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EUROPEAN COMMUNITIES – MEASURES AFFECTING THE APPROVAL AND MARKETING OF BIOTECH PRODUCTS

Reports of the Panel

Addendum

This addendum contains Annex E to the Reports of the Panel to be found in document WT/DS291/R, WT/DS292/R, WT/DS293/R. The other annexes can be found in the following addenda:

- Annex C: Add.1
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ANNEX E

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

ANNEX E-1

REPLIES BY THE UNITED STATES TO QUESTIONS POSED BY THE EUROPEAN COMMUNITIES

For all complainants:

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

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

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

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

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

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

4. What would it take in your opinion for the alleged moratorium to be removed? Would the European Communities have to grant one more approval, ten more approval, or how many? Would the European Communities have to stop asking for more information under the approval procedures? Would all MS have to vote in favour of proposals to grant authorisations for the products at issues in the Regulatory Committees and in the Council? (see paras. 24 and 27 of the oral statement of Canada)

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

For Canada and the United States:

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

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

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

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

For the United States:

1. If a declaration of political intent by five EU ministers constitutes a measure that may constitute a violation of the WTO Agreement on the part of the European Communities, would the same be true of a declaration by 60 Members of the US Congress that they would block any attempt to not repeal the Byrd amendment also constitute a violation by the US of its obligation to implement the Panel report in that case?

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

ANNEX E-2

REPLIES BY CANADA TO QUESTIONS POSED BY THE EUROPEAN COMMUNITIES

For all complainants:

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

1. No, it is not the position of Canada that new scientific information should be disregarded. There is nothing in the *SPS Agreement* that precludes a Member from considering new scientific information. If an SPS measure is based on a risk assessment, and new scientific information emerges that was not factored into that risk assessment, a Member is entitled to redo the risk assessment in the light of the new information. If, given this new information the conclusions of the risk assessment change, then the Member is entitled to change its SPS measure.

2. This is apparently how the safeguard procedures under the relevant EC approval legislation are supposed to work. Following the adoption of the Member State national bans ("safeguard measures"), the Commission referred the safeguard measures to an independent scientific committee at the community level to review the purported "new scientific evidence" cited by the Member State in support of the invocation of the safeguard measure. In all cases, the independent scientific committee concluded that there was no basis for the national ban. Had the independent scientific committee considered that there actually was "new scientific information" affecting the original risk assessment, then the EC may have been justified in refusing to require the Member States to remove the national bans. This, as the EC knows, was not the case.

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

3. Yes. This decision must not be arbitrary or unjustifiable and must be done in a manner consistent with the *SPS Agreement* and, in particular, Article 5.5.

3. In a federal entity, have sub-entities the right to have different appropriate levels of protection?

If you do not agree, could you indicate the basis for your position in the *SPS Agreement*?

4. Whether sub-entities in a federal entity have the right to set different appropriate levels of protection is a function of the internal laws of the federal entity in question, and more particularly a matter of constitutional law and the division of powers ("competencies" in EC terminology) established within that federal entity.

5. In terms of the *SPS Agreement*, the issue is not whether the sub-federal entities have the "right" to set and apply their own appropriate levels of protection. The issue is whether the WTO Members, in setting and applying their appropriate levels of protection – whatever their constitutional arrangement – do so in a manner consistent with the *SPS Agreement*.

6. This requires, *inter alia*, that the WTO Member concerned avoid arbitrary or unjustifiable distinctions in the levels of protection it considers to be appropriate in different situations that are comparable, if those distinctions result in discrimination or a disguised restriction on international trade.

4. What would it take in your opinion for the alleged moratorium to be removed? Would the European Communities have to grant one more approval, ten more approval, or how many? Would the European Communities have to stop asking for more information under the approval procedures? Would all MS have to vote in favour of proposals to grant authorisations for the products at issues in the Regulatory Committees and in the Council? (see paras. 24 and 27 of the oral statement of Canada)

7. Canada considers that there is no "magic" number of approvals that has to be reached before it can be said that the moratorium has been lifted. As a start, it would be helpful if the European Communities and its Member States acknowledged that a *de facto* moratorium on approvals on biotech products was put in place as of October 1998, and stated their commitment to lift this moratorium. Given the *de facto* nature of the moratorium, whether the moratorium has been lifted can only be determined with reference to demonstrable progress being made on individual applications at the Community level, with key reference points being the relevant regulatory committee. In particular, speedy decisions on those applications for which multiple risk assessments have already been completed would be helpful.

For Argentina and Canada:

1. Do you agree with the United States' position as stated at DSB meeting of 10 December 2003 and again implied in its oral statement of last week (para. 56) that the burden of proof for Article 5.7 of the *SPS Agreement* is on the Complainants and not on the European Communities as the defendant?

8. Paragraph 56 of the US oral intervention does not imply that the burden of proof under Article 5.7 is on the complainants. Rather, it demonstrates systematically that none of the EC Member State measures meets any of the four requirements of Article 5.7. Canada made the same points at paragraphs 80-85 of its Oral Statement at the first hearing.

9. In any event, where the burden of proof falls with respect to Article 5.7 must be determined with reference to the text of the WTO Agreement, and the relevant jurisprudence, and not individual Member statements in the DSB.

For Canada and the United States:

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

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

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

10. Notifications of measures are made for the purposes of transparency and do not have any legal effect. This has been recognized in the jurisprudence (*EC – Asbestos*, Report of the Panel, para. 8.60). Canada is committed to transparency within the WTO, and to the notification process as the appropriate means by which to advise WTO Members of potential regulatory changes within Canada. These notifications cannot in any way be interpreted as being representative of Canada's legal position as to which measures are covered by which WTO agreements.

For Canada:

1. The European Communities takes note of Canada's view that risks posed by GM plants are the same as or similar to risks posed by conventionally bred plants. It also notes that in describing the potential risks of GMOs in its submission Canada does not mention the issue of antibiotic resistance markers? Does Canada believe that this potential risk does not exist?

If Canada is of the opinion that the risk does not exist could Canada explain why its own scientific expert committee (the Royal Society of Canada) has identified this issue to be a potential risk?

Does Canada not agree with its own scientific experts' Committee?

11. Canada considers that there could be a potential risk, however unlikely, posed by antibiotic resistance markers. This risk is typically assessed through the risk assessment process for each product, taking into consideration the clinical and veterinary importance of the antibiotic in question, the likely occurrence of horizontal gene transfer from genetically modified plants to microbes and the potential impact of horizontal gene transfer where naturally occurring resistance to the relevant antibiotics exists in the microbial gene pool.

12. For the biotech products in question, the scientific evidence (including that from the relevant EC Scientific committees) demonstrates that there is, no risk to human or animal health posed by the antibiotic resistance markers used in those products.

2. In its Oral Statement (para. 102), CAN suggests that the safety of the BT11, Mon810 and BT176 maize is comparable because "they rely on the same gene for their insect resistance trait". This statement has flaws as regards the scientific grounds for their case by case risk assessment (for instance as regards the known differences between these products in respect of the presence or not of antibiotic resistance genes or parts thereof).

Would Canada not agree that, if, as a working hypothesis, it had followed an independent scientific risk assessment opinion, such as the one issued on antibiotic resistance marker genes of its Royal Society, it might have come to different conclusions on these three products?

13. Canada disagrees with the EC, if it is suggesting that corn derived from events Bt-176, MON 810 and Bt-11 are not comparable situations for the purposes of Article 5.5.

14. According to the Appellate Body, whether situations are comparable for the purposes of Article 5.5 depends on whether they present some common element or elements sufficient to render them comparable.[1] In *Australia – Salmon*, the panel concluded that:

[1] *EC – Hormones*, para. 217.

> … in the circumstances of this dispute, we can compare situations under Article 5.5 if these situations involve either a risk of 'entry, establishment or spread' of the same or a similar disease *or* of the same or similar 'associated biological and economic consequences' and this irrespective of whether they arise from the same product or other products.[2]

15. The Appellate Body agreed with this statement.[3]

16. This approach is equally applicable when the risks involved relate to the potential adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

17. Bt-176, Bt-11 and MON810 can all be legally marketed as food or in food products in the EC. All have been assessed for potential risks relating to human toxicity, including allergenicity, and horizontal gene transfer of antibiotic-resistant marker genes. In its opinion in response to Austria's invocation of Article 16 of Directive 90/220 as a basis for its national ban on MON810, the Scientific Committee on Plants grouped all genetically modified corn/maize lines derived using the CRY1A-proteins together. The conclusion to its opinion with respect to Austria's invocation of Article 16 with respect to MON810, stated that "there is no reason to change [the Committee's] previous advice to the [European] Commission on the risk assessments of the Bt crops which it has evaluated to date".[4]

[2] *Australia – Salmon*, Report of the Panel, para. 8.117.

[3] *Australia – Salmon*, Report of the Appellate Body, para. 146.

[4] *Opinion of the Scientific Committee on Plants on the Invocation by Austria of Article 16 ('safeguard' clause) of Council Directive 90/220/EEC with respect to the placing on the market of the Monsanto genetically modified maize (MON810) expressing the BT cry1a(b) gene, notification C/F/95/12-02* (Opinion expressed by the Scientific Committee on Plants on 24 September 1999), at p. 5. (Exhibit US-55)

ANNEX E-3

REPLIES BY ARGENTINA TO QUESTIONS POSED BY THE EUROPEAN COMMUNITIES

A. <u>For all complainants</u>:

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

Argentina states that scientific evidence -rather than a broad concept as "scientific information"- is the one to be regarded whenever there is any former scientific evidence at hand. A mere reference to information with "concerns", " possibilities", "hypothetical risks" rather than evidence do not match against scientific evidence on specific products made on a case-by-case basis, and does not entitle any general measure on all agricultural biotech products as the " de facto" moratorium by the EC.

Argentina's position is based on the SPS Agreement, which specifically establishes that sanitary and phytosanitary measures be based on scientific evidence.

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

Any Member is entitled to adopt a higher level of protection, as long as it complies with its obligations under the SPS Agreement.

3. In a federal entity, have sub-entities the right to have different appropriate levels of protection?

If you do not agree, could you indicate the basis for your position in the *SPS Agreement*?

This is a theoretical question, which Argentina believes is not related to the measures at issue in this case.

4. What would it take in your opinion for the alleged moratorium to be removed? Would the European Communities have to grant one more approval, ten more approval, or how many? Would the European Communities have to stop asking for more information under the approval procedures? Would all MS have to vote in favour of proposals to grant authorisations for the products at issues in the Regulatory Committees and in the Council? (see paras. 24 and 27 of the oral statement of Canada)

The question refers to implementation issues. In Argentina's view, these issues are not to be discussed at this stage.

B. <u>For Argentina and Canada</u>:

1. Do you agree with the United States' position as stated at DSB meeting of 10 December 2003 and again implied in its oral statement of last week (para. 56) that the burden of proof for

Article 5.7 of the *SPS Agreement* is on the Complainants and not on the European Communities as the defendant?

Argentina is not aware of any reference by the US in its oral statement, paragraph 56, to any burden of proof allocated to the complainants' side. Nevertheless, paragraph 56 proves that the EC did not satisfy the requirements of Article 5.7 of the SPS Agreement. Paragraph 56 discharges the burden of proof from the United States and the co-complainants.

D. <u>For Argentina</u>:

1. Argentina argues that special differentiated treatment (SDT) obligations are not subordinate to other obligations. The European Communities agrees, but could Argentina explain what the EC must do pursuant to SDT provisions? Are such obligations independent of the issues of possible SPS risks and related risk assessments? In other words, if one forgot the other claims (5.1, 5.6, …), what would Argentina claim under the SDT provisions ?

Precisely, other claims -in particular 2.2 and 5.1 of the SPS Agreement- should not be forgotten. Even if the EC measure had had scientific basis, the EC would have had an obligation to take into account the interest of Argentina -being a developing country that produces and exports GMO's- anyway. Not having the EC measure any scientific support, the absence of any reference to the interest of developing countries (i. e. Argentina) infringes the SPS Agreement.

2. Is it the position of Argentina that the decision of the Appellate Body in the US Shrimps Case permitting recourse to other rules of international law interpreting WTO Agreements was wrongly decided?

If not, why would this approach not apply to the current case?

Argentina will not make any comments on whether a decision by the Appellate Body was correct or not. Additionally, the EC is stating in its question something that Argentina did not express[1]. In casu, it is not necessary to resort to other tool of interpretation to define the scope of the obligations embodied in the covered Agreements.

[1] Argentina's First Oral Intervention, paragraphs 6 and 7.

ANNEX E-4

REPLIES BY THE EUROPEAN COMMUNITIES TO QUESTIONS POSED BY ARGENTINA

Regarding the impact of the new Directive 2001/18/EC on the approval procedures.

1. Did the coming into force of Directive 2001/18/EC imply any step-back with respect to the stage of the approval procedure in which applications were under Directive 90/220/EEC?

2. Did the applicants have to submit additional information, as a consequence from the coming in force of Directive 2001/18/EC?

3. If yes, could the EC please precise what this additional information consisted in?

1. Please refer to the response to question 12 from the Panel to the European Communities.

2. The pending applications were only required to be up-dated ("complemented"), not to be re-submitted as a whole. Hence all results and conclusions reached on the existing data were still valid and would not be re-examined again. However, with regard to the up-dated information a new assessment was required and that assessment was to follow the normal stages of procedure. There was thus no "step-back". There was rather a step forward, in terms of changes in the legislation to meet the legitimate concerns of scientists and legislators. Naturally pending applications were also to benefit from the improved rules and procedures. The additional information to be submitted would depend on the precise product in question – it would be what was needed to satisfy the additional requirements of the new legislation.

Regarding the evidence in addition to the scientific opinions.

The EC mentions in paragraph 36[1] that the scientific opinions would require additional evidence to complete the risk assessment.

4. Apart from the opinions of the scientific committees, what are the other elements that the EC's authorities do consider for the approval of the respective biotech product?

3. Please refer to the response to questions 17 and 18 from the Panel to the European Communities.

4. The scientific committees give opinions on what they are asked. If it subsequently appears that further questions might be elucidated by scientific opinion, such questions may be put to the committee. If an opinion of the scientific committee is limited or qualified in some way, the legislator may take the view that definitive legislative action is premature.

5. Please also refer to the response to question 102 from the Panel to the European Communities.

[1] *Oral Intervention of the European Communities in the First Audience of the Panel with the Parties, 2 June 2004.*

6. Article 26(1) of the Biosafety Protocol provides as follows:

> "The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."

7. By virtue of their signature of the 2000 Protocol and Article 18 of the 1969 Vienna Convention on the Law of Treaties, Argentina and Canada are bound to "refrain from acts which would defeat the object and purpose" of Article 26. By participating in the Protocol's Clearing House Mechanism the United States recognises the validity of Article 26 of the Protocol.

8. The object and purpose of socio-economic considerations have been assessed by the head of the Indian delegation in the final negotiations of the Biosafety Protocol. Article 26: as he puts it, "the fundamental purpose of Article 26 is to empower parties of import to analyse carefully what possible adverse impacts the import of LMOs would have on their socio-economic conditions", and it reflected an exercise of "inherent sovereign powers".[2] Socio-economic considerations include implications for existing patterns of agricultural practises, having regard to the effects of biotech products for biodiversity.

5. What is the legal basis within the SPS Agreement which allows the EC to consider elements additional to the opinion of the scientific committee?

9. Nothing in the *SPS Agreement* precludes a Member from seeking scientific opinions several times, or on a continuous basis. Under the *SPS Agreement* the level of acceptable risk is fixed by the Member, and is likely to influence a legislator's view of the science available to-date, and the measures it is therefore appropriate to take or the manner in which it is appropriate to proceed. The Appellate Body has stated that science includes the assessment of risk in human societies as they actually exist, in the real world, where people live and work and die. The *SPS Agreement* refers expressly to international agreements – as to which, please see the response to the previous question, and to question 11 below.

6. With respect to the products of interest to Argentina with positive scientific opinion - Bt531 cotton, RRC 1445 cotton, NK603 maize and GA21 maize-:

(a) What were the elements that determined that the positive scientific opinion was not sufficient?

(b) Were those elements of a scientific nature?

(c) Where are those elements memorialized?

(d) Could the EC provide the Panel and the parties with those elements which determine that, up to the present, these products did not receive any approval or rejection?

[2] Rajen Habib Khwaja, "Socio-economic considerations", in C. Bail, R. Falkner and H. Marquard, *The Cartagena Protocol on Biosafety – Reconciling Trade in Biotechnology with Environment and Development*?" (2002), 361 at 361 and 364.

10. The European Communities has described in details the developments of each notification procedures, including the products which are at stake in the Argentinean case, in its first written submission (Section II.D and Exhibits EC-62 to EC-110). Further available evidence will be submitted to the Panel by the European Communities on 18 June 2004. However, for the sake of clarity, the European Communities will explain again what happened, as requested by Argentina.

11. **Bt531 cotton** is dealt with in section II.D.1(a)(iv) and Exhibit EC-65 of the EC first written submission. There it is explained that

> Following the opinion of the SCP, the notifier entered in discussions with some CAs on an insect-resistance management plan and on rat feeding.[3]

These are clearly issues of a scientific nature.

The chronology for this product then highlights that Monsanto provided information to the Member States competent authorities on insect-resistance monitoring plan on 29 September 1998 (the letter is attached as attachment 18) and on 06 October 1998 a requested study on rat feeding (attachment 19). Further issues, documented in attachments 20 and 21, were raised by the competent authorities of Denmark and the United Kingdom.

With regards to the elements necessary to determine why, up to the present, these products have not received any approval or rejection, the European Communities refers Argentina to the above mentioned parts of its first written submission.

12. **RRC 1445 cotton**, is dealt with in section II.D.1(a)(v) and Exhibit EC-66 of the EC first written submission. There it is explained that

> Following the opinion of the SCP, the notifier entered in discussions with the lead CA on rat feeding.[4]

This is clearly an issue of a scientific nature.

The chronology for this product then highlights that Monsanto provided further information after the opinion of the Scientific Committee on Plants that was circulated to Member States on 20 November 1998. Further issues, documented in attachments 20 and 21, were raised by the competent authorities of Denmark and the United Kingdom.

With regards to the elements necessary to determine why, up to the present, these products have not received any approval or rejection, the European Communities refers Argentina to the above mentioned parts of its first written submission.

13. **NK603 maize** is dealt with in section II.D.1(a)(xv) and Exhibit EC-76 of the EC first written submission. There it is explained that

> Following the positive opinion rendered by EFSA, in February this year the Commission has presented a draft decision for market authorisation of the product to the Regulatory Committee. In the absence of a qualified majority vote in the

[3] EC first written submission, para. 225.
[4] EC first written submission, para. 232.

> Committee, the Commission has presented its proposal for a decision authorising NK603 to the Council on 26 March. The Council's position on this draft decision is expected for late June.[5]

No issue was therefore raised on the sufficiency the opinion of EFSA and the notification is proceeding steadily through the various steps of the procedure foreseen in the EC legislation towards a decision.

14. **GA21 maize** is dealt with in section II.D.2(a)(i) and Exhibit EC-91 of the EC first written submission. There it is explained that the Scientific Committee on Food gave its opinion February 2002 and that

> In view of the pending legislative proposal for "Food and Feed" Monsanto, in June 2002 on a voluntary basis committed to providing detection and validation methods for its product in collaboration with the Commission's Joint Research Centre (JRC). The amount of data and material and the circumstances of their submission to the JRC had to be negotiated and laid down in an agreement, the conclusion of which took a considerable amount of time (February 2003). All the necessary data were received in proper condition in mid-September of 2003. The pre-validation study was initiated in October and could be concluded only after Monsanto delivered the full data set in the end of November. Some additional testing on the method and materials was carried out in early 2004 the collaborative study of method validation was launched on the 14/04/2004 and is foreseen to be finished by the end of June 2004.[6]

In this case, therefore, the elements which determined the insufficiency of the scientific committee's opinion related to the issues of detection and validation methods, which were requirements to be included in the new legislation and on whose importance the applicant agreed. The relevant correspondence with Monsanto on these issues is recorded in the chronology and in its attachment.

Regarding the "case by case" assessment

7. How do the EC explain that, if the assessment of agricultural biotech products is to be made on a "case by case" basis, there has been not a single approval for over five years? How does the EC explain, as it confirmed in the oral hearing, that during the same period there has been no rejection either?

15. For each product the explanation for the time elapsed is different. The European Communities refers in this respect to the summaries in its first written submission. If there is something in any one of these summaries that is unclear to Argentina, the European Communities invites Argentina to pose a specific question, to which the European Communities would be happy to give a specific response. It is, in any event, inaccurate to state that there have been no approvals or rejections for five years. The European Communities refers in this respect to paras. 547 to 552 of its first written submission.

[5] EC first written submission, para. 284.
[6] EC first written submission, para. 304.

8. In paragraph 36 of the EC's Oral Statement during the first substantive meeting of the Panel with the parties, the EC stated the following:

> **".. the views of the European Communities' scientific committees, now regrouped under the European Food Safety Authority, have no formal overriding effect on the opinions of the corresponding national committees ..."**

Upon a question by the Panel in that meeting on whether there was any hierarchy between the different scientific committees, the EC answered:

> **"There is no hierarchy in science"**

Afterwards, in its answer to question number 1 by the Panel, the EC held that after the positive opinion of the Scientific Committee on Food on the Bt 11 maize, there were three opinions by national scientific committees (France, Austria and Belgium) which rejected the opinion of the SCF, and that after the rejection of one of those national opinions (the Austrian) by the EFSA, the Commission, despite the fact that the Regulatory Committee had not issued its opinion, upheld the opinion of the SCF.

(a) How do the EC explain that there is no "hierarchy in science" when the Commission gave priority to the scientific opinion of the EFSA?

(b) On the contrary, if the EC holds that there is no hierarchy in science, how could it be affirmed, in consistence with the SPS Agreement, that the opinions of the EC's own scientific committees be rejected?

16. Please refer to the response to questions 17 and 18 from the Panel to the European Communities.

17. The European Communities does not always and systematically give priority to any particular scientific opinion – it considers and weighs them all, taking into account any legislative changes designed to meet the legitimate concerns of scientists and legislators.

Regarding the "Inter-Service Consultation"

9. Is the period of suspension during the "Inter-Service Consultation" regulated anywhere?

10. If not, and given that the "Inter-Service Consultation" implies more than two years of suspension for two products of interest of Argentina -Bt531 cotton and RRC 1445 cotton-, in what provision of the SPS Agreement the EC believes that "Inter-Service Consultations" are based on?

18. Argentina will know that in a government administration competence for the various different activities of government is generally broken down in a structured way to make it manageable – as in any large organization with a diversified portfolio. Argentina will also know that, along these lines, the European Commission is divided up into about 40 departments or services. Argentina will also know than when a new matter comes to be considered, one or two departments or services will generally take the lead role, and co-ordinate with the other interested services. "Inter-service consultations" are, as the name suggests, the process by which the "lead" services consult with the other interested services. When a matter is in inter-service consultation, one may say that the

organization is "thinking about" the problem. The time necessary is a function of the nature of the problem. See generally the Commission Rules of Procedure (*Official Journal of the European Communities* L 308/26 of 8.12.2000, as amended and implemented).

19. This process takes place in the context of the control, inspection and approval procedures referred to in Annex C *SPS Agreement*.

20. For more details, the European Communities refers Argentina to its response to question 94 from the Panel to the European Communities.

Regarding the precautionary principle

11. Given that the EC state that the precautionary principle has become a general principle of international law[7], what is the formal source -creating International Law- that determines that "the precautionary principle is a general principle of International Law"?

21. The precautionary principle is a general principle of international law applicable to decision-making in relation to biotech products (GMOs).

22. The 1992 Convention on Biological Diversity obliges Contracting parties "to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology" (Article 8(g)). In the preamble to that Convention the parties note that "where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat". The Contracting Parties thus accept the language of the precautionary approach (see Principle 15 of the Rio Declaration on Environment and Development). Argentina, Canada and the EU are parties to the 1992 Convention, and the United States is a signatory (and is thus bound to "refrain from acts which would defeat the object and purpose" of the 1992 Convention: see 1969 Vienna Convention on the Law of Treaties, Article 18).

23. The precautionary principle is then expressly applied in the 2000 Biosafety Protocol. Article 1 states that the Protocol's objective is to be pursued "in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development" (see generally First Written Submission by the European Communities, paras. 105-108, and ain particular Articles 10(6) and 11(8) of the 2000 Protocol). The EU is a party to the 2000 Protocol and Argentina and Canada are signatories. The United States is participating in the Protocol's Clearing-House Mechanisms (under Articles 11 and 20) and must therefore be taken to have no objection to the precautionary principle is applicable (for the protection of biodiversity) as treaty or customary international law to decision-making in relation to biotech products. As such the principle must be relied upon in construing and applying WTO law. As one leading commentator has put it:

> "WTO law thus requires that measures based upon the precautionary principle or any other rule of the protocol must respond to the needs of conserving biodiversity."[8]

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[7] Oral Intervention of the European Communities in the First Audience of the Panel with the Parties, 2 June 2004, paragraph 56.

[8] Thomas Cottier, "Implications for trade law and policy: towards convergence and integration", in C. Bail, R. Falkner and H. Marquard, *The Cartagena Protocol on Biosafety – Reconciling Trade in Biotechnology with Environment and Development*?" (2002), 467 at 475.