

**EUROPEAN COMMUNITIES – MEASURES AFFECTING THE APPROVAL AND  
MARKETING OF BIOTECH PRODUCTS  
(WT/DS291, WT/DS292, WT/DS293)**

**FINAL VERSION OF QUESTIONS BY THE PANEL POSED DURING AND AFTER THE  
SECOND SUBSTANTIVE MEETING WITH THE PARTIES**

*Note: The parties are free to reply to questions posed to the other parties.*

*While answers need not be lengthy, simple yes or no answers would not be sufficient. Also, please clearly indicate if any information provided in your response to these questions contains explicit reference to any materials identified as SCI.*

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?

**Answer by Argentina:**

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."<sup>1</sup> 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"?

**Answer by Argentina:**

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

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<sup>1</sup> Exhibit US-123, p. 34.

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.

**Answer by Argentina:**

**Yes. One example is damage referred to fitness.**

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

**Answer by Argentina:**

**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)?

**Answer by Argentina:**

**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?

**Answer by Argentina:**

**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?

**Answer by Argentina:**

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?

**Answer by Argentina:**

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" (emphasis in original)?

**Answer by Argentina:**

**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<sup>2</sup> and Article 5.7 of the SPS Agreement (adoption of provisional measures based on available pertinent information).

**Answer by Argentina:**

**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**

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<sup>2</sup> 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).

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 “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.

**Answer by Argentina:**

**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.”<sup>3</sup>**

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

127. At para. 42 of Canada’s supplementary rebuttal, Canada suggests that crop husbandry includes breeding and that if a scientist employs selective breeding methods in the laboratory, this should qualify as crop husbandry because the scientist would be performing the same operations as a farmer who employs selective breeding methods on the farm. But is the insertion of a transgene part of the breeding of biotech crops? Or is the breeding rather the re-production of the biotech seed?

**Questions 128 to 139 for the European Communities:**

**For all parties:**

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<sup>3</sup> EC Responses to Panel Question, para. 57.

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?

**Answer by Argentina:**

**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".**

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)?

**Answer by Argentina:**

**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".

**Answer by Argentina:**

**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?

**Answer by Argentina:**

**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?

**Answer by Argentina:**

**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.**

**For all complaining parties:**

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"?

**Answer by Argentina:**

**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)?

**Answer by Argentina:**

**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.**

Questions 147 to 148 for Canada:

Questions 149 to 151 for the United States

Questions 152 to 164 for the European Communities:

Questions 165 to 167 for the European Communities and the United States:

Question 168 for Canada, European Communities and the United States:

For Argentina, European Communities and the United States:

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

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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.

Answer from Argentina:

**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, toxigenicity, 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?

**Answer from Argentina:**

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.)

**Answer from Argentina:**

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)?

**Answer from Argentina:**

**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?

**Answer from Argentina:**

**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.

**Answer from Argentina:**

**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 strictness 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?

**Answer from Argentina:**

**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)?

**Answer from Argentina:**

**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?

**Answer from Argentina:**

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

Question 177 for the United States and the European Communities:

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).

**Answer from Argentina:**

**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).

**Answer from Argentina:**

**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).

**Answer from Argentina:**

**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).

**Answer from Argentina:**

**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:**

180. In relation to antibiotic marker genes, please answer the following questions:

a) Do you agree with the United States that antibiotic marker genes can be considered as food "additives" within the meaning of Annex A(1)(b) of the SPS Agreement (see para. 22 of attachment II

of the US rebuttal)? If not, is the protection against any human health risks arising from the development of diseases which relevant antibiotics would be used to treat covered by another subparagraph of Annex A(1)?

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

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?

**Answer from Argentina:**

**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.**

Question 182 for Canada and the United 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?

**Answer from Argentina:**

**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.**

Questions 184 to 190 for Canada:

Questions 191 to 197 for the United States:

Questions 198 to 201 for the European Communities:

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