities notes that, as this differentiation is mandated by law and Canada has not attacked the legislation in this case[13], such distinction is outside the terms of reference of this Panel and cannot therefore be assessed under Article 5.5 of the *SPS Agreement*.

164. In paragraph 94 of Canada's second written submission, Canada indicates that, according to a decision of the European Court, if the Regulatory Committee disregards the scientific opinion of the relevant EC scientific body "it must provide specific reasons for its findings" and it must explain why it is disregarding the opinion of the scientific committee. Please explain when this explanation must be provided, ie, when the Regulatory Committee decides to seek further information on concerns already considered by the scientific committee, or only when the Regulatory Committee takes a decision on the application? What explanation must be provided by the Regulatory Committee if it decides not to vote, or if no qualified majority it achieved in a vote?

123. Canada's assertion in paragraph 94 of its second written submission is based on an erroneous understanding of the Comitology procedure in general as well as the case law referred to in that paragraph.

124. The role of a Regulatory Committee is to vote on a proposal for a decision presented by the Commission. It cannot itself propose any decision nor amend the one proposed by the Commission. Equally, it does not itself have any power to seek further information from the applicant. If the Regulatory Committee does not endorse the Commission's proposal, the procedure moves up to the next level. There is no requirement in law to motivate the vote as this is an internal procedural step.

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[12] Official Journal of the European Communities, N° L 193 of 20.7.2002, page 1.

[13] The European Communities wishes to recall that Canada's request for establishment of this Panel (WT/DS292/17 of 8 August 2003) identifies as the measures at issue in this dispute:

1. the general suspension by the EC of its own processes for the consideration of applications for, and the granting of, approval for biotech products;
2. the failure by the EC to consider or approve, without undue delay, applications for approval of the products identified in Annex I; and

the national measures identified in Annex II prohibiting the importation, marketing or sale of the specified EC-approved biotech products."

125. The case law that Canada refers to applies to Community institutions adopting acts that have (external) legal effect. These are the legislator (Council and Parliament) or the Commission (by virtue of direct powers in the EC Treaty or delegated powers from the legislator), but not an auxiliary body such as the Regulatory Committee that is merely involved in preparing such an act. The case law, as explained above in the reply to question 135, is a concretisation of the legal principle in Community law that legal acts need to be reasoned. Thus, the final decision as adopted, either by the Commission or the Council, has to be reasoned and namely has to provide an explanation if it deviates from advice provided by a relevant scientific committee.

165. (EC-73): It appears that all of the relevant documentation was not provided in the context of the application contained in EC-73. However, the chronology provided by the European Communities shows no action on this application between the 02/00 requests for further information from the CA, and the 1/03 relaunch of the application under Directive 2001/18. Did the notifier fail to provide the information requested in 02/00, and if so, why?

126. The notifier did fail to provide the information requested on 2 February 2002 and the European Communities ignores why. It can only suppose, on the basis of the letter of Bayer Crop Science of 15 January 2003 (EC-73/Att.007) that this might be due to the numerous changes in the ownership of the producing company as well as in the rights on the pending applications. In fact, the initial notifier, the French pharmaceutical and chemical company Rhône-Poulenc, merged with Hoechst to become Aventis. Hoechst was the majority shareholder of AgrEvo. As a result, AgrEvo and Rhône-Poulenc Agro were combined into Aventis CropScience. Aventis CropScience was bought in 2001 by the German limited liability company Bayer A.G., which created Bayer CropScience. On 15 January 2003, Bayer CropScience then informs the lead CA that it has "assigned to Stoneville Pedigreed Seed Company any pending regulation application for BXN Cotton seeds".

166. (EC-74): As was noted in the replies by the experts, the complete documentation related to this dossier was not provided to the Panel. In some instances, the attachment provided only the titles of annexes, but not their contents. Please clarify whether the missing documentation had been provided to the lead CA, and if so, when?

127. The European Communities assumes that the documents for which the attachments provided only the titles of the annexes were probably provided to the lead CA as confidential, and hence not re-transmitted, on the same date as the rest of the documentation to which they were annexed. However, since the European Communities has not managed to trace back a copy of such documents (otherwise the Panel would have received it too), it cannot be more precise than this.

167. (EC-93): It appears that some of the documentation relevant to the safety assessment was not provided to the Panel. Please clarify whether the missing documentation had been provided to the lead CA, and if so, when?

128. The European Communities assumes that with this question the Panel is referring to its questions 49 and 50 to which Dr. Nutti provided a reply stating several times that she could not find the necessary information in the dossier.

129. Thus, in her reply to question 49 Dr. Nutti states five times that she could not find (or that the notification did not contain) this necessary information in the dossier. In all of these instances the information she is referring to was indeed not contained in the dossier as it had not been submitted by the applicant to the lead CA.

130. By contrast, in question 50, Dr. Nutti points out that attachments 21 and 22 of EC 93 only contain cover letters and no annexes. This is correct. In both instances the applicant had provided information contained in annexes which were not submitted to the Panel. The information submitted, however, did not contain the data packages referred to in the lead CA's request contained in Attachment 23. Equally, the original dossier (as can be seen from Att. 1) did not contain the broiler study referred to in the same request.

168. (EC-72): The Panel notes that the chronology provided by the European Communities shows no actions on this application between 12/99 (when according to the European Communities the UK CA allegedly advised the company that the dossier required substantial revision and clarification) and its re-submission in 1/03 under Directive 2001/18. Could the parties please explain the lack of action?

131. The European Communities is not aware of the reasons why the notifier did not react to the advice that the dossier needed substantial revision and clarification before January 2003.

132. Similarly to what pointed out under answer to question 165, one of the reasons could be the numerous changes in the ownership of the producing company. In fact, the initial notifier, AgrEvo was initially owned by Hoechst, which in 1999 merged with Rhône-Poulenc to become Aventis. As a result, AgrEvo and Rhône-Poulenc Agro were combined into Aventis CropScience. Aventis CropScience was bought in 2001 by the German limited liability company Bayer A.G., which created Bayer CropScience.

133. It may also be that some contacts took place between the lead CA and the notifier but that these were not officially documented. The letter of Bayer of 16 January 2003 accompanying the submission of the new SNIF (EC-73/Att.015) points in this direction when it mentions an email of the lead CA of 20 December 2002.

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

134. In the following paragraphs, the European Communities again summarises the reasons given by Austria and Germany when adopting their measures under Directive 90/220/EC, with particular reference to non-target organisms. For the original text, the European Communities refers to the measures and notifying letters themselves, and the footnotes that they contain to the scientific papers listed below.

135. According to Austria and Germany, during the risk assessment of this GM product, the majority of Competent Authorities from the different Member States of the Community expressed serious concerns, mainly in relation to ampicillin resistance, insecticidal Bt toxin and labelling, and the associated risks for human and animal health and for the environment.

136. About 50 or more published studies up to August 2003 were reviewed in a scientific paper by Oberhauser and Rivers in 2003 (Agbionet 5: ABN 117: 1-7). These authors state in the Abstract on page 1 that "[a]lthough the risk to monarch butterfly larvae from most varieties of Bt maize proved to be negligible, one variety (Event 176) posed a significant threat to monarchs. Since this variety was registered and commercialised without complete understanding of its potential risk to non-target species, we suggest several ways pre-commercialisation regulation and risk assessment might be improved, with the hope of preventing future negative impacts to non-targets". In the conclusions (at page 6) the authors state that "current EPA risk assessment requirements rely heavily on assessment

of representative non-target species… According to Murphy and Krimsky (New Genetics and Society 22: 127-143, 2003; referred to by Oberhauser and Rivers) a lack of good data on non-target species means that much of this research is conducted using indirect measurements and extrapolations from ecological models." Since both target non-target species differ widely in their sensitivity to Bt toxins (Wolt et al., 2003; Wraight et al 2003; Zangerl et al 2001 – see Oberhauser and Rivers review) and Austria had not conducted studies on regionally - or country - appropriate target and non-target species, Austria considers that it was justified to request studies which were relevant to Austrian non-target species and agro-ecosystems. As the monarch case revealed, the best available scientific risk assessment practices can in fact serve to elucidate non-target risks, thus requiring further research and monitoring after release.

137. According to Austria and Germany, existing conventional substances (insecticidal Bt sprays) containing Bt toxins are not used constantly, but are applied only when necessary. In addition, commercially available Bt sprays do not contain active Bt toxins, but inactive protoxins which must be activated in a multi-stage process, requiring a gut environment with an alkaline pH greater than about 9 or 10, allowing a breakdown by the digestive enzymes of insects. All of this reduces the extent, frequency and duration of exposure of Bt sprays. Furthermore, Bt toxins applied as sprays onto plant surfaces and onto soils are rapidly inactivated by naturally occurring ultra-violet light in sunlight. In contrast to the short persistence of Bt sprays, Bt toxins produced by GM crops expressing Bt toxin 'cry' genes (e.g. maize event, 176 by root exudation and decay of plant material into the soil) can persist in some soils (e.g. those with higher clay content) for more than 200 days (Tapp and Stotzky 1995; Saxena, Flores and Stotzky 2002; Zwahlen et al 2003).

138. Today, about 50 "Cry" proteins are known with sequential and specific differences for certain insects. The issues associated with the development of such GM products are therefore potentially complex and far reaching, extending beyond the specific crop, *cry* gene and insect to which the notification relates.

139. According to the Member States, the introduction of *cry* genes into GM crops (including the gene cry 1A(b) in the notified maize product) cause situations to arise that differ from those that arise from the conventional use of Bt sprays: there will be a permanent production of toxins all season long; the Bt toxin will be expressed in most parts of the plant; and all Bt-plants express a modified shortened variant (called a truncated Bt toxin) compared with the Bt protoxin used in Bt sprays. As Bt maize plant material does normally get into the soil, over one or more growing seasons there may be higher concentrations of Bt toxin compared with conventional use of Bt sprays. The resulting accumulation of Bt toxins in soil may influence non-target organisms negatively, positively or have no effect (this requires study in the receiving environment) or speed up the selection of Bt resistant non-target insects in the soil.

140. Austria and Germany considered that the qualitative and quantitative differences of the use of genetically modified plants expressing Bt toxins in comparison with conventional use of microbial Bt substances in sprays were not considered sufficiently in the application, in particular when basing the analysis on studies conducted with surrogate Bt proteins.

141. According to the Member States, in the application there were no data concerning the toxicity of maize expressing the *cry* 1A(b) gene for a species of Collembolan (*Folsoma candida*) that were considered in a similar procedure conducted in the United States. The available summary describes the toxic effect on the tested species but gives no comprehensible reason why this effect is negligible in practice.

142. According to Austria and Germany, there are other possible indirect effects that may arise through the development of resistance to Bt toxin. So far Bt toxins have been sprayed onto plants, where they were broken down under the influence of light within a few days. By contrast, the Bt toxins in transgenic plants are produced continuously over a growing season and not according to necessity (i.e. equivalent to prophylactic use). Moreover, the expression of Bt toxin in the plant can be variable (depending on the GM event and its growing environment) and so far only one Bt toxin variant has been produced in each GM maize event - not stacked Bt genes (as are now appearing in Bollgard II cotton). Often, there is no tissue-specific expression in the GM plant, due to use of constitutive promoters and 'leakiness' of any more tissue-specific promoters. This not only increases the efficiency of the toxin to the target pest but may also speed up the development of Bt resistance in pest insects, due to the level of exposure to the expressed toxin in the plant, for most or all of the growing season. The United States itself has imposed certain conditions before authorising the introduction of such Bt maize products.

143. Austria and Germany consider that it is particularly important that there should be an Insect Resistance Management programme to reduce resistance development in pest insects, which is tailored to the specific regional target and non-target insect species and to the receiving environment (in this case particularly the Austrian range of agro-ecosystems associated with maize production). To authorise the product without such a programme would constitute a step backwards compared to the United States in terms of safety for the environment and human health.

144. The Members States observe that in 1995 the United States authorised the introduction of genetically modified insect resistant Bt cotton, with a state-of-the-art resistance management programme. The crop was planted out for the first time in 1996. There are, however, reports of a serious infestation of cotton bollworm, the subject of close scientific and regulatory scrutiny. There are several possible reasons. It may be that extraordinary climatic conditions, including temperature, resulted in an increased reproduction of the pest insects or in stress to the plant's metabolism, reducing its ability to produce high levels of Bt toxin. It may be that an unstable expression of the *cry* gene resulted in an inactive Bt toxin. It may be that resistance developed in the pest insects within a very short period of time. It may be that there was an inefficient resistance management programme. As long as the reasons for such events remain unclear the risks associated with the introduction of such products in Austria remain unacceptably high. If such events were due in part to the development of rapid resistance by the pest to decreased Bt toxin production under elevated growing temperatures, then the whole approach to GM plants with Bt toxins may require a fundamental re-thinking. A minimum requirement would be the development of an elaborate resistance management programme involving industry, scientists, farmers and authorities – as was done in the USA.

145. In the view of Austria and Germany, such considerations, as well as those in the previous paragraphs, are re-enforced when it is recalled that there are already adequate maize products available which do not have these risks associated with them. There is no reason to accept risks which cannot at present be assessed with any sufficient degree of certainty or without further, targeted research in typical growing conditions in the member state. Furthermore, once admitted to the market, plant breeding could lead to further products (maize varieties) containing GM material that could be disseminated without any further need for authorisation, control or labelling.

146. Germany refers specifically to the fact that the corn borer is a Lepidopteran, and that the Bt toxin, which is expressed in both leaves and pollen of Bt maize, might thus have a negative effect on other Lepidoptera, as demonstrated by studies on the monarch butterfly in USA and even beyond the order of Lepidoptera. It also points out that the Bt toxin may be present in the roots and root exudates of Bt maize, and reach the soil by those means.

147. In respect to both Bt toxin and antibiotic resistance Germany is particularly concerned about the risk associated with large scale and unrestricted cultivation. This is because exposure to Bt toxin and/or its metabolites by non-target organisms increases with scale of Bt maize production.

148. In this context, the following papers were expressly referred to (see Austria's letter to the Commission dated 14 February 1997 and Germany's letter to the Commission dated 18 April 2000):

> Hokkanen, H. and Deacon, J. (eds) (1994): Special Issue: OECD Workshop on Ecological Implications of Transgenic Crop Plants Containing Bacillus thuringiensis Toxin Genes. In: Biocontrol Science and Technology Vol. 4
>
> Milner, R. (ed.) (1994): Special Issue: Bacillus Thuringiensis Agric., Ecosys. Env. Vol 49
>
> Tapp, H. and Stotzky, G (1995): Insecticidal Activity of the Toxins from Bacillus thuringiensis subspecies kurstaki and tenebrionis Adsorbed and Bound on Pure and Soil Clays. Appl. Env. Microbiol. 61(5), 1786-1790
>
> Losey et al., (1999) Nature 399:214
>
> Hilbeck et al. (Entomol. Exp. Appl. 91:305-316, 1999; Environmental Entomol 27:1255-1263, 1998; Environmental Entomol. 27:480-487, 1998)

149. Furthermore, in its letter dated 1 June 1999 to the Commission (in relation to Mon810 but also in relation to Bt toxin and non-target organisms), Austria also referred expressly to the following papers:

> Armstrong, C.L., et al. (1995) Crop Sci. 35, 550-557
>
> EPA (1995) Pesticide fact sheet, *Bacillus thuringiensis* CryIA(b) delta-endotoxin and the genetic material necessary for its production (plasmid vector pCIB4431) in corn
>
> Gill, S.S., et al. (1992) Annual Review of Entomology 37, 615-636
>
> Hafex et al., (1997)
>
> Hilbeck, A., et al. (1998a) Environmental Entomology 27, 1-8
>
> Hilbeck, A., et al. (1998b) Environmental Entomology 27, 1255-1263
>
> Hill, C.A. and Pinnock, D.E. (1998) Journal of Invertebrate Pathology 72, 9-20
>
> Höfte, H., and Whiteley, H. R. (1989) Microbiloigical Review 53, 242-255
>
> Hua, G., et al. (1998) Gene 214, 177-185
>
> Koziel, M.G. (1993) Bio/technology 11, 194-200
>
> Losey, J.E., et al. (1999) Nature 399, 214
>
> Losi et al. (1996)

Riegler, M., and Stauffer, C. (1998) Rekombinante *Bacillus thuringiensis* Toxin Pflanzen in Land- und Forstwirtschauft, Universität für Bodenkultur, Wien

ANNEX F-10

**REPLIES BY THE EUROPEAN COMMUNITIES
TO ADDITIONAL QUESTIONS POSED BY THE PANEL
IN THE CONTEXT OF THE SECOND SUBSTANTIVE MEETING
11 MARCH 2005**

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

A. Directive 2001/18/EC, Annex II, Section C.2.1

1. For each of the potential adverse effects listed in Directive 2001/18/EC, Annex II, Section C.2.1, (in bold italics below), we provide a commentary on whether or not it falls within or outside the defined scope of the *SPS Agreement*.

2. As a preliminary remark, the European Communities notes that each case will have to be considered on its merits, as Directive 2001/18/EC, Annex II, Section C.2.1 recalls that:

> Potential adverse effects of GMOs will vary from case to case […]

3. Thus, it is not possible to say, in general and abstract terms, whether or not, in all specific cases, the matters generally referred to in Annex C.2.1 of Directive 2001/18/EC fall entirely inside or outside the scope of the *SPS Agreement*, as set out, also in general and abstract terms, in Annex A.1 of the *SPS Agreement*. That said, in the commentary that follows, the European Communities sets out its best effort to respond to this question in abstract terms – it being understood that each specific product application must be considered on its merits.

– ***disease to humans including allergenic or toxic effects (see for example items II.A.11. and II.C.2(i) in Annex III A, and B 7 in Annex III B);***

4. These risks are partially within and partially outside the scope of the *SPS Agreement*.

5. Disease to humans does not fall within Annex A.1(a), because that provision does not relate to humans.

6. If a measure is taken to protect against human life or health from risks arising from a disease-causing organism in food or beverage, it could fall within the scope of Annex A.1(b).[1] However, since a GMO is not in itself a disease, nor generally considered a disease-causing organism, a measure would not, on the basis of such reasoning alone, fall within Annex A.1(b).[2] Furthermore, if the possible effects on human life or health did not relate to food or beverage (but, for example, exposure to the skin), the measure would not fall within Annex A.1(b).[3]

[1] European Communities First Written Submission, para. 421 and 427.
[2] European Communities First Written Submission, paras. 407 to 409.
[3] European Communities First Written Submission, para. 398.

7. If a measure is taken to protect against human life or health from risks arising from diseases carried by animals, plants or products thereof, it could fall within the scope of Annex A.1(c).[4] However, since a GMO is not in itself a disease, nor a disease-carrying organism, a measure would not, on the basis of such reasoning alone, fall within Annex A.1(c).[5]

8. As long as the GMO would not be characterised, in the specific context of disease to humans, as a pest, it would not fall within Annex A.1(d).[6] Furthermore, the term "other damage" in Annex A.1(d) refers to damage other than to the life or health of humans.

9. Toxic effects on humans do not fall within Annex A.1(a), because that provision does not relate to humans.

10. If a measure is taken to protect against human life or health from risks arising from a toxin in food or beverage, it could fall within the scope of Annex A.1(b). That could include the toxic effects on humans of the increased use of herbicide[7] or insecticide.[8] However, since a GMO is not in itself a toxin, a measure would not, on the basis of such reasoning alone, fall within Annex A.1(b).[9] Furthermore, if the possible effects on human life or health did not relate to food or beverage (but, for example, exposure to the skin), the measure would not fall within Annex A.1(b).[10] Finally, a toxin is generally something that is not intentionally present in food or beverage, and this could also take concerns about the toxic properties of GMOs outside the scope of the *SPS Agreement*.[11]

11. Toxic effects do not fall within Annex A.1(c).

12. As long as the GMO would not be characterised, in the specific context of toxic effects on humans, as a pest, it would not fall within Annex A.1(d).[12] Furthermore, the term "other damage" in Annex A.1(d) refers to damage other than to the life or health of humans.

13. Allergenic effects on humans do not fall within Annex A.1(a), because that provision does not relate to humans. They do not fall within Annex A.1(b) or (c).[13] They do not fall within Annex A.1(d) for the reasons indicated above.

– ***disease to animals and plants including toxic, and where appropriate, allergenic effects (see for example items II.A.11. and II.C.2(i) in Annex III A, and B 7 and D 8 in Annex III B);***

14. These risks are partially within and partially outside the scope of the *SPS Agreement*.

15. The reasoning is similar to that indicated in relation to the preceding point, but here we are concerned with animals or plants, rather than humans.

[4] European Communities First Written Submission, para. 421 and 427 (by implication).
[5] European Communities First Written Submission, paras. 407 to 409.
[6] European Communities First Written Submission, paras. 410 to 411.
[7] European Communities First Written Submission, para. 422.
[8] European Communities First Written Submission, para. 428.
[9] European Communities First Written Submission, para. 405.
[10] European Communities First Written Submisson, para. 398.
[11] European Communities First Written Submission, para. 405.
[12] European Communities First Written Submission, paras. 410 to 411.
[13] European Communities First Written Submission, paras. 409, 421 and 427.

16. Disease to animals: if a measure is taken to protect animal life or health from risks arising from the entry, establishment or spread of diseases, disease-carrying organisms or disease-causing organisms, it could fall within the scope of Annex A.1(a). However, since a GMO is not in itself a disease, nor a disease-carrying organism, nor generally considered a disease-causing organism, a measure would not, on the basis of such reasoning alone, fall within Annex A.1(a).[14]

17. If a measure is taken to protect animal life or health from risks arising from a disease-causing organism in feedstuffs, it could fall within the scope of Annex A.1(b).[15] However, since a GMO is not in itself a disease, a measure would not, on the basis of such reasoning alone, fall within Annex A.1(b).[16] Furthermore, if the possible effects on animal life or health did not relate to feedstuffs (that is, farmed animals) but, for example, wild fauna, the measure would not fall within Annex A.1(b).[17]

18. Animal life or health does not fall within Annex A.1(c).

19. As long as the GMO would not be characterised, in the specific context of disease to animals, as a pest, it would not fall within Annex A.1(d).[18] Furthermore, the term "other damage" in Annex A.1(d) refers to damage other than to the life or health of animals.

20. Toxic effects on animals do not fall within Annex A.1(a).

21. If a measure is taken to protect against animal life or health from risks arising from a toxin in a feedstuff, it could fall within the scope of Annex A.1(b). That could include the toxic effects on farmed animals of the increased use of herbicide[19] or insecticide.[20] However, since a GMO is not in itself a toxin, a measure would not, on the basis of such reasoning alone, fall within Annex A.1(b).[21] Furthermore, if the possible effects on animal life or health did not relate to feedstuffs (that is, farmed animals) but, for example, wild fauna, the measure would not fall within Annex A.1(b).[22] Finally, a toxin is generally something that is not intentionally present in feedstuffs, and this could also take concerns about the toxic properties of GMOs outside the scope of the *SPS Agreement*.[23]

22. Toxic effects do not fall within Annex A.1(c).

23. As long as the GMO would not be characterised, in the specific context of toxic effects on animals, as a pest, it would not fall within Annex A.1(d).[24] Furthermore, the term "other damage" in Annex A.1(d) refers to damage other than to the life or health of animals.

24. Allergenic effects on animals do not fall within Annex A.1(a) or (b), which do not refer to allergens; (c), which does not refer to animal life or health;[25] or (d), for the reasons indicated above.

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[14] European Communities First Written Submission, paras. 407 to 409.
[15] European Communities First Written Submission, para. 421 and 427.
[16] European Communities First Written Submission, paras. 407 to 409.
[17] European Communities First Written Submission, paras. 398.
[18] European Communities First Written Submission, paras. 410 to 411.
[19] European Communities First Written Submission, para. 422.
[20] European Communities First Written Submission, para. 428.
[21] European Communities First Written Submission, para. 405.
[22] European Communities First Written Submission, para. 398.
[23] European Communities First Written Submission, para. 405.
[24] European Communities First Written Submission, paras. 410 to 411.
[25] European Communities First Written Submission, paras. 409, 421 and 427.

25. Disease to plants: if a measure is taken to protect plant life or health from risks arising from the entry, establishment or spread of diseases, disease-carrying organisms or diseases organisms, it could fall within the scope of Annex A.1(a). However, since a GMO is not in itself a disease, nor a disease-carrying organism, nor generally considered a disease-causing organism, a measure would not, on the basis of such reasoning alone, fall within Annex A.1(a).[26]

26. Plant life or health does not fall within Annex A.1(b) or (c).

27. As long as the GMO would not be characterised, in the specific context of disease to plants, as a pest, it would not fall within Annex A.1(d).[27] Furthermore, the term "other damage" in Annex A.1(d) refers to damage other than to the life or health of plants.

28. Toxic effects on plants do not fall within Annex A.1(a).

29. Plant life or health does not fall within Annex A.1(b) or (c).

30. As long as the GMO would not be characterised, in the specific context of toxic effects on plants, as a pest, it would not fall within Annex A.1(d).[28] Furthermore, the term "other damage" in Annex A.1(d) refers to damage other than to the life or health of plants.

– ***effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these populations (see for example items IV B 8, 9 and 12 in Annex III A);***

31. These risks are outside the scope of the *SPS Agreement.*

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

32. Partially within and partially outside the scope of the *SPS Agreement*, depending on the context.

– ***compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine (see for example items II.A.11(e) and II.C.2(i)(iv) in Annex III A);***

33. Outside the scope of the *SPS Agreement*, insofar as the GMO in question is neither the cause of a disease nor a pest.[29]

– ***effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11(f) and IV.B.15 in Annex III A, and D 11 in Annex III B).***

34. These risks are outside the scope of the *SPS Agreement*, since these are environmental concerns.

[26] European Communities First Written Submission, paras. 407 to 409.
[27] European Communities First Written Submission, paras. 410 to 411.
[28] European Communities First Written Submission, paras. 410 to 411.
[29] European Communites First Written Submission, paras. 431 to 432.

35. The Directive further refers to adverse effects that may occur directly or indirectly through mechanisms which may include:

– ***the spread of the GMO(s) in the environment,***

36. These risks are outside the scope of the *SPS Agreement*, since this is an environmental concern.

– ***the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not,***

37. These risks are partially within (for example, on the question of cross-breeding and volunteers on agricultural land) and partially outside (for example, on the question of anti-biotic resistance) the scope of the *SPS Agreement*.

– ***phenotypic and genetic instability,***

38. Similarly, these risks are partially within and partially outside the scope of the *SPS Agreement*, depending on the context.

– ***interactions with other organisms,***

39. Similarly, these risks are partially within and partially outside the scope of the *SPS Agreement*, depending on the context.

– ***changes in management, including, where applicable, in agricultural practices.***

40. Similarly, these risks are partially within and partially outside the scope of the *SPS Agreement*, depending on the context.

B. Directive 2001/18 Annex D

41. The question also refers to Annex D of the Directive.

42. With regard to Annex D.2 of the Directive, in the case of genetically modified higher plants (GMHP), the European Communities would respond as follows.

– ***Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.***

43. These risks are outside the scope of the *SPS Agreement*, insofar as they concern natural habitats or environmental concerns about agro-ecosystems.[30]

– ***Any selective advantage or disadvantage conferred to the GMHP.***

44. These risks are partially within (for example, in the agricultural context) and partially outside (for example, in the context of environment and biodiversity) the scope of the *SPS Agreement*, depending on the context.

[30] European Communities First Written Submission, paras. 420, 423, 424, 429 and 430.

– ***Potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species.***

45. These risks are partially within (for example, in the agricultural context) and partially outside (for example, in the context of environment and biodiversity) the scope of the *SPS Agreement*, depending on the context.

– ***Potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable).***

46. These risks are outside the scope of the *SPS Agreement*, insofar as this concerns the environment and biodiversity.

– ***Possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens.***

47. These risks are outside the scope of the *SPS Agreement*, since they concern the environment and biodiversity.

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

48. Please refer to the discussion regarding human health above. These risks are partially within and partially outside the scope of the *SPS Agreement*, depending on the context. They are not necessarily entirely within Annex A.1(b), since this does not necessarily relate only to food and beverage.

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

49. Please refer to the discussion regarding animal health above. These risks are partially within and partially outside the scope of the *SPS Agreement*, depending on the context. Feedstuffs concerns may fall within Annex A.1(b). The consequences on the feed/food chain are more environmental, and will often fall outside the scope of the *SPS Agreement*.

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

50. These risks are outside the scope of the *SPS Agreement*, insofar as this concerns the environment and biodiversity.

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

51. These risks are outside the scope of the *SPS Agreement*, insofar as this concerns the environment and biodiversity.

52. With regard to Annex D.1 of the Directive, the responses are the same or very similar as for Annex D.2, and the European Communities does not believe that it is necessary to repeat them. However, the European Communities stands ready to answer further questions on this point, should the Panel so wish.

171. In Japan – Apples, the Appellate Body interpreted Article 5.7 of the SPS Agreement and notably the phrase "in cases where relevant scientific evidence is insufficient". It stated at para. 179 that:

> **Article 5.1 [...] informs the other provisions of Article 5, including Article 5.7. We note, as well, that the second sentence of Article 5.7 refers to a "more objective assessment of risks". These contextual elements militate in favour of a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1: "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement. [...] The question is whether the relevant evidence [...] is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.**

In this regard, please answer the following questions:

(a) Is there a reason to believe that a lack of relevant scientific evidence could prevent a Member from performing a risk assessment "as required under Article 5.1 and as defined in Annex A to the SPS Agreement"? Or is it rather a question of that Member perhaps being unable, due to the insufficiency of scientific evidence, to conduct a fully objective risk assessment, such that any measure based on that assessment might be maintained without sufficient scientific evidence?

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

53. The relevant obligation in Article 5.7 of the *SPS Agreement* is that a Member adopting a provisional measure does so "on the basis of available pertinent information". There is no cross-reference in Article 5.7 either to Article 5.1 or Annex A.4 of the *SPS Agreement*. There is therefore no basis for the proposition that measures adopted on the basis of Article 5.7 must be adopted on the basis of a full "risk assessment" within the meaning of Article 5.1 and Annex A.4.

54. The words "more objective assessment of risk" in Article 5.7 simply imply that the action taken "on the basis of available pertinent information" is less objective than a risk assessment under Article 5.1 and Annex A.4. That is perfectly understandable. The less scientific evidence there is in relation to a given issue, the more likely it is that there are different scientific views, some of which might eventually come to be considered more "objective", as more scientific evidence emerges. Until then, and at least in retrospect, those scientific and other views or concerns that do not withstand the passage of time may be considered to have been less objective.

55. It is correct that some of the issues considered, information and methods used, and procedures followed by a Member when adopting a provisional measure under Article 5.7 may be similar as when carrying out a risk assessment under Article 5.1 and Annex A.4 of the SPS Agreement. No doubt, when relying on the "available pertinent information" a Member may attempt in general terms to consider, and even assess, risk. That does not mean, however, that under Article 5.7 there is a full "risk assessment" within the meaning of Article 5.1 and Annex A.4. Where there are genuine concerns, but little or no information, it will simply not be possible to conduct a full risk assessment under Article 5.1 and Annex A.4, according to the required endpoint of the risk assessment of a particular Member, and its own acceptable level of risk. And this is particularly so if there is a desire to act quickly, or particularly to preserve a situation from potentially irreversible consequences.

56. In other words, even if there would be a "risk assessment" of some type under Article 5.7, that does not mean that it constitutes a full risk assessment under Article 5.1, such as might be the basis for a measure adopted under Article 2.2 of the *SPS Agreement*.

57. The final phrase of the question "such that any measure based on that assessment might be maintained without sufficient scientific evidence" requires special attention. The word "sufficient" in this phrase is not being used in the sense of the opposite of the word "insufficiency", in the first phrase of the second sentence of the question. This reflects a core difference between the parties in this dispute. The European Communities believes that a measure can be adopted under Article 5.7 even if the scientific evidence is "insufficient" – that is what the text of Article 5.7 expressly provides for. This does not mean, of course, that automatically the measure falls foul of Article 2.2, because it is "maintained without sufficient scientific evidence" (as the Complainants would have it). The concept of sufficiency or insufficiency in Article 5.7 relates to the extent of the body of scientific information, and whether or not it is enough to decide definitively, one way or the other, according to the required endpoint of the risk assessment of a particular Member, and its own acceptable level of risk. The concept of sufficiency or insufficiency in Article 2.2 relates to the question of whether or not the measure (presumed to be trade restrictive) is justified by the science. Thus, the only way these provisions make sense is if they are exclusionary – provisional measures under Article 5.7 and definitive measures under Article 2.2.

58. The European Communities does not find anything in para 179 of the Appellate Body Report in the *Japan – Apples* case, which was addressing Japan's attempt to distinguish between "general" and "specific" evidence, which contradicts this analysis. In particular, the European Communities would again recall that this entire section of the Appellate Body Report in *Japan – Apples* begins with para. 175 and footnote 316, which recall that: Japan relied on Article 5.7 in the alternative and only in the event that it failed on Article 2.2; that it was in this particular context that the panel in that case assigned the burden of proof to Japan. (Indeed the United States expressly contested the assignment of the burden of proof under Article 5.7 SPS to the defending party.)[31] By contrast, in these proceedings, the European Communities has pointed out that the Member State safeguard measures were adopted

[31] See para. 56 of the Oral Statement of the European Communities to the first meeting of the Panel with the Parties

pursuant to Article 5.7 of the *SPS Agreement*, and that the Complainants, for whatever reason, have not invoked this provision in their requests for establishment; that the burden of proof is on the Complainants; and the European Communities vigorously contests the various attempts by the Complainants to unlawfully shift the burden of proof on to the European Communities.

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

59. As the European Communities has already explained in previous submissions[32] in this case, the *SPS Agreement* distinguishes between (the development of) SPS measures and their application (Article 1).

60. Approval procedures as such (i.e. the general rules of prospective application set out in a normative act), to the extent they address risks coming under the *SPS Agreement*, are indeed SPS measures as can be clearly inferred from Annex A(1).

61. Article 8 and Annex C, on the other hand, leave no doubt that it is in the context of the *application* of that measure ("in the *operation* of …approval procedures", Article 8; "the procedure to check and ensure the fulfilment of sanitary or phytosanitary measures", Annex C) that "decisions" to delay and other procedural steps are examined for their compatibility with the *SPS Agreement*.

62. Indeed, if every delay - that is: a failure to act - were considered to constitute an SPS measure – that is: an action to be reviewed under Article 5 and other provisions of the *SPS Agreement* – the undue delay provision in Annex C(1)(a) would be devoid of any meaning.

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

63. The European Communities is not quite sure which scenario this question addresses: Read literally, it seems to refer to a situation where an application procedure would have been delayed (put on hold) on the grounds that certain risk management measures, which would appear necessary, could not be required from the applicant for want of a legal basis in the existing legislation. The European Communities is not aware of a specific instance where this has been the case. Indeed, as it has described at length, the whole point of the interim approach was precisely to request these risk management measures (with the agreement of the applicant) in order not to delay the application procedure until the entry into force of the new legislation.

64. However, if the question were to be understood this way, it would generally raise the issue of whether a procedure can be put on hold while the entry into force of new legislation is awaited. As has been pointed out before, the European Communities and the Complainants seem to share the

[32] First Written Submission, paras. 466ff ; Second Written Submission paras. 269ff.

view, in this regard, that such delays, subject to reasonable limits can be considered a justification for procedural delays.[33]

65. The question may also be read to refer to the delays caused by the actual requests for such risk management measures not explicitly provided for in the existing legislation. The question would then more generally be whether such delays are "undue" because there was no (explicit) legal basis in existing law to impose such requirements. As it has argued before, the European Communities takes the view that such requests need to be assessed on their own merits, that is, the Panel is to examine whether they were scientifically justified in the case at hand.[34] Delays caused by such requests would not be "undue" by the sheer fact that domestic law does not (explicitly) provide for such requests.

66. As regards the relevance of Article 27 of the Vienna Convention, that provision states the following:

> A party may not invoke the provisions of its internal law as justification for its failure to perform a treaty. This rule is without prejudice to article 46.

67. Article 27, thus, excludes the possibility for a party to an agreement to refer to its domestic law in order to derogate from an obligation it has undertaken. In the present case, however, this is not the situation.

68. In the present case, the obligation is not to cause "undue delays." The issue is what is "undue", and thus, what the content of the obligation is. That notion is to be determined in WTO law and is neither derived from nor dependent on domestic law. The European Communities has put forward a number of factual reasons to explain these delays. It is for the Panel to assess these reasons. The European Communities takes the view that they are not "undue." It has not argued that they are justified even though they would be "undue" under the *SPS Agreement* (which is the scenario envisaged by Article 27).

69. However, the Panel's question may aim at assessing, in the light of the principle expressed in Article 27, whether it is possible to invoke a WTO inconsistent aspect of domestic law to argue that a delay is not undue. The European Communities would have the following comments on this reading of the question: What is possible or not possible under domestic law is a question of fact which the Panel must take into account in assessing whether a delay is undue. Of course, a Member cannot rely on WTO-inconsistent requirements of domestic law to justify a delay but such inconsistency must be established and cannot be presumed. If the Complainants thought that the EC GMO legislation was incompatible with the *SPS Agreement* because it contains requirements with which they disagree or does not provide for options which they would like to see, they could have made such a claim and made the necessary arguments. They have not done so and so the EC GMO legislation must be accepted as is for the purposes of assessing what may be undue.

[33] EC Second Written Submission, para. 281 point c.
[34] See for example First Written Submission, para. 490.

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

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

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

70. The European Communities agrees that the words "non-fulfilment" in Article 2.2 of the *TBT Agreement* refer back to the word "fulfil" in Article 2.2, which in turn refers to a "legitimate objective". Thus, if a "legitimate objective" were not "fulfilled", that might "create a risk". That risk must be taken into account when determining whether or not a technical regulation is more trade restrictive than necessary.

71. For example, a technical regulation may require all electrical plugs to be correctly fused. The legitimate objective is that, in the event of a surge of current, the fuse should blow, rather than the plug catch fire. The risk created by the plug catching fire would be that a building might be damaged or destroyed, and persons might be injured or killed. These risks must be taken into account when assessing whether or not the technical regulation is more trade restrictive than necessary.

72. As another example, a technical regulation may require that a product specification (for instance on a label) lays down the range of technical values or other technical conditions within which a product may be properly used to achieve its end use purpose. For instance, a light bulb may specify the proper voltage of use, or a battery may specify valid end date of use, or a mobile telephone may specify the range of temperature and humidity for proper use. The risk of not providing or displaying this information here would be improper use or malfunction of the product, which may itself lead to technical difficulties for the user, economic loss for the user, or commercial impact, including civil liability incurred by the producer, due to possible deceptive practices.

73. Thus the trade effect must be weighed against the seriousness, severity, irreversability etc of the consequences of non-fulfilment of the objective in assessing consistency with Article 2.2. of the *TBT Agreement*.

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

74. As mentioned the Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming (ECOJ N° L189 of 29 July 2003), for the European Communities, the concept of coexistence refers to the ability of farmers to make a practical choice between conventional, organic or GM crop production in compliance with the legal obligation for labelling and/or purity standard. The issue of coexistence concerns the potential economic loss and impact of the admixture of approved GM crops with non-GM crops. As a result, measures taken with respect to co-existence of GMO and non-GMO crops and products fall outside the scope of the *SPS Agreement*.

75. In case where specific segregation measures are needed to protect the environment or human health (for instance in the case of a GM plant aimed at producing pharmaceuticals – potentially toxic to humans – to be segregated from the food chain), such measures would be prescribed in the final

consent of the authorisation procedure of Directive 2001/18/EC or Regulation (EC) 1829/2003. In such a case and only in such a case, the said segregation measures would fall within the scope of the *SPS Agreement*, in so far as the risk involved falls within the scope of Annex A.1 of the *SPS Agreement*.

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

76. The Austrian safeguard measure on Bt-176 refers to "insufficient labelling requirements" as one of the "reasons for Austria's decision to prohibit the use and sale" of the Bt-176 GM maize lines. In particular, the cover letter of the notification of the Austria reasons for its safeguard measure (Exhibit EC-158 att.7) states that "furthermore, Austria maintains its position that the labelling laid down in the Commission's Decision is insufficient. Consumers should be informed precisely about the fact that this product has been genetically modified."

77. There are two labelling issues addressed in the Austrian statement (the insufficiency of the labelling laid down in the Commission Decision, and the insufficient labelling for the purpose of precise consumer information), neither of which is covered by the *SPS Agreement*, as explained below.

78. The first concern (the insufficiency of the labelling laid down in the Commission Decision) relates to an issue which is also referred to in the Austrian reasons for its safeguard measure (Exhibit EC-158 att.7), namely "the unclear possibilities of the use of the herbicide resistance [by the farmer]." This issue is independent and not related to any component of the risk analysis process of the risks to human, animal or plant life or health at stake in the Austrian provisional measure, but rather refers to a labelling requirement aimed at ensuring that the appropriate information is provided to the end user, ie the farmers, as regards the proper technical use of the product.

79. The Commission Decision[35] authorising the placing on the market of Bt-176 laid down the following labelling requirement for seed packages of this product (paragraph 3 of Article 1 of the Decision):

> 3. Without prejudice to other labelling required by Community legislation, the label of each package of seeds shall indicate that the product:
>
> – protects itself against corn borers, and
>
> – has increased tolerance to the herbicide glufosinate-ammonium.

80. To properly understand the basis for this first Austrian concern, it is necessary to explain the technical basis for the requirement that "the label should indicate that the plants have increased

[35] Commission Decision 97/98/EC, see Exhibit US-97. Commission Decision 97/98/EC of 23 January 1997 concerning the placing on the market of genetically modified maize (Zea mays L.) with the combined modification for insecticidal properties conferred by the Bt-endotoxin gene and increased tolerance to the herbicide glufosinate ammonium pursuant to Council Directive 90/220/EEC.

tolerance to the herbicide glufosinate ammonium" (fifth recital, 7th indent of the Decision), which aims at providing appropriate technical information on the product to the end user.

81. Indeed, the introduction, in this particular Bt-176 transformation event, of one copy of the *bar* gene, encoding a phosphinothricin acetyltransferase which confers increased tolerance to the herbicide glufosinate ammonium, was not aimed at conferring herbicide tolerance to the end product, as a relevant agronomic trait of the GM plant, but was rather introduced as the genetic tool to be used *in vitro*, in the genetic engineering process, at the stage of the selection of the proper GM transformation events, in the early steps of the development of this particular Bt-176 product[36].

82. The presence in this Bt-176 transformation event of the prokaryotic gene *bla* (conferring resistance to the antibiotic ampicillin) was unintentional (it is present in the plant as a consequence of the accidental integration of some elements of the backbone of the bacterial vector plasmid), and could not have been used in this case as a plant genetic tool to select the desired transformation events, as it was only controlled under a prokaryotic (bacterial) promoter that could not have been used in the plant itself.

83. As a collateral consequence of the introduction in the plant of this *bar* gene, the regenerated Bt-176 GM lines had an increased tolerance to the herbicide glufosinate ammonium due to the presence of this gene. But the *bar* gene was not expressed at a level which would have proved efficient for its use as an agronomic trait in the field, and herbicide tolerance was therefore not claimed by the applicant as one of the commercial traits of this Bt-176 product in its notification.

84. However, should the farmer or any other end user have used glufosinate ammonium for any purpose, in the presence of this Bt-176 GM maize (as a current crop or as volunteers in subsequent crops in rotation or in non-agricultural land), the residual tolerance to this herbicide in this maize would have lead the farmer to encounter unexpected technical and/or agronomical problems with this herbicide related to imporper specifications for the use of this herbicide on Bt-176, if he had not been informed through an appropriate technical labelling requirement of the presence of this increased tolerance to this herbicide in Bt-176, which was the reason for the inclusion of the relevant labelling requirement in the Commission Decision.

85. The basis of this first Austrian concern was therefore the following: the labelling requirement provided in the Commission Decision did ensure that the end users of the Bt-176 seeds were indeed informed of the increased tolerance to this herbicide of this particular maize, so that they could address some of the technical issues related to the potential use of glufosinate ammonium in the presence of Bt-176. However, without further specification, the information provided could have misled, in Austria's opinion, the end user, and let him or her believe that one could in fact exploit this increased herbicide tolerance as an agronomic trait on this Bt-176 product, because the labelling requirement did not address the issue of separate herbicide registration procedures, and even more importantly, because the labelling requirement did not mention, as a further technical labelling specification, that this increased tolerance was improper and/or insufficient to be used as an agronomic trait to select the Bt-176 maize. Austria felt that both of these two technical issues should also have been included in the labelling requirement of the Commssion Decision for Bt-176, for the benefit of the technical information of the end user.

[36] The generation of a GM plant through genetic engineering techniques requires the fulfilment of three necessary steps, ie (i) the introduction of foreign DNA in the genome of a parent plant cell line, (ii) the selection, usually *in vitro*, of the desired GM transformation events, and (iii) the regeneration from the selected transformed plant cells of the new GM fertile plants. It is the second step which is at stake here.

86. The second concern (the insufficient labelling for the purpose of effective and fair consumer information) is also an issue that is independent and not related to any component of the risk analysis process to tackle any of the risks to human, animal or plant life or health, which may be at stake in the Austrian provisional measure.

87. Indeed, the Commission Decision for this product states (fifth recital, 6th indent) that "there are no safety grounds for mentioning on the label that the product has been obtained by genetic modification techniques".

88. However, the legitimate objective of consumer information (ie that an accurate and effective information on the fact that a product is genetically modified should have been provided to the consumers and other users of GM products) had been intensely debated within the European Communities since 1996. This concern was only finally clarified at the time of the application in April 2004 of Regulations 1829/2003/EC and 1830/2003/EC, which completed the labelling requirements for GM products now set out in the legislation, by providing, together with Directive 2001/18/EC, compulsory consumer and other end user information on the genetically modified character of GM products, independently of safety concerns. These labelling provisions aimed at addressing the legitimate objective of ensuring the possibility for the expression of consumers' and other end users' choices and preferences, and to ensure that these GM products would be marketed in a transparent, fair and commercial way.

89. As early as the end of 1996/the beginning of 1997, and before the publication of the Commission Decision for this product, Directive 97/35/EC[37] was elaborated and adopted, to amend Annex III of Directive 90/220/EEC in order to include specifications for compulsory labelling requirements for consumer and other user information, as a part of the additional information required in the case of notification for placing on the market of genetically modified organisms (GMOs). Directive 97/35 introduced the following requirement in part C of Annex III of Directive 90/220/EEC:

> C. The following information shall be provided in the notification, in accordance with Article 11 of [] Directive [90/220]:
>
> > Proposed labelling. This must include in a label or an accompanying document an indication that the product contains, or consists of genetically modified organisms. In the case of products to be placed on the market in mixtures with non-genetically modified organisms, information on the possibility that the genetically modified organisms may be present, is sufficient.

90. Although this provision was later viewed as insufficient by the European Communities legislator, in particular as regards the case of mixtures or adventitious presence of GMOs with non-genetically modified organisms (and was complemented by further, more precise, labelling requirements in Directive 2001/18/EC, and Regulations 1829 and 1830/2003/EC), this initial, generic, labelling requirement of GM products, for the purpose of consumer and other end user information, was not addressed in the Commission Decision 97/98/EC authorising the Bt-176 product, and this perceived gap was the basis of the second concern of the Austrian reference to insufficient labelling requirements.

[37] Commission Directive 97/35/EC of 18 June 1997 adapting to technical progress for the second time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms.

91. As has been clearly explained above, neither of the two Austrian concerns addresses any food safety concerns, nor risks to human, animal or plant life or health, nor even any safety issues in general.

92. As is stated in Annex A.1 of the *SPS Agreement*, "Sanitary or phytosanitary measures include all relevant [ ] requirements [ ] including, inter alia, [ ] labelling requirements directly related to food safety".

93. It is therefore obvious that these two concerns are not covered by the *SPS Agreement*, and, at least as far as they are concerned, do not qualify the Austrian provisional safeguard measure as a sanitary or phytosanitary measure.

94. On the contrary, the reasons concerning labelling that the Austrian authorities referred to when notifying the safeguard measure to the Community are clearly matters that could be covered by the *TBT Agreement*.

95. The Austrian safeguard measure in itself is not a technical regulation for all the reasons already explained by the European Communities.[38] However, it goes without saying that once such labelling requirements would be integrated in the general normative legislation, they would be covered by the concept of "technical regulation" referred to in the *TBT Agreement*. The first requirement (the technical specification of the product as regard the proper use of the increased tolerance to the herbicide) would be covered by the notion of a "*document which lays down product characteristics"*, and the first and second requirements (labelling requirements for consumer and end user information) would both be covered by the notion of the "*labelling requirements as they apply to a product, process or production method*", both notions being referred to in the above mentioned definition of a technical regulation in the *TBT Agreement*.

96. Both issues address the legitimate objectives, referred to in Article 2.2 of the *TBT Agreement*, of the prevention of deceptive practices, which includes effective and accurate consumer and end user information. Both issues also include the consideration of the relevant intended end-uses of the product, which is also referred to in the same provision of the *TBT Agreement*.

97. Without prejudice to the further analysis of the coverage by the *SPS Agreement*, the *TBT Agreement*, or the *GATT* of the other reasons of the Austrian safeguard measure, the consequence of the analysis of the two claims of insufficiency of labelling requirements, as two of Austria's reasons for its measure, is that it is obvious that this Austrian provisional measure falls, at least in part, outside the scope of the *SPS Agreement*, as they stand. They would, once integrated in the general normative legislation, also become "technical regulations" within the meaning of the *TBT Agreement*.

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

[38] EC First Written Submission, paras. 642ff.

agree with the interpretation offered at para. 100, and (b) explain in detail how this interpretation could be applied in practice?

98. The European Communities does not agree with Argentina and Canada. The underlying issue first has to be considered from the perspective of the general legislation. The Complainants do not assert that the European Communities general legislation regarding GMOs is inconsistent with the *SPS Agreement* or the *TBT Agreement*, and understandably so. It is perfectly reasonable for a Member to have different general legislation relating to GMOs and non-GMOs. This is so because GMO products and non-GMO products, as groups of products, cannot be considered like products. This is also consistent with the relevant international standards and norms, including the Biosafety Protocol which all distinguish between GMO and non GM products, which would , in particular, make such distinction also consistent with Article 2.4 of the *TBT Agreement*. This being so, the analysis does not change in the context of a Member State safeguard measure. This case is not about discrimination between imported products and domestic products. It is about whether or not the European Communities has complied with certain specific obligations under the WTO Agreement and the covered agreements, in relation to certain specific GMO product applications. As the Panel's own independent experts repeatedly observed, nothing is going to be clarified as long as the Complainants insist on comparing "apples and pears".

99. It is also noteworthy in this context that international norms, such as the Biosafety Protocol, recognise the necessity to distinguish GMO and non GMO product, *independently* of any safety concern, by requiring for instance that *all* living modified organisms that are intended for intentional introduction into the environment, whether found safe or not, be clearly identified as living modified organisms on an accompanying document (Article 18.2 (c)).

100. Since the issue of "less favourable treatment" must arise in relation to like products, the fact that GMOs and non-GMOs are not like products means that there can be no issue of "less favourable treatment" within the meaning of Article 2.1 of the *TBT Agreement* in this case, as alleged by the Complainants.

101. As regards the Appellate Body Report in *EC-Asbestos*, the European Communities would like to make the following comments. First, the analysis there set out relates to Article III:4 of the *GATT 1994*, not Article 2.1 of the *TBT Agreement*. Second, the Appellate Body correctly observes (at para. 88) that each provision where the term "like product" is used must be interpreted in light of the context, and object and purpose of the provision at issue. Third, the Appellate Body does not state that the competitive relationship in the marketplace between products is the only criterion. It is particularly evident that this is so when the underlying issue is a long term concern of general interest to society (such as effects on the environment or biodiversity) that may not be sufficiently taken into account by more short term "economic" market forces. As one Member of the Appellate Body stressed in his concurring statement in that case, a purely economic assessment of likeness is not always appropriate. In any event, the Appellate Body clearly states that not "*all* products which are in *some* competitive relationship are "like products" under Article III:4" (para.99 of the report; italics as in the original).

102. Furthermore, the European Communities recalls that the Appellate Body is discussing the issue of "less favourable treatment" under Article III:4 of the *GATT 1994*. However, the Appellate Body did not consider the point in great detail because the panel's findings on this point had not been appealed. However, the European Communities considers that the approach sketched out in para.100 is a sound one. Indeed, a finding of "likeness" does not by any means lead to a finding of "less favourable treatment". As the Appellate Body put it, "*a Member may draw distinctions between products which have been found to be "like" without, for that reason alone, according to the group of "like" domestic products "less favourable treatment" than that accorded to the group of "like"*

domestic products". Therefore, it rests upon a complaining party to prove that imported goods are treated less favourably than the like domestic products. The European Communities would also like to point out that, when examining a measure under Article III:4, a Panel is not obliged to follow any specific order of analysis of the several conditions set out in Article III:4.

103. In addition, in para. 100 of its Report, the Appellate Body makes clear that a finding of "less favourable treatment" requires an analysis not of individual products, but of the "group" of imported products and the "group" of domestic products. Therefore, even if one leaves aside for one moment the issue of "likeness", it is not possible to narrow down the comparison to imported GM products, on the one hand, and to domestic conventional counterparts, on the other hand. As a matter of fact, the comparison must logically start with a comparison between *imported and domestic GM products*, as those are the goods that are affected by the national safeguard measures. But the fact is that the national safeguard measures affect the production of GM products within certain parts of the EC *in the same way as* they affect the import of those very same products from other WTO Members: GM products whose authorisation has been provisionally suspended by an EC Member State cannot either be produced or imported into the territory of that Member State.

198. Please comment on para. 37 of Canada's second oral statement where it is said that "there is no a priori reason why cultivation cannot be introduced on a smaller and progressive scale" and that this has been "demonstrated to be a feasible option".

104. The context in which Canada has made this remark is not entirely clear, as Canada refers vaguely to "some of the EC Member State questions" which allegedly would have been based "on the presumption that the product necessarily will be cultivated on a large scale."

105. As a general remark, if an application is for *unlimited* cultivation, the risk assessment will obviously consider the possible effects of such unlimited cultivation, that is, of cultivation on a large scale.

106. Assuming that those "some Member State questions" may have been about assessing large scale effects through field studies, the issue here would be the following: rather than delaying the authorisation process by a request for additional data on large scale effects through field studies should the product not be authorised on a limited scale with a requirement to provide (that kind of data) data through monitoring?

107. There is a difference between a field study and a (limited) commercial cultivation and it is precisely for that reason that the EC legislation distinguishes between field study authorisations (Part B of Directive 90/220 and later 2001/18) and authorisations for any other release into the environment (Part C of Directive 90/220 and later 2001/18). The difference is one of degree of control. Cultivation conditions for field studies are very closely defined, including the location of where the crop is grown, buffer zones, crop protection, reproductive isolation conditions etc. This degree of control would be needed in order to (1) obtain the desired data and at the same time (2) contain any potential risks. Commercial cultivation is usually not subject to such strict conditions and this for the very good reason that, if it were, the authorisation would effectively be one under Part B and not Part C. Commercial cultivation, therefore, even if done only on a restricted scale, does not provide the same possibilities of control. On the other hand, the Panel should note that large scale trials have been carried out in the EU, for example the UK Farm Scale Evaluation. These trials have provided scientific information which incidently were not fully expected but which in any case would not have been obtained under commercial cultivation.

108. Any release of GMOs into the environment raising an issue of irreversibility, choosing the stricter option of requiring field studies and hence exercising greater control over the cultivation, therefore, is a question of choice of the acceptable threshold of risk.

199. Please comment on para. 62 of Canada's second oral statement where it is said that "[i]f the concern is that the herbicide used in conjunction with Ms8/Rf3 will be too effective, the simple answer is to encourage or require, as a condition of use, that farmers apply the herbicide in a manner that leaves more weeds in the field".

109. This assertion by Canada, in paragraph 62 of its Second Oral Statement, concerns the positive responses given by the Panel's experts to the scientific validity of the Belgian's request for additional information on ecological effects of Ms8/Rf3 on agricultural systems.[39] Such assertion appears, to the eyes of the European Communities, as a desperate last attempt to redress a lost argument. More substantially, there are several levels at which the European Communities can comment on such an assertion.

110. From a scientific point of view, as Canada itself recognises in the very same paragraph, the Panel's experts recognised the legitimacy of such a request, and therefore of such a concern, on the part of the Belgian authority.[40] Far from being a matter of "more weeds in the field", it has to do with how to preserve biodiversity and it is strictly dependant on the specificities of the crop species and varieties and of the regions in which these are grown.

111. From a practical point of view, Canada's assertion is completely out of reality. On the one hand, how can be realistically conceived that a farmer which buys GM HT seeds, and pays a premium for them precisely because they are herbicide-resistant (and so herbicide can be used at any time and in any quantity without fear of damaging the crop), would accept on a *voluntary* basis to limit the use of the herbicide? This issue can therefore not be left to the good willingness of individuals and it must therefore be dealt with by the regulatory authorities.

112. On the other hand, even though from the regulatory point of view it might be theoretically feasible to limit to some extent the rate of use of the herbicide, while achieving an acceptable level of efficacy, any such kind of requirements would in practice be as ineffective as a voluntary measure. Indeed, such requirements would be extremely difficult to enforce or let alone police.

113. In that connection, from a strictly WTO point of view, the European Communities would point out that, as far as the risks associated with GM HT crops are phytosanitary risks, the *SPS Agreement* recognises that problems of control and fraud are legitimate factors that can be taken into account by risk assessors/managers.[41]

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

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[39] Question 19 to Panel's experts, which refers to Exhibit EC-63/Att.149.

[40] See Responses by Dr. Andow, Squire and Snow to question 19, and Comments by the European Communities on the Scientific and Technical Advice to the Panel, paragraphs 364 and ff, as well as more generally on the persistence of HT crops, paragraph 154 and ff.

[41] Appellate Body Report, *EC – Hormones*, para. 205; and Panel report, *Japan – Apples*, paragraph 8.161.

114. Paragraph 20 of the European Communities' Second Oral Statement addresses the comments by the United States that "nothing in the record indicates that the applicant was ever requested to submit additional information to address Member States objections, nor that the basis of these objections was ever even notified to the applicant,"[42] and by Argentina, that "information provided by the EC in CD Roms does not mention any specific request by the EC to the applicant to provide this information."[43] These comments refer, respectively, to the period before February 1999 and to a letter by the applicant of 25 July 2002.

115. In paragraph 20, the European Communities is indeed asserting that the applicant was formally requested to submit the information in question. It is normal procedure,[44] in fact, that any request, comment or objection by a Member State on an application is automatically forwarded, through the lead CA, to the applicant.

116. In the specifics of Bt cotton 531, the comments and objections of the Member States raised before February 1999 are contained in Exhibit EC-65/Att.16 to 25, 27, 31 to 41, 65. A simple reading of the correspondence of the applicant demonstrates that the applicant referred always to "questions" raised by the Member States and that its answers were punctually reflecting such objections.[45] For instance, with its letter of 3rd February 1998, Monsanto forwards "responses to most of the questions raised during the discussion of the dossier … by representatives of the Competent Authorities in the Commission on 27th January."[46] In that meeting, the Competent Authorities discussed all their comments and objections sent that far[47]. Hence it is clear that all objections and comments had been brought to its attention.

117. Similarly inapposite is the remark of Argentina with regard to the letter of 25 July 2002. With this letter Monsanto was transmitting the updated molecular characterisation. Monsanto could not ignore that objections based on the lack of certain molecular data were formulated by Member States as of the very beginning of this application.[48] Furthermore, by then Directive 2001/18 had been adopted and was about to enter into force and, as mentioned several times, applicants were updating their dossiers to match the new requirements.

201. With regard to glufosinate tolerant soybean (AgrEvo) (EC-71), do the provision(s) of the relevant EC regulations prohibit the submission of applications for approvals to more than one EC member State? If so, please identify the relevant provision(s).

118. The relevant provision is to be found in Article 13, paragraph 1, of Directive 2001/18, which requires that:

> Before a GMO or a combination of GMOs as or in products is placed on the market, a notification shall be submitted to the competent authority of the Member State where such a GMO is to be placed on the market for the first time." (emphasis added)

[42] US Supplementary Rebuttal, para. 44.
[43] Supplementary Rebuttal of Argentina, page 17.
[44] See also Answers to the Questions by the Panel Posed During and After the Second Substantive Meeting with the Parties, answer to question 138, para. 83 and ff.
[45] See, for instance, Exhibit EC-65/Att.28 and 49.
[46] Exhibit EC-65/Att.28.
[47] See, for instance, the comments from the UK CA of 23 January 1998 (Exhibit EC-65/Att.18), where it is stated that the CA "will participate to the technical meeting on the 27th January to discuss these issues further".
[48] See, for instance, Exhibit EC-65/Att.16, 18, 19.

119. The same provision existed in Directive 90/220/EEC.

120. However, a company has always the possibility to withdraw an application from a Member State, and submit a dossier to another Member State. Furthermore, a negative assessment opinion of a lead competent authority, or a rejection of an application at community level, is without prejudice to the resubmission of the same application in another Member States. These situations are all provided for in whereas 35, 36 and 38 of Directive 2001/18/EC.

ANNEX F-11

COMMENTS BY THE EUROPEAN COMMUNITIES ON THE REPLIES BY THE COMPLAINANTS TO QUESTIONS POSED BY THE PANEL IN THE CONTEXT OF THE SECOND SUBSTANTIVE MEETING 18 MARCH 2005

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I. INTRODUCTION

1. The European Communities here comments on the responses of the Complainants ("the Responses") to the questions from the Panel which have been asked during and after the second susbtantive meeting of the Parties. The European Communities is conscious that there have now been extensive written pleadings in these proceedings, and does not wish to repeat the matters which have already been fully addressed by the Parties. In many respects the Complainants have simply repeated their earlier arguments of law and fact. It is apparent from the Responses that the differences between the views of the Complainants and the European Communities are clear and have very significant implications. In particular, the broad and extensive approach to interpretation relied upon by the Complainants will extend the scope of the *SPS Agreement* into areas which the drafters of that Agreement did not intend.

2. Rather than repeat the differences between the parties – or reiterate arguments already made – the European Communities considers that it would be more useful to comment on the approaches taken by the Complainants on some of the key issues which remain outstanding.

3. Accordingly, in these Comments the European Communities will not proceed by addressing in numerical order each and every Response given by each of the Complainants to each particular question. Instead, the European Communities comments on categories of questions and on those Responses which merit attention because they indicate a material and generic difference of approach. In proceeding in this way the European Communities wishes to stress two points. First, and for the avoidance of doubt, it maintains in their totality all of the legal and factual arguments which have been raised at earlier phases of these proceedings: the fact that no comment is given to a particular Response cannot be taken as an indication that the European Communities is agreeing with the Response. Second, in adopting this approach, the European Communities will go directly to the Complainants Responses and will refrain from advancing any arguments that go beyond the issues specifically discussed in those Responses.

II. THE SCOPE OF THE *SPS AGREEMENT* (ANNEX A.1): COMMENTS ON QUESTIONS 119, 120, 127, 170, 175, 176, 178, 180, 182, 187, 188, 191, 192

4. The issue of the scope of the *SPS Agreement* is one where it is easy to contrast the several approaches followed by the parties. The parties' replies to the Panel's questions show that those approaches are fundamentally different.

5. The European Communities notes that the Complainants recognize that their claims are dependent upon the adoption of a broad interpretation of the terms identified:

- "Argentina agrees that the term "pest" in the *SPS Agreement* should be given a broad interpretation in the light of the broad interpretation given to the term "pest" in the IPPC and the ISPM No. 11" (Argentina's reply to Question 119)

- "*[T]he broad definition given to the term "pest" in ISPM No.11 confirms that the ordinary meaning of the term "pest" in the SPS Agreement, in its context and in the light of the object and purpose of the SPS Agreement, should be given a broad interpretation*" (Canada's reply to Question 119)

6. The European Communities, on its side, reiterates that all processes of interpretation must follow the requirements of the Vienna Convention, and that it can never be a question of broad or

narrow interpretations as such. Applying the requirements of the Vienna Convention leads inevitably to the conclusion that the text, context and purpose of the *SPS Agreement*, as well as its negotiating history and the application of relevant principles of treaty interpretation (and in particular the principle of *expressio unius est exclusio alterius* (to express one thing is to exclude another)), which is relevant in relation to the failure of the negotiators to include the environment as such in the *SPS Agreement*, strongly support the conclusion that, for instance, environmental risks as such do not fall within the scope of the *SPS Agreement*.

7. Incidentally, while Canada admits that the Panel should make use of supplementary means of interpretation, as foreseen in Article 32 of the 1969 Vienna Convention (see Canada's replies to Questions 119 and 140), it has failed to address "*the preparatory work of the treaty and the circumstances of its conclusion*". The other Complainants also make no effort to address the negotiating history of the *SPS Agreement*, surely because the negotiating history of the *SPS Agreement* clearly demonstrates that it was not the intention of the drafters to include the protection of the environment as such within the disciplines of that text. It is the European Communities which has provided the Panel with the key elements as regards this particular aspect.[1]

8. The Complainants also ignore the consequences which their approach will plainly have in extending the application of the *SPS Agreement* to measures and acts which were never intended to be subject to it. This is obvious, for instance, when the United States affirms rather astonishingly that Annex A(1)(d) could apply to measure to prevent damage other than damage to plants, animals or humans (see US reply to Question 120, subpart (b) and (c)), without further qualification. The United States fails to discuss how this odd interpretation would fit in the overall scheme of the *SPS Agreement*. As a matter of fact, the Preamble of the *SPS Agreement* refers exclusively to "*human, animal or plant life or health*"[2]. As the European Communities has explained, in the light of the context and purpose of the *SPS Agreement*, as well as its negotiating history, the terms "other damage" must refer to damage that is closely related (i.e. that is of a similar kind) to damage to human, animal or plant life or health. This is a basic rule of interpretation. The European Communities has shown that there are dozens of examples where pests cause damage in particular to fruits without compromising in any way the life or health of the plant. There is therefore no need to look for eccentric examples, as Canada does in its reply to Question 120 (e.g. "*effects ... on recreational uses, tourism*"), and it would be legally incorrect to broaden the scope of the *SPS Agreement* to cover measures addressing risks concerning ecological processes, for the reasons already explained.

9. When examining concretely the interpretation given by the Complainants to the 4 sub-paragraphs (a to d) of Annex A.1 of the *SPS Agreement*, it is clear that they are in plain disagreement on the meaning of the relevant terms and on their application to the case at hand. The resolution of their differences is principally a matter of treaty intrepretation, which should be conducted in accordance with Articles 31 and 32 of the Vienna Convention. In this connection, the European Communities wishes to make the following points:

10. First of all, the Complainants disagree on which would be the relevant paragraphs of Annex A.1 to assess the potential adverse effects listed in Annex II of Directive 2001/18 (see their replies to Question 170). For instance, Argentina considers that disease to humans, animal and plants, including toxic and allergenic effects "*fall squarely within Annex A(1)(b) of the SPS Agreement*"; Canada in principle shares that view, but it adds that some of those risks "*also could fall within Annex A(1)(a) of*

[1] See the Reply of the European Communities to Question 120, as well as the EC Second Written Submission, paras. 57-59.

[2] First Recital of the Preamble of the *SPS Agreement*.

the SPS Agreement"; the United States considers that those risks fall under Annex A.1(c) (in so far as humans are concerned) and Annex A.1(a).

11. Second, the Complainants also advance differing interpretations to specific terms of Annex A.1. For instance, although Canada considers that the United States' interpretation of the term "additive" is "*linguistically plausible*", it does not actually support the interpretation (see Canada's reply to Question 180). Further on, Canada suggests that antibiotic marker genes "*might be considered contaminants*" (see reply to Question 180). This is in open contradiction with the United States' interpretation[3], which, in any event, maintains that the risks relating to antibiotic marker genes generally fall within paragraph 1(a), even though that paragraph does not make any reference to additives or contaminants (see US reply to Question 170, para.10). In any event, the European Communities recalls its position that antibiotic resistant marker genes cannot be considered as "additives" or "contaminants".[4] The European Communities further notes that, contrary to the United States' views, the technological purpose of antibiotic marker genes is not "*to aid in the manufacture of the food from the biotech plant*" (see US reply to Question 191(a)(i)). They are generally present by accidental integration of bacterial vector sequences. If at all, antibiotic marker genes aid in the process of selection of the GM plants themselves (not the food).

12. Third, the United States goes as far as contradicting itself in the very same paragraph, when it states without any reasoning that "*[w]hile the United States would not typically consider toxic and allergenic effects to be diseases, measures taken to address concerns that a biotech plant might cause disease to humans would appear to fall squarely within the scope of paragraph 1(c) – "to protect human life or health ... from risks arising from diseases carried by ... plants or products thereof*" (see US reply to Question 170, para. 3). In this regard, the European Communities definitely agrees that toxic and allergenic effects are not "diseases". The European Communities would further note that the United States considers that concerns that a GM plant "*might cause disease*" (sic) would fall under paragraph 1(c), which in fact deals with diseases "*carried by animals, plants or products thereof*". This is yet another example of the United States' disregard for the basic rules of treaty interpretation, in particular the wording of the treaty, as there is no doubt that Annex A.1 the *SPS Agreement* distinguishes between "diseases", diseases "caused" by an organism and diseases "carried" by an organism (see, for instance, Annex.1(a): "*to protect animal or plant life or health ... from risks arising from ... diseases, disease-carrying organisms or disease-causing organisms*"). Lastly, it is enough to point out that the United States seems to suggest that the terms of the *SPS Agreement* should in the context of this particular dispute be interpreted in a manner that it would not typically consider correct.

13. Fourth, the broad, untenable interpretation of the term "pest" illustrates clearly the fact that the Complainants most often put forward mere unsubstantiated assertions, which are unsupported by a rigorous reading of the *SPS Agreement*. The United States claims, for instance, that allergic and toxic effects on humans would be "*risks to human health arising from the entry, establishment or spread of pests*". The United States refers specifically to "*toxic or allergic effects arising from occupational or residential exposures*" (see reply to Question 170, para.4). However, the European Communities fails to see why a GMO should be necessarily be qualified as a "pest" in those circumstances. Indeed, a GM plant can provoke occupational allergies regardless of its invasiveness or persistence. It could provoke occupational allergies even under controlled cultivation conditions, as the allergenicity depends on the intrinsic characteristics of the plant other than its weediness potential[5]. The United

[3] Argentina appears not to have replied to Question 180.
[4] See, for example, EC First Written Submission, paras 399 to 404.
[5] The same applies to potential impacts on biogeochemical cycles (see US reply to Question 170, para.13).

States again contradicts itself when it affirms that a measure aimed at preventing human health risks arising from occupational exposure to a substance that is a toxin for insects "*would fall within the scope of paragraph A(1)(b)*" – see US reply to Question 178(c). Similar considerations apply to the allegations by Argentina and Canada (see their replies to Question 170).

14. Fifth, on some occasions, the Complainants' disregard for the actual wording of the *SPS Agreement* is even more egregious. For instance, Argentina, Canada and the United States consider that measures to prevent the risks arising from antibiotic marker genes, which can compromise "*prophylactic or therapeutic medical, veterinary, or plant protection treatments*", fall within the scope of Annex A(1)(a) of the *SPS Agreement* (see their replies to Question 170). The European Communities would simply note that Annex A.1(a) refers only to animal or plant life or health, so it is not clear at all which is the relevance of that parapraph to the loss of effectiveness of "medical treatments" (that is, treatments for humans).

15. Finally, the Complainants often argue that some of the potential risks relevant for a risk assessment under Directive 2001/18 are not relevant in the context of the present dispute because "*the question is ... whether the risks that the EC has raised with respect to the products at issue in this dispute, either in whole or in part, fall within the Scope of the SPS Agreement*" (US reply to Question 178(a), para.50). The Complainants seem to forget that they have challenged (wrongly) an alleged "general moratorium" that would apply to all GM products, *beyond* the specific product applications examined by the EC authorities. The European Communities has made clear that no such thing as a "general moratorium" is applied. In any event, if the Complainants' views on the "general moratorium" were upheld, the "products at issue in this dispute" would be *all* GM products, and therefore *all* potential risks ought to be considered.

16. Aside from the above issues, the Complainants also make a number of arguments regarding the relationship between the *SPS Agreement* and other WTO Agreements (in particular *GATT 1994* and the *TBT Agreement*). Their main point seems to be that the obligations contained in the WTO Agreement are "generally cumulative", and that the fact that a measure may pursue several legitimate objectives, some of which are not SPS objectives, is not relevant to their coverage under the *SPS Agreement* (Canada's reply to Question 175, paras.32, 38). The European Communities will not repeat its extensive arguments on this issue. At this stage, it is enough to recall that the European Communities does not have any particular problem with the suggestion that measures that pursue multiple objectives, some of which are SPS objectives, fall *partly* under the scope of the *SPS Agreement*. The real point is a different one: in a nutshell, if a measure pursues two different objectives, one of which is deemed legitimate by a Panel and one of which is not, the Member that adopted the measure is under no obligation to withdraw it. In other words, if those two objectives are to be assessed under two different WTO Agreements (for instance, the *SPS Agreement* and the *TBT Agreement*), a recommendation to withdraw the measure can only be made after an examination under the two Agreements.

17. As regards the question of whether co-existence concerns come under the scope of the *SPS Agreement* (Question 175), the European Communities notes that all parties agree that the economic risks arising from the mere admixture of approved GM crops with non GM crops do not come under the scope of the *SPS Agreement*. Disagreement only exists with regard to whether such concerns are legitimate under other WTO Agreements and if so, how that fact would affect an assessment of a measure under the *SPS Agreement* (see immediately above).

III. THE RELEVANT OBLIGATIONS UNDER THE *SPS AGREEMENT* – APPLICATION OF SPS MEASURES: COMMENTS ON QUESTIONS 125, 172, 186

18. The Complainants fail to draw any meaningful distinction between a measure and its application. This is particularly evident in their replies to Question 172. All Complainants seem to agree that a decision to delay an application procedure may well constitute a case of *application* of an SPS measure (Canada, para. 15, US para. 30, ARG first paragraph). All three, however, then argue, that such a decision to delay may nevertheless, under certain circumstances, constitute a distinct SPS measure. The criteria they offer differ widely, but have in common that they are useless for the purposes of distinguishing between a measure and the application of a measure. The US proposes to distinguish between delaying for a day or a week and delaying for an indefinite period of time. Applied to the facts of the present case such a criterion simply does not make any sense: There were a number of requests for additional information that delayed the application procedure. How long the delay would take depended entirely on the nature of the additional information requested and the applicant's ability and willingness to provide it. It is simply not possible, for the requesting authority, to determine (much less impose) how long the delay will be.

19. Canada invites the Panel to assess whether "the source of the delay supersedes the approval procedure as the measure that exerts effective control over subject matter of the … product applications." One feels tempted to wish the Panel good luck in giving meaning to such grandiose sounding notions as "superseding", and "exerting effective control over subject matter."

20. By contrast the approach offered by Argentina seems simple: Delays cease to be the application of an SPS measure when they occur "systematically." However, how the Panel is supposed to assess whether a "decision" to delay the completion of an approval procedure for a number of days is of the "systematic" kind or not, Argentina leaves open.

21. All three Complainants, finally, share the inability to apply any logic in their approaches. If, as they claim, the delays that have occurred in the present case actually constitute a *distinct SPS measure*, why then are these very same delays challenged at the same time as the *application of an SPS measure*?

22. This lack of logic is due to the Complainants' further failure to make any meaningful distinction between an action and a failure to act. Obligations under the *SPS Agreement* (or any other WTO agreement for that matter) are either "negative" ones, that is an obligation not to undertake/to refrain from a certain action, or they are "positive" ones, that is an obligation to undertake a certain action. In order to be subject to an obligation conduct must be qualified as either action or inaction. Action and inaction are mutually exclusive concepts. Annex C 1(a) contains an obligation to act without undue delay. The conduct it addresses, consequently, is failure to act, not action. By contrast, Articles 5.1 or 5.7 contain negative obligations and thus address a conduct that is action (i.e. the adoption of a trade-restrictive SPS measure).[6]

23. Canada's failure to grasp this difference is particularly blatant in its reply to Question 125. That question is about the concept of "undue delays" in Annex C 1(a) in the context of a precautionary approach. While eagerly discussing "undue delays" as "a failure to make a decision" in Question 186 (see para. 59), for the purposes of its reply to Question 125, Canada qualifies them as a "decision not to complete the approval procedure" which "amounts to a ban on the product." That ban, then, according to Canada, must satisfy the requirements of Article 5.7 in order not to be qualified as an "undue delay" under Annex C 1(a). By contrast, the United States seems to be more aware of the

[6] See EC First Written Submission, paras. 463ff.

schizophrenia of qualifying something as failure to act and as action at the same time, and, thus, more prudently, proposes to assimilate the "effects" of delays to that of the adoption of a ban (see para. 19). Article 5.7, under the US proposal, could then be "relevant context to be examined in deciding how to apply the "undue delay" provision under Annex C", but would not be directly applicable.[7]

24. It may be that the Complainants are starting to realise that a measure consisting of a decision not to approve a product for a period would be a provisional measure to which Article 5.7 *SPS Agreement* would be applicable. However, they cannot allege a violation of Article 5.7 because they have not based any claim on this provision.

25. As stated in its second oral statement at the second meeting of the Panel with the Parties, the European Communities holds the view that the precautionary principle as such (and not Article 5.7) should be of relevance when assessing whether a delay is undue.[8]

IV. THE *SPS AGREEMENT* - SCIENTIFIC EVIDENCE, RISK ASSESSMENTS AND ARTICLE 5.7: COMMENTS ON QUESTIONS 122, 123, 125, 126, 142

26. In response to Question 122, the European Communities explained that the ALOP may be relevant to the conduct of a risk assessment, taking into account different objective conditions, different types of values or concerns, or different levels of protection. According to Argentina, the "appropriate level of protection and risk assessment are related", whilst according to the United States they are "distinct". According to Canada, "the appropriate level of protection (ALOP) is not directly relevant to the conduct of the risk assessment. It is, however, relevant once the risk assessment has been completed and, assuming that a risk has been identified, a risk management measure has to be selected." Canada concludes that "*whether the chosen level of protection is low or high does not affect the risk assessor's need to have sufficient information at his or her disposal to come to a conclusion that is as certain as possible. A risk assessment that is characterized by significant uncertainty as to the likelihood or magnitude of adverse effects occurring is less helpful to the risk manager, regardless of the level of protection sought to be achieved because it is less likely to serve as an accurate predictor with respect to whether that level of protection will actually be achieved*."

27. The European Communities therefore notes that the Complainants are not in agreement: Argentina and the United States take diametrically opposed views, whilst Canada effectively agrees with the European Communities. Canada effectively agrees with the European Communities because it acknowledges that a risk assessment may be more or less helpful to a risk manager according to the extent to which it is characterised by significant uncertainty. Canada attempts but fails to avoid the inevitable logical consequence: given this premise, it is evident that a risk manager with a lower level of concern will be satisfied with a less developed risk assessment than a risk manager with a higher level of concern.

28. In response to Question 123, the European Communities explained that it considered the underlying premise to be legally erroneous, and referred to its previous submissions concerning the relationship between Article 5.7 and 2.2 and 5.1 of the *SPS Agreement*. Argentina replies "no" to the first part of the question and "yes" to the second part of the question. Canada, on the other hand, considers that it would be "technically" possible to consider Article 5.7 first, but "naturally" preferable to consider Article 2.2 first. Remarkably, Canada considers that any measure adopted under Article

[7] See also US reply to Question 173 in para. 34, where the US suggests "an analogy to provisional measures under Article 5.7."

[8] Second Oral Statement of the European Communities to the Second Meeting of the Panel with the Parties, para. 54.

5.7 is "*ipso facto*" inconsistent with Articles 2.2 and 5.1. Canada offers an incomplete summary of the precise circumstances of the appeal in the *Japan-Apples* case. Taking a slightly different line, the United States considers that it would be "possible" but not "practicable" to first consider Article 5.7, unless the European Communities first concedes an inconsistency with Articles 2.2 and 5.1, and that it would be most "efficient" to first consider Articles 2.2 and 5.1.

29. The European Communities concludes that the Complainants are not in agreement amongst themselves. The European Communities re-iterates its view that the legal point is the exclusionary nature of the relationship between the provisions. This is not a question of what is "technically" possible or "natural" or "possible" or "practical" or "efficient". Rather, the legal question is to be settled by applying customary rules of interpretation of international law to the text of the *SPS Agreement*. The European Communities believes that this view is shared by the Appellate Body.

30. The heart of the problem is burden of proof. The European Communities believes that, faced with a request for authorisation of a new product, and faced with a legitimate concern, the absence or insufficiency of scientific evidence may justify a situation in which, provisionally, the new product is not approved. The European Communities believes that the burden of proving that the new product is safe falls on the applicant, just as the burden of proving that any provisional measure is unjustified because the scientific evidence is complete and demonstrates that the new product is safe, falls on the Complainants. The Complainants cannot shirk-off the burden of proof that falls on their shoulders by invoking, instead of Article 5.7 (on the basis of which the provisional measure has been adopted) Article 2.2 – twisting the word "sufficient" in Article 2.2 to make it refer to the quantity, rather than the quality, of the scientific reasoning. The proof of that is that the European Communities agrees with the Complainants (as it has already stated) that, where it has adopted provisional measures, it has done so precisely because the science is insufficient for the purposes of the specific legislator. To accept the Complainants' reasoning would be to shift the burden of proof on to the Member adopting the provisional measure, as opposed to the Member bringing the case under the DSU. And that would constitute a legal error.

31. With regard to Question 125, Argentina's answer, by implication, accepts the premise reflected in the Panel's question concerning the relevant legal framework and analytical approach : the relevance of the precautionary principle in the context of Annex C.1(a) – and (but only if there would be a measure) Article 5.7. Argentina merely confines itself to asserting that, in fact, at the date of establishment of this Panel, the science was, on all points, sufficient and meant that the only possible course of action for the European Communities was an immediate definitive approval. Argentina asserts that the concerns referred to by the European Communities are no different from the residual uncertainty inherent in all science. Canada essentially takes the same line, but with the additional assertion that the European Communities has not invoked Article 5.7 other than in relation to the safeguard measures. That is not correct. The European Communities position is that if the Panel were to make the (in the opinion of the European Communities) legal error of finding that the product specific delays were measures or that something generally referred to by the Complainants as the "moratorium" existed, then, indeed, the relevant provision of the *SPS Agreement* would be Article 5.7, that being the provision relevant to provisional situations, in which the science is as yet insufficient for a final decision to be taken. However, since the issue is one of delays, not measures, the correct approach would be to assess the situation under Annex C.1 (giving due account to the precautionary principle), not Article 5.7 (see above Comments under Section III). The United States avoids the question as "too vague and general" and returns to its erroneous assertions about the alleged "moratorium". It states that "broad generalisations" are not helpful when considering individual products – a statement with which the European Communities wholeheartedly agrees. It goes on to assert that the European Communities considers that Member can delay "indefinitely" on the basis of "theoretical" risks.

32. The European Communities concludes that all the Complainants appear to be generally in agreement about the correct analytical framework – it is just a question of considering the facts in each case.

33. The European Communities would respectfully recall the advice provided to the Panel by the independent experts; the meeting with the experts; and the subsequent comments by the European Communities. The European Communities believes that it is not possible to dismiss out of hand, as the Complainants seek to do, that scientific advice as "theoretical" or as relating to, or equivalent to, the residual uncertainty that may always be present in science.

34. With regard to Question 126, the European Communities notes that, on the question of risk assessments, and particularly risk management, all of the Complainants urge the Panel to ignore the Codex. The European Communities believes that it was and is entitled to refer to the Codex for this purpose, and that to find otherwise would constitute a legal error.

35. With regard to Question 142, the European Communities explained both the similarities and differences between scientific "evidence" and scientific "principles", placing its response also in the context of Article 5.7. The Complainants broadly agree – but once again entirely miss the point about Article 5.7.

36. In summary, the European Communities notes that on these issues, such as the sufficiency or insufficiency of the science, burden of proof, and provisionality or the precautionary principle, which in many respect go to the core of this case, the Complaints remain, in many important respects, in disagreement amongst themselves. In truth, the assertions they make seek to set at naught the advice from the independent experts, and to steer the Panel towards the wrong provisions of the *SPS Agreement*. The European Communities would respectfully request the Panel to reject the Complainants' arguments on these points.

V. THE *TBT AGREEMENT*: COMMENTS ON QUESTIONS 174 AND 181

37. The European Communities notes that the United States has expressly declined to answer Question 174, on the interpretation of Article 2.2 of the *TBT Agreement*, on the grounds that the issues in dispute are governed by the *SPS Agreement* and not the *TBT Agreement*. The three other parties are in agreement in recognising the need to answer the question. Canada and Argentina do not appear to challenge the view of the European Communities that a "trade effect must be weighed against the seriousness, severity, irreversibility, etc. of the consequences of non-fulfilment of the objective in assessing consistency with Article 2.2 of the *TBT Agreement*."

38. However, as regards the meaning and scope of the terms "scientific information" in Article 2.2 of the *TBT Agreement*, Argentina and Canada appear to be in disagreement (see their replies to Question 174(b)). Argentina considers that "scientific information" in the *TBT Agreement* refers to a broader range of matters than health or environment matters, such as "national security" and "deceptive practices". Argentina also considers that "scientific information" is to be interpreted as being "equal to "scientific evidence"". Canada adopts a different approach, concluding that "the distinction between "scientific evidence" in Article 5.2 of the *SPS Agreement* and "scientific information" in Article 2.2 of the *TBT Agreement* relates to the differences in the respective obligations of the two agreements for measures to have a factual and/or scientific basis."

39. The European Communities considers that the drafters of the *SPS Agreement* and the *TBT Agreement* must have intended to use the concepts of "scientific evidence" and "scientific

information" to mean different things, or they would not have distinguished between the use of the terms. The European Communities notes that Canada appears to share this view (and notes that Canada is inconsistent with its own approach to treaty interpretation when elsewhere in its replies it proposes the view that the *SPS Agreement* must be interpreted to include effects on biodiversity and the environment, notwithstanding the fact that the drafters of the *SPS Agreement* purposely did not include the term "environment", which is in turn found in the *TBT Agreement*).

40. With regard to Article 2.1 of the *TBT Agreement*, both Argentina and Canada agree that the Member State safeguard measures apply to the relevant GM products when imported into the territory of the respective Member States and when they are produced in those Member States. The parties seem therefore to agree that the Member State safeguard measures cannot be considered to be discriminating in any way against imported GM products (see replies to Question 181). Furthermore, the European Communities notes the confirmation by Canada that it does **not** claim that the Greek measure violates Article 2.1 of the *TBT Agreement*. In this context, the European Communities reaffirms its position that "*it is clear that the nature and aim of the Greek measure does not differ from those of the other national measures*"[9], contrary to Canada's allegations regarding the "*explicit wording of the measure*". Indeed, Canada entirely misses the point, as it is obvious that the Greek measure is entitled "import ban" merely because only an import authorisation had previously been granted at EC level. The reality is that in Greece, the *production, import, marketing or use of the product at stake is not authorised*. Therefore, the Greek measure simply re-establishes the situation that existed before the EC approval was granted, and that situation certainly applies to import in the same way as to domestic production. The Panel should look at the situation prevailing in Greece as a whole, and not simply make legal findings on a measure on the basis of its "label".

VI. THE BURDEN OF PROOF: COMMENTS ON QUESTIONS 145 AND 146

41. The European Communities notes that there is a fundamental disagreement between the parties as to the burden of proof which arises once the European Communities has put forward the evidence which it considers justifies actions which may have led to delays in authorization procedures. In such circumstances it *must* be for the Complainants to respond by rebutting that evidence. It cannot be enough to argue, as the United States does for example, that there existed an "*across-the-board general moratorium*" which obviates the need to rebut the evidence put forward by the European Communities (See US reply to Question 145). First, the Complainants have not proven the existence of an alleged "moratorium" or its application to any of the authorizations which form the subject of these proceedings. Second, the independent scientific experts appointed by the Panel have confirmed that the evidence put forward by the European Communities confirms that the scientific concerns raised by the EC Competent Authorities and the resulting delays were justified. In such circumstances the European Communities fails to understand how it can be said that it has failed to justify its actions, or how in such circumstances the relevant action could be said to arise from the application of an alleged "moratorium".

42. The European Communities would further note that the United States considers that it "*does not have the burden of establishing that particular delays were justified or unjustified*" (Reply to Question 145). The European Communities would simply point out the fact that, when a WTO Member alleges a violation of Annex C(1)(a) of the *SPS Agreement* (or, for that matter, of Article 5.2.1 of the *TBT Agreement*), that Member bears the burden of proving that there are "delays" and that

[9] First Written Submission of the European Communities, para. 640.

such delays are "undue". Canada, on the other hand, seems to agree that the Complainants bear the burden of proving "undue delays" (see Canada's reply to Question 145 [10]).

43. Finally, Argentina's position is striking, as it seems to be based on a general, unsubstantiated dismissal of all the evidence submitted by the European Communities as not being "evidence" (see Reply to Question 145: "*We do not agree with this statement, because it assumes that the EC has submitted evidence…*"). Apparently, Argentina considers that any scientific paper, any technical element or any established fact that does not support its case is not "evidence", but second-class information that should not be taken into account. Such approach is obviously biased and untenable, as exemplified in Argentina's reply to Question 146. The European Communities fails to understand how Argentina can assert that the studies and analysis undertaken by the Commission du Génie Biomoléculaire and the French AFSSA cannot be said to be "scientific evidence". Both are well-renowned and reputable institutions which purported to take their decisions on the basis of scientific elements (or lack thereof) which were placed before them in the relevant dossiers. The fact that Argentina does not agree with the outcome cannot of itself determine the characterisation of the process by which the relevant decisions were taken.

VII. RELEVANT INTERNATIONAL STANDARDS: COMMENTS ON QUESTIONS 121 AND 140

44. The European Communities notes the plain disagreement between the United States, on the one hand, and Canada and Argentina, on the other hand, as regards the issue of the relevant international standards that the European Communities had to take into account prior to August 2003. Argentina and Canada believe that **no** relevant risk assessment techniques had been developed by relevant international organisations in the period October 1998 to August 2003 (see their replies to Question 121). By contrast, the United States believes that such techniques had been established, and identifies no less than six Codex and IPPC standards which it considers to be relevant (see US reply to Question 121). The European Communities submits that these standards – as well as those identified by the Communities in its answer to Question 121 – are properly to be taken into account in assessing the compatibility of the Communities' actions with the relevant rules of WTO law. However, the European Communities would recall two fundamental points:

45. First, Codex and IPPC standards do not exhaust the range of issues ariring from the products of biotechnology, in particular as regards environmental risks.

46. Second, the IPPC and Codex standards were developed precisely during the period 1998-2003, and they were not adopted until July 2003 (in the case of the Codex principles on risk assessment of food derived from modern biotechnology) and April 2004 (in the case of ISPM 11). However, they incorporate many of the issues and concerns that were being raised at the time by the EC Competent Authorites in connection with the assessment of specific GMO products. This fact provides further confirmation that the behaviour of the EC Competent Authorities was perfectly justified.

47. Otherwise, there appears to be broad agreement amongst the parties that the Codex standards and ISPM 11 are not "rules of international law" within the meaning of Article 31(3)(c) of the Vienna Convention, in the sense that they are not binding international law instruments as such (See replies to

[10] However, Canada fails once again to clarify what is the nature of its claims and of the challenged measures, as in its Reply to Question 145 it refers to "delays" as the *result* of an alleged "moratorium", or as *confirmation* of the alleged "moratorium". On this issue, see the Comments in Section VIII.

Question 140; the United States does not express a view on this point, considering the matter to be theoretical).

48. As regards the IPPC, there appears to be agreement that the 1979 version is a rule of international law within the meaning of Article 31(3)(c). Insofar as the 1997 IPPC is concerned, this had been accepted by Argentina, Canada and the United States by the time the Panel was constituted, but had not yet entered into force. The European Communities had not accepted the instrument. In the case of the 2000 Biosafety Protocol this too had not entered into forced by the time the panel was constituted, but it had been signed by Argentina, Canada and the European Communities.

49. As the European Communities has previously mentioned, in previous disputes the WTO Appellate Body has referred to instruments which were not binding on all the parties to a WTO dispute in interpreting WTO rules. In particular, in *United States – Shrimps* (1998) the Appellate Body relied on: UNCLOS (which had not been signed by US, but which arguably reflects for the most part international customary law), the Convention on Biological Diversity (which had been signed but not ratified by Thailand and the US), Agenda 21 (which is a "programme" or a "plan of action" to be developed through several means, including the further development of international law on sustainable development), the Convention on the Conservation of Migratory Species of Wild Animals (to which Malaysia, Thailand and the US were not parties). In this connection, the European Communities notes that under Article 18 of the Vienna Convention a state, which has signed a treaty is bound not to take any steps to defeat its object and purpose. These considerations indicate that it is appropriate to take account the international instruments referred to in the reply of the European Communities to Question 121 in construing and interpreting WTO rules, such as the *SPS Agreement*, although it does not provide a basis for reading into the *SPS Agreement* matters which the drafters plainly intended to exclude (such as biodiversity and the protection of the environment in general).

50. Finally, the United States appears to be isolated in its view that the Codex standards, then IPPC and ISPM 11 can be used as "additional factual evidence" of the ordinary meaning of terms contained in Annex A of the *SPS Agreement*. The European Communities and Canada consider that they are aids to interpretation and do not have evidentiary status as such (see replies to Question 140).

VIII. THE CHALLENGED MEASURES: COMMENTS ON QUESTIONS 179, 185, 193, 194, 195, 197

51. The European Communities would like to provide the following comments on the Complainants' replies to Questions 179, 185, 193, 194, 195 and 197. Those questions are useful to demonstrate the identity and nature of the "challenged measures", and to demonstrate that the approach that the Complainants have pursued since the very beginning of this dispute is misconceived.

52. First of all, the Complainants' replies constitute further evidence of the insufficient characterisation of the "challenged measures" and the sweeping approach to law, facts and evidence adopted by the Complainants. This is nicely illustrated by the Complainants' inability to distinguish between their claims on the *alleged 'de facto' moratorium* and the alleged *product-specific moratoria* (or *marketing bans*, in Canada's parlance) and the circularity of many of their arguments:

53. The United States, in its reply to Question 197, bluntly states that *"[s]ince the general moratorium applied to all products, a necessary corollary is that the EC also adopted product-specific moratoria on each of the product applications covered in the US panel request.*"

54. Canada contends that it "*has provided ample evidence of the existence of the moratorium and the product-specific marketing bans, being the manifestation of the moratorium in the context of the approval procedures of the four specific products of concern to Canada.*" (Reply to Question 179)

55. Canada further argues that *"[t]he product-specific marketing bans are a direct consequence of the moratorium as applied to individual product applications. They are also proof of the moratorium and, for Canada, the most injurious manifestation of the moratorium. They are however distinct measures from the moratorium and give rise to distinct violations of the WTO Agreement. The arguments in relation to the product-specific bans are intended to focus on the direct and detrimental impact of the moratorium on specific product applications*". According to Canada, *"[i]n principle, the adoption of the moratorium led to the adoption of the product-specific marketing bans.*"(Reply to Question 185)

56. Argentina dismisses the importance of looking at individual product applications because, in its view, "*the number of the selected product applications should not be relevant because this does not change the fact that there is a "de facto" moratorium.*" (Reply to Question 179).

57. It is clear from the Complainants' replies that there is no distinction between the "*general*" claims and the "*product-specific*" claims. Instead of characterising the alleged product specific moratoria as distinct measures, the Complainants describe them as the "*corollary*", the "*manifestation*", the "*direct consequence*" or the "*impact*" of the alleged general moratorium.

58. The Panel should not be misled by this kind of circular reasoning whose only purpose is to prevent an examination of the reasons that explain and justify the behaviour of the European Communities during the relevant time period.

59. In the circumstances, the European Communities can only conclude that the Complainants have failed to identify with any degree of precision what is the measure or measures that they are challenging, and what would be the nature of such measures (an act? a delay? both things at the same time?).

60. Secondly, as regards the alleged general moratorium, the Complainants contest the European Communities' view that, for the purposes of proving a 'moratorium' that applies across the board, it does not suffice to address only a limited selection of product applications. In their views, they have proved that there were no approvals between October 1998 and August 2003 (see United States' reply to Question 179), or between October 1998 and May 2004 (see Canada's reply to Question 179). Argentina argues that "*[t]he EC assertion is flawed because, as a result of the moratorium, there have been neither approvals nor rejections*" (see reply to Question 179).

61. However, if the Complainants argue that the European Communities has adopted a 'de facto moratorium' on approvals of *all* GM products, they should prove that such measure applies *beyond* the specific product applications at stake in these proceedings. Conversely, if the European Communities establishes, as it has done, that there is no such thing as a *general* suspension of approval procedures (and, for that purpose, it is enough to put forward *one* specific example), then the claims of the Complainants against a general abstract measure should be dismissed.

62. The European Communities would point out that, contrary to the United States' and Canada's assertions, the absence of any approval[11] between October 1998 and August 2003, or between October

[11] The European Communities would however recall that several products have been authorised since 1998 under the simplified procedure of Regulation 258/97.

1998 and May 2004, is by no means evidence of the existence of a general suspension of approvals. At this stage, the European Communities would limit itself to recalling that Directive 2001/18 entered into force in October 2002; that applicants were given the opportunity to resubmit their dossiers by the end of January 2003; and that the European Communities started the assessment of those dossiers forthwith, in accordance with the provisions of the Directive. Needless to say that, before approvals could be granted, the European Communities needed to complete the required risk assessment. But that does not mean that the procedure was suspended in 2003: to the contrary, the proof that the procedure was running is that the European Communities approved Maize Roundup Ready NK 603 on 19 July 2004. The European Communities would recall that the Complainants have not challenged Directive 2001/18 and, therefore, they cannot complain that the European Communities follows the provisions of the Directive for the purposes of making decisions on specific GM products. The Complainants can simply not argue that the European Communities was supposed to suddenly make final decisions on all pending applications on the date of the request for consultations, or on the date of Panel establishment, or on any other relevant date.

63. Similarly, the approvals of Maize Bt 11 and Maize NK 603 for food use on 19 May 2004 and 26 October 2004 respectively, together with the chronologies submitted by the European Communities, also show that the procedures were not suspended in 2003, contrary to the Complainants' allegations.

64. Finally, the European Communities takes note of the United States' replies to Questions 193, 194 and 195 that the "*examples*" of statements referring to a supposed 'de facto moratorium' show that countries that were arguably not in favour of any such thing as a moratorium nevertheless "*allowed the moratorium to continue*". The European Communities considers that the Complainants, and specifically the United States, have failed to establish that a measure was *adopted*, or that a course of action which was considered *binding* by *all authorities* was decided and *consistently* implemented[12]. Sweeping and imprecise statements such as the replies to Questions 193, 194, and 195 can hardly be a substitute for a complete and rigorous examination of each product application. Tellingly, when it comes to analysing specific products like Maize GA 21 (UK application), the United States refrains from discussing the science and the current state of play and it simply makes unqualified statements about an alleged seven-month delay back in 1999. The European Communities wonders what is the usefulness of such arguments for the purposes of finding a positive solution to the dispute today.

IX. FACTUAL AND SCIENTIFIC ISSUES: COMMENTS ON QUESTIONS 127, 143, 144, 148, 150, 165, 166, 167, 168, 169, 196

65. The European Communities would like to provide the following comments on the Complainants' replies to Questions 127, 143, 144, 148, 150, 165, 166, 167, 168, 169 and 196. Those questions usefully address a number of factual issues of timeframes and approval procedures for some individual product applications, and related scientific and technical evidence. They are very useful to clarify the nature and the extent of delays in these specific chronologies, and why they were justified in the actual context of these applications, at the time of the "challenged measures". They illustrate the disagreements, misunderstandings and misleading assertions on the part of the Complainants, with regard to the facts and the EC approval procedures and institutions. These individual procedures and facts were addressed only at a late stage in the Complainants' submissions.

66. On factual and technical issues also, the Complainants are wrongfully and artificially trying to widen as much as possible the scope of the issues at stake, or to bring them into conformity with their claims, and to maintain their confusion between apples and pears.

[12] EC Second Written Submission, para. 298.

67. For example, in their replies to Question 127, they mistakenly assert that breeding encompasses the genetic engineering steps to produce a GM plant in the laboratory. Rather, the core of breeding, as stated by Dr. Andow (referred to in Canada's answer), is the natural cross between different parent lines holding different genomic characteristics, and carrying different intrinsic genetic properties/traits (including, where appropriate, those obtained earlier through genetic engineering), in order to introgress and combine the desired properties/traits in the offspring. This in turn enables the selection of the desired agronomic or other phenotypic traits in the field (as well as multiplying the relevant offspring).

68. Because breeding is performed through a process of crosses, reproduction and selection occurring naturally, it is itself explicitly excluded as such from the scope of the EC legislation on GMOs. New breeding opportunities may indeed arise from genetic engineering, but breeding does not include *per se* the introduction in a parent line *in vitro*, through genetic engineering, of a particular transgene which may be of non plant origin. This is done for the sake of introducing a particular desired property, which may not occur naturally and may not be available for natural selection through breeding, and is therefore related, but distinct from the breeding itself.

69. As another example, in their replies to Questions 143 and 144, besides the striking disagreements among the Complainants as regards the possibility to use the risk assessment of one product for one specific use, in the process of assessing another product, or for another use (see for instance the first paragraph of the answers of Canada, the United States and Argentina for Question 143), they again try to swiftly eliminate all the issues that need to be considered in this context, as is well recognised now by international consensus on these issues.

70. First the European Communities notes that the Complainants all avoid addressing the issue of the stacked products referred to in the Questions of the Panel, as their arguments would not hold in this case for reasons explained extensively by the European Communities in its comments on the scientific advice.

71. They fail in particular to recognise what they themselves implement, namely that the basis of any sound and thorough risk assessment of a particular product is the unique *transformation event*, NOT the trait introduced or the generic nature of a protein expressed.

72. Consequently, they fail to address the issue of transformation specific unintended effects, as well as one of the critical criteria of the assessment of risks, which is, besides hazard identification, the exposure to that hazard, which is fundamentally different for each individual product and each individual use. This is because one protein ("trait") expressed in different plants may be – even slightly, as pointed out by Argentina in response to Question 144 – different, expressed at significantly different levels, and often in completely different plant organs.

73. These case by case situations will both affect dramatically the particular exposure data to any potential hazard, for human health, and for target and non target organisms. In turn, this critically needs to be informed by the specific end use which will affect any exposure assessment, and by the organisms associated with the plant species which may be target or non target of the expressed trait, and which are of course fundamentally different between different plant product species . Maize is not be compared with oilseed rape, as suggested by Argentina and Canada in reply to Question 144; and non target organisms are different for each plant species, which may result in possible different modes of action of any expressed new protein, contrarily to what the US is stating in its reply to Question 144.

74. Moreover, the European Communities notes that the Complainants make some misleading statements when they seek to eliminate any consideration of scientific uncertainties, such as the statement made by Canada in its reply to Question 144 that : *" these transgenic modifications, and their associated potential risks, are well understood"* – that being a statement that is in absolute contradiction with the overwhelming evidence for scientific uncertainties and for the striking evolution of scientific knowledge in the relevant period, which was provided by the Panel's experts in their advice.

75. Yet another artificial simplification in the Complainants' responses is the answer provided by Canada to Question 148 on the concerns about biogeochemical cycles, where Canada claims that the only instance where that concern was raised was in two documents issued by one Member State, for two similar oilseed rape applications. Not only does Canada fail to mention that this issue was also extensively discussed in the context of Bt maize applications[13], but more importantly that it was a concern identified by the EC legislator, which required that *all* pending applications would be updated at the latest in January 2003 to address that particular concern.

76. Indeed, as early as the end of the year 2000, the final text of Annex II of Directive 2001/18/EC[14] had been agreed, and it included in its section C2 (steps of the environmental risk assessment), as one particular characteristic which may cause adverse effects and needs to be identified, "the effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material (see for example items II.A.11(f) and IV.B.15 in Annex III A, and D 11 in Annex III B)".

77. Another instance where the Complainants mislead the Panel on the facts and the timing of the EC procedures for GMO applications is to be found in the answer of the United States to Question 150. The premise of the reply (no more than one year is contemplated for a procedure under Directive 90/220) is the hypothetical situation of a product application where *no single* scientific or technical concern would be raised, where the data provided by the applicant would not necessitate any clarification or amendment, and where *no single* request for further information would be issued. This was of course never the case for the products at stake, given all the scientific uncertainties and issues raised, as also witnessed by the advice of the Panel's experts.

78. This situation is well known by the United States, where such product applications in the relevant period also usually took several years under their own framework, for the same reasons. There is simply no legal basis to assume that there was a time frame to reach a decision in roughly one year – on the contrary the United States seems to demonstrate factually that one should not normally expect a decision earlier than the minimum timeframe for reviewing applications that the United States presents (when no scientific/technical difficulties are raised).

79. And of course, the clarification to be made that the Directive provides for the clock to stop each time a request for clarification or further information is made, pending additional information from the applicant, would extend that minimal timeframe to several years, even before the entry into force of Directive 2001/18/EC, which required further updates of the applications. This is exemplified by most of the chronologies provided by the European Communities.

[13] This discussion refers to the effect on biogeochemical cycles of the biodegradability of the Bt toxin in the soil, or of the effect of alleged higher lignin content of Bt maize on its own biodegradability in the soil.

[14] The purpose of the Annex is, as defined in its title, to set the "Principles for the Environmental risk assessment" to be conducted under Directive 2001/18.

80. As the EC experience has developed with the assessment of dossiers, it appears that the deadlines, when set in Directive 90/220/EEC, could not be met because time was so frequently frozen pending replies from the notifier to questions from regulatory authorities. Therefore, the timeframes to be considered have in reality to take into account these delays due to outstanding replies from the notifier and the time necessary for the authorities and independent scientific bodies to properly review and assess the updated data or pending concerns in the light of the complexity and evolution of the science at stake.

81. Incidentally, the European Communities notes in the United States' reply to Question 166 that it was able to identify and access all the information submitted by the applicant, in one application procedure (EC-74), where in particular Dr. Nutti said she was unable to find the necessary documentation in preparing her responses.

82. On the contrary, when the United States claims that the applicant provided all the information requested in 1999 and in 2001 by the authorities in another application procedure (EC-93, reply to Question 167), it again misleads the Panel, as the information was *not* provided in a satisfactory manner by the applicant, as witnessed by the content of attachments 23, 25 and 26 of the relevant chronology, where it is clearly stated what information requested in 1999 and later was still missing. When the United States claims that its understanding is that : " the applicant provided the information requested", and that "the applicant responded to the 31 August 2001 letter" (attachment 23), "explaining that the information requested had already been provided or could be addressed with information that the BCS had already provided", it bluntly fails to submit any evidence to support this misleading allegation, nor does it address the fact that even if it were true that information proved was not satisfactory for the lead competent authority, as witnessed by the evidence presented in that chronology and cited above.

83. Finally, the Complainants also mislead the Panel in their interpretation of the EC arguments on facts and science. In its reply to Question 196, the United States confuses the notion of using the parent line as a comparator in the (limited) substantial equivalence analysis of a GM plant, with the notion of the requirement to complete a thorough risk assessment of any of both GM parent lines, when they are used as the two parents in a GM stacked product, before one can complete the assessment of the risks of the stacked GM offspring itself.

84. The European Communities would refer the Panel to its comments on expert advice as regards the issue of assessing stacked genes in GM plants, and in particular to its comment on the advice provided by the Panel experts in reply to Question 111 in paragraphs 887ff of its submission. But it would like to also correct here the misleading alleged inconsistency presented in footnote 25 to the United States reply to this question. As is recognised by all expert advice today (see the references provided by the European Communities in the comments on expert advice cited above) GM products made of stacked genes need to have a thorough and completed assessment of the risks of each of the parent transformation events that constitute the stack, and, *in addition*, an assessment of any interaction, or of any positive or negative synergistic effect, that may occur *between* the individual insertions present in the stacked hybrid.

85. These two requirements are cumulative, not exclusive or contradictory, as is also evidenced by the advice provided to the United States by its own independent expert advisory opinions (see again the quoted recommendations cited in paragraphs 887ff of the EC submission on comments on expert advice, addressing this very issue) and which it fails to implement.

86. This is simply one example of the necessary case by case approach, which is applied in all instances and requires that each GM product is assessed on its own merits, and which the Complainants seem to fail to implement.