ANNEX D-4

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

For the European Communities:

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

1. By way of a preliminary remark and as stated already at the first hearing, facts occurring after the establishment of a Panel may be relevant for the resolution of a case in different ways.

2. First of all, they may serve as evidence to underline or corroborate an argument made by a party with regard to the measure that is being attacked. For example, a further specific instance of application of a measure that is being attacked has occurred, and it may constitute additional evidence that the Member in question applies that measure in a specific way. Specifically, the European Communities has submitted to the Panel abundant information on the implementation of its Directive 2001/18 and its Regulation 258/97 up to the present moment, as evidence *inter alia* that its approval procedures were and are running. To cite but one example: since approval of GM products in the EU cannot occur overnight (because of the need to undergo a pre-marketing assessment), the fact that a further use of Bt11 sweet corn has been recently authorised in the European Communities proves that approval procedures were not generally stalled in the past, as the complainants contend (i.e. their claims on the existence of a general "moratorium").

3. Secondly, facts occurring after the establishment of a Panel, may also affect the very subject matter of the dispute if, for instance, the challenged measure ceases to exist or there is a fundamental change in its effects. The measure that is being challenged may be abolished or, in the case of a provisional measure, it may expire; or a Member may make a formal statement that it will exercise its discretion in a given way.

4. In the view of the European Communities, the Panel, generally, must base its findings and conclusions not only on facts as they existed at the time of the establishment of the Panel, but also on facts that have occurred after the establishment of the Panel. With regard specifically to the second aspect mentioned above, therefore, if facts occur that terminate a measure that has been identified in the Panel's terms of reference, the Panel has to take this fact into account. It is in this situation that the question of mootness arises. The European Communities will comment on that issue below under question 7.

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

5. Paragraph 4 of Annex A defines "risk assessment" for the purposes of the *SPS Agreement* as:

> *Risk assessment* - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for

> adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

6. Although, as the Panel observes, this appears to contain two definitions, possibly applying to different categories of risk in paragraph 1, in reality these definitions are not entirely alternative but complementary. If it were otherwise, it would mean, for example, that when the first definition is applied the health effects of a disease could not be examined (only the "biological and economic consequences") and that, when the second is applied, economic effects would have to be ignored.

7. In any event, the European Communities considers that both definitions are relevant to address risks associated with GMOs which have characteristics and effects coming within both branches. However, neither individually nor together do they provide for a full coverage of all potential risks associated with GMOs. The European Communities refers to its first written submission in which it identifies certain risks that come under the *SPS Agreement* and others that do not.[1]

8. The European Communities wishes to anticipate the answer to Question 103 and draw the attention of the Panel to another important feature of this definition – that it includes what is elsewhere considered to be risk management issues. It does this because the concept of risk management is important for a number of other questions. With its Question 103 the Panel asked the European Communities:

Could the European Communities please further explain its comment made during the first substantive meeting to the effect that the European Communities considers risk management to be part of risk assessment for the purposes of the SPS Agreement?

9. The commonly-used definitions of "risk assessment" and "risk analysis" are those developed by the Codex Alimentarius. These distinguish between "risk assessment", "risk management" and "risk communication", which are together referred to as "risk analysis". The precise definitions are:

Risk analysis. A process consisting of three components: risk assessment, risk management and risk communication.

Risk assessment: A scientifically based process consisting of the following steps:

(i) hazard identification,
(ii) hazard characterization,
(iii) exposure assessment, and
(iv) risk characterization.

Risk management: The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

Risk communication: The interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.[2]

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[1] First written submission, paras. 418 et seq.

[2] The definitions were adopted by the 22nd Session of the Codex Alimentarius Commission (1997) and are published in the tenth edition of the procedural manual of the Codex Alimentarius Commission, in the section "Definitions for the Purposes of the Codex Alimentarius" [FAO, 1997], see Exhibit EC-117. The same

10. Comparing this definition to that in the *SPS Agreement*, it is immediately apparent that the term "risk assessment" as used in the *SPS Agreement* includes at least both of what the Codex refers to as "risk assessment" and "risk management". First, the *SPS Agreement* definition of "risk assessment" requires an "evaluation" whereas the Codex definition requires primarily an "identification" and "characterisation" of the hazards. The weighing of the results is a matter for "risk management" under the Codex definitions. Second, the *SPS Agreement* definition of risk assessment includes an "evaluation … according to the sanitary or phytosanitary measures which might be applied." 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 of "risk management".

11. It also appears that, since labelling requirements are part of the *SPS Agreement* definition of an SPS measure in annex A.1, and the *SPS Agreement* definition of risk assessment requires an "evaluation … according to the sanitary or phytosanitary measures which might be applied" that the *SPS Agreement* definition of "risk assessment" includes also elements of risk communication (*e.g.* labelling). The term "risk assessment" as used in the *SPS Agreement* can therefore be considered to correspond broadly to the concept of "risk analysis" as defined by the Codex Alimentarius.

12. The term "risk assessment" in the EC GMO or food legislation[3] is used more in the Codex sense in that the risk management decisions are left to regulatory bodies whilst the risk assessment *strictu sensu* belongs mainly to technical bodies. This explains part of the misconceptions about the EC system that prevails on the part of the Complainants.

13. The European Communities would add that this feature of use of the term "risk assessment" in the *SPS Agreement* has already been noted by the Appellate Body when it chided the panel in *EC – Hormones* for having assumed that the *SPS Agreement* did not allow for taking into consideration of what are usually termed "risk management" issues. It stated that:

> The second preliminary consideration relates to the Panel's effort to distinguish between "risk assessment" and "risk management". The Panel observed that an assessment of risk is, at least with respect to risks to human life and health, a "scientific" examination of data and factual studies; it is not, in the view of the Panel, a "policy" exercise involving social value judgments made by political bodies. The Panel describes the latter as "non-scientific" and as pertaining to "risk management" rather than to "risk assessment". We must stress, in this connection, that Article 5 and Annex A of the *SPS Agreement* speak of "risk assessment" only and that the term "risk management" is not to be found either in Article 5 or in any other provision of the *SPS Agreement*. Thus, the Panel's distinction, which it apparently employs to achieve or support what appears to be a restrictive notion of risk assessment, has no textual basis. …[4]

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document also contains definition of the components of risk characterization being the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment..

[3] See for instance article 6 "risk analysis", which differentiates between risk assessment and risk management, of Regulation (EC) 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

[4] Appellate Body report, *EC – Hormones*, para. 86.

14. The European Communities trusts that the Panel will not be similarly misled and will understand that the term "risk assessment" as used in the *SPS Agreement* comports more than simply a scientific identification, characterisation and assessment of hazards but also permits and indeed requires a broader evaluation of the risks, their consequences and of the measures that may be employed to control and manage them.

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

15. A toxin is "a poisonous substance produced during the metabolism and growth of certain microorganisms and some higher plant and animal species."[5] An allergen is defined as "pertaining to antigens[6] that induce an allergic response in an organism or any substance that can cause an allergy."[7] Allergenic responses are only provoked in certain individuals that exhibit sensitivity to the allergen and are not of a general nature. Hence a food allergen cannot be considered as a toxin.

16. A food allergen is also not a disease-causing organism. Neither is a food allergen an organism (i.e. a biological entity capable of replication). Nor is an allergy a disease, but rather a medical condition. A "disease" is a clinical or pathological manifestation of infection (see also reply to question 78). A "medical condition" is an individual-based response to different environmental factors such as allergies to food, pollen, insects (see also reply to question 78).

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

17. In its First Written Submission the European Communities set out its support for the approach taken by the Appellate Body in *US-Shrimp*.[8] It follows from that decision that the Panel is required to interpret the relevant rules of WTO law consistently with other rules of international law that may be relevant to these proceedings. In this regard it is important to note that the Appellate Body has interpreted WTO rules by reference to treaties which are not binding on all parties to the proceedings. In *US-Shrimp*, it invoked – in support of arguments made by the United States – treaties which that country had not signed or had signed but not ratified. One such treaty was the 1992 Convention on Biological Diversity.

18. As regards "binding international law instruments", the European Communities considers that the 1992 Convention on Biological Diversity and its 2000 Biosafety Protocol "are relevant to this case". The 1992 Convention is binding on the European Communities, Argentina and Canada and has been signed by the United States. The 2000 Protocol is binding on the European Communities (which has obligations under the Protocol vis-à-vis third parties: see Article 24), and has been signed by Argentina and Canada. The European Communities is not inviting the panel to "apply" these instruments as such, but rather to ensure that the WTO rules are interpreted consistently with them.

19. Under Article 18 of the 1969 Vienna Convention on the Law of Treaties (which reflects customary international law) a state which has signed a treaty is thus bound to "refrain from acts which would defeat [its] object and purpose". Further, as noted in the response to Question 11 from

[5] See http://www.biology-online.org/dictionary.asp [last visited on 15 June 2004]
[6] Antigens are defined as substances that are recognized by the immune system and induce an immune reaction.
[7] *Ibidem.*
[8] See first written submission of the European Communties, paras. 453 et seq.

Argentina, 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 approach required by the Protocol.

20. With regard to the specific provisions that the European Communities considers to be relevant to this case,[9] the following is a non-exhaustive set of examples (the European Communities reserves its right to identify further provisions of these instruments and of other conventions as these proceedings develop):

(a) the Preamble to the 1992 Convention and Articles 1, 10(6) and 11(8) of the 2000 Protocol are relevant to the application of the precautionary principle;

(b) Article 8(g) of the 1992 Convention and the whole of the 2000 Protocol are relevant to demonstrate that biotech products and their non-biotech equivalents are not to be treated as "like products";

(c) Articles 8, 10, 15 and 11 and Annex III of the 2000 Protocol are relevant to the determination of the nature of a risk assessment that the international community considers to be relevant in decision-making for biotech products, and they confirm that the approach taken by the *SPS Agreement* is not considered to be sufficient in and of itself to address all the risks posed by biotech products;

(d) Article 26 of the 2000 Protocol is relevant for establishing that the international community has determined that socio-economic considerations may be taken into account in taking import decisions in respect of biotech products;

(e) Article 23 of the 2000 Protocol is relevant in confirming that the international community has determined that public opinion is a relevant public policy consideration in relation to biotech products; and

(f) Paragraph 8(f) of Annex III of the 2000 Protocol is relevant in confirming the view of the international community that "risk management" is to be treated as part of the risk assessment process, and that "risk management" includes monitoring the living modified organism in the receiving environment.

21. Finally, the European Communities considers that the provisions of *inter alia* the Codex Alimentarius Commission and other equivalent standards are highly relevant to these proceedings. However, these are to be treated as *inter alia* "international standards, guidelines and recommendations" within the meaning of Articles 3 and 5, Annex A point 3, of the *SPS Agreement* and Article 2 of the *TBT Agreement*. For the purposes of the response to this Question the European Communities proceeds on the basis that the Panel does not consider these instruments to be "binding international law instruments" within the meaning of the question.

[9] The European Communities reserves the right to argue that the standards established by these two conventions may be treated as "international standards, guidelines and recommendations" within the meaning of the *SPS Agreement* and/or the *TBT Agreement*.

For all complaining parties:

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

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

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

22. As stated above, the European Communities takes the view that the concept of mootness arises where facts occur after the establishment of the Panel that affect the very existence of a "measure" identified in the Panel's terms of reference. Thus, if a measure is terminated after the establishment of the Panel, the case has become moot in respect of this measure and the Panel is in principle not to rule on it any longer. No mootness exists, on the other hand, where a challenged measure did not exist already at the time of the panel establishment. In this case, the dispute is simply inadmissible as it lacks any material object.

23. The distinction is of some importance in the present case as it covers a variety of different situations which need to be distinguished one from the other.

24. To begin with, the European Communities does not consider that the concept of mootness applies to claims regarding products withdrawn already before the establishment of the Panel, or to the alleged "general suspension" or "moratorium". With respect to either, there cannot have been any measure in existence already at the time of the establishment of the Panel. The approval procedures have never been suspended or stalled as alleged by the Complainants. In any event, even if certain delays that occurred in the application of Directive 90/220 were to be seen to constitute a "moratorium," these must have ended with the application of Directive 2001/18. The European Communities would like to recall the US statement at the DSB meeting of 18 August DSB, where the panel requests were being considered: "*EC legislation sets out such procedures [for the approval of crops and food products], and those procedures, as written, are not the focus of the US complaint. The United States only asks that those procedures be permitted to proceed to their normal conclusion.*" The European Communities wonders how one could seriously question the plain fact that, in August 2003, the EC procedures were proceeding to their normal conclusion

25. Therefore, the European Communities respectfully requests the Panel to find that, with regard to applications withdrawn before the panel establishment and the alleged "moratorium", the Complainants' case is without object and, hence, inadmissible *ab initio*.

26. Mootness can apply to claims regarding all those product applications that have been withdrawn after the establishment of the Panel. The European Communities' position is that the Panel should not rule on these products.

27. The concept of mootness is well established in the jurisdictional systems of national and international law. To name but two examples: Under Article III of the US Constitution federal courts

may adjudicate only actual ongoing cases or controversies. The US Supreme Court has interpreted this provision to require that parties must continue to have a personal stake in the outcome of the lawsuit.[10] The International Court of Justice on several occasions held that applications had become moot following events subsequent to the filing of an application and that, therefore, there was no ground for proceeding to judgment on the merits any longer.[11]

28. The European Communities believes that the concept of mootness applies in the WTO dispute settlement system as in any other dispute settlement system, and therefore panels are entitled to consider case by case whether events subsequent to the establishment of their terms of reference affect their capacity to adjudicate a given dispute. This position is confirmed by the provisions of the *DSU*. The *DSU*, and in particular its Article 3, defines generally the purpose of the dispute settlement. Article 3.3 refers to "the prompt settlement of situations in which a Member considers that any benefits accruing to it directly or indirectly under the covered agreements *are being* impaired by measures taken by another Member" [emphasis added]. As is clear from this provision, the purpose of the dispute settlement is to address and redress situations that are in actual existence. Similarly, Article 3.4 of the *DSU* stipulates that "recommendations or rulings made by the DSB shall be aimed at achieving a satisfactory settlement of the matter…" something that cannot be achieved if there is no matter to settle any longer. Finally, Article 3.7 of the *DSU* requires a Member to "exercise [before bringing a case] its judgment as to whether action under these procedures would be fruitful." Clearly,

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[10] "'Under Article III of the Constitution, federal courts may adjudicate only actual, ongoing cases or controversies ... . Article III denies federal courts the power 'to decide questions that cannot affect the rights of litigants in the case before them, ... and confines them to resolving 'real and substantial controvers[ies] admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.' This case-or-controversy requirement subsists through all stages of federal judicial proceedings, trial and appellate. To sustain our jurisdiction in the present case, it is not enough that a dispute was very much alive when suit was filed, or when review was obtained in the Court of Appeals ... . The parties must continue to have a 'personal stake in the outcome' of the lawsuit." *Lewis v. Continental Bank Corp*., 494 U.S. 472, 477-478 (1990) (internal citations omitted). The Court's emphasis upon mootness as a constitutional rule mandated by Article III is long stated in the cases. *E.g.*, Liner v. Jafco, 375 U.S. 301, 306 n. 3 (1964); DeFunis v. Odegaard, 416 U.S. 312, 316 (1974); Sibron v. New York, 392 U.S. 40, 57 (1968). See Honig v. Doe, 484 U.S. 305, 317 (1988), and id., 332 (Justice Scalia dissenting).

[11] Questions of Interpretation and Application of the 1971 Montreal Convention raising from the Aerial Incident at Lockerbie (Libyan Arab Jamahiriya v United States of America), Judgment, ICJ Reports 1998, at 131, para 45 where the Court said:

> "The Court has already acknowledged, on several occasions in the past, that events subsequent to the filing of an application may "render an application without object" (Border and Transborder Armed Actions (Nicaragua v. Honduras), Jurisdiction and Admissibility, Judgment, I.C.J. Reports 1988, p. 95, para. 66) and "therefore the Court is not called upon to give a decision thereon" (Nuclear Tests (Australia v. France), Judgment, I.C.J. Reports 1974, p. 272, para. 62) (cf. Northern Cameroons, Judgment, I.C.J. Reports 1963, p. 38).
>
> Thus formulated, the Respondent's objection is that there is no ground for proceeding to judgment on the merits, which objection must be examined within the framework of this jurisprudence.
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> In the view of the Court, this last submission of Libya must be upheld. The date, 3 March 1992, on which Libya filed its Application , is in fact the only relevant date for determining the admissibility of the Application. Security Council resolutions 748 (1992) and 883 (1993) cannot be taken into consideration in this regard, since they were adopted at a later date. As to Security Council resolution 731 (1992), adopted before the filing of the Application, it could not form a legal impediment to the admissibility of the latter because it was a mere recommendation without binding effect, as was recognized moreover by the United States. Consequently, Libya's Application cannot be held inadmissible on these grounds."

See also *Nuclear Tests, Australia v France*, Judgment, ICJ Reports 1974, p.272, para 62 and Border and Transborder Armed Actions (Nicaragua v. Honduras), Jurisdiction and Admissibility, Judgment, I.C.J Reports 1998, p.95, para. 66.

a case on a measure that is not in existence any longer would be devoid of any practical purpose and, therefore, not fruitful.

29. Consistent with these principles and as pointed out by the panel in *Japan - Film*, "it is not the practice of GATT/WTO panels to rule on measures which have expired or which have been repealed or withdrawn."[12] Where there have nevertheless been rulings on such measures, usually there was either an agreement of the parties to do so[13] or the measure had been terminated so shortly before the panel's ruling that the panel could not take that fact into account any longer.[14] Neither case applies in the present situation.

For the European Communities:

11. With regard to the diagrams concerning the relevant EC approval procedures (Exhibits CDA-21, CDA-22 and CDA-23), could the European Communities indicate whether these diagrams correctly summarize the relevant EC approval procedures? If not, why not?

30. The diagrams contained in Exhibits CDA-21, CDA-22 and CDA-23 do not accurately describe the notification or application procedures contained, respectively, in Directive 2001/18, Directive 90/220 and Regulation 258/97.

31. The European Communities has provided summaries of this legislation in its First Written Submission (section II.C). However, in order to further ease the work of the Panel, it now attaches flowcharts of the main notification and application procedures contained in this legislation in Exhibits EC-118, EC-119 and EC-120.

12. With the entry into force of EC Directive 2001/18, were all pending applications required to be re-filed and re-examined as if new applications, irrespective of what step in the procedure they had previously reached under EC Directive 90/220?

32. No. The relevant provision governing the transition between the two legislative acts is as far as ongoing notifications were concerned is Article 35 of Directive 2001/18 according to which

> 1. Notifications concerning placing on the market of GMOs as or in products received pursuant to Directive 90/220/EEC, and in respect of which the procedures of that Directive have not been completed by 17 October 2002 shall be subject to the provisions of this Directive.
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> 2. By 17 January 2003 notifiers shall have *complemented* their notification in accordance with this Directive. [emphasis added]

33. As can be seen from this provision 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 relevant and would in principle 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.

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[12] Panel Report *Japan – Film*, para. 10.58.

[13] See *e.g. EEC – Restrictions on Imports of Apples from Chile* (BISD 27S/98) and *United States – Prohibitions on Imports of Tuna and Tuna Products from Canada*, (BISD 29S/91)

[14] See *e.g. US – Wool Shirts and Blouses*

13. With reference to para. 559 of the EC first written submission, please explain further (i) what is the "interim approach", (ii) when it was adopted, (iii) whether it was still being followed when this Panel was established, and (iv) how it is relevant to this dispute. In answering this question, please also address whether a similar approach was followed with respect to biotech products which were approved for marketing in the European Communities prior to October 1998. If not, why not?

34. The "interim approach" consisted in anticipating certain stricter requirements which were to be put in Directive 2001/18 as identified in the Council Common Position of June 1999 (see also reply to question 92 on this point) in line with the precautionary principle. With regard, in particular, to requirements on monitoring, labelling and traceability, it was clear that the existing legislation, i.e. Directive 90/220, did not provide a legal basis to impose these requirements on pending applications. The notifiers, therefore, were approached to see whether they would be willing to implement such requirements on a voluntary basis. Most agreed to do so and entered in a dialogue with the competent authorities to work out the details, in particular of monitoring plans and codes of practice. With the entry into force of Directive 2001/18 the "interim approach" ended as applications could now be assessed under the new legal basis.[15] The interim approach has not resulted in a decision on these applications before the entry into force of Directive 2001/18, because the relevant issues – most often monitoring plans – could not be solved in time.[16] Dialogue on such issues continued and is continuing under Directive 2001/18. Even if it has not resulted in a decision, the "interim approach" proves that there has at no time been a suspension of the approval process.

35. The "interim approach", thus, is not an act that was "adopted" in any form, it is merely a practice that was followed on the basis of a political intent to try and achieve results in the approval procedures despite the transitional period of legislative changes.

36. Applying stricter requirements to products already authorised would have meant withdrawing the market authorisation for these products and obliging the applicants to re-apply under the new Directive. Under Directive 90/220, this would have been legally impossible or at least questionable given that the legal basis to terminate an authorisation under Directive 90/220 was framed to apply to risk issues addressed under the Directive. Approaching the holder of the authorisation to inquire, whether on a voluntary basis, they would withdraw their products was not an option (what would the incentive have been for them?).

37. At the moment of the adoption of Directive 2001/18 the legislator opted for the solution to require the authorisation holders to apply for renewal of their authorisation before October 2006.[17] The decision was based on considerations of legitimate expectations. The market authorisations had been granted without any time limit applying. To impose a requirement of renewal by 2006 approximately corresponded to a period of ten years of market authorisation (most products authorised were authorised around 1996) which is the maximum period possible under Directive 2001/18.[18]

14. During the period from October 1998 to the present, has the European Communities rejected any applications for the placing on the market of biotech products under the legislation at issue (EC Directives 90/220 and 2001/18 and Regulation 258/97)?

[15] See Article 35 of Directive 2001/18.
[16] See chronologies for notifications under Directive 2001/18, Exhibits EC 62 to 110.
[17] See Article 17(1)(b) of Directive 2001/18.
[18] See Article 13(2)(d) of Directive 2001/18.

38. No. There was one product that was withdrawn after it had received a negative assessment (GM potato from Avebe).

15. With reference to para. 549 of the EC first written submission, is the simplified procedure under EC Regulation 258/97 a procedure whereby the relevant food products – i.e., products which are produced from but do not contain genetically modified organisms – require prior approval before they may be placed on the market? If so, please explain, including by identifying relevant legislative provisions, the competent body authorised to grant approval, etc. If not, is the fact that thirteen such food products have been placed on the market since 1998 relevant to assessing the correctness of the complaining parties' assertion that the European Communities has failed to "approve" any new biotech products since October 1998?

39. GM products that are produced from but do not contain GMOs, which are placed on the market under the simplified procedure laid down in Articles 3(4) and 5 of Regulation 258/97 require prior recognition of "substantial equivalence" through a national competent authority and, therefore, do effectively require prior approval.

40. Under the simplified procedure products cannot be placed on the market without having been notified. Notification in turn is only possible if it has been demonstrated that the product in question is substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein (see Article 3(4)).

41. Substantial equivalence, according to Article 3(4), in principle can be demonstrated in two ways: (1) by relying on scientific evidence available and generally recognized and (2) by relying on an opinion delivered by one of the competent food assessment bodies of the EU Member States (see Article 4(3)). Only the latter option, however, is *de facto* applicable to GM products as there exists no generally recognised scientific evidence on the substantial equivalence of these products. Accordingly, no applicant for GM products under the simplified procedure has ever even tried to demonstrate substantial equivalence under this first option.

42. In order to obtain an opinion from a competent food assessment body in an EU Member State, an applicant has to submit a dossier on, and the competent body proceeds to a full assessment of, the product in question.

43. Once the competent body has reached a positive opinion, the applicant may proceed to notifying the product on the basis of that opinion. The notification is made to the Commission. Neither the Commission nor another Member States, at this stage, can prevent the notification on the basis that it would not agree with the opinion. Note, however, that under Article 3(4) second subparagraph, the Regulatory Committee established at Community level has the possibility to determine whether a type of food or food ingredient can claim substantial equivalence. The Regulatory Committee, thus, established in January 1998, that only GM products that do not contain any more traces of novel proteins or foreign DNA would be admitted for a substantial equivalence assessment under the simplified procedure.

44. Upon notification, the product may be placed on the market in the European Union.[19]

16. Please describe the nature and type of assessment the relevant Regulatory Committees undertake of draft "measures"/"decisions" submitted to them by the Commission.

[19] See also Exhibit EC-120.

45. Regulatory Committees have their origin in Article 202 of the EC Treaty and act on the basis of Article 5 of Council Decision 1999/468/EC (so-called "Comitology" Decision) and of their rules of procedures. They assist the Commission in the exercise of the powers delegated to it by the Council for the implementation of its acts.[20] They are composed of representatives of the Member States and are presided over by a Commission representative. As their name suggests, they are regulatory bodies, involved in a decision-making process.[21]

46. As any regulatory body that has to deliver an opinion on an act which involves consideration of complex facts, including facts of a technical and scientific nature, the assessment undertaken by the Regulatory Committees of the draft Commission measures is a complete one and covers all its aspects. The Regulatory Committees fulfils risk management functions and, as such, they have to take into account all relevant factors, the first of which is of course risk assessment *strictu sensu* (seeabove reply to question 2).

47. In practice, the Regulatory Committees receive the texts of the draft Commission's measures at least 14 days before their meeting. Each draft measure is supported by scientific assessments and addresses relevant appropriate risk management issues. In addition, draft measures may take account also of other justifications and considerations, such as the degree of social acceptance of an existing risk (that is, the desired level of protection), the possibility of fraud or misuse, the need to provide accurate information to consumers etc.. Furthermore, as the Regulatory Committees are composed of representatives of the Member States, they also dispose of the Member States' scientific assessments and other justifications and considerations. On top of this, Regulatory Committees can base their decision on any other available scientific or other information, such as publications and studies of scientists or research centres, or reports produced by international, Community and national bodies, which are available on the matter (on this point see also reply on question 17, para. 52).

48. Finally, it is important to note that each Regulatory Committee fulfils its tasks within the framework of a specific legislation. As regards GM products, the relevant legislation is currently contained in Directive 2001/18 and Regulation 1829/2003. Those texts determine the elements that are relevant for the assessment and authorisation (or rejection) of GM products.

17. On what basis does the European Communities proceed when it decides to take a measure that does not follow the advice/opinion of the relevant scientific committee?

49. The European Communities understands this question *not* to be referring to the situation that a measure is adopted for reasons that lie *outside* the scope of the scientific advice/opinion provided by a scientific committee. It is clear, for example, that the choice of the acceptable level of protection is made by the risk regulator and not by a scientific committee. Equally, in taking its decision, a risk regulator has to take into account a number of management considerations (e.g. other legitimate factors) which go well beyond scientific considerations and are thus not addressed (and much less, decided upon) by a scientific committee (see also replies to questions 2, 18 and 86).

50. Rather, the European Communities understands this question to be referring to the specific situation that it would adopt a measure based on scientific grounds that do not follow the advice/opinion given by its own scientific committee on that issue. In particular, the scientific

[20] See case T-188/97, Rothmans v. Commission, [1999] ECR II-2463, para. 57-60.
[21] See case T-70/99 *Alpharma Inc. Against Council*, [2002] ECR II-03495, para. 283.

advice would have concluded that there is no clear evidence of harm of a given product, but a measure would be adopted based on the grounds that there may be a risk of possible harm.[22]

51. At the outset, it should be stated that in the EU legal system, like in so many other legal systems, including that of the USA, the opinions of scientific committees are only of an advisory, not binding, nature. EU law, in principle, has defined *a priori* the areas where a regulatory measure should take into account a scientific assessment. In such situations, the relevant provisions in the EC legislation allow or require the relevant institutions to "consult" the competent scientific committee.[23] The advisory nature of scientific opinions has also been confirmed in numerous decisions of the European Court of Justice.[24]

52. In forming a view on the scientific issues of risk regulation, the EC institutions are required to take into account the opinion of the relevant scientific committee, where one is provided, and the latest scientific information available from any other reliable national, Community or international source.[25] This is a universally recognised principle of the way to conduct a proper risk assessment. On the basis of such scientific information they may decide not to follow, partly or totally, the views of a specific scientific committee when the balance of all the scientific evidence available suggests that the chosen level of protection is not likely to be achieved by following the opinion of the specific scientific committee, or when other legitimate factors so require. Since the late 1980s, 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.

53. These principles are well illustrated in a case that involved a measure taken in the field of risk regulation on additives in feedingstuffs. The Council had adopted a regulation which effectively withdrew a marketing authorisation for a number of antibiotics used as additive in feedingstuff.[26] The Council based its decision on the grounds that there was a possible risk for human health

[22] Generally speaking, it is not uncommon, in the EU as in many other regulatory systems, for opinions of scientific committees to provide incomplete or inconclusive guidance to risk managers because they are termed with phrases like: "there seems to be no reasonable ground to believe, on the basis of the information available, that a significant risk to health or the environment is likely to arise", etc. In particular, scientific committees frequently have a hard time to evaluate scientific uncertainty and its implications to risk.

[23] See also for example the relevant provisions in Regulation 1829/2003 on genetically modified food and feed. Article 6 lays down the rules for obtaining an opinion from the "Authority » (i.e. EFSA). Article 7(1) then states that the Commission is to take a decision "*taking into account"* the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. » [emphasis added].

[24] See, *e.g.*, Case C-120/97, *Upjohn*, [1999] ECR I-223, at paragraph 47, and Case C-405/92, *Armand Mondiet* [1993] ECR I-6133, at paragraphs 31-32 and 36 (both judgments holding that the opinion of the scientific committee is not of mandatory but of advisory nature only); see also Case T-13/99, *Pfizer* [2002] ECR II-3305, at paragraphs 196 and 201 (holding that the Commission is not obliged to follow the opinion of the scientific committee because its opinion is of advisory nature only. On *Pfizer* more generally, see also below).

[25] See, *e.g.*, third recital of preamble to Council Regulation (EEC) 2377/90 establishing a procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, (OJ No L 224, 18.08.1990, p.1-8), which provides: "Whereas in order to protect public health, maximum residue limits must be established in accordance with generally recognized principles of safety assessment, taking into account any other scientific assessment of the safety of the substances concerned which may have been undertaken by international organizations, in particular the Codex Alimentarius or, where such substances are used for other purposes, by other scientific committees established within the Community".

[26] Council Regulation (EC) N° 2821/98 of 17 December 1998 amending, as regards withdrawal of the authorisation of certain antibiotics, Directive 70/524/EEC concerning additives in feedingstuffs (OJ 1998 L 351, p.4)

(development of antibiotic resistance) and that in the light of scientific uncertainty based on a number of scientific reports and studies from several sources it was necessary to take preventive action.

54. The relevant scientific committee which had been consulted by the European Commission in preparation of the decision (and had dealt specifically with the question of risk of development of antibiotic resistance) had concluded that the use of a specific antibiotic did not seem to constitute an immediate and significant risk to public health. The Community institutions, however, while relying in parts on that opinion, disagreed with its conclusions on the basis of a broader set of scientific evidence coming from several other sources. They did so on the basis of other scientific information, namely of conclusions and recommendations in a number of reports produced by other international, Community and national bodies, published in the years preceding the adoption of the contested measure. In particular, they took account of several studies presented by scientific bodies of the EU Member States.

55. The Council's decision was challenged before the Court (of First Instance) of the European Communities.[27] The applicant alleged, amongst other claims, an error of risk assessment and risk management and a misapplication of the precautionary principle. The applicant challenged, *inter alia*, the fact that the Community institutions had not followed the opinion of its own specific scientific committee.

56. The Court first recalled that the scientific committee was merely an advisory body, that its opinions, therefore, were not binding on the Community institutions, and that its role, in a procedure designed to culminate in a decision or a legislative measure, is restricted, as regards the answer to questions which the competent institution has asked it, to providing a reasoned analysis of the relevant facts of the case in the light of the current knowledge about the subject, in order to provide the institution with the factual knowledge which will enable it to take an informed decision.[28]

57. The Court pointing to the competent institution's obligation to assess the probative value of the opinion delivered by the committee went on to state:

> To the extent to which the Community institution opts to disregard the 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. In such a case, the institution may take as its basis either a supplementary opinion from the same committee of experts or other evidence, whose probative value is at least commensurate with that of the opinion concerned.* In the event that the Community institution disregards only part of the opinion, it may also avail itself of those parts of the scientific reasoning which it does not dispute.[29] [emphasis added]

58. On the basis of these principles, the Court found that the Community institutions were entitled in that specific case to disregard the conclusions drawn by the relevant scientific committee.

59. The Court recalled in this context that a scientific opinion is a necessary but not sufficient condition for risk regulation. It stated:

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[27] Case T-13/99, *Pfizer* [2002] ECR II-330.
[28] *Ibidem* at paras. 196 and 197.
[29] *Ibidem* at para. 199.

> That finding can also be justified on grounds of principle relating to the political responsibilities and democratic legitimacy of the Commission. Whilst the Commission's exercise of public authority is rendered legitimate, pursuant to Article 155 of the EC Treaty (now Article 211 EC), by the European Parliament's political control, the members of SCAN [i.e. the scientific committee in question], although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities. *Scientific legitimacy is not a sufficient basis for the exercise of public authority*.[30] [emphasis added]

60. On the basis of the above principles the Court examined whether the Community institutions, in relying on the other relevant scientific information, had erred in concluding that the use as a growth promoter of the antibiotic in question constituted a risk to human health. The Court heard experts on the question of whether there is a risk of development of antibiotic resistance and drew from that discussion the following conclusion:

> It is not for the Court to assess the merits of either of the scientific points of view argued before it and to substitute its assessment for that of the Community institutions, on which the Treaty confers sole responsibility in that regard. In the light of the foregoing, the Court nevertheless finds that the parties' arguments, supported in each case by the opinions of eminent scientists, show that there was great uncertainty, at the time of adoption of the contested regulation, about the link between the use of virginiamycin as an additive in feedingstuffs and the development of streptogramin resistance in humans. Since the Community institutions could reasonably take the view that they had a proper scientific basis for a possible link, the mere fact that there were scientific indications to the contrary does not establish that they exceeded the bounds of their discretion in finding that there was a risk to human health.[31]

61. On the basis of that conclusion the Court found that the applicant had not established that the Community institutions had erred when disregarding the opinion of the relevant scientific committee and concluding, on the basis of all scientific knowledge available at the time of the adoption of the contested regulation, the use as additive in feedingstuffs of the antibiotic in question entailed a risk to human health.[32]

62. In providing the above reply the European Communities hopes to have addressed also, in parts at least, the additional questions raised at the first hearing by Mr. Kumar. Mr. Kumar had inquired whether there are multiple committees involved in a risk assessment process. The answer generally speaking and as regards GMOs and GM products is "yes", as EU Member States usually have independent scientific bodies or in house experts (i.e. within the competent authority) that advise the competent authorities on scientific issues in risk regulation.[33] This is for example the case of

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[30] *Ibidem* at para. 201.

[31] *Ibidem* at para. 393.

[32] See *Ibidem* para. 40. Note that on the same day the Court decided on another case that dealt with similar facts, i.e. the withdrawal of a market authorisation for another antibiotic used as additive in feedingstuffs. In this case, the Community institutions had taken the decision without specifically consulting their own scientific committee. Instead they had relied on the scientific committee's opinion in the above case and on the relevant reports and conclusions of other national and international bodies mentioned above. The Court found that the Community institutions were entitled to rely on that information, see Case T-70/99 *Alpharma Inc. v. Council*, [2002] ECR II-03495, in particular at para. 240.

[33] The only exception to this statement would seem to arise when exclusive competence has been granted to the EU and a unique risk assessment agency at EU level has been established, *e.g.* in the area of providing marketing authorisation and supervision of medicinal products for human health (see Council

France (Commission de Génie Biomoléculaire - CGB), Belgium (Biosafety Advisory Council/Bioveiligheidsraad/Conseil consultative de Biosécurité), the Netherlands, (Committee on Genetic Modification - COGEM), Spain (Comisión de Bioseguridad), Germany (Robert-Koch-Institut), Italy (Istituto Superiore di Sanità), the UK (Advisory Committee on Release to the Environment – ACRE) and Sweden (Swedish Board of Agriculture.

63. Mr. Kumar also inquired whether the opinions of the EC scientific committees had an overriding effect over the opinions issued by such bodies at the Member State level. This is not the case. In light of the above principles it is clear that the EC scientific committee's opinion is merely of an advisory nature and that the EC institutions may disagree with its conclusions on the basis of other relevant scientific information, including that of scientific bodies in the Member States.

64. Furthermore, Mr. Kumar inquired whether the relevant scientific committees were specifically set up to provide advice on GMOs only or whether they would also provide advice on non-GMO issues. At the EC level, up to the establishment of the European Food Safety Authority (EFSA) in 2003, three scientific committees were consulted on GMOs, namely the Scientific Committee on Plants, the Scientific Committee on Foods and the Scientific Committee on Animal Nutrition. Neither was specifically established for issues concerning GMOs only, but had a broader mandate.[34] With the establishment of EFSA, a scientific Panel specifically for GMO issues has been established. This Panel deals both with release into the environment and with food use questions. As for scientific bodies in the Member States, a considerable number of them were established specifically to provide advice on GMOs only. This is, for example the case of the Biosafety Advisory Council in Belgium or the COGEM in the Netherlands.

65. Mr. Kumar's last question, finally, namely whether the Commission had ever disregarded the advice of EC scientific committees, has been answered in the affirmative by the above examples.

18. In the consideration of notifications submitted since October 1998, what aspects of potential risks have not been specifically or sufficiently addressed by the relevant scientific committees?

66. In light of its reply to question 17, it is clear that the "relevant scientific committees" in the risk assessment of GMOs and GM products were and are not only the EC scientific committees but also Member State scientific committees as well as other international scientific bodies. The European Communities, however, understands this question to specifically mean the committees at the Community level, namely the Scientific Committee on Plants and the Scientific Committee on Foods, both of which are now united as one specific panel on GMOs under the European Food Safety Authority (EFSA).

Regulation (EEC) 2309/93 of 22 July 1993), although even in such a situation the derogations laid down in Article 95 of the EC Treaty may still apply.

[34] The SCPs mandate was : "Scientific and technical questions relating to plants intended for human or animal consumption, production or processing of non-food products as regards characteristics liable to affect human or animal health or the environment, including the use of pesticides."

The SCFs mandate was: "Scientific and technical questions concerning consumer health and food safety associated with the consumption of food products and in particular questions relating to toxicology and hygiene in the entire food production chain, nutrition, and applications of agrifood technologies, as well as those relating to materials coming into contact with foodstuffs, such as packaging."

The Animal Nutrition's Committee's mandate was: "Scientific and technical questions concerning animal nutrition, its effect on animal health, on the quality and health of products of animal origin, and concerning the technologies applied to animal nutrition."

67. In general terms, the following can be said: First, the role of these scientific committees was (and is) to provide advice on scientific issues only. These committees' role was (and is) not to *decide* on the granting of a market authorisation as that decision has to be taken not only on the basis of the scientific considerations referred to the Committee but also in taking into account other legitimate factors and, in particular, risk management considerations (see also reply on question 16) The Committees' role and mandate was (and is) not to address such risk management considerations, which include a number of other issues among which traceability, post-market monitoring and codes of good agricultural practice. It should be pointed out, however, that the committees, in the relevant period would sometimes address such issues, and in particular issues of post-market monitoring and codes of good agricultural practices. Indeed, as has been shown in the first submission, in four cases, the SCP recommended the development of such monitoring plans and/or codes of good agricultural practices.[35]

68. Second, the committees' mandate to address scientific issues was limited in that it was based on Directive 90/220 and, thus, did not take into account new standards as they were to be implemented through the new legislation. In particular, standards for a comprehensive risk assessment were only developed through Directive 2001/18. Certain risk considerations were only added through the new legislation, such as, for example, the impact on the environment and on biodiversity of changed agricultural practices.

69. Third, on some of the scientific issues that the opinions of the committees would address, other scientific committees in the Member States would sometimes have divergent opinions. In its first submission the European Communities has described for each individual application, which Member States raised (and maintained) objections or requested additional information, including where an opinion of the relevant EC scientific committee had already been issued. These cases will be further documented through the additional documents which the Panel has requested the European Communities to provide.

70. Finally, the opinions of the scientific committees would sometimes become "outdated" by virtue of new research data. As has been explained, many of the scientific issues surrounding the risk assessment of GMOs are in constant evolution. To take one example: the scientific requirements on molecular characterisation have developed rapidly in the past years. Thus, on the basis of new methods of molecular characterisation it was found in 2001, that the molecular characterisation, on the basis of which the product Roundup Ready Soybean (C/UK/94/M3/1) had been authorised in 1996, did not correspond to the molecular description of the actual product on the market: i.e. extra DNA fragments were found to be inserted in the plant genome contrary to what had been indicated and notified in the application for the market authorisation. This is one example of a new scientific issue that has arisen in the course of examination of GMO products and which has motivated greater emphasis on molecular characterisation in recent years.

19. Please comment on Canada's remarks at para. 101 of Canada's first oral statement, specifically with respect to Austria's different treatment of maize and oilseed rape.

71. The European Communities recalls that Article 5.7, rather than Article 5.5 *SPS Agreement* is the relevant provision to assess the national safeguard measures (see also reply to question 110). The European Communities further recalls that Article 5.5 *SPS Agreement* is concerned with, if anything,

[35] See products Ms8Rf3 oilseed rape, Liberator oilseed rape, Falcon GS40/90 oilseed rape and A5/15 fodder beet.

the consistency of definitive behaviour of the European Communities rather than with provisional steps in the application process taken at regional level (see the answer to question 38).

72. Contrary to what Canada asserts at para. 101 of its oral statement, namely that it is not clear to what the European Communities refers, the relevant matters are summarised in annex CDA-77, at page 3. For the avoidance of doubt, the public document there referred to is attached to this response.[36]

73. Similarly, Canada's assertion that "Austria's concerns had no basis in the scientific information provided to the committee" is not an accurate summary of the opinion of the Scientific Committee on Plants (Exhibit CDA-77). In that opinion, the scientific committee first pointed out to the Commission that the Austrian document did not contain any new science. It thus signalled to the Commission that the outstanding issues were issues for the regulator, rather than issues for the scientists.

74. As regards Austria's "different treatment" of maize and oilseed rape, the European Communities has pointed out that no two risk assessments are the same, and that is certainly the case when the crops concerned are different. Furthermore, the primary issue in the case of oilseed rape concerns herbicide resistance; whereas in the case of Maize (Bt-176 and MON 810) the concerns rather centre on questions of insecticidal properties and antibiotic resistance. Nor should it be forgotten that the oilseed rape Community authorisations were adopted in 1996 and 1998, whereas the Austrian measures with regard to Maize T-25 were adopted in 2000, at a time when both scientists and legislators were in the process of re-assessing both the scientific issues on the one hand, and the appropriate legislation on the other hand.

20. Please explain to what extent and how the European Communities took into consideration the provisions of Annex C of the SPS Agreement in the preparation of EC Directive 2001/18.

75. The European Communities always drafts its legislation in light of its international obligations including its WTO obligations. Accordingly, recital 13 of Directive 2001/18 states that

> The content of this Directive duly takes into account international experience in this field *and international trade commitments* and should respect the requirements of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. As soon as possible, and in any case before July 2001, the Commission should, in the context of the ratification of the Protocol, submit the appropriate proposals for its implementation. [emphasis added]

76. As the European Communities has stated in its submission, to the extent that it addresses risks coming under point 1 of Annex A of the *SPS Agreement*, the European Communities accepts that the approval system set up under Directive 2001/18 (as well as under Directive 90/220) is a "procedure to check and ensure the fulfilment of sanitary and phytosanitary measures" within the meaning of Point 1 of Annex C.[37] The system is designed to be applied in a way that is compatible with the obligations set out in Annex C. This fact has not been put into question by the Complainants who have not challenged the system as such.

[36] Exhibit EC-121.
[37] First written submission of the European Communities, para. 474.

21. At para. 34 of its oral statement, the European Communities notes that it "cannot believe that the Panel would rule on this case without taking [scientific and technical] advice". To date, the European Communities has not, however, identified any specific scientific or technical issues. In order to allow the Panel to continue reflecting on this issue, the Panel would appreciate it if the EC could identify, during today's session, specific scientific or technical issues which it considers would justify the Panel in seeking expert advice.

77. The European Communities would first of all want to refer the Panel to all the issues it has highlighted with regard to each specific product notification in this case in the chronologies and attached documents contained in its First Written Submission.[38] Furthermore, the European Communities would also refer to its answers to the three questions of the Panel on scientific and technical advice, issued on the 3 June, which specifically address the issue of the need for scientific and technical advice.

78. In short, as regards the identification of any specific or technical issue which would justify seeking expert advice, and on the basis of the first hearing, where the complainants admitted to be in agreement with the favourable, positive scientific opinions of the scientific committees at community level, but only with these opinions, the European Communities considers that *all* scientific and technical issues that it had submitted to justify the time necessary for the full consideration of all the applications referred to in the complainants claims, and which are not in agreement with these positive opinions, or which were not considered in the issuance of these positive opinion, or which cover new scientific information available after the positive opinion, or which cover different, unresolved issues at the time, warrants seeking technical and scientific advice, as the complainants would be in disagreement with them being a sound basis for the necessity to have further considered these applications.

79. The Communities are therefore confirmed in their view of the need for such advice, and repeat their request for a meeting with scientific and technical experts, covering at least these issues found in dispute between the parties.

80. Some of the Panel's questions, either to all parties or to some of them, for example questions 23 to 34, or question 78, are of a scientific and technical nature, or have a strong scientific and technical background. These are all questions that are also the subject of ongoing scientific and technical debate. Hence, as it may be anticipated that different views will be expressed by the Parties on these questions, the European Communities considers that they would also justify the Panel in seeking expert advice.

For all parties:

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

81. Seven GM products have been approved under the simplified procedure since October 1998 (including one, MON 809 - approved during that same month). Altogether, thirteen such products have been approved since the entry into force of Regulation 258/97 on the 15 May 1997.

23. The European Communities states at paras. 26-28 of its first written submission that none of the current biotech gene transfer methods are able to precisely control where the foreign gene will insert into the recipient cell's genome, or whether that insertion will be stable,

[38] Exhibits EC-62 to 110.

and further describes the screening for the desired traits. How do the points described here compare with the results of conventional selective breeding techniques?

82. The Panel question only addresses the introduction of foreign DNA into plants, as referred to in these paragraphs of our first written submission.

83. There are several fundamental differences between the methods of introduction of a genetic modification through genetic engineering, as referred to in paragraphs 21 to 25 of the first written submission by the European Communities, and conventional selective breeding techniques.

84. First, as regards conventional selective breeding techniques, whether the organism is obtained through the selection of single or multiple mutations, or through the inbreeding of characters from related or heterologous parents, all the desired traits are generally expressed from genes (mutated or not) which are located in their natural chromosomal context, because the genes have either been mutated on site or have undergone homologous recombination.

85. Indeed, when an organism is expressing a new character due to a mutation, whether in one or in several genes, these genes reside in their normal genomic context. Furthermore, the inbreeding of several character from different parents leads to a new combination of genes, for example by virtue of natural recombination at meiosis, or by virtue of polyploidy, but again *only* with the genes being generally located in their natural chromosomal context.

86. In these conventional selective breeding techniques, only accidental and rare events may lead to the change of chromosomal location of the genes responsible for the new desired traits.

87. On the contrary, the techniques of plant genetic modification through genetic engineering lead systematically to the "accidental" introduction of the new genes, conferring the new desired traits, at random location in the plant chromosomes. In fact there is scarce scientific evidence of the biological basis for any possible preference of the chromosomal context or location that may be consequential to using one or the other of the transformation techniques.

88. This has very significant consequences as regards the differences with conventional selective breeding techniques.

89. Firstly, the chromosomal context is known to have a critical importance on the level, the stability, and the regulation of the expression of genes. Genes that have a particular chromosomal location maintained through evolutionary time have acquired, with the selection of their mutual interaction with other genes and their particular natural chromosomal context, a fine tuned expression, including the level, the stability and the regulation of their expression.

90. On the contrary, the very rudimentary techniques available today for the genetic engineering of plants lead to the introduction of the new genes in a chromosomal context, unknown to the scientist performing that introduction, and also "unknown" to the genes introduced.

91. This chromosomal context may be one which is highly expressed, or generally silent, or composed of redundant non expressed DNA, etc… It may contain in the close or more distant vicinity of the insertion, critical important regulatory sequences and elements which will affect the expression or the stability of the newly inserted gene.

92. Some of this may be assessed in the process of the risk assessment of the GMO and in the collection of relevant data on the new genetically modified plant, while much of it will remain cryptic

and will only manifest itself in particular circumstances, for example in very specific environmental or pedo-climatic conditions.

93. This may eventually lead to specific uncertainties as regards the risk assessment of a particular GMO.

94. There is, on that first aspect, both a significant qualitative and quantitative difference with conventional selective breeding techniques, with regard to the scale of time that has been available for the presence in their natural location, and hence also to some extent for their empirical assessment, of the genes which are responsible for the desired traits, as well as with regards to the time that has been available for the possible identification of some issues relevant for their expression or potential secondary or pleïotropic effects.

95. Secondly, a very important consequence, as regards the difference with conventional selective breeding techniques, derives from the unique ability of genes newly introduced by these genetic engineering techniques to disrupt, in the process of their chromosomal integration, some endogenous genes of the organism, thereby interrupting or modifying their expression, or creating the expression of a newly chimaeric protein.

96. Again, some of these consequences may be assessed in the process of the risk assessment of the GMO, and in the collection of relevant data on the new genetically modified plant, but much of it may remain cryptic and will only manifest itself in particular circumstances, for example in very specific environmental or pedo-climatic conditions. This may be particularly true if the disruption of the endogenous gene affects a regulatory gene, or a regulatory pathway, that is relevant only in specific environmental conditions. This may lead again to pleïtropic effects only in these specific environmental conditions.

97. For instance, as a theoretical example, the disruption of a gene that is only necessary for the production of a metabolite or a signalling molecule necessary for the survival of a soil micro-organism associated with the roots of that plant, but which is neither detrimental nor beneficial to that plant and hence not a pest for that plant, might remain unnoticed in the collection of the risk assessment data. However, if that micro organism is a key component of the equilibrium of the soil ecology, the disruption of the plant gene may have significant indirect environmental consequences.

98. Also, if there is a new chimaeric protein expressed, and especially if its expression only occurs in particular environmental circumstances which may remain unnoticed in the risk assessment process, there may be relevant toxicity and allergenicity questions to be addressed if that expression is nevertheless exposing animals or humans to the new chimaeric protein in those circumstances. In fact, earlier applications for the placing on the market of GMOs showed that this was a real situation, as the identification of such fusion protein happened by accident through questions of competent authorities and required further analysis to show the safety of the fusion protein.

99. There is also, on this second aspect, both a significant qualitative and quantitative difference with conventional selective breeding techniques.

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

100. It is important for the context of this question, to clarify that there is currently no scientific method available to ascertain whether a peptide, a protein, or another metabolite or molecule, contains

an allergen that could give rise to significant allergies in humans, either as food, or as a source of allergen exposure by other means (respiratory, contact,…). The same is also true for susceptible animals.

101. All data from the methods currently available to test for the potential for allergenicity (sequence comparison, *in vitro* protein digestibility tests, *in vitro* tests on cultured cells from atopic individuals, etc..) are not always provided in the applications for placing on the market of GMOs, and these methods are only indicative, *i.e.* they provide for a limited ground to assess the potential for allergenicity as a scientific basis for a possible measure. The only test that would provide for such answers with some certainty would be to conduct allergenicity tests on humans, which, for obvious ethical reasons, can not be performed as a pre marketing risk assessment pre-requisite.

102. There is therefore generally a significant degree of uncertainty as regards the issue of allergenicity, whether for GMO or for novel food. However, there are major differences as regards the potential for allergenicity between a GMO and a non-GM novel food.

103. The first one relates to the origin of the novel trait introduced in the plant, or the novel food itself. As has been said elsewhere, one of the specificity of genetic engineering is the ability to combine genes across species, or even kingdom's barriers. In a GMO, when the trait introduced originates from another "donor" organism, such as a bacterium or another species, as compared to the "recipient" plant, that "donor" organism may have no history of consumption as a food (this is the case, for example, of *Bacillus thurigiensis*, the "donor" organism of Bt genes), and there is therefore no historical data in this situation as to whether that "donor" organism has a significant allergenic potential as a food source, let alone the allergenic potential of the individual product of the new gene inserted, or any metabolite derived from the activity of the new gene product. There is therefore no data available, apart from the indicative methods referred above, that would indicate whether a GMO may or may not have a different allergenicity potential.

104. On the contrary, when a non-GM novel food has not been consumed significantly in a given population which has a particular genetic set-up, there may also be issues regarding the potential for allergenicity in that population. But contrary to the potential allergenicity of the GMO cases described above, there would be some history of consumption for that non-GM novel food, at least in some other populations, or in the history of mankind. Conceptually, the two cases are therefore radically different.

105. The second major difference relates to the situation where the non-GM food, or the "donor" organism of the new trait of a GMO, is *known* to be an allergen of significant impact. In this situation, the non-GM food can be assessed on the basis of its known allergenicity. On the contrary, for a GMO, it may not be known *what* molecule is responsible for the allergenic potential of the "donor" organism. Furthermore, whether the gene responsible for that potential is the gene transferred or not in the GMO, the conditions of expression of that gene (in which plant tissues, at what stage of the plant development) may be significantly different from that of the "donor" organism or from the expected expression of the GM construct, due to the random integration of that gene in the genome of the GMO (see answer to question 23), and thereby modify radically its allergenicity potential. Also the differences in the localisation in the cell or in the plant organism of the gene product, or the metabolites produced by that gene product, may lead to significant differences in the exposure to the allergen, and therefore significant differences regarding the allergenic potential.

106. As an example from earlier cases at the stage of research and development in the development of GMOs, the introduction in another plant species of an "housekeeping" gene from the Brazil nut (a food known to be responsible for allergies) because of the potential of that gene product as an

interesting food or feed source, corresponded to the unforeseen transfer of one of the potent allergens of the Brazil nut and required the interruption of that development program.

107. The third major difference regarding the potential for allergenicity between GMOs and non-GM novel foods is a consequence of the random integration of the genetic construct in the genome of the GMO (see answer to question 23), which may lead to the production of new and unforeseen chimaeric fusion protein.

108. There is, in this third aspect, a whole range of relevant differences in the type of fusion proteins that may be generated at the genomic integration site(s) in a GMO (involving or not the introduced new protein gene, if its sequence is interrupted or modified in the integration event, involving or not genes at the site of integration in the host genome, involving or not further distinct genetic elements, when the integration is leading to significant genetic rearrangements at the site of integration), many of which are specific to the GMO situation compared to a non-GM novel food situation. However, in all cases, the potential generation and expression of a new fusion protein in the GMO may or may not have a significant allergenic potential, and its assessment is relevant in the context of the allergenic potential of a GMO compared to a non-GM food. Even if the unexpected production of a fusion protein is identified in the GMO in its risk assessment process, the inability to assess with certainty its allergenic potential remains true.

109. There may be exceptional or marginal situations where a fusion protein may be generated in non-GM novel food, as well as in traditional foods, but never as often, nor with the same level of heterology, as for the different sources of the fusion protein in a GMO.

110. There are further scientific reasons that may be elaborated and which also warrants significant differences in the potential for allergenicity between GMOs and non-GM novel food, but already for the reasons stated above, it is again obvious that there are both qualitative and quantitative differences between both.

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

111. A new character conferred to a plant, through the introduction of a new trait into a GM plant or by the conventional selection of a new trait, may confer a selective advantage to that plant. If it is the case, it may result in the invasiveness or persistence, in the natural or agronomic environment where the relevant selection pressure is present, of any plant where that trait is expressed and where it confers the necessary selective advantage.

112. Thereby, "resistance genes", conferring resistance to a given selection pressure, natural or agronomic, may be responsible for some invasiveness or persistence under the relevant selection pressure, if they outcross in other plant species such as wild relatives, in neighbouring non GM crops of the same species, or if they remain in the next generations of the original GMO, present as volunteers.

113. There are however significant differences for the issue of potential invasiveness or persistence in the environment between herbicide/pesticide resistance in GM plants and in conventional crops, which remain, as always, to be necessarily assessed on a case by case basis.

114. First, the traits conferring herbicide/pesticide resistance in conventional crops, even if present as a multiple resistances, have no *a priori* reason to be genetically linked between themselves, or to any other relevant character that may have otherwise negative impacts, *i.e.* have no *a priori* reason to be transferred together into interfertile plants from the same or from a different species.

115. On the contrary, the construction of GMOs, especially those from the first generation, were obtained from single transformation events, where all genes introduced were tightly linked in the same genetic construct. For that reason, any herbicide/pesticide resistance gene from a GMO plant that would have the potential to confer to the organism where it is expressed the character of invasiveness or persistence in the relevant environment, would lead to the maintenance, and possible spread, in that environment of a gene set comprising all the characters originally present in the construct that would be genetically linked together, including any other character present in the construct that may have potential negative impacts.

116. For instance, the presence in the original construct of a particular GMO of a gene conferring herbicide resistance, genetically linked together with an antibiotic resistance marker gene, would lead to the maintenance, and possible amplification in the environment, under the relevant herbicide selection pressure, of a gene pool containing that antibiotic resistance marker gene. This could never be the case for a conventional herbicide resistance crop.

117. Secondly there is a major difference in the impact of any potential concerns of invasiveness or persistence between herbicide/pesticide resistance in GMO and in conventional crops, linked to the type of resistance conferred in one or the other type of crops.

118. As regards herbicide resistance, the herbicides conventionally used for weed control in crops are selective herbicides, *i.e*. they kill selectively specific weeds, and the selectivity of such herbicides is often limited to one crop, or group of crop species; their use is sometimes only limited to some varieties of that crop. In general the efficacy of these selective herbicides has a limited spectrum, *i.e*. certain weed species may not be controlled. The management of their use also takes into account the very important parameter of crop rotation, namely how a selective herbicide may be effective to manage the volunteers from the previous harvest in the next crop season.

119. By opposition, the herbicide resistance currently conferred by genetic modification to GMOs are radically different, as they confer resistance to non selective (total) herbicides, *i.e.* an herbicide that kill all plant species. But they can be used on a specific crop that has no natural tolerance to it when that crop has been engineered to resist to that total herbicide by the introduction of bacterial genes. The aim to tailor a target crop to resist a non selective herbicide is to have a broader spectrum of weed control, as well as tying together herbicide producers and seed companies in order to try expand their market shares.

120. At present two non-selective herbicides, glyphosate and glufosinate, are the dominant compounds; they have also relatively more benign environmental impacts than some other non selective or even selective herbicides.

121. It would be devious logic to believe that the issues of potential persistence and invasiveness that may be conferred by herbicide resistance in the different types of crops are similar (through GM and non GM crops), as far as it is currently not possible to confer resistance to these "environmentally friendly" non selective herbicide through conventional breeding.

122. For instance a limited list of the specific concerns of these non selective herbicide traits that need to be assessed in GMOs, relate to the building of unexpected resistance pattern, such as multiple

resistance in *Brassica napus* volunteers or related wild plants, including resistance to these two non selective herbicide[39]; the management of these multiple resistant volunteers or wild relatives, especially under climatic conditions where they may remain dormant for long period of time in the environment; the new problems related to crop management when successive crop species in rotation (oilseed rape, maize, sugar beet, soybean, possibly also soon wheat) do contain one of these two non selective herbicide resistance (and potentially the two in volunteers of these plants, due to unintentional gene stacking), and therefore generate new herbicide management problems due to reliance on a single technology; the loss of the ability to use these "environmental friendly" non selective herbicides in certain circumstances, including in agronomic, non agronomic or industrial environments, due for instance to the building of multiple resistance in feral plants, or to overtaking by resistant volunteers because of successive use of the same crops, no tillage and careless crop management, and the need therefore to resort on other weed killers that may have negative effect on the environment[40]; etc.

123. For further illustrations of the specific questions raised by herbicide resistance traits in GM crops, compared to conventional herbicide resistant crops, see recent accounts of the relevant scientific expertise[41], or an example of an agronomy technical note addressing what farmers need to know about transgenic crops, developed under a grant from the USDA[42].

124. As regards pesticide resistance, again there is no possible logical comparison between pesticide resistant GM crops and conventional crops, as the character of pesticide resistance used are different in both types of crops, and their respective impact assessment concerning potential invasiveness and persistence, on a case by case basis, may not be comparable.

125. For instance, most pesticide resistant GM crops application covered by the claims of the complainants have been engineered to resist to some lepidopteron insects (European corn borer) by the introduction of the bacterial insecticidal toxin Bt. This cannot be achieved through conventional breeding.

126. Likewise, the specific introduction of genetic elements conferring specific and potent virus resistance, which may be obtained by genetic engineering, but not by conventional breeding, may raise specific question regarding their potential for invasiveness or persistence, including any relevant biohazard issue that may need to be assessed as regards to the evolution of the target and non target pathogenic virus population.

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[39] See for instance in Canada: Hall L. et al. 2000. Pollen flow between herbicide-resistant Brassica napus is the cause of multiple-resistant B. napus volunteers. Weed Science 48, 688-694. Ellstrand, Norman C. 2001. When transgenes wander, should we worry ? Plant physiology Vol. 125, p. 1543-1545.

[40] See the account of GM herbicide resistance management problems due to the mishandling of the technology in Argentina. New Scientist. 17 April 2004. Argentina's bitter harvest. Sue Branford. pp. 40-43. Exhibit EC-122.

[41] 1st European Conference on the co-existence of genetically modified crops with conventional and organic crops. Exhibit EC-123.

FAO technical meeting on benefits and risks of transgenic herbicide resistant crops, Rome 1999. Exhibit EC 124

[42] Genetic engineering of crop plants. What farmers need to know about transgenic crops. By Nancy Matheson, NCAT Agriculture Specialist. Agronomy technical note. ATTRA (Appropriate technology transfer for rural areas). October 2001. Exhibit EC-125

127. For further information and examples regarding the specificity of the risk assessment issues of invasiveness and persistence of GM plants as compared to herbicide/pesticide resistant conventional crops, see some recent review papers or reports from the relevant scientific expertise[43].

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

128. "Europe" is a term covering different concepts that may affect the answer to this question. As the region usually referred to under the United Nations Economic Commission for Europe, it covers a much wider geographical scope than the western European region. If it refers to the geopolitical entity corresponding to the European Communities, as referred to in the EC legislation, which is relevant here, however, it is again a different environmental scope, which now covers twenty-five states.

129. The notion of "centre of origin" may cover different scientifically or technically related concepts, and is open for interpretation by the risk assessors in a proper risk assessment process. It is however a useful reference to address some issues, such as the issue of inter-specific crosses and the sexual compatibility with other cultivated or wild plant species, including the distribution of compatible species. Science has not defined once and for all the notion of "centre of origin", but usually it refers to the environmental "region" (including its specific biological, ecological, physical, pedo-climatic and other relevant conditions), where a particular crop plant species has originated. It may however extend to a much wider region, namely to the whole region or regions where sexually compatible plant species exist naturally.

130. For instance, it is said that maize originates from the Mexican region, from teosinte, or that wheat originates from hybridization between several species in the Mediterranean basin. Results from phylogeny and molecular biology studies have supported these claims to some extent. But it can also be said that the "centre of origins" of these plant species expand to some of central and south American regions, for the former, or to part of Africa and the whole of Europe, for the latter, on the basis of the natural presence of related species.

131. There are several major crop species for which Western Europe is obviously the so-called "centre of origin", which have been genetically modified, and which are the subject of applications for their placing on the market at issue in this case. These include for instance oilseed rape or sugar beet.

132. However, the jurisdiction of some of the Member States of the European Communities extend much more widely than Western Europe, and covers territories in South and Central America, Asia and the Pacific, Africa, and North America, and these may be part of the "centres of origin", in its wider meaning, for other crop species, such as maize for instance.

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[43] The Ecological risks and benefits of genetically engineered plants. L.L. Wolfenbarger and P.R. Phifer. Science. vol. 290. 15 December 2000. pp. 2088-2093. Exhibit EC-126.
FAO. Report of the FAO expert consultation on environmental effects of Genetically Modified Crops. 16-18 June 2003. Exhibit EC-127.
The Royal Society. GM crops, modern agriculture and the environment. Report of a Royal Society Discussion Meeting held on 11 February 2003. pp. 1-16. Exhibit EC-128.
Snow AA. Et al. (2004) Genetically engineered organisms and the environment: current status and recommendations. The Ecological Society of America. Exhibit EC-129.
Marvier MA. (2002) Improving risk assessment for non target safety of transgenic crops. Ecological applications12:1119-1124.

133. Obviously the scope of the crops species for which one region may be considered the centre of origin depends on what is meant by that region and by the "centre of origin".

134. What is covered by the concept of the centre of origin of a particular plant species has a significant, albeit limited, impact in the process of a case by case risk assessment, prior to the possible release into the environment of a particular GM construct introduced in that plant species, as far as it is concerned with the issue of compatibility with wild plant species, including the distribution of the sexually compatible species, as well as with the relationships with other organisms which interact normally with that crop species or other compatible species, and are present in its "natural" environment .

135. However, the concept of a centre of origin is only one of the many possible concepts that are taken into account in an appropriate environmental impact assessment, which may not be performed in a binary way, namely the assessment of the release of a particular GM crop plant in its centre of origin or not.

136. For instance, one other very important element which is largely unrelated to the centre of origin is the biology of the reproduction of the plant species being considered, for instance its allogamous or autogamous properties, and the possibility of intra-specific crosses, leading to the out crossing of the genetic modification in non GM plants, but of the same species.

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

137. The definition of a "Contaminant", for the purpose of the Codex Alimentarius, is:

> any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.[44]

138. The question of the Panel refers to the "modification or reaction created by gene transfers, or the resulting protein." The European Communities understand the question of the Panel to refer to the genetic modification introduced by the relevant transformation methods in a GMO, or the resulting protein expressed from that genetic modification of a GMO. In the view of the European Communities, the question is not meant to cover modification or reaction created by *natural* gene transfer, such as out-crossing, which may occur naturally, between different plant species that are sexually compatible.

139. Furthermore, the reference to "the reaction created by gene transfers" being scientifically and technically unclear and not precise as to what is meant by "reaction", the European Communities is not in a position to specifically address that part of the question.

140. The scientific ambiguity in the question between *natural* gene transfers and genetic modifications obtained by genetic engineering illustrates clearly that such modifications of GMOs,

[44] Tenth edition of the procedural manual of the Codex Alimentarius Commission. FAO. 1997. Exhibit EC-117.

and the resulting proteins that are expressed, cannot be considered to be covered by the Codex definition of contaminants.

141. The Codex definition of contaminants has been merely developed to address, as regards plants, any substance unintentionally added to food as a result, *inter alia*, of the production of such *food*, and further industrial processes related to it, or as a result of environmental contamination, and not as a result of the production of the *plant* itself.

142. As an example to further illustrate this, the Codex also defines, as a distinct definition, the notion of pesticide residue, which covers the presence in food of any derivative of a pesticide, namely any substance used at the stage of plant growth and intended to control pests.

143. If that Codex definition of contaminant were to cover any substance unintentionally present as a result of the production of the *plant*, and include the modification created by gene transfers, or the resulting protein, then most if not all genes and the resulting proteins of conventional plants would be contaminants, as all genes and proteins result from genetic modifications created by gene transfers through sexual crosses, making gradually the genetic makeup of the plant over long evolutionary times!

144. Even if the hypothesis above would be limited, for any particular reason, to major changes in the genetic makeup of the plant brought about by the genetic modification, this would also cover a large subset of genes and corresponding proteins in conventional plants.

145. There is, on top of that, absolutely no basis in the Codex definition of contaminant to enable the distinction of such genes and proteins, whether from GM or non-GM plants, and to cover selectively those of GM origin. Furthermore, that artificial distinction, if it were to be retained, would not withstand the most rudimentary scientific scrutiny.

146. Finally, as the European Communities has stated already in its first written submission,[45] a genetic modification is introduced into a GMO intentionally, as the genes and the expressed proteins are first designed and created on a "vector", outside of the plant, with the final aim of their expression in the GM plant, before being intentionally introduced into the plant. As a consequence, the genetic construct is indeed introduced intentionally into the plant genome, and these introduced genetic modifications, as well as the expressed proteins, can therefore not satisfy the Codex definition of a contaminant.

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

147. A toxin is "a poisonous substance produced during the metabolism and growth of certain microorganisms and some higher plant and animal species."[46] (see also reply to question 3). The Codex working definition of a contaminant is referred to in the previous question.

148. The unintentional production of a poisonous substance during the metabolism and growth of a plant may, therefore, be covered by both definitions of toxin and contaminant[47]. This may apply

[45] First written submission of the European Communities, paragraph 404,
[46] See http://www.biology-online.org/dictionary.asp [last visited on 15 June 2004]

equally to both GM and non-GM plants. In these cases, the production by GM or non-GM plantes of such unintentional toxins may be considered as toxins in the context of the Annex A *SPS Agreement.*

149. In this respect, any individual GMO must be assessed on its own individual merits, among other things, for the presence or not of toxic substances. In doing so, the procedure of risk assessment looks primarily and first of all at the potential toxicity of the intentionally introduced specific genetic modification and the newly expressed proteins and characters. These, as explained in the first written submission of the European Communities, may *not* be covered by either the definition of contaminant, or the scope of annex A of the *SPS Agreement.*

150. Furthermore, the expression of an unintended protein in a GM plant may cover many distinct potential impacts, including some falling outside of the *SPS Agreement.* These impacts may be distinct from any toxic properties and relate to human health issue (for instance the allergenic potential of the protein), to plant or animal health, or to other ecological issues.

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

151. Yes. There are many different means by which a GMO can affect biological diversity without affecting the relevant wild flora and/or fauna.

152. Biological diversity is defined in international law as:

> the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.[48]

153. A very narrow perception that the negative effects of GMOs on biological diversity may only result from a negative impact on the wild flora (plants) and/or fauna (animals) would represent an extremely reductionist analysis of the causal relationships at stake, and be the consequence of a significant lack of appropriate scientific expertise in the relevant ecological sciences[49].

154. Only as a few examples, these negative impacts on biological diversity may result from:

- A positive effect on the wild fauna and/or flora. For instance, the GMO may have a positive impact on one or more of the species of the relevant ecological area, thereby disrupting the delicate equilibrium between living organisms in a particular ecosystem, and, through complex population behaviours, have a negative impact on the variability of organisms, the ecological complexes, or the diversity within species, between species and of ecosystems, without affecting directly any of the species at stake.

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[47] See also paragraphs 405 and 406 of the first written submission of the European Communities.

[48] See Article 2 ("use of terms") of the Convention on Biological Diversity, 5 June 1992.

[49] For some background information, see The Ecological risks and benefits of genetically engineered plants. L.L. Wolfenbarger and P.R. Phifer. Science. vol. 290. 15 December 2000. pp. 2088-2093. Exhibit EC-126. Also Snow AA. Et al. (2004) Genetically engineered organisms and the environment: current status and recommendations. The Ecological Society of America. See Exhibit EC-129.

- A negative effect of the GMO on micro-organisms which are neither plant pests nor disease causing organisms (and thereby outside of the scope of the *SPS Agreement*). For instance the GMO may have a negative impact on some soil or aquatic micro-organisms, which in turn may have a key role in the interaction between species, and may thereby dramatically disrupt the equilibrium between all organisms in a particular ecosystem, and through complex interactions, have a negative impact on the variability of organisms, the stability of ecological complexes, and the diversity within species, between species and of ecosystems.

- A modification of the mutual interaction between two organisms of the ecological complex, without having any negative impact on the wild flora and/or fauna. For instance a GMO plant may influence the trophic interaction between two other species of the ecological complex, for instance through its mere physical presence, or through the synthesis of a chemical having a pheromone activity towards some animal species, or having a chemotactic activity towards some soil micro-organisms. The modification of the trophic interactions between these two other species may in turn indirectly result in a significant disequilibrium of the biological diversity of the relevant ecosystem.

- A negative impact on the biogeochemical processes in a particular ecosystem. A GMO may, for instance through its roots exudates, modify the biogeochemical composition of the soil, in a way which does not affect directly the wild fauna or flora, but which will modify the equilibrium of the ecosystem, and potentially affect the variability between species, or the diversity within species, between species and of ecosystems.

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

155. As explained in the answer to question 25, the herbicides conventionally used for weed control in crops are selective herbicides, *i.e*. they kill selectively specific weeds, and the selectivity of such herbicides is often limited to one crop, or group of crop species; their use is sometimes only limited to some varieties of that crop. In general the efficacy of these selective herbicides has a limited spectrum, *i.e*. certain weed species may not be controlled.

156. By contrast, the herbicide resistance currently conferred by genetic modification to GMOs are radically different, as they confer resistance to non selective (total) herbicides, *i.e.* an herbicide that kill all plant species. But they can be used on a specific crop that has no natural tolerance to it when that crop has been engineered to resist to that total herbicide by the introduction of bacterial genes. The aim to tailor a target crop to resist a non selective herbicide is to have a broader spectrum of weed control, as well as tying together herbicide producers and seed companies in order to try expand their market shares.[50]

157. At present two non-selective herbicides, glyphosate and glufosinate, are the dominant compounds; they have also relatively more benign environmental and human health impacts than some other non selective or even selective herbicides.

[50] See first written submission of the European Communities, Fn. 137, 145.

158. As said earlier, there would be an obvious lack of logic to believe that the issues of potential negative impact on human or animal life or health that may be associated with herbicide resistance in the different types of crops are similar as regards GM and non GM crops, given that it is currently not possible to confer resistance to these "environmentally friendly" non-selective herbicide through conventional breeding.

159. Some examples of concerns have been identified earlier: building of unexpected resistance pattern, such as multiple resistance,[51] management of multiple resistant volunteers or wild relatives, new problems related to crop management when successive crops in rotation do contain non selective herbicide resistance and therefore generate new herbicide management problems; loss of the ability to use these "environmental and human health friendly" non selective herbicides in certain circumstances, overtaking by resistant volunteers because of successive use of the same crops, no tillage and careless crop management, need to resort on other weed killers that may have negative effect on the environment,[52] etc…

160. The situation referred above for Argentina gives an indication of some potential health effects that may result from difficulties in properly managing the use of the technology, and as a consequence, the need to resort to other more dangerous herbicides.

161. For further references on the specific questions raised by herbicide resistance traits in GM crops, see the answer to question 25.

162. Furthermore, reliance on a single limited technology, if it is adopted by a majority of farmers, may lead to a dramatic increase of the surface where the corresponding herbicide will be used. This may in turn increase significantly the presence of the two non selective herbicides or their corresponding metabolites in table water, and drinking water reserves, possibly above maximum limits of residues.

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

163. See answers to questions 25 and 30.

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

[51] See for instance in Canada:
Hall L. et al. 2000. Pollen flow between herbicide-resistant Brassica napus is the cause of multiple-resistant B. napus volunteers. Weed Science 48, 688-694.

Ellstrand, Norman C. 2001. When transgenes wander, should we worry ? Plant physiology Vol. 125, p. 1543-1545.

[52] See the account of GM herbicide resistance management problems due to the mishandling of the technology in Argentina. New Scientist. 17 April 2004. Argentina's bitter harvest. Sue Branford. pp. 40-43. See Exhibit EC-122.

164. The IPPC definition of "pest" refers to

> any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.[53]

165. Obviously, to be a pest, according to the IPPC definition, the plant has to be directly or indirectly injurious to plant or plant products.

166. The recently adopted International Standards for Phytosanitary Measures N°11[54], which is relevant to perform the pest risk analysis of a GMO, further indicates in paragraph 1.1 (initiation point) that

> In order to be categorized as a pest, an LMO [GMO] has to be injurious or potentially injurious to plants or plant products under conditions in the pest risk analysis area. This damage may be in the form of direct effects on plants or plant products, or indirect effects.

167. In its annex 3, that ISPM outlines potential categories of phytosanitary risks relevant for an LMO [GMO] to be a pest:

> Potential phytosanitary risks for LMOs may include:
>
> a. Changes in adaptive characteristics which may increase the potential for introduction or spread, for example alterations in:
>
> – Tolerance to adverse environmental conditions (e.g. drought, freezing, salinity etc.)
>
> – Reproductive biology
>
> – Dispersal ability of pests
>
> – Growth rate or vigour
>
> – host range
>
> – Pest resistance
>
> – Pesticide (including herbicide) resistance or tolerance.
>
> b. Adverse effects of gene flow or gene transfer including, for example:
>
> – Transfer of pesticide or pest resistance genes to compatible species
>
> – The potential to overcome existing reproductive and recombination barriers resulting in pest risks

[53] ISPM N° 11: Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms [FAO, April 2004]. Exhibit EC-130.

[54] *Ibidem*.

– potential for hybridization with existing organisms or pathogens to result in pathogenicity or increased pathogenicity.

c. Adverse effects on non-target organisms including, for example:

– changes in host range of the LMO, including the cases where it is intended for use as a biological control agent or organism otherwise claimed to be beneficial

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

– capacity to vector other pests

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

d. Genotypic and phenotypic instability including, for example:

– reversion of an organism intended as a biocontrol agent to a virulent form.

e. Other injurious effects including, for example:

– phytosanitary risks presented by new traits in organisms that do not normally pose phytosanitary risk

– novel or enhanced capacity for virus recombination, trans-encapsidation and synergy events related to the presence of virus sequences

– phytosanitary risks resulting from nucleic acid sequences (markers, promoters, terminators, etc.) present in the insert.

168. In the specific case of gene flow, that annex clarifies that

> In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk.

169. It follows from this that the pest analysis of a plant in order to determine whether it is a pest, including in the case of gene flow, or rather as a consequence of gene flow, is based on the traditional case by case approach, which requires in the case of the pest risk analysis to identify whether the introduced gene has a potential phytosanitary risk.

170. As a consequence, to answer the Panel's question, it is not the undesirable character of a cross-breed of plant that would make it considered, as a general rule, to be a "pest", but rather, on a case by case basis, the specific properties of the gene(s) introduced in that cross-breed, and in particular its potential phytosanitary risk.

171. Therefore, there cannot be a general rule that any undesirable cross-breed of plant be considered to be a "pest", because the mere presence of a transgene may be undesirable but not present any phytosanitary risk.

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

172. As explained in para. 425, the development of resistance in target insects is not a question of establishment or spread of a pest. The pest, i.e., the insect in question, is already there and will also not spread to other areas. The problem is rather one of treatment of a pest. Where insects have become resistant to Bt crops, the field will need to be sprayed with additional insecticides in order to get rid of the pest. The increased use of insecticides raises environmental concerns falling outside the scope of the *SPS Agreement* (on the differences between pesticide resistance issues in GMO crops and in conventional crops see reply to question 25, paras. 118 et seq.).

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

173. The impact of any GMO, transgene, or product of expression of such transgene on soil micro-organisms may not be systematically considered as a pest risk, as it requires, as has been explained in the reply to question 32, a case by case analysis of the phytosanitary risk at stake (the potential to be injurious to plant or plant products).

174. Furthermore, as regards the case of the effect of the protein Bt on soil microorganisms as referred to in paragraph 46 of the EC's first oral statement, the protein in itself, once present in the soil, cannot be considered as a pest, as the protein in itself has no injurious effect on plant or plant product.

175. The potential maintenance of the Bt protein in the soil can manifest itself after the plant has been harvested, or destroyed. Therefore, neither the Bt protein itself, which cannot be considered in itself as a pest, nor the Bt plant, which would not be a pest *per se*, as defined in the IPPC, since it will primarily affect insects and other organisms of the trophic chain, would enable to meet the criteria of "damage from entry, establishment or spread of a pest".

176. Lastly, even if the Bt plant were considered to be a pest according to the IPPC criteria, once the plant has been harvested or destroyed, it cannot satisfy anymore the requirements of entry, establishment, or spread, while the effect of the Bt protein may still manifest itself on the soil microorganisms. These requirements being not met, this situation would not be covered by Annex A 1 (d) of the *SPS Agreement*

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

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

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

177. To (a): The object and purpose of this requirement, as of all others in Annex C, is to provide certain minimum guarantees in the application of control, inspection and approval procedures. International trade is affected if Members abuse such procedures to prevent the import of goods. The procedural requirements in Annex C are designed to foil such abuse.

178. The requirement to undertake and complete procedures without undue delay is particularly important in the context of approval procedures, as the marketing of products depends on the outcome of such procedures. Clearly, the SPS provisions dealing with substantive measures such as bans or import conditions cannot be applied to mere delays, and therefore a correct application of Annex C(1)(a) is essential to tackle problems relating to the *application* of SPS measures.

179. To (b): The provision does not provide for or define a specific timeframe, which means that it has to be determined on a case by case basis whether undue delays have occurred. It is correct that a delay in the completion of procedures does not result *ipso facto* in a breach of Annex C(1)(a). Instead it has to be demonstrated that such a delay is "undue." Whether a "delay" is "undue" is not a question of a "threshold level" in the duration of the delay, but rather of the reason(s) for that delay. Those reasons have to be legitimate. It constitutes a legitimate reason, *inter alia*, if procedures are delayed because of requests for additional information pertaining to risk assessment and risk management concerns, which are considered necessary to achieve an outcome that meets the desired level of protection.

36. With respect to those applications originally submitted under EC Directive 90/220 and subsequently "re-submitted" under EC Directive 2001/18, did the re-submission of these applications mark the beginning/opening of a new procedure for the purposes of Annex C(1)(a) of the SPS Agreement, or is/was there only one single procedure? What are the implications of your reply for the calculation of the length/duration of the relevant approval procedure(s)? Specifically, from what time/event should the length be calculated (e.g., when the original procedure was initiated under EC Directive 90/220; when the second procedure was initiated under EC Directive 2001/18)?

180. The re-submission of the pending applications, from a point of view of EC law, did not mean the beginning of a new procedure, but merely the completion of an existing procedure (see also reply to question 12). In the European Communities' view, the reply remains the same, if the question is looked at from a WTO law point of view, and more specifically from the point of view of Annex C point 1 (a).

181. However, for the purpose of identifying delays, and more importantly undue delays, the re-submission represents the starting date for the reasonable period of time needed to examine the new information and to conduct a risk assessment of the newly identified issues. The EC notes that the re-submission requirement in the new legislation has, as such, not been challenged by the Complainants (or, for that matter, by any of the applicants at national judicial level).

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

182. According to Annex A, Point 1, sanitary or phytosanitary measures include … "testing, inspection, certification and *approval procedures*."[emphasis added]. It would seem clear from this provision that an approval procedure can constitute an SPS measure.

183. As it has stated in its first written submission, to the extent that it addresses risks coming under point 1 of Annex A of the *SPS Agreement*, the European Communities accepts that the approval system set up under the relevant EC GMO legislation is an approval procedure within the meaning of the *SPS Agreement* and, in particular its Annex C.[55]

184. The European Communities would first observe that according to its Article 1.1, the provisions of the *SPS Agreement* apply to both the development and the application of SPS measures and different provisions of the agreement address development and application.

185. Whether or not the development of approval procedures such as those of the GMO legislation are subject to Articles 2.2, 5.1, 5.5 and 5.6 of the *SPS Agreement* need not be decided because the Complainants have not attacked the development or the content of the approval procedures.

186. They have only contested the application of these procedures and specifically the delay that they consider has been unduly incurred in a number of cases. The provisions that address this issue are Article 8 and Annex C. Articles 2.2, 5.1, 5.5 and 5.6 by their terms apply to the development, adoption and maintenance of SPS measures rather than their application. To the extent that any of these provisions may be relevant to the application of an approval procedure and especially alleged delays, the matter is dealt with more specifically in Annex C which the Panel should therefore address first.

187. Article 8 offers clear textual support for this interpretation. In its first sentence, it speaks about "the operation of approval procedures," and specifies that Annex C contains the relevant rules in that regard. On the other hand, the second sentence speaks of "procedures" as such, that is, the SPS measure itself and not its application. There, it also specifies that the other SPS obligations may be relevant. Therefore, Article 8 reaffirms the distinction made in Article 1.1 between the development and the application of an SPS measure.

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

(a) Which is the relevant "Member" for the purposes of the Panel's analysis of the complaining parties' challenges? Is it: (i) the member State applying the safeguard measure or (ii) the European Communities as a whole?

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

188. Article 5.5 *SPS Agreement* uses the words "distinctions" and "discrimination". There are many different types of distinction or discrimination. The obvious example of discrimination within the meaning of Article 5.5 *SPS Agreement* would be if a Member fixed different appropriate levels of protection for essentially identical products, according to the Member of origin. That is not at all the

[55] First written submission of the European Communities, para. 474.

type of distinction with which we are here concerned. Rather, the type of distinction with which we are here concerned relates to the various parts of the territory of the Member applying the measure.

189. Thus, at the heart of this question is the question of whether or not, as a matter of WTO law, the appropriate level of protection can be different for different parts of a territory. The answer to that question is certainly: yes.

190. This emerges clearly, for example, from Article 5.2 *SPS Agreement*, according to which the factors that must be taken into account include : the existence of pest- or disease-free areas. The use of the word "areas" is significant. It indicates that there may be a certain area or territory – it might, for example, be a national park of some kind – in which a certain pest or disease is currently unknown. For that area, the appropriate level of protection might be different compared to the rest of the relevant territory.

191. Similarly, Article 5.2 *SPS Agreement* also refers to "relevant ecological and environmental conditions" – again, a factor that may differ according to the territory under consideration.

192. Furthermore, Article 6 *SPS Agreement*, which is entitled Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence, provides in relevant part :

> 1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area - whether all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, *inter alia*, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.
>
> 2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

193. Finally, the European Communities would also draw the Panel's attention to the important difference between a *definitive* measure, and a *provisional* measure, adopted, for example, pursuant to Article 5.7 *SPS Agreement*, the two types of measure being different in a number of important respects.

194. This is the context within which Article 5.5 *SPS Agreement* must be interpreted. In this context, "the Member" referred to in Article 5.5 *SPS Agreement* is, in the present case, the European Communities. Thus, in principle, what the Panel would have to consider would be whether or not the actions of the European Communities on the question of the appropriate level of protection are consistent.

195. It is correct that the European Communities is also responsible for the actions of the Member States of the European Communities. However, the Panel must note that the Member State measures in this case are *provisional* measures adopted on the basis of Article 5.7 *SPS Agreement*. As explained in the first written submission of the European Communities, the sufficiency or insufficiency of scientific evidence is a function of the appropriate level of protection sought by the legislator; and that

in turn is a function of the specific objectives sought by, and the risks and benefits weighed by, the specific legislator. That in turn is a function of the specific territory with which the specific legislator is concerned. In other words, one cannot, in the context of Article 5.5 *SPS Agreement*, meaningfully assert an inconsistency between the *definitive* actions of the European Communities on the one hand, and the *provisional* actions of the Member States (for which the European Communities are responsible in the WTO) on the other hand, because the two types of measures are fundamentally different. For the same reason, it is meaningless to assert an inconsistency between the different *provisional* actions of legislators concerned with different territories, precisely because they are not concerned with the same territory. Similarly, the European Communities does not consider that Article 5.5 *SPS Agreement* is concerned with the consistency of the behaviour of regional authorities within a Member's territory within a provisional temporal frame of reference.

196. What the European Communities does accept is that the various situations referred to by the Complainants cannot endure indefinitely. That is why, over the relevant period and today, it has engaged in a process of taking the steps necessary to bring matters into line : on the one hand, where appropriate, adapting legislation at Community level to take into account the legitimate concerns of legislators and scientists across the Community; and, on the other hand, taking such reasonable measures as are available to it with respect to the Member States. None of the Complainants have alleged, let alone proven, that in respect of these matters the European Communities has acted inconsistently with Article 5.5 *SPS Agreement*.

197. Two further comments. First, as regards the alleged moratoria, the European Communities recalls that Article 5.5 *SPS Agreement* is irrelevant, because it only applies when Members have *determined* the appropriate level of protection, in accordance with Article 5.4 *SPS Agreement* – that is, when they have adopted a measure. If the complaint in reality relates to alleged delay, the relevant provision is Annex C *SPS Agreement*. Second, a measure adopted for reasons that fall outside the defined scope of the *SPS Agreement* cannot disclose any inconsistency with Article 5.5 *SPS Agreement*. All the Member State measures were adopted for reasons that fall, in whole or in part, outside the scope of the *SPS Agreement*.

198. The answer to question 38(a) is thus the European Communities as a whole and 38(b) yes, either permanently or provisionally.

For the European Communities:

78. With reference to para. 409 of the EC's first written submission, could the European Communities please indicate what is the difference between a "disease" and a "medical condition"?

199. The EC legislation is differentiating between "disease," "disorder" and "medical condition"[56]

200. A "disease" refers to a pathological situation: according to the IOE definition quoted in para. 407 of the EC's first written submission, the clinical and/or pathological manifestation of infection.

201. A "medical condition" could, in some cases, be the result of a disease but is not a disease in itself (*e.g.* some types of blindness); it is however generally of a broader acceptance and covers conditions, originating from some specific disorders, which may be the consequence of, for instance,

[56] See for instance article 4, paragraph 4 (a) of the Commission Directive (EC) 1999/21 of 25 of March 1999 on dietary foods for special medical purposes. OJ of the EC N° L 91 of 07.04.1999, p. 29.

living behaviour, and may be fully independent of diseases; these medical conditions may require specific medical attention, such as obesity, blindness, allergy, amputation, post operation treatment.

202. Further examples of a medical condition are the need for a special diet, because you cannot eat after an operation, or the fact that you may not expose yourself to specific allergens because of either atopic reactions, or because of specific allergies to certain epitopes (e.g. a specific diet devoid of any contact with certain food components, due to an allergy to these components, in the same way as confinement at the time of flowering due to allergy to pollen, or obligation to carry in the summer antihistaminic treatment due to allergy to wasp venom; etc…).

79. With reference to para. 126 of the US first written submission, what is the extent of use of GM processing aids within the European Communities?

203. The definition of "Processing aid" for the purpose of the Codex Alimentarius, is:

> any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.[57]

204. In practice, genetically modified micro organisms may have been and have been used as sources of processing aid, for instance in the production of specific enzymes used as a processing aids.

205. As regards the question of the extent of the use of genetically modified processing aids within the European Communities, such processing aids were not regulated at the Community level, first and foremost because they did not fall within the definition of food ingredient, nor within the scope of the legislation on Novel food[58] covering food ingredients containing or derived from GMOs. The situation at the time was equivalent to that of some other substances falling outside of the definition of food ingredient, such as additives or flavouring substances.

206. Processing aids are not covered by the definition of food in the new EC general food law[59] and have remained unregulated at the Community level, on the grounds that they are not meant to be intentionally present in the final food product.

207. The fact that processing aids are not regulated, at least at the Community level, as a consequence, does not allow to have directly available relevant information regarding the extent of use of GM processing aid within the EC. This information may be partially available in some Member States, or with the food industry, but would require more time to be collected.

208. However, the scarce information available indicates that GM processing aids have been widely used within the European Communities, since at least 15 years, but it is not possible at this stage to indicate what is the percentage of GM processing aids (or additives isolated from GMOs) in the total quantity of processing aids (or additives) used.

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[57] Tenth edition of the procedural manual of the Codex Alimentarius Commission. FAO. 1997, see Exhibit EC-117.

[58] Regulation (EC) 258/97.

[59] Regulation (EC) 178/2002.

80. Please summarize the conclusions of the "Opinion of the Scientific Panel on GMOs on the use of antibiotic resistance genes as marker genes in genetically modified plants". Explain what relevance, if any, this report may have in light of the EC arguments at para. 49 of its first written submission.

209. EFSA issued its "Opinion of the Scientific Panel on Genetically Modified Organisms on the use of antibiotic resistance genes as marker genes in genetically modified plants. (Question N° EFSA-Q-2003-109)" on 2 April and published it on 16 April 2004. As usual, EFSA also provided a Summary of this opinion,[60] which best synthesises EFSA conclusions:

> Directive 2001/18/EC (EC, 2001) states that Member States and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment. This is with a view to identify and phase out antibiotic resistance marker genes (ARMGs) in GMOs which may have adverse effects on human health and the environment.
>
> The Scientific Panel on genetically modified organisms (GMO Panel) of the European Food Safety Authority (EFSA) has evaluated the potential risks associated with specific ARMGs taking into account their current usage in clinical and veterinary medicine, the likely occurrence of horizontal gene transfer from genetically modified (GM) 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. These factors will impact on the likelihood of any adverse effects on humans or the environment of ARMGs used in GM plants.
>
> The GMO Panel considers the frequency of horizontal gene transfer from GM plants to other organisms as very low for all ARMGs considered. This, in itself, is an important consideration with regard to any risk posed by the use of ARMGs. However, with respect to clinical importance the Panel has categorised ARMGs into three groups with different potentials for compromising human health and the environment. ARMGs in the first group include genes conferring resistance to kanamycin and hygromycin. In this group the nptII gene, which confers kanamycin resistance, has a 13-year history of safe use in food crops and resistance to this group of antibiotics is widespread in naturally occurring microbes in humans and the environment. The Panel is of the opinion that with regard to safety there is no rationale for inhibiting or restricting the use of genes in this category, either for field experimentation or for the purpose of placing on the market. The second group of ARMGs, which includes resistance to chloramphenicol, ampicillin, streptomycin and spectinomycin, should be restricted to field trial purposes and should not be present in GM plants to be placed on the market. Given their current importance in clinical usage, the GMO Panel recommends that ARMGs placed in the third group, which includes those conferring resistance to amikacin and tetracyclines, are not present in GM plants to be placed on the market or in plants used for experimental field trials.

210. The Opinion thus confirms, with regard to the second and especially the third group of ARMGs, the concerns expressed in paragraph 49 of the EC first written submission that

[60] The opinion and its Summary are available at <http://www.efsa.eu.int/science/gmo/gmo_opinions/384_en.html> (last visited on 11 June 2004).

> The uptake of antibiotic resistance genes could potentially result in the development of antibiotic resistance of human bacteria against known antibiotic medication. Thus, important and existing medical treatments may become ineffective in the fight against severe diseases.

81. Regarding the operation of the EC approval procedures, has the European Communities in recent years been guided by the Codex principles and guidelines for the safety assessment of GM foods, including assessment for potential allergenicity?

211. Yes. Although the Codex principles and guidelines for the safety assessment of GM foods are indeed very recent (July 2002), the European Communities has traditionally been guided in the safety assessment of GM foods, including in the assessment for potential allergenicity, by principles that are analogous to the ones now codified by Codex.

212. The recent "Draft guidance document for the risk assessment of genetically modified plants and derived food and feed" published by EFSA in April 2004[61] (and to be adopted soon) well demonstrates this correspondence. In particular, in section 7.9 dealing with allergenicity, it states that:

> In line with the recommendations of the Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (Codex Alimentarius, 2003), an integrated, stepwise, case-by-case approach, as described below, should be used in the assessment of possible allergenicity of newly expressed proteins[62].

213. Thus, Codex and EFSA suggest similar methodology for the assessment of allergenicity based on identification of the protein, amino acid sequence homology, specific serum test, in vitro tests and, if necessary, specific (targeted) serum screening analysis. EFSA guidelines follow the same approach of Codex also with regard to the assessment of possible toxicity as well as on a number of other aspects.

214. Moreover, both the Codex and the EFSA guidelines refer in several parts to the Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology, entitled "Evaluation of Allergenicity of Genetically Modified Foods" (22-25 January 2001, Rome, Italy)[63].

215. Finally, it should be noted that the new legislation on GM food and feed (Regulation 1829/03, Exhibit CDA-20) establishes an authorisation system which takes into account to a large extent Codex principles of risk analysis (such as the case-by-case approach) and of risk management (e.g., post market monitoring, detection methods, reference material, traceability, etc.).

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[61] Available at <http://www.efsa.eu.int/consultation/372/consultation_guidance_gmo_01_en1.pdf> (last visited on 12 June 2004) (Exhibit EC-131).

[62] *Ibidem*, page 26.

[63] Available at <http://www.who.int/foodsafety/publications/biotech/en/ec_jan2001.pdf> (last visited 12 June 2004).

82. Other than "reasoned requests" for additional information referred to at para. 149 of the EC first written submission, on what other grounds can the competent authority justify not issuing its opinion within 90 days?

216. Paragraph 149 of the EC First Written Submission paraphrases Article 14.4 of Directive 2001/18 which expressly excludes from the calculation of the 90 day period, within which the competent authority has to issue its opinion on the notification, "any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier." However, the same Article 14, at paragraph 3, requires the competent authority to send to the Commission its assessment report

> together with the information referred to in paragraph 4 and any other information on which it has based its report … (emphasis added).

217. It is therefore considered that any time spent by the competent authority to collect and analyse such other information, if justified, can warrant a suspension of the 90 day period (in the EC jargon a "clock-stop"). Finally, exceptional, unforeseen circumstances could also play a role in delaying the issuing of the competent authority's assessment report. In any case, a "clock-stop" must always be justified and communicated to the notifier (see Article 14.4 of Directive 2001/18).

218. In the notifications procedure at issue in this case, all "clock-stops" can be easily identified in the individual chronologies attached to the EC first written submission[64]. Thus, for instance, in the case of notification C/SE/96/3501, potato with an altered starch composition (Amylogene HB),[65] the "clock stopped" a number of times because of various requests for additional data. Below, the Panel will find an extract of the chronology already submitted for this notification as Exhibit EC-67, with the details of the count of the "clock stops" at Member State level under Directive 2001/18/EC.

17/01/2003 Updated notification

Day 1 – Start of the 90-day period

23/01/2003 SNIF not complete

Day 6– Clock stopped

24/01/2003 SNIF updated and complete

Day 7 – Clock restarted

10/02/2003 Request for additional information (Exhibit EC-67, attachment 30)

Day 23 – Clock stopped

23/06/2003 Updated risk assessment and monitoring program are provided

Day 24 – Clock restarted

30/07/2003 Request for additional information (Exhibit EC-67, attachment 31)

[64] See Exhibits EC-62 to EC-76.
[65] See Exhibit EC-67.

Day 60 – Clock stopped

25/09/2003 Information received and additional information requested at the same meeting

Day 60 – No time elapsed between provision and request

25/09/2003, 04/12/2003 Partial answers

Day 60 – No time elapsed, CA still waiting for parts of answer

20/02/2004 Complete answers received and additional information requested at the same meeting

Day 60 – No time elapsed between provision and request

10/03/2004 Information received

Day 61 – Clock restarted

15/03/2004 Request for additional information

Day 65 – Clock stopped

18/03/2004 Information provided (complete notification)

Day 66 – Clock restarted

08/04/2004 Submission of assessment report and notification to the Commission

Day 86 – Assessment completed

83. With reference to para. 151 of the EC first written submission, on what grounds can the "normally 60 days" period be exceeded?

219. Article 15.1 of Directive 2001/18 (and, previously, Article 13.2 of Directive 90/220) provides for a period of 60 days, from the date the Commission circulates the lead CA's assessment report, in which the other Member States can make comments or raise reasoned objections. In the presence of any of these, another period of 45 days is warranted in order to "discuss outstanding issues with the aim of arriving at an agreement". According to this provision, any periods of time during which further information from the notifier is awaited is not taken into account to calculate this 45 day period (so-called "clock stop").[66]

220. In practice, requests for further information following comments or objections raised by Member States are forwarded to the notifier at the expiry of the 60 day period, i.e. as soon as the issues which are outstanding become clear, and before the starting of the 45 day period. The procedures followed by the Commission can be resumed along these lines:

[66] For all the details of the procedure, see Exhibit EC-118.

– if, at the end of the 60 day period, there are requests for additional information, the clock is stopped, i.e. before the 45 day period begins;

– all requests for additional information are channelled by the lead CA to the notifier;

– when the notifier supplies additional information, this is circulated in the same way as the full notification, i.e. the lead CA forwards it to the Commission who circulates to the other competent authorities;

– the clock re-starts, i.e. the 45-day period begins, on the date of circulation of the additional information. As with the 60-day deadline, the clock is not stopped during this 45-day period, i.e. the 45-day deadline is set when the additional information is circulated and does not change. Competent authorities who requested additional information thus have a maximum of 45 days to inform the Commission whether or not they intend to maintain their objections. Competent authorities may decide to confirm their intentions sooner than the 45 day maximum limit.

221. Thus, for instance, in the case of notification C/ES/00/01, Roundup Ready maize NK 603,[67] the "clock stopped" for five months between the end of the 60 day period and the beginning of the 45 day period in order to gather the information necessary to address the comments and/or objections raised by the Member States. Below, the Panel will find an extract of the chronology already submitted for this notification as Exhibit EC-76, completed by the details of the count of the "clock stops".

24/01/03	Circulation to all CAs of application and assessment report
Day 1 – Start of the 60-day period	
25/03/03	Additional data are required. Comments/objections are raised by CAs
Day 60 – Clock stopped	
26/03/03 - 04/04/03	Circulation to all CAs of comments/objections/requests for further information (Exhibit EC-76, attachments 8 and 11-20)
09/04/03	Meeting with COM, lead CA and the notifier
28/04/03	Meeting with COM, notifier and all CAs in order to solve the outstanding issues
11/06/03	Notifier provided lead CA with additional data (Exhibit EC-76, attachment 21)
25/06/03	Lead CA provided COM with additional non-confidential data
08/07/03	Lead CA provided COM with additional confidential data
15/07/03	Additional data have been circulated to all CAs

[67] See Exhibit EC-76.

Day 1 – 45-day period started

27/08/03 UK, DK maintain their objections raised during the 60-day period

Deadline for the 45-day period

84. Regarding a decision by an EC member State to take a safeguard action, what is the normal time frame under relevant EC legislation for the various steps to be taken under this procedure (e.g., decision by the member State; informing of the Commission and other member States, etc.)?

222. The response is different according to which legislation is concerned.

223. Directive 90/220, Article 16 does not specify what the period of time may be between the written consent under the Directive and the provisional measure that may be adopted by the Member State. In these circumstances, it is not really possible to identify a "normal" time frame within which such provisional measures may be adopted. In principle, they might be adopted some time after the consent, especially if new information had come to light, or existing information had been re-assessed. That said, the provisional Member State measures in this case were generally adopted shortly after the written consents.

224. Directive 90/220, Article 16 provides that the Member State shall immediately inform the Commission and the other Member States. Normally, therefore, a Member State would inform the Commission very quickly – generally within a few days or weeks – and would also keep the Commission abreast of any subsequent developments, such as extensions of the provisional measures, or any developments in the information or assessments on the basis of which the measures are maintained.

225. Directive 90/220, Article 16(2) provides that a decision shall be taken within three months in accordance with the procedure laid down in Article 21. In practice, this is generally understood to refer to three months from the date on which the Commission receives information from the Member State adopting or maintaining the provisional measure. In principle, each time the Commission receives new information from the Member State, whether in relation to the adoption or maintenance of the same provisional measure, then, if specific action is required, the time for such action would be three months.

226. Directive 90/220, Article 16(2) does not specify what specific decision must be taken within three months – only that "a decision" shall be taken within three months in accordance with the procedure provided for in Directive 90/220, Article 21. Pursuant to that provision, the first decision that might be taken would be a decision by the Commission to submit to the committee a draft of the measures to be taken – if any measures are required. The last decision that might be taken would be the adoption of any proposed measures by the Commission, on the expiry of the further three month period referred to in the final paragraph of Article 21. The amount of time that might intervene in the meantime would depend on all the specific circumstances of the case.

227. The Commission might also decide that no measures need to be taken, in which case it would be unnecessary to make a proposal to the committee.

228. In the present case, normally, that is, with respect to all the Member State measures, there was no further decision within the meaning of the final three paragraphs of Article 21.

229. The provisions of Directive 2001/18, Articles 23 and 30(2), which refers to Decision 1999/468/EC, Articles 5, 7 and 8, are similar. These provisions are summarised in the flowcharts in Exhibits EC-118 and EC-120. The Commission should be informed immediately and a decision should be taken within 60 days, although this period is suspended for up to 60 days if the Scientific Committee is consulted, and longer if more information is requested from the notifier.

230. The equivalent provisions of Regulation 258/97 are Articles 12 and 13.

85. Can the European Communities identify other situations where the replacement or revision of EC legislation has resulted in a suspension of decisions, or suspension of imports, pending the revision of existing legislation?

231. In the regulatory policy history of the Community (as well as probably in that of many other WTO Members), it is common that in relation to emerging issues of human and/or animal health and the environment, the revision of existing legislation on specific products, brought about by changes in scientific knowledge or different awareness of the risks at stake, implies a temporary prohibition of their use (and not just their import) which remains in force until they become regulated.

232. Thus, for instance, in 1990, it became clear that not all effects of certain growth hormones administered to cows in order to increase milk productivity, such as Bovine Somatotrophin, were sufficiently known. Thus, while awaiting further information, the Community provisionally prohibited the administration to dairy cows of the substance in question, suspending the operation of two previous Directives.[68] In 1999, this Regulation was finally repealed and substituted by definitive legislation that prohibited any placing on the market of Bovine Somatotrophin.[69]

233. Similarly, in the year 2000, the Commission identified systematic failures in the implementation of Community rules related to the control of certain processed animal protein into ruminant feed, relevant to prevent cases of bovine spongiform encephalopathy ("BSE") from entering into the feed chain. Thus, pending a re-evaluation of Community legislation and its consequent revision, the Community enacted a total ban on the use of animal protein in animal feed.[70] The prohibition on the use in animal feed of proteins derived from certain animals or animals from certain regions has been maintained by subsequent legislation on BSE.[71]

234. In the case of food supplements, as in many other cases, instead, it's the legislation itself that regulates the hypothesis of a temporary suspension or restriction of the use of these products where:

> … a Member State, as a result of new information or of a reassessment of existing information made since this Directive or one of the implementing Community acts

[68] See Council Decision No 90/218/EEC of 25 April 1990 concerning the administration of Bovine Somatotrophin (BST), Official Journal of the European Communities L116 of 8 May 1990, page 27.

[69] See Council Decision No 1999/879/EC of 17 December 1999 concerning the placing on the market and administration of bovine somatotrophin (BST) and repealing Decision 90/218/EEC Official Journal of the European Communities L331 of 23 December 1999, page 71.

[70] See Whereas (5) to (7) of Council Decision No 2000/76/EC of 4 December 2000 concerning certain protection measures with regard to transmissible BSE and the feeding of animal protein, Official Journal of the European Communities L306 of 7 December 2000, page 32.

[71] See Article 7 and Annex IV, point 1, of Regulation (EC) No 999/2001 of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, Official Journal of the European Communities L347 of 31 May 2001, page 1.

> was adopted, has detailed grounds for establishing that a product referred to in Article 1 endangers human health though it complies with the said Directive or said acts…[72]

235. The Panel's question does not, however, appear to reflect what happened in the case of the Community legislation on GMOs and GM products, where no suspension or prohibition of use was decided.

86. Please explain to what extent the competent authority of a member State can request further information from the notifier following a positive opinion by the SCP or EFSA? Can this include requests for further information on matters specifically examined by the SCP (e.g., persistence, invasiveness, out-crossing, etc.)?

236. In accordance with international standards, and in particular with the Codex working principles for risk analysis,[73] the European Communities have implemented:

> a functional separation of risk assessment and risk management [in the risk analysis] [of GMOs], in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers, and to reduce conflict of interest.

237. However, as the Codex working principles for risk analysis notes, the European Communities recognise that:

> risk analysis is an iterative process, and interactions between risk managers and risk assessors is essential for practical application.

238. Accordingly, risk assessment opinions are released at the EU, and also often at national level, by scientific bodies, such as the SCP, or now the EFSA, which are separate and independent from the risk management level or bodies.

239. As the European Communities has indicated earlier, there is no hierarchy in sound science, and several scientific opinions on a risk assessment or part thereof may therefore coexist, and may even be potentially conflicting (see for example as an illustration, the answers of the European Communities to the 3 questions of the Panel dated 3rd of June, on the request for scientific and technical advice).

240. In the risk analysis process, it is up to the risk management level (the Commission and the Member States together) to take appropriately into account all the independent risk assessment information and opinions, as well as other relevant scientific information, such as for instance relevant articles in scientific peer reviewed journals, in order to appropriately base their opinions on them (see reply to questions 16 and 17).

241. The so-called competent authority(ies) from a Member State are part of that risk management level, which includes a sophisticated institutional framework, distinct from the risk assessment

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[72] See Article 12 of Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, OJ of the EC L183 of 12 July 2002, page 51.

[73] The Codex principles for the risk analysis of foods derived from modern biotechnology requires (paragraph 9 of CAC/GL 44-2003) that this risk analysis process be consistent with the Codex Working Principles for Risk Analysis adopted by the 26th Session of the Codex Alimentarius Commission, 2003, and presented in the Appendix IV of its report (EXH), see Exhibit EC-44.

framework, and encompassing the information exchange network between the competent authorities and the Commission.

242. In this process of risk analysis, any competent authority of a Member State is therefore entitled to request (before or after a positive opinion, e.g. by the SCP or EFSA) any further risk assessment information that it deems necessary as an appropriate scientific basis to inform its own risk management opinion. The possibility of such requests are based on the same principle that enables any Member State or the Commission to request further information, after a positive opinion of the first risk assessment which has been performed by the lead competent authority having initially received the application.

243. These requests for further information from a competent authority of a Member State may aim, for example, at resolving conflicting scientific risk assessment opinions or information at Member State and Community level, or between different Member States, at addressing any new relevant scientific information that may have become available after the issuance of a positive scientific opinion, at addressing other issues that are not covered by the scope of the request for scientific advice, which has been forwarded to the independent risk assessment body having issued a positive opinion, or at requesting, as a condition for the placing on the market of a product, risk management information or proposals to appropriately cover risk assessment issues, that are more detailed or more prescriptive than the one initially supplied by the notifier (e.g. a monitoring plan, …).

244. These requests for further information, when addressed to the notifier, are channelled through the Commission and, where appropriate, to the relevant "lead competent authority" having initially received the application and having issued the first risk assessment. The lead competent authority may, or may not, judge the request as appropriate, and forward it to the notifier. In doing so, that lead competent authority may take into account, for instance, whether the matter has been specifically and sufficiently examined in, e.g. the SCP opinion.

245. However, whether the request for further information has been forwarded or not to the notifier, and whether it has received an answer or not, it still remains within the competence of that Member State that filed the request to judge whether it has received sufficient scientific basis, according to its own appropriate level of protection, to support or not the application for a specific product. The available scientific information and opinions will form therefore the basis on which each Member State will finally vote in the "comitology" procedure to adopt the draft community measure.

246. That "comitology" procedure (see reply to question 11) is therefore *in fine* the procedure for the adoption of a specific measure based on the risk assessment, at the risk management level. In this procedure, each Member States risk management opinion is weighted against the others according to the corresponding voting rules.

87. Between October 1998 and the date of establishment of this Panel, have there been any occasions on which the five member States which had announced their intention to suspend the approval of GMOs have voted in support of the approval of a GMO?

247. There have been several instances between October 1998 and the 4th of March 2004 where the Member States, which had announced their intention to suspend the approval of GMOs, have supported the approval for placing on the market of a particular GMO, in line with a case by case approach.

248. As a few examples, this happened, for instance, for applications:

- **C/ES/96/02** (Cotton line 531): The Regulatory Committee of Directive 90/220/EEC was consulted by written procedure. Deadline for response was first 18/12/1998, then extended to 08/01/1999, then extended to 27/01/1999 and finally extended to 11/02/1999. Italy voted in favour.

- **C/ES/97/01 (**Cotton line 1445): The Regulatory Committee of Directive 90/220/EEC was consulted by written procedure. Deadline for response was first 18/12/1998, then extended to 08/01/1999, and then extended to 27/01/1999 and finally extended to 11/02/1999. Italy voted in favour.

- **C/F/95/12-01/B (**Maize MON 809): The Regulatory Committee of Directive 90/220/EEC was consulted in written procedure. Deadline for response was first 02/10/1998, and then extended to 23/10/1998. Italy voted in favour.

- **C/ES/96/02 (**Zeneca tomato**):** The Regulatory Committee of Directive 90/220/EEC was consulted in written procedure. Deadline for response was first 18/12/1998. Italy and Denmark voted in favour.

- **C/ES/00/01** (Maize NK603): The Regulatory Committee of Directive 2001/18/EC was consulted on the updated notification on 18 February 2004. France and Belgium voted in favour.

- **C/F/96/05-10** (Maize Bt11 for cultivation): The application was submitted in France. The notification was transmitted to the Commission with a favourable recommendation in April 1999. After the update of the application in January 2003, the favourable recommendation was again confirmed by the lead competent authority when the updated dossier was transmitted at Community level in June 2003.

88. At para. 11 of its first oral statement, the European Communities indicates that there has been a need identified as early as the end of the 1970s to address the potential risks of GMOs for human health and the environment differently from non-biotech products. Where was the need identified and was there subsequent action?

249. The creation of the first artificial recombinant DNA molecules in the early 70ies raised immediately issues regarding their safety, primarily human health safety issues. As an example, on experiment planned in California in 1971, to make a recombinant chimaeric molecule between genes present in bacteria and in a Simian Virus (SV40, a virus able to transform monkey as well as human cells into a cancerous state), was the source of intense scientific debate globally in the following years, regarding the need for appropriate oversight of this new technology.

250. By 1973[74] the initial developments of the powerful technique of genetic engineering, and the subsequent demonstrations that it enabled to cross kingdom's natural barriers by the engineering of one of the first genetically modified organisms (e.g. the cloning of an African frog gene (*Xenopus*) into a bacterium found in the intestinal tract of animals (*Escherichia* coli)), was the subject of much

[74] Construction of Biologically Functional Bacterial Plasmids In Vitro S. N. COHEN, A. C. Y. CHANG, H. W. BOYER, AND R. B. HELLING Proceedings of the National Academy of Sciences USA (1973) 70:3240–3244. Exhibit EC-132.

excitement of the scientific community regarding its potential uses, as well as much questioning regarding its "biohazard" at international scientific meetings. These safety questions were the consequence of this new technological ability to create novel individual combinations of genes, not present naturally, and their potential unforeseen effects, in particular on human health. This activity peaked at the infamous February 1975 Asilomar conference on recombinant DNA molecules.

251. There, the academic community made recommendations[75] for ways to deal with the potential biohazards of the work on recombinant DNA, including the development of appropriate safeguards such as the use of fastidious hosts unable to survive in natural environments, the use of non transmissible vectors, or the design of different levels of physical and biological containment procedures proportionate to the level of risks. It also recommended the development of guidelines to address these safety concerns, as well as an oversight of this research by scientific advisory committees.

252. These recommendations led to the development of such advisory bodies in several OECD countries in the following years, as well as different initiatives to regulate the products of that technology. In 1976, the first set of recombinant DNA research guidelines was issued in the USA by the National Institute of Health (NIH) in the Federal Register.[76] Despite several subsequent amendments, they have remained until now as the main source of inspiration for the regulation of contained use of GMO, and the design of appropriate containment measures for individual recombinant DNA experiments. They are certainly a definitive proof that GMOs do necessitate a specific oversight.

253. Several initiatives for appropriate governance and legislation followed (e.g. from the US Congress[77]), which initiated a strong lobbying from the academic world against the regulatory consequences of its own initiative, as it wished the guidelines to remain only voluntary and under the strict control of the research community, in order to avoid what was perceived then as unnecessary burdens. Thereafter, different regulatory paths, and drastically different scientific views, emerged gradually in different OECD countries involved with the use of that technology.

254. In retrospect, the recommendations of the 1975 Asilomar conference were actually too narrow, because the debate was essentially among molecular biologists, which were not trained enough in infectious diseases, epidemiology or human health, let alone animal health or even environmental science and ecology. There was therefore some overstating of some biohazards of recombinant DNA, as well as some safety issues that never were addressed at the time. As has been stated later regarding the relationship between the NIH guidelines for research in containment and the deliberate release of GMOs, by Allan Campbell, one of the eminent scientist participating in the Asilomar Conference, a member of the NIH recombinant Advisory Committee (RAC) from 1977 to 1981, and one of the strongest proponent of the technology, and strongest opponent of its strict research oversight:

> Both deliberate release and large-scale production were among the few areas to which Guidelines would have continued to apply under the most liberal revisions ever

[75] Asilomar Conference on Recombinant DNA Molecules. Paul Berg, David Baltimore, Sydney Brenner, Richard O. Roblin III, Maxine F. Singer. Science (1975) 188:991-994. Exhibit EC-133.

[76] Department of Health Education and Welfare. National Institutes of Health. Recombinant DNA Research Guidelines. Draft Environmental Impact Assessment. Federal Register (September 9, 1976) 41(176) 38126-38483. Exhibit EC 134.

[77] Letter of the Committee on Labor and Public Welfare, United States Senate to the President of the United States; July 19, 1976. 3 pages. Exhibit EC 135

> proposed. Attempts by others to extend exemptions for small-scale laboratory experiments to these other levels have generally rested on devious logic which I cannot endorse.[78]

255. In fact, only one presentation made at Asilomar addressed agricultural research in the light of this technological revolution in life sciences. At that presentation, Ray Valentine, the later co-founder of the company Calgene, is said to have invented the word "molecular farming" by presenting the idea of transferring the bacterial nitrogen-fixing ability to crop plant in order to enable them to fix atmospheric nitrogen. That potential achievement has been used throughout the 80ies and the beginning of the 90ies as an argument to support the recombinant DNA research in plants, but has not yet been realised.

256. At the beginning of the 80ies, the discovery of the ability to transform and generate GMOs from plant species, and by 1986, their first deliberate releases, were the origin of a different, albeit related, and important scientific debate on their human health and environmental safety, in particular as regards their unique characteristics when compared to some traditional counterpart, where available. For instance, the development, at a later stage, of the OECD "substantial equivalence" paradigm, namely as a tool to perform GM plant risk assessment by comparison with the properties of traditional varieties of the same species, has always addressed the comparison of these plants, GM and non GM, with the exception of the new expressed trait introduced in the GM plant variety, which could never have been stated as being "substantially equivalent" to a non existing traditional counterpart. Anyhow, that concept as it had been developed then, has now received scientific criticism due to its limited and reductionist approach, calling for its revision if it were to be further applied.

257. Even if the worries of the initial scientific controversy were claimed by some to be overstated, there were opportunities that proved that there was much rationality in these initial concerns that the GM technology may, on a case by case basis, lead to significant new risks, as compared to the safety of the combinations of genes obtained by traditional methods.

258. To take a recent example, as announced in January 2001, an Australian research group had found previously an unforeseen and troublesome result: in the search of a mouse contraceptive vaccine for pest control, they introduced a gene that produces large amounts of interleukin 4, a natural molecule found in mammals, and involved in the immune response, into the genome of a mousepox virus, closely related to smallpox. The aim was to boost antibody production against mouse eggs, but totally unexpectedly, they found that they had generated a deadly virus for the mice, even those that had been vaccinated against this virus, by completely wiping out their immune system[79]. This experiment was later repeated in experiments in the USA, even more dramatically as all mice in this latter experiment died, thereby showing previously unforeseen means to enhance the virulence of viruses from the smallpox family (and by the way also thereby raising recent fears of bioterrorism)[80].

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[78] Introduction of Genetically Modified Organisms into the Environment - Scientific Committee On Problems of the Environment (1990) Eds H.A. Mooney and G. Bernardi. Chapter 2 : Recombinant DNA: Past Lessons and Current Concerns. Allan Campbell.

[79] Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox. RONALD J. JACKSON, ALISTAIR J. RAMSAY, CARINA D. CHRISTENSEN, SANDRA BEATON, DIANA F. HALL, AND IAN A. RAMSHAW. JOURNAL OF VIROLOGY (Feb. 2001) Vol. 75, No. 3 p. 1205–1210. Exhibit EC-136.

[80] 10th International Symposium of the European Federation of Defence Technology Associations. Geneva May 7th, 1998 Biological Weapons: New Threats (Biological warfare and rDNA technology) Dr. Martin Schütz, AC-Laboratorium Spiez. Exhibit EC-137; ENHANCEMENT CHAPTER Infectious Disease and Bioterrorism (George Johnson, Washington University, St. Louis). pp 1-14. Exhibit EC-138

259. Extracts from the recommendations from Asilomar's conference stated:

> The new techniques, which permit combination of genetic information from very different organisms, place us in an era of biology with many unknowns.
>
> Accurate estimates of the risks associated with different types of experiments are difficult to obtain because of our ignorance of the probability that the anticipated dangers will manifest themselves

260. These statements made at the time by the scientific community remain, at least in part, true.

89. With regard to the European Communities' reference to the precautionary principle as stated in the Rio Declaration, how can the condition of "where there are threats of serious or irreversible damage ..." be met in situations in which a substantial number of scientific evaluations and risk assessments have concluded that there is no evidence of potential harm to health or the environment?

261. The 1992 Biodiversity Convention and the 2000 Biosafety Protocol recognize that the precautionary principle is applicable *a priori* to all biotech products, having regard to the potential impacts on biodiversity and taking account human health (see first written submission of the European Communities, para. 105 *et seq*., and answer to Question 11 from Argentina).

262. As described in the first written submission of the European Communities and amplified in these answers to questions, there remain significant differences of opinion between various scientific committees at the EC and national levels, as well as in the academic literature, in relation to the potential harm posed to the environment and human health by biotech products which are the subject of these proceedings. It is not the case in relation to the products which are the subject of these proceedings that there is, as the question implies, "no evidence of potential harm to health or the environment." In such circumstances the precautionary principle continues to apply. The conduct of risk assessment is but one element of the application of the precautionary principle; the management of potential risks which may emerge and the continual evaluation of risks by reference to the emergence of new scientific understanding (for example in relation to antibiotic marker genes) are further examples of the application of the principle.

263. These principles are reflected in the Biosafety Protocol, which permits prohibitions on imports where there is uncertainty as to the effects on biological diversity, even if it cannot be demonstrated that a particular GMO poses risks to human or animal health. The negotiators of the Protocol expressly recognised this fact, and rejected alternative language which would follow more closely the language of the *SPS Agreement*. For example, the Japanese delegation proposed a modification using some elements of the *SPS Agreement* (without specifically referring to the *SPS Agreement*), and in particular a reference "to the provisional nature of the measures concerned and to the need for a review within a reasonable period of time".[81] The proposal was rejected. It is therefore clear that the negotiators of the Protocol recognised that decisions relating to biotech products should be based on precautionary approach which went beyond the general requirements of the *SPS Agreement*. Notwithstanding the rejection of its proposed modification, Japan has become a party to the Protocol, which lowers the threshold at which actions can be taken to prohibit imports of certain GMOs has been lowered by the Protocol.

[81] See Kiyo Akasaka, "Japan", in C. Bail, R. Falkner and H. Marquard, *The Cartagena Protocol on Biosafety – Reconciling Trade in Biotechnology with Environment and Development*?" (2002), 200 at 204.

90. Are food products containing, or consisting of, genetically modified organisms subject to EC Regulation 258/97 only, or are/were they also subject to EC Directives 2001/18 and 90/220? If the latter, which rules would prevail in the event of differences?

264. Food products containing, or consisting of, genetically modified organisms were subject to Directive 90/220 until May 1997, the date of entry into force of Regulation 258/97. After that date, food products containing, or consisting of, genetically modified organisms, as well as food derived from GMOs but no longer containing them have been subject only to Regulation 258/97. Its Article 9 specifies, in fact, that

> Articles 11 to 18 of Directive 90/220/EEC shall not apply to foods or food ingredients which contain or consist of genetically modified organisms.

265. Furthermore, according to Article 9(2), the notification under Regulation 258/97 covered also the environmental assessment of the effects of placing on the market of novel food and novel food ingredients containing or consisting of GMOs:

> In the case of foods or food ingredients falling within the scope of this Regulation containing or consisting of genetically modified organisms, the decision referred to in Article 7 shall respect the environmental safety requirements laid down by Directive 90/220/EEC to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of genetically modified organisms. During evaluation of requests for the placing on the market of products containing or consisting of genetically modified organisms, the necessary consultations shall be held by the Commission or the Member States with the bodies set up by the Community or the Member States in accordance with Directive 90/220/EEC.

266. Thus, as of May 1997, the placing on the market of products containing, or consisting of, genetically modified organisms had to be authorised under Regulation 258/97 for use as food, and under Directive 90/220 (now Directive 2001/18) for use as feed and cultivation. Decisions under the two pieces of legislation were taken according to the rules laid down in such legislation.

91. With reference to paras. 561 and 562 of the EC first written submission, it appears that the European Communities acknowledges the existence of a certain "situation" in the context of a legislative change, which situation was referred to by some as a "moratorium" or "de facto moratorium". Is the European Communities implying that since the new EC legislation (EC Directive 2001/18 and EC Regulation 1829/2003 (replacing Regulation 258/97)) has been in effect, the "situation" has changed? If so, did the new "situation" result in examination of applications in accordance with the timetable provided for by the new EC legislation? If not, why not?

267. As a preliminary point, the European Communities would like to stress once again that the situation prevailing in the EC for some time after 1998 was not one of "suspension" of procedures, contrary to what the complainants have suggested. The "situation" to what the question refers was one of improvement of the regulatory oversight on GM products, which implied the upgrade of pending applications in order to satisfy the EC requirements in terms of environmental protection, food safety, consumer information etc.

268. The legislative changes had been necessary because existing legislation had been identified to be inadequate to address all concerns relating to GMOs. Pending applications because and to the

extent that they did not contain the data/information necessary to address these concerns (since they were based on the old legislation) were affected. Attempts were made to anticipate the new legislation (on that see replies to question 92 below and also question 13). With the adoption and entry into force of the new legislation all relevant concerns have been addressed. Pending applications, thus, are required to provide all relevant information/data to address these issues.

269. For release into the environment this "situation" existed with respect to Directive 90/220. Directive 90/220 was replaced by Directive 2001/18, which addresses all relevant concerns including certain issues of risk assessment, as well as labelling, traceability and monitoring. With the application of Directive 2001/18 in October 2002 notification procedures have been (re-)launched according to the provisions set out in that Directive. The notifications are proceeding smoothly and in accordance with the timetable provided for in the Directive. In some cases the clock has been stopped in accordance with Articles 14(4) or 15(1) subparagraph 4, because further information has been requested.

270. An example is Monsanto Roundup Ready Corn NK 603 (see also first written submission paras. 279 et seq.). The application has gone through all stages of the procedure with only minor delays due to some questions on additional information. EFSA was requested to provide an opinion in September and has done so within less than three months. The draft decision has been presented to the Regulatory Committee in February and has, because it has not reached a qualified majority there, been presented to the Council in March. As provided in the legislation, the Council has three months to decide. A decision, thus, is expected in late June. Thus, all in all, a decision will have been taken within a year and a half's time (i.e. about 550 days). By comparison, the average time required for the regulatory review and approval of Bt-transgenic crop cultivars by the Environmental Protection Agency and the USDA's animal plant and health inspection services in the United States is 701 days (see table in Exhibit EC-111).

271. The next products "in the pipeline" are: GT 73 oilseed rape (notification C/NL/98/11) to be discussed at the Regulatory Committee on 16 June 2004 and MON 863 maize (C/DE/02/9) to be presented to the Regulatory Committee in autumn 2004.

272. For food use of GMOs and GM products the situation was somewhat different. Regulation 258/97, in general terms, provided an adequate framework for a risk assessment for GM food products. However, in terms of risk management, it became clear in 1999 that there would have to be new legislation addressing some issues such as labelling and traceability, and also the development and validation of detection methods. These issues have been addressed through Regulations 1830/2003 (labelling and traceability) and 1829/2003 (food and feed).[82]

273. Only three products under Regulation 258/97 were partially affected by this situation as they were the only ones that had reached the Community level and the stage of risk management considerations. Thus, for GA 21 maize, NK 603 and Bt 11, it was considered necessary to require the validation of a detection method as a pre-condition for marketing approval. This was done on the basis of a voluntary agreement with the applicants. In the cases of Bt11 and NK 603 these detection methods have been validated and the decision-making process has been launched immediately after. In the case of Bt11 this has already led to a final decision on a market authorisation on 19 May, in the

[82] See in particular its Article 5.3(i), 65(f) on detection and validation methods and 13 on labelling requirements.

case of NK 603 the decision is pending.[83] As for GA 21, as explained in the first written submission, the development of detection methods being delayed for reasons lying in the sphere of the applicant.[84]

92. The European Communities argues that the processing of the applications at issue has never been halted, but that at most it was delayed. The European Communities also argues that any delays in the processing of applications were caused because the European Communities found that EC Directive 90/220 would not address scientific issues sufficiently.

(a) When did the European Communities reach the conclusion that the existing regulatory framework would not address scientific issues sufficiently?

(b) The European Communities seems to submit that even after the situation mentioned in sub-question (a) occurred, the processing of the applications went on, if at a delayed pace. On what basis (regulatory framework, guidelines, etc.) did the European Communities continue processing the applications, given that the existing Directive had been determined to be insufficient?

274. As a preliminary remark the European Communities observes that it cannot be said to have "reached a conclusion" until the moment the new legislation was adopted. There is no formal act of any kind until the legislator has decided how to modify the relevant legislation. This said, as described below, a long debate has preceded the adoption of Directive 2001/18.

275. On (a): In 1994 the Commission issued a Communication on Biotechnology and the White Paper on Growth, Competitiveness and Employment, in which it identified the need to review Directive 90/220 in order to improve certain aspects which could not be addressed through simple technical adaptation. The Commission, in the end of 1996, followed up on this Communication with a report on the revision of Directive 90/220. In this report it identified a number of risk assessment and risk management issues in the application of Directive 90/220 which needed to be modified and adapted. In particular, the Commission identified the problems related to the absence of a harmonised set of risk assessment criteria, the absence of post market monitoring provisions and labelling provisions. On the basis of this report, the Commission, in the beginning of 1998, tabled a proposal for a Directive amending Directive 90/220.[85] The proposal addresses the above issues. According to the provisions of the so-called co-decision procedure, the proposal was presented to the European Parliament and to the Council. At the end of the first reading in either institution, the Council adopted a Common Position in June 1999. The Common Position, although by no means a final text, is a strong indicator of what the final legislation will look like as it identifies the common grounds between the two institutions (but also issues that are still contested between the two institutions) (see also reply to question 93). On the basis of this Common Position it was clear that the future legislation would contain harmonised risk assessment criteria, provisions on labelling and traceability as well as provisions on monitoring.

276. On (b): Formally speaking, Directive 90/220 continued to be the basis for the handling of the applications. However, the European Communities had to find ways to overcome the shortcomings of the legislation in order to ensure that the applicant provided the necessary data for an improved assessment and made commitments on issues pertaining to risk management. This is why, in the so-called "interim approach" the competent authorities and the Commission entered in a dialogue with the applicants in order to see whether they would be willing to comply with the requirements of the

[83] The draft decision is expected to be transmitted to the Council by the end of June.
[84] First written submission of the European Communities, paras. 301 et seq.
[85] OJ of the EC C N° 139 of 04.05.1998, p. 1.

future legislation (as identified in the 1999 Council Common Position) on a voluntary basis. Most applicants agreed to do so.

93. With reference, e.g., to para. 206 of the EC first written submission, could the European Communities elaborate on the content of the "Common Position of the Council" and its relevance to the operation of the relevant EC approval procedures for biotech products?

277. In the European Communities legislative process, the common position of the Council is a political decision which intervenes after the European Parliament has expressed its opinion on a Commission proposal. With it, the Council takes a position on those amendments by the Parliament on which it disagrees and that it cannot approve[86].

278. Paragraph 206 of the EC's first written submission refers to the Common Position agreed by the Council on 24 June 1999 on the Commission proposal for a directive amending Directive 90/220

[86] On the full so-called "co-decision" procedure, see Article 251, paragraphs 2 to 6 of the EC Treaty:

2. The Commission shall submit a proposal to the European Parliament and the Council. The Council, acting by a qualified majority after obtaining the opinion of the European Parliament:
— if it approves all the amendments contained in the European Parliament's opinion, may adopt the proposed act thus amended,
— if the European Parliament does not propose any amendments, may adopt the proposed act,
— shall otherwise adopt a common position and communicate it to the European Parliament. The Council shall inform the European Parliament fully of the reasons which led it to adopt its common position. The Commission shall inform the European Parliament fully of its position.

If, within three months of such communication, the European Parliament:
(a) approves the common position or has not taken a decision, the act in question shall be deemed to have been adopted in accordance with that common position;
(b) rejects, by an absolute majority of its component members, the common position, the proposed act shall be deemed not to have been adopted;
(c) proposes amendments to the common position by an absolute majority of its component members, the amended text shall be forwarded to the Council and to the Commission, which shall deliver an opinion on those amendments.

3. If, within three months of the matter being referred to it, the Council, acting by a qualified majority, approves all the amendments of the European Parliament, the act in question shall be deemed to have been adopted in the form of the common position thus amended; however, the Council shall act unanimously on the amendments on which the Commission has delivered a negative opinion. If the Council does not approve all the amendments, the President of the Council, in agreement with the President of the European Parliament, shall within six weeks convene a meeting of the Conciliation Committee.

4. The Conciliation Committee, which shall be composed of the Members of the Council or their representatives and an equal number of representatives of the European Parliament, shall have the task of reaching agreement on a joint text, by a qualified majority of the Members of the Council or their representatives and by a majority of the representatives of the European Parliament. The Commission shall take part in the Conciliation Committee's proceedings and shall take all the necessary initiatives with a view to reconciling the positions of the European Parliament and the Council. In fulfilling this task, the Conciliation Committee shall address the common position on the basis of the amendments proposed by the European Parliament.

5. If, within six weeks of its being convened, the Conciliation Committee approves a joint text, the European Parliament, acting by an absolute majority of the votes cast, and the Council, acting by a qualified majority, shall each have a period of six weeks from that approval in which to adopt the act in question in accordance with the joint text. If either of the two institutions fails to approve the proposed act within that period, it shall be deemed not to have been adopted.

6. Where the Conciliation Committee does not approve a joint text, the proposed act shall be deemed not to have been adopted.

(that was to become Directive 2001/18).[87] With it, the Council reached a political consensus among the Member States on a number of issues which were still outstanding in the draft legislative text, such as time limitation for consent of a maximum of 10 years, compulsory labelling, explicit consent, the strengthening of the precautionary principle, use of Regulatory Committee, etc.

279. In the case of Bayer Oilseed Rape FALCON GS40/90, as well as in the case of other notifications, such as Bayer Oilseed Rape Ms8xRf3 or the Monsanto Fodder Beet, the notifier agreed to anticipate in its notification a number of the additional requirements to Directive 90/220 contained in the Common Position adopted by the Council. These consisted in particular of commitments related to an updated risk assessment, good agricultural practices, post-market monitoring, traceability and labelling and an updated risk assessment.

94. With reference, e.g., to paras. 206, 212, 225 and 232 of the EC first written submission, could the European Communities explain in more detail what it means when it says that "in the meantime, the European Communities' internal procedures for authorisation were proceeding"?

280. With this expression (that is only present in paras. 212, 225 and 232), the European Communities refers to the fact that the internal procedures for the preparation of a Commission's proposal for decision were ongoing. It is what, in the detailed chronologies annexed to the first written submission, is also referred to as the "interservice consultation" phase.

281. A close and coordinated action of all Commission services involved on a given matter is mandated for the preparation and implementation of each Commission decision by Article 21 of its Rules of Procedures,[88] which reads:

> In order to ensure the effectiveness of Commission action, departments shall work in close cooperation and in coordinated fashion in the preparation or implementation of Commission decisions.
>
> Before submitting a document to the Commission, the department responsible shall, in sufficient time, consult other departments which are associated or concerned by virtue of their powers or responsibilities or the nature of the subject, and shall inform the Secretariat-General where it is not consulted. The Legal Service shall be consulted on all drafts or proposals for legal instruments and on all documents which may have legal implications. …
>
> The department responsible shall endeavour to frame a proposal that has the agreement of the departments consulted. In the event of a disagreement it shall append to its proposal the differing views expressed by these departments, without prejudice to Article 12.

282. The Commission's Rules of Procedures attach great importance to internal coordination; Article 21 and Article 17 (third paragraph) require departments to work together as closely as possible and liaise with the Secretariat-General in preparing and implementing Community instruments.

[87] The political agreement reached by the Council in June 1999 resulted into a formally adopted Common Position of December 1999. See OJ of the EC N° C 64 of 6.3.2000, p. 1.

[88] See "Rules of Procedure of the Commission", C(2000)3614, Official Journal of the European Communities No L308 of 8 December 2000, page 26.

Cooperation between departments is essential at all stages in their work, from conception to presentation of a proposal to the Commission.

283. Responsibility for coordination lies with the lead department (service), which should contact other departments with a legitimate interest in the matter of the proposed decision as soon as substantial drawing up begins. It tells them informally what the likely stages will be and consults them on the planned approach. It also draws up a timetable for the work, allowing sufficient time for formal consultation of the other departments concerned and for the proposal to be submitted for a decision. As work progresses, the lead department and the departments associated or consulted continue to exchange the necessary information. By virtue of its horizontal responsibilities, the Secretariat-General's role is to stimulate and assist interdepartmental coordination. The Legal Service is consulted and associated from the outset if the proposal involves drafting legislation.

284. Formal interservice consultation is initiated by the lead department - possibly in cooperation with associated departments that have been involved from the outset - when a proposal, usually for adoption by the Commission, has reached a sufficiently advanced stage within the department. Interservice consultation, then, is the stage in interdepartmental coordination when the lead department seeks officially the opinion of all the directorates-general and services with a legitimate interest in the substance of the proposal.

285. Once the consultation period is over, the lead department closes the procedure and revises the texts to incorporate the changes requested by other departments in order to achieve as broad a consensus as possible. If the requested changes alter substantially the text, further coordination or a second round of interservice consultation may be needed.

286. This phase aims at reaching high quality and consistency in the Commission's and its departments' work through effective coordination not only between all the departments concerned but also with those outside the Commission who are affected. In complex or highly sensitive dossiers it can last several months.[89]

95. With reference to para. 198 of the EC first written submission, could the European Communities be more specific regarding the nature and legal basis of the discussions which have taken place, in some cases, "before and/or after the opinion of the European Communities' scientific committees, among the competent authorities of the various Member States"?

287. The European Communities has specified the chronology of each notification and application procedure at issue in this case in its Exhibits EC-62 to EC-110. The sentence in paragraph 198 to which this question refers was meant to give a general and introductory overview of what is more specifically detailed in the chronologies. In particular, with this sentence, the European Communities intends to refer to the requests for further information, to the comments and to the reasoned objections that Member States are entitled to submit, and have indeed submitted, in the notification and application procedures for the placing of the market of GMOs envisaged by Directive 2001/18 (previously Directive 90/220) and Regulation 258/97.

288. The legal bases for the submission of such requests for further information, comments and reasoned objections are Article 15 of Directive 2001/18 and Article 6.4 of Regulation 258/97.

96. With reference to the submission by the Commission to the Regulatory Committee of a draft measure:

[89] See also Case C- 151/98P *Pharos against Commission [1999] ECR I-* 8157, paras. 24 and 26.

(a) Is it correct that in the event of objections by member States or the Commission, the Commission must submit to the relevant Regulatory Committee a draft measure? (Please refer to relevant provisions of Directives 90/220 and 2001/18 and Regulation 258/97.)

(b) If the answer to sub-question (a) is yes, is there a time limit within which the Commission must do so?

(c) Is it correct that from 1998 to the date of establishment of this Panel, the Commission submitted a draft measure to the Regulatory Committee in only two cases?

(d) If the answer to sub-question (d) above is yes, what explains this? Please provide support.

289. On (a): Yes. Under Directive 90/220, the relevant provision is Article 13(3) which states:

> In cases where the competent authority of another Member State raises an objection – for which the reasons must be stated - and should it not be possible for the competent authorities concerned to reach an agreement within the period specified in paragraph 2, the Commission shall take a decision in accordance with the procedure laid down in Article 21.

290. Under Directive 2001/18 the relevant provision is Article 18 (1) which states:

> 1. In cases where an objection is raised and maintained by a competent authority or the Commission in accordance with Articles 15, 17 and 20, a decision shall be adopted and published within 120 days in accordance with the procedure laid down in Article 30(2). This decision shall contain the same information as in Article 19(3).
>
> For the purpose of calculating the 120 day period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the Scientific Committee which has been consulted in accordance with Article 28 shall not be taken into account. The Commission shall state reasons in any request for further information and inform the competent authorities of its requests to the notifier. The period of time during which the Commission is awaiting the opinion of the Scientific Committee shall not exceed 90 days.
>
> The period of time that the Council takes to act in accordance with the procedure laid down in Article 30(2) shall not be taken into account.

291. The relevant provision in Regulation 258/97 is Article 7(1) which states in its relevant part

> Where […] an objection is raised in accordance with Article 6(4), an authorization decision shall be taken in accordance with the procedure laid down in Article 13.

292. On (b): As is apparent from the above provisions, neither Directive 90/220 nor Regulation 258/97 provide for a time limit within which the Commission is to present a draft decision to the Regulatory Committee. Under Directive 2001/18, on the other hand, a decision, in principle, is to be

adopted within 120 days. However, as can be seen in subparagraph 2 of the above Article 18(1) if the Commission requests further information, the clock is stopped. Equally, the time to await the opinion of the scientific committee (EFSA), which may be maximally 90 days, is not counted in the 120 days either.[90]

293. On (c): The Commission submitted altogether six draft measures to the Regulatory Committee but asked for a formal vote on only three of them. The six products are:

> Falcon GS40/90 (C/DE/96/05), presented to the Regulatory Committee on 29.10.99 and 09.03.00 (no vote).
>
> Ms8xRf3 (C/BE/96/01), presented to the Regulatory Committee on 29.10.99 and 09.03.00 (no vote)
>
> A5/15 fodder beet (C/DK/97/01), presented to the Regulatory Committee on 29.10.99 and 09.03.00 (no vote)
>
> 1445 RoundupReady cotton (C/ES/97/01) presented to the Regulatory Committee by written procedure: negative vote
>
> 531 Bt cotton (C/ES/96/02) presented to the Regulatory Committee by written procedure: negative vote
>
> Bt 176 maize (safeguard measure) presented to the Regulatory Committee on 09.01.98 and on 16.03.98: negative vote

294. On (d): The European Communities refers to its first written submission in which it has explained in detail the history of each individual application.[91] As can be seen from these individual histories, between 1998 and the date of the establishment of the Panel only the three cases mentioned above were judged to be in a state to be presented to the Regulatory Committee for a final decision. The reasons vary from case to case, although they were all related to new scientific developments, the need to set up appropriate risk management measures (e.g. the monitoring plans required by EC scientific committees) as well as, more generally, the review of the EC regulatory framework. For instance, one of the elements that has delayed the submission of a draft decision to the relevant regulatory committees in a number of cases is the development and validation of a detection method. However, the circumstances around each product must be looked at separately.

97. With reference to the submission by the Commission to the Council of a proposal relating to the measure:

> **(a) Is it correct that in the event the relevant Regulatory Committee does not render an opinion, or renders a negative opinion, the Commission must submit to the Council, without delay, a proposal relating to the measure to be taken? (Please refer to relevant provisions of Directives 90/220 and 2001/18 and Regulation 258/97.)**
>
> **(b) Is it correct that from 1998 to the date of establishment of this Panel, the Commission failed to submit any proposals to the Council?**

[90] See flowcharts in Exhibits EC-118 to 120.
[91] See Chap. II. D, see also Exhibits EC-62 to EC-110.

(c) If the answer to sub-question (b) above is yes, what explains this? Please provide support.

295. On (a) Yes. The relevant provision under Directive 90/220 is Article 21 which states in its relevant part:

> If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, *without delay*, submit to the Council a proposal relating to the measures to be taken. [emphasis added]

296. Under Directive 2001/18 the applicable provision is Article 30 which refers to Article 5 and 7 of Decision 1999/468/EC. Article 5 of the Comitology Decision states in its relevant part:

> If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, *without delay*, submit to the Council a proposal relating to the measures to be taken and shall inform the European Parliament. [emphasis added]

297. Under Regulation 258/97 the relevant provision is Article 13(4)(b) which states

> If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, *without delay*, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority. […] [emphasis added].

298. It should be pointed out that the words "without delay" have been interpreted extensively in the case law of the European Court of Justice. The Court, in the case *Pharos*,[92] examined an identical requirement to submit to a regulatory committee "without delay" in the context of legislation on the setting of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (Regulation 2377/90), a legislation similar in structure to Directive 2001/18. A Commission proposal on maximum residue limits for recombinant somatrophin (rBST) (a bio-engineered hormonal substance) failed to obtain a favourable opinion in the regulatory committee, following which the Commission sought a second opinion from the relevant scientific committee and took some time considering the various risk management options available. The Court started its analysis by stating that nothing in the wording of the relevant provision

> suggests any conclusion regarding the length of time indicated by the expression 'without delay', other than that, while a certain degree of rapidity is required, the Commission is not required to act within a precise period of time nor at once, contrary to the appellant's submission.[93]

299. The Court, then, pointed out that the Commission was free to modify its proposal before submitting it to the Council and concluded from this fact:

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[92] Case C- 151/98P *Pharos against Commission [1999] ECR I-* 8157.
[93] *Ibidem*, para. 20.

> Accordingly, if the Commission has the right to amend the proposal relating to the measures to be taken which it submits to the Council, it must have sufficient time to consider the various courses of action open to it.[94]

300. In the case at hand, therefore, the Court of Justice confirmed the finding of the Court of First Instance that the Commission (which had taken over eleven months) had not violated its obligation to act "without delay." The Court pointed to the fact that the matter which the Commission was confronted was "highly complex and sensitive."[95] The Court also made it clear that the Commission could not be criticised for having sought additional advice in an effort to prevent its proposal from being rejected by the Council.[96]

301. On (b): The question is only relevant where decisions have been submitted to the Regulatory Committee and have not received a favourable opinion since only in this case a proposal is to be submitted to the Council. As seen above in the reply to question 96, this has been the case only in the three instances, namely for the two Monsanto products Bt cotton 531 and Roundup Ready Cotton 1445 and for the safeguard measures on Bt 176 Maize. On the latter the Commission submitted a draft measure to the Council on 11.06.1998. The Council failed to act within the delay of three months.

302. On (c): In the only instances where this situation arose the Commission considered that the impending legislative changes affected also the two product applications in question and that further reflection was necessary before proceeding further. This is in line with the case law described above.

98. With reference to the forwarding by the competent member State authority of a dossier/assessment report to the Commission:

> **(a) Is it correct that the competent member State authority must, within a specified time period, forward a dossier/assessment report to the Commission (except where, under Directive 90/220, the competent authority rejects an application)? (Please refer to relevant provisions of Directives 90/220 and 2001/18 and Regulation 258/97.)**
>
> **(b) Have there been cases, from 1998 to the date of establishment of this Panel, where member States have failed to forward dossiers/assessment reports within the specified time period?**
>
> **(c) If the answer to sub-question (c) above is yes, what explains this? Please provide support.**

303. On (a): Yes. As highlighted in the flowcharts in Exhibits EC-118 to EC-120, the relevant provisions are the following. Article 12 (2) of Directive 90/220 which provides:

> At the latest 90 days after receipt of the notification, the competent authority shall either:
>
> (a) forward the dossier to the Commission with a favourable opinion, or

[94] *Ibidem*, para. 24.
[95] *Ibidem*, para. 26.
[96] *Ibidem* para. 27.

(b) inform the notifier that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected.

304. For the case of a positive assessment report Article 14(2) of Directive 2001/18 provides

Within 90 days after receipt of the notification the competent authority shall:

[…]

– in the case referred to in paragraph 3(a) [i.e. the assessment report indicates that the GMO(s) in question should be placed on the market and under which conditions], send its report, together with the information referred to in paragraph 4 and any other information on which it has based its report, to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

305. For the case of a negative assessment report Article 14(2) of Directive 2001/18 provides

In the case referred to paragraph 3(b), [i.e. the assessment report indicates that the GMO(s) should not be placed on the market] the competent authority shall send its report, together with the information referred to in paragraph 4 and any other information on which it has based its report, to the Commission no earlier than 15 days after sending the assessment report to the notifier and no later than 105 days after receipt of the notification. The Commission shall, within 30 days of its receipt, forward the report to the competent authorities of the other Member States.

306. Article 6(3) and (4) of Regulation 258/97 provides:

3. The initial assessment report shall be drawn up within a period of three months from receipt of a request meeting the conditions laid down in paragraph 1, in accordance with the recommendations referred to in Article 4 (4), and shall decide whether or not the food or food ingredient requires additional assessment in accordance with Article 7.

4. The Member State concerned shall without delay forward the report of the competent food assessment body to the Commission, which shall forward it to the other Member States. […]

307. With regard to these provisions it should be pointed out that delays do not run where further information has been requested by the competent authority.

308. This is explicitly set out in the release into the environment legislation. Thus, Article 12(5) of Directive 90/220 states that

For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account.

309. Similarly, Article 14(4) of Directive 2001/18 which provides that

> For the purpose of calculating the 90 day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account. The competent authority shall state the reasons in any request for further information.

310. In Regulation 258/97, it can be inferred from the above provision that the specified time-limits only apply where a request meets the conditions as set out in paragraph 1 of Article 6. That paragraph states that

> The request referred to in Article 4 (1) shall contain the necessary information, including a copy of the studies which have been carried out and any other material which is available to demonstrate that the food or food ingredient complies with the criteria laid down in Article 3 (1), as well as an appropriate proposal for the presentation and labelling, in accordance with the requirements of Article 8, of the food or food ingredient. In addition, the request shall be accompanied by a summary of the dossier.

311. On (b): The European Communities, in its first written submission, has provided a detailed account of each and every application. From these accounts it can be seen that in a number of cases the application dossiers were not forwarded to the Community within the specified time limits that is, 90 days or three months). The accounts also provide the explanation for why this is so.

312. On (c): As stated immediately above the detailed accounts of the individual applications explain the reasons why an assessment report has not been forwarded within the specified time-limits. In all these cases, the competent authorities requested additional information and the clock was stopped according to the provisions described above. The European Communities has annexed to its first written submission all these requests for additional information. The Panel will see from these requests that in all cases data were missing which the competent authority considered necessary to complete its risk assessment.

99. With reference to the applications for approval of canola/oilseed rape MS1/RF1 and MS1/RF2:

(a) Did France still withhold its consent to the placement of these products on the market on the date of establishment of this Panel?

(b) Did the Commission initiate proceedings against France? If not, why not?

313. On (a): The answer is "yes." It should be added, as stated at the first hearing, that from a legal point of view, the absence of the final consent does not mean that the applicant is not entitled to place these products on the market. The products have obtained a market authorisation by virtue of Commission decisions of the 6 June 1997. While that decision is addressed to France and places an obligation upon France to grant final consent, it can nevertheless develop a direct effect vis-à-vis the applicant as well.

314. In the case law of the European Court of Justice, the EU Member States cannot prevail themselves of the fact that they have not implemented (or refuse to implement) Community obligations addressed to them in order to deny an individual a right which he or she has been granted through those same Community provisions.[97] The individual, therefore, can assert his or her right by

[97] See only Case 9/70 *Leberpfennig*, [1970] ECR 825.

directly relying on the Community law in question. These principles form the so-called doctrine of "direct effect." The Court has based this doctrine on a teleological interpretation of Community law, and in particular, on the so-called "effet utile" principle.

315. On (b): The Commission did initiate infringement proceedings against France in 1998. However, in light of the circumstances at the time it decided not to take the case to the Court. The Commission has discretion in deciding on the opportunity of launching infringement proceedings.[98] These circumstances were in particular the following: the fact that the very legislation on the basis of which the authorisation had been granted had been identified to be insufficient and was being revised, as well as the fact that France had raised the same environmental risk concerns regarding these two products as it had for the products for which it had adopted safeguard measures (i.e. the identical product oilseed rape MS1,RF1 which had obtained an authorisation for breeding activities in 1996 as well as the product swede rape Topas 19/2).

100. With reference to Exhibits CDA-3 and CDA-38, could the European Communities explain what is the legal status and effect, under EC law, of the declarations by the relevant EC member States?

316. Declarations to Council minutes, such as those contained in Exhibits CAN-3 and CAN-38 have no legal significance or effect in the European Communities. This has been the constant legal position in the European Communities as confirmed by the Court of Justice of the European Communities most recently in Case C-375/98 *Ministério Público and Fazenda Pública v Epson Europe BV*:[99]

> Moreover, according to settled case-law, declarations recorded in Council minutes in the course of preparatory work leading to the adoption of a directive cannot be used for the purpose of interpreting that directive where no reference is made to the content of the declaration in the wording of the provision in question, and, moreover, such declarations have no legal significance (see Case C-292/89 Antonissen [1991] ECR I-745, paragraph 18, and Joined Cases C-197/94 and C-252/94 Bautiaa and Société Française Maritime [1996] ECR I-505, paragraph 51).

317. The Member States of the European Communities are fully aware of this position but have recourse to such declarations for political purposes – to pass a message to other institutions, to the public or to satisfy a political need.

101. With reference to the member State safeguard measures challenged by the complaining parties, please answer the following questions:

(a) Were these measures still in force on the date of the establishment of this Panel, and if so, are they still in force at present?

(b) As of the date of establishment of this Panel, or subsequently, had any "decisions"/"measures" been taken at Community level in respect of these measures?

(c) What would be the kind of "decision"/"measure" that might be taken at Community level if it were determined that the member States concerned (i)

[98] See only Case 247/87 *Star Fruit against Commission*, [1989] ECR 291, para. 11.
[99] [2000] ECR I-4243 at para 26.

have justifiable reasons for maintaining their safeguard measures, or (ii) do not have justifiable reasons? Specifically, is it correct that under the first scenario, the member State concerned could not apply the safeguard measure permanently (EC first written submission, paras. 154 and 572), but that the restriction or prohibition would be extended to the entire Community? What is the position under the second scenario?

(d) Were the EC member State safeguard measures at issue in this dispute reviewed within a reasonable period of time within the meaning of Article 5.7 of the SPS Agreement? If yes, please provide support for your reply.

318. On (a): The measures were still in force on the date of establishment of this Panel and are still in force today.

319. On (b): No "measures" within the meaning of Annex A.1 or Article 5.1 *SPS Agreement* have been taken at Community level in respect of the provisional Member State measures. Furthermore, no "decisions" within the meaning of the final three paragraphs of Directive 90/220, Article 21, or the equivalent provisions, have been adopted at Community level.

320. On (c)(i): If the provisional Member State measures are considered justified, a decision on the matter should be taken in accordance with Directive 90/220, Article 16, now Article 23 of Directive 2001/18. If the Commission would decide that the provisional measures were, for the time being, justified, then it may be that no *further* legislative action would be necessary. If further measures were not, for the time being, considered necessary, then it is possible that none would be proposed by the Commission.

321. This situation cannot last forever. The Member State must seek to obtain the additional information necessary for a more objective assessment of the risk and review the provisional measure within a reasonable period of time. Once the scientific evidence is sufficient, the provisional measure must be terminated, or replaced with a definitive measure. The definitive measure (whether consent or prohibition) will be adopted at Community level. In adopting the definitive measure at Community level, account would be taken of any intervening changes in Community legislation, or any re-assessment of the level of acceptable risk, in the context of the Community as a whole, and taking into account the specific circumstances of each Member State. Thus, it is possible either that the provisional restriction or prohibition would be terminated, or that it would be definitively extended to the entire Community.

322. On (c)(ii): If the provisional Member State measures are considered unjustified, either when adopted, or at least at some later point with the passage of time, then a decision should be taken on the matter within three months. The Commission may propose a decision addressed to the Member State that has adopted the provisional measure, to the effect that the provisional measure shall be withdrawn. The Commission may also initiate the procedure provided for in Articles 228 of the EC Treaty. According to that procedure, the European Court of Justice may find that a Member State has failed to fulfil an obligation under the EC Treaty, and require the Member State to take the necessary measures to comply with the judgment of the Court. Another Member State may also bring the matter before the European Court of Justice, pursuant to Article 227 of the EC Treaty.

323. In this scenario, the provisional measure would be terminated. It would not be definitively extended to the entire Community – unless, in the intervening period, changes in the Community legislation or a re-assessment of the level of acceptable risk justified such extension.

324. On (d): The Member State measures are constantly subject to review. However, the specific review to which Article 5.7 *SPS Agreement* refers is the review that follows the obtaining of the additional information necessary for a more objective assessment. That is, it is the review that takes place once the scientific evidence is sufficient – the review pursuant to which the provisional measure is either terminated, or transposed into a definitive measure. A necessary pre-requisite for the carrying out of that type of review is therefore sufficient scientific evidence. As recalled above, the sufficiency of scientific evidence is a function of the level of acceptable risk, which, in this case, is determined by the Member State. The lower the level of acceptable risk – and under the *SPS Agreement* this remains the sovereign decision of the WTO Member concerned - the longer the reasonable period of time referred to in Article 5.7 *SPS Agreement* is likely to be. In all the circumstances of this case, and having regard to the specific objectives of the legislators in the Member States, the European Communities considers that, as a matter of WTO law, it cannot be said that the period of time for which the provisional Member State measures have been in force is not "reasonable" within the meaning of Article 5.7 *SPS Agreement*.

102. Could the European Communities please elaborate further on the "societal values" referred to at para. 1 of its first oral statement and the "political and social controversies" referred to at paras. 3 and 4 of its first written submission, and explain how they are relevant to the measures and WTO rules at issue in this dispute?

325. It is beyond doubt that risk analysis involves consideration of "societal values" or social perceptions. The clearest example relates to the social acceptability of a given risk –which is usually referred as the level of protection. The desired level of protection is a function not only of scientific or technical considerations on the nature and extent of the risk, but also of the willingness of a society to accept or not the negative effects associated to a product. Therefore, for instance, the reasons for which a given WTO Member may accept the sale of some carginogenic products such as tobacco, and not accept the sale of other carcinogenic substances, are to a great extent related to its own scale of social values.

326. But "political and social controversies" are also relevant for the process of risk assessment itself (understood in a narrow, non-SPS, sense). Indeed, the emphasis that risk assessors put on one or another aspect of the scientific or technical analysis of a given product depends in most cases on the analytical framework that they adopt, which is itself influenced by the concerns expressed by society.

327. The European Communities would also recall that, for instance, under the SPS agreement, regulators may take into account "relevant economic factors" in the context of a risk assessment, and that 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.

328. Socio-economic considerations, in this context, include implications for existing patterns of agricultural practises, having regard to the effects of biotech products for biodiversity.

103. Could the European Communities please further explain its comment made during the first substantive meeting to the effect that the European Communities considers risk management to be part of risk assessment for the purposes of the SPS Agreement?

329. See reply to question 2.

104. At para. 416 of the EC first written submission it is stated that Annex A of the SPS Agreement does not address environmental protection and that the SPS Agreement was not intended to address the prevention of risks to the environment. Could the European Communities indicate how this position can be reconciled with (i) Article 5.2 of the SPS Agreement, and in particular its phrase "relevant ecological and environmental conditions" and (ii) Annex A(1)(d) ("other damage")?

330. (i) The scope of the *SPS Agreement* is expressly defined pursuant to Articles 1.1, 1.2 and 1.3 and Annex A.1 *SPS Agreement*. The purpose of defining something is to apply it consistently throughout the relevant legal analysis. A "scope" definition is a particularly fundamental type of definition, and must be respected when applying the relevant legal provisions.

331. It is possible that other provisions of the *SPS Agreement* might provide useful context for the purposes of settling interpretative questions about the definition contained in Annex A.1 *SPS Agreement*. However, such other provisions cannot lawfully be considered to change the scope of the definition itself. They cannot be used to come to a result that contradicts the definition, or which enlarges or restricts the scope of the definition in a manner inconsistent with the text. The Panel should proceed with particular caution when it comes to using context to settle the meaning of a definition, and particularly a scope definition. By its very nature a scope definition establishes a demarcation line, which line determines, at the same time, both what is covered (in this case) by the *SPS Agreement*, and what is not covered by the *SPS Agreement*. When the drafters decide to proceed by means of a "definition" it is clear that they are engaged in a process of weighing with the maximum degree of precision and clarity that they can the meaning of the words and phrases they are defining. They are not expected to have overlooked specific issues, nor to have themselves relied on "context" to settle the meaning of what they are defining, or expected a Panel to rely on context. In the case of a definition, an appropriate and special weight must be given to the text.

332. Article 5.2 *SPS Agreement* is not a provision that defines the types of risks covered by the *SPS Agreement*. It is rather a provision that explains what matters shall be taken into consideration when assessing risks within the defined scope of the *SPS Agreement*. One of those matters is "relevant ecological and environmental *conditions*." The use of the word "conditions" is significant. It confirms that this phrase does not concern *risks* to the environmental *per se*, but rather environmental *conditions*, which is a different matter.

333. For example, consider the situation in which a Member is considering whether or not to act to protect animal health within its territory from the entry of a disease-carrying organism (Annex A.1(a) *SPS Agreement*). Thus, the contemplated measure, if adopted, will fall within the defined scope of the *SPS Agreement*. In considering whether or not to adopt the measure, the Member may consider "relevant ecological or environmental conditions". For example, the disease in question, or its vector, might particularly prosper in a wet climate. For a Member with a wet climate, that might increase the risk. For a Member with a dry climate, the measure might not be justified at all. This is the sense in which environmental conditions must be taken into consideration. This does not, in itself, alter the defined scope of the *SPS Agreement*, by bringing within the scope of the *SPS Agreement* in a general and broad manner each and every *risk* to the environment.

334. (ii) The words "other damage" in Annex A.1(d) *SPS Agreement* are, in the opinion of the European Communities, to be interpreted in juxtaposition to human, animal or plant life or health. In particular, it is generally accepted that they refer to economic damage (particularly, for example,

economic damage to farmed crops or animals). Such damage might also include ecological or environmental damage. The critical point to note, however, is that the words "other damage" are expressly linked in the text only to the risks arising from the entry, establishment or spread of a pest. A GMO is not a pest. This provision is therefore incapable of bringing within the scope of the *SPS Agreement*, in a broad and general way, all measures applied to protect against damage to ecology or environment arising from the introduction of a GMO.

105. With reference to footnote 197 of the US first written submission, has the European Communities prepared a risk assessment which covers any and all biotech products as opposed to risk assessments covering only certain individual biotech products?

335. Firstly, footnote 197 relates to paragraph 105 of the US first written submission, which only addresses the two definitions of risk assessment, contained in Annex A, paragraph 4, of the *SPS Agreement*. As indicated in detail in our answer to question 2 of the Panel, it is the view of the European Communities that these two definitions together do not cover all potential risks that have to be assessed to address fully the safety issues of each GMO.

336. Secondly, based on international standards, the risk assessment approach for GMOs enshrined in the EC legislation, which has been implemented in accordance with these rules, is based on a case by case approach. This case by case approach has required the European Communities to address each GMO on its own individual merits, namely to address each individual combination of a new gene coding for a particular character with a specific host organism, for each use. The implementation of this approach contradicts the statement from the Complainants that the European Communities has enacted a so called "moratorium on any and all biotech products", *i.e.*, the general moratorium," and that, in doing so, it has failed to put forth an appropriate risk assessment.

337. Hence, it follows from that case by case approach that (i) the European Communities has not adopted such a so called "moratorium", and, (ii) has not prepared any risk assessment which covers any and all biotech products as opposed to risk assessments covering only certain individual biotech products.

338. For the sake of completeness, the case by case approach has nevertheless led to the identification of risk assessment issues which were systemic to a particular type of character, or species.

339. For instance, there have been some risk assessment opinions or data prepared by the relevant advisory bodies, on specific traits (*e.g.* on the use of antibiotic resistance genes as marker genes in GMOs), on specific species (*e.g.* OECD consensus documents on the biology of individual species, or relevant opinions on out crossing properties of species indigenous to Europe, such as oilseed rape or sugar beet), or on the general combination of a specific character with a specific species (*e.g.* on the risk for the agro environmental management of the use of several distinct non selective herbicide genes in oilseed rape, or on the risk of development of resistance to Bt in the European corn borer and recommended monitoring practices). These "systemic" risk assessment opinions are however all in compliance with the case by case approach, as they all have addressed the specific risks of individual cases, whether for a specific trait, species or combination.

106. With reference to footnote 294 of the US first written submission, does an SCP opinion concerning Luxembourg and Bt-176 exist? If so, could the European Communities please provide a copy?

340. The Commission relied on the Scientific Opinions in relation to the Austrian measure concerning Bt-176 also in the case of Luxembourg.

107. With reference to paras. 604 to 609 of the EC first written submission, could the European Communities explain more clearly how and why the alleged lack of sufficient evidence leads to the conclusion that the member State safeguard measures are based on a risk assessment that is/was appropriate to the circumstances, as required by Article 5.1 of the SPS Agreement?

341. The European Communities' basic point is that the relevant provision, if any, is Article 5.7 *SPS Agreement* (the provision expressly dealing with provisional measures), not Article 5.1 *SPS Agreement*.

342. If the Panel nevertheless assesses the Member State provisional measures by reference to Article 5.1 *SPS Agreement* (which the European Communities considers would be an error of law), the European Communities first argues, in the alternative, that the words "as appropriate to the circumstances" in Article 5.1 *SPS Agreement* would send the Panel right back to Article 5.7 *SPS Agreement*, because the measures in question are provisional measures, and the circumstances are that the scientific evidence is insufficient for the specific legislator and its specific level of protection. Under the first sentence of Article 5.7 *SPS Agreement* an assessment is necessary, but not a "risk assessment" as that term is defined in the *SPS Agreement*. Furthermore, Article 5.1 *SPS Agreement* does not expressly require a "risk assessment" – it only requires that the Member take into account risk assessment techniques developed by the relevant international organisations. The risk assessment techniques developed by the relevant international organisations generally recognise that in certain circumstances, namely in the adoption of provisional measures, an assessment, but no risk assessment within the meaning of the *SPS Agreement*, is necessary.

343. If the Panel nevertheless considers that the Member State measures could only lawfully be adopted on the basis of a risk assessment (which the European Communities considers would be an error of law), then the European Communities argues, again in the alternative, that there is such a risk assessment. A risk assessment was carried out at the time when the original Community consent was given. The Complainants agree (otherwise, that original Community consent would be unlawful, at least as a matter of Community law). That risk assessment can serve, at least *temporarily*, as a basis both for the original Community consent, and for the Member State provisional measures. Furthermore, the Member States have made their own assessments and further risk assessments may be forthcoming.

344. The differences between the Community and the Member States lie not only in the science, but also in the acceptable level of protection – so that even if they would agree on the science, they might still disagree on the measures to be taken. As set out in para. 610 of the first written submission of the European Communities, the Appellate Body has made it very clear that "based on" does not mean "conform to," that a legislator can rely on someone else's risk assessment; and that the same risk assessment can reasonably support divergent responses by equally responsible and representative governments.

108. With reference to Article 5.5 of the SPS Agreement, what is the appropriate level of protection sought to be achieved by the relevant provisions of (i) EC Directive 90/220, (ii) EC Directive 2001/18 and (iii) Regulation 258/97?

345. The measures do not define a level of protection. They are designed to keep risk at an acceptable level, but this has to be judged on a case by case basis. Guidance is provided by the EC Treaty, which requires a high level of protection.

109. With reference to para. 470 of Canada's first written submission, could the European Communities please indicate whether Canada's translation of Article 1 of the Greek Ministerial Decision is correct?

346. The translation is correct but it does not translate the entire Article. It omits the last half sentence which states "because this involves risks for the natural environment of Greece."

110. With reference to the European Communities' interpretation of Article 5.7 of the SPS Agreement:

(a) Please elaborate further upon why Article 5.6 is not "relevant" where Article 5.7 applies? (EC first written submission, para. 612)

(b) Please elaborate further on why Article 5.7 "effectively" excludes Article 5.5? (EC first written submission, para. 618)

(c) The European Communities argues that the member State safeguard measures fall to be assessed under Article 5.7 and not, as the complaining parties argue, Article 2.2 and 5.1 of the SPS Agreement. Article 5.7 appears to apply only in circumstances where relevant scientific evidence is insufficient. Is this an issue of fact? If so, which side bears the burden of proof in respect of this issue?

347. Please note that the order of response is different from the order in which the questions are posed.

348. On (c): The European Communities considers that the Appellate Body has made it clear that the relationship between Article 5.7 *SPS Agreement* and Articles 2.2 and 5.1 *SPS Agreement* is one of exclusion, not exception – it is the same relationship as between Articles 3.1 and 3.3 *SPS Agreement*, worded in substantially identical terms. The question is, what is the demarcation line ?

349. The European Communities does not agree that the demarcation line between Articles 2.2 and 5.7 *SPS Agreement* is the sufficiency or insufficiency of scientific evidence. The word "sufficient" in Article 2.2 *SPS Agreement* is used in a different sense to the word "insufficient" in Article 5.7 *SPS Agreement*. In Article 5.7 *SPS Agreement*, the phrase "relevant scientific evidence is insufficient" refers to a situation in which the evidence is insufficient to make a definitive decision, whether that decision is yes or no (consent or prohibition). That is why a provisional measure is permitted. Put simply, there is not yet enough science on the table. On the other hand, the word "sufficient" in Article 2.2 *SPS Agreement* has a different meaning. Article 2.2 *SPS Agreement* presumes that there is enough science on the table to make a decision (yes or no). It also presumes that the decision that has been taken is a "no". It contains an obligation on Members to ensure that such a prohibition is indeed the decision supported by and justified by the science. Thus, given the different senses in which the word "sufficient" is used, that word does not provide an incisive tool for tracing the demarcation line between these two provisions.

350. Rather, the European Communities draws the Panel's attention to the use of the word "maintained" in Article 2.2 *SPS Agreement*, juxtaposed to the use of the words "provisionally adopt" in Article 5.7 *SPS Agreement*. These are the words that indicate the demarcation line : provisional

measures under Article 5.7 *SPS Agreement*; definitive measures under Articles 2.2 and 5.1 *SPS Agreement*.

351. Strong contextual support for this view may be derived from the fact that the Appellate Body has made it clear that, in order to be consistent with Article 5.7 *SPS Agreement*, a measure must satisfy the four conditions contained therein: relevant scientific evidence insufficient; use of available pertinent information; seek to obtain additional information; reasonable period of time. Failure to comply with any one of these four conditions would mean that a Member acts inconsistently with Article 5.7 *SPS Agreement*. It would not mean that the entire discussion must suddenly be flipped out of Article 5.7 *SPS Agreement* and into some other provision of the *SPS Agreement*.

352. For example, if a Complainant proves that, in adopting a provisional measure, a Member acts other than on the basis of available pertinent information, the conclusion would be that the Member had acted inconsistently with Article 5.7 *SPS Agreement*. The conclusion would not be that the whole question of consistency or not with the *SPS Agreement* suddenly needs to be assessed on the basis of some other provision of the *SPS Agreement*. The Appellate Body has not indicated that any one of these four conditions has a special status – in principle they are all to be considered of equivalent status. As a matter of logic it is not possible to settle a question about the exclusionary scope of a provision, by referring to the obligations contained within that provision – those obligations only become relevant at all if it is *first* determined that the measure under scrutiny is within the *scope* of that provision. In these circumstances, the Panel must first verify whether or not there is in fact some other demarcation line between Article 5.7 *SPS Agreement* and Articles 5.1 and 2.2 *SPS Agreement.*

353. Such a demarcation line appears in the text of Article 5.7 *SPS Agreement* itself : that provision concerns *provisional* measures. This is not one of the four conditions referred to by the Appellate Body. It is the only reasonable candidate for the "exclusionary" demarcation line that we have established must exist. This is confirmed by the juxtaposition of the words "maintained" in Article 2.2 *SPS Agreement* and "provisionally adopt" in Article 5.7 *SPS Agreement*, as outlined above.

354. Further strong contextual support for this view results from the Appellate Body's observation that the word "sufficient" in Article 5.7 *SPS Agreement* must mean sufficient for something. It can only mean sufficient for the making of a risk assessment, as defined by the *SPS Agreement.* Under the *SPS Agreement*, a risk assessment must *evaluate* likelihood or potential. This is not to be confused with risk of what is unknown or not sufficiently known. Nor are the roles of science and legislator to be confused. The legislator sets the level of acceptable risk. The scientist evaluates. The key point is that all of these processes are linked. The lower the level of acceptable risk fixed by the legislator, the longer it will take the scientific community to gather sufficient evidence – that is, evidence sufficient to evaluate likelihood or potential in a manner that finally allows the legislator to make a definitive decision, one way or another. Until then, provisional measures are possible, subject to the four conditions set out in Article 5.7 *SPS Agreement*.

355. The view of the European Communities is that it was and remains abundantly clear to the Complainants that the Member State measures are provisional measures. That is what the Community legislation repeatedly states. That is what the Member State national legislation implementing Community legislation repeatedly states. That is what the Member State measures themselves state. That is what the Court of Justice of the European Communities has stated. That is what the Complainants themselves state in their submissions. Objectively, the question is therefore whether or not they are consistent with Article 5.7 *SPS Agreement*, which is the provision that relates to provisional measures. These are the obligations that the European Communities must comply with. And the Complainants cannot change the benchmark simply by invoking some or other provision of

the *SPS Agreement*, which provision has actually got strictly nothing to do with the relevant behaviour of the European Communities in this case.

356. These considerations are further re-enforced when one considers the matter from a burden of proof perspective – also a question on which the Appellate Body has clearly expressed itself. Under the correct approach, the Complainants have the burden of proof to show that, under Article 5.7 *SPS Agreement*, the relevant scientific evidence is not insufficient – that is, that it is sufficient - for making a decision either way, yes or no. The Complainants must show that, given the science on the table, there is no longer any basis for hesitation – a definitive decision must now be made.

357. On the other hand, under their twisted approach, the Complainants, referring to Article 2.2 *SPS Agreement*, merely assert that the science on the table is "insufficient" to justify a "no" - and they purport to do this essentially by pointing to what they assert is the paucity of evidence suggesting there might be some problems with GMOs. This is simply the wrong test from a burden of proof perspective. And the proof of *that* is that the European Communities *agrees* with the Complainants – for the specific legislator the scientific evidence was or is insufficient – that is precisely why the Member States adopted *provisional* measures.

358. Thus, what is happening is that the Complainants, by invoking the wrong provision of the *SPS Agreement*, whether intentionally or not, are seeking unlawfully to shift the burden of proof onto the European Communities. Since the burden of proof issue is at the very heart of this case, this vitiates the Complainants' entire case. The European Communities has not said "no" or even "decided not to decide". It has just said "maybe, but not yet".

359. The irony is that the United States actually agrees with this analysis, as it indicated in the DSB following the *Japan-Apples* Panel Report, which Panel Report was not appealed on this point. This being so, it is highly perplexing that the United States nevertheless attempts to shift the burden of proof onto the European Communities, by invoking an irrelevant provision of the *SPS Agreement*. The position of the United States is logically internally incoherent.

360. To conclude, the European Communities considers that the issue of fact is whether or not the Member State measures are or are not provisional measures. If the Complainants wish the Panel to assess those measures other than on the basis of Article 5.7 *SPS Agreement*, the Complainants have the burden of proving that the Member State measures are not provisional measures. However, the Complainants have not even alleged that the Member State measures are not provisional measures, let alone taken any steps to discharge their burden of proof in this respect. On the contrary, the Complainants have actually asserted that the Member State measures *are* provisional measures. Since there is no disagreement between the parties on this point, the Panel can only conclude that the Member State measures are provisional measures, and that their conformity with the *SPS Agreement* therefore falls to be assessed by reference to Article 5.7 *SPS Agreement*.

361. (b) The European Communities considers that the essence of the type of situation covered by Article 5.7 *SPS Agreement* includes one in which, as in the present case, there is a huge question mark over certain issues, at least from the point of view of certain specific legislators. In such circumstances, just as Article 5.7 *SPS Agreement* excludes Articles 2.2 and hence 5.1 *SPS Agreement*, so it should also be considered to exclude Article 5.5 *SPS Agreement*. If the problem is one in relation to which a great deal remains unknown, there is little sense in which one can make the type of comparison envisaged by Article 5.5 *SPS Agreement*. The most one can generally say is that both situations involve an unknown, which is hardly a sound basis on which to measure consistency.

362. In any event, the European Communities would point out that it has indicated in its first written submission, in the alternative, why it considers that, in any event, the Complainants have not proven any inconsistency with Article 5.5 *SPS Agreement*.

363. (a) Similar comments apply with regard to Article 5.6 *SPS Agreement*, which requires measures to be no more trade restrictive than necessary. In the context of a provisional measure, Article 5.6 *SPS Agreement* adds little if anything to Article 5.7 *SPS Agreement*. The whole point of a provisional measure is that the science is insufficient to form a definitive view. In these circumstances, the legislator sets out to preserve the situation, pending the arrival of the science necessary to take a definitive decision on the matter. The very nature of preserving the situation, that is, the precautionary approach adopted by the legislator, very strongly implies that, for the time being, the authorisation sought will not be given. The legislator is concerned to ensure that no irreversible steps are taken. Thus, in the logic and structure of the *SPS Agreement*, the relevant provision is Article 5.7 *SPS Agreement*, not Article 5.6.

111. With reference to para. 328 of Canada's first written submission and para. 382 of Argentina's first written submission, does the European Communities agree that such requirements as the requirement that biotech products not cause adverse effects to health or the environment or the requirement that biotech foods not present a danger are "product characteristics"? If not, why not?

364. The European Communities agrees that Directive 2001/18 and Regulation 258/97 lay down "product characteristics" within the meaning of Annex 1.1 *TBT Agreement*. This is however, irrelevant, since the consistency of those measures with the *TBT Agreement* is not before this Panel. Rather, Canada and Argentina assert that the Member State measures are inconsistent with the *TBT Agreement*. And those Member State measures do not lay down product characteristics, within the meaning of Annex 1.1 *TBT Agreement.*

365. More generally, the European Communities considers it doubtful that the phrases referred to, in themselves, lay down "product characteristics". Most everything may be said to potentially have an adverse effect on health or the environment or to present a danger – or not – depending on all the circumstances (amount, dose, configuration, exposure and so on). In the opinion of the European Communities, some more specificity would probably be required before it could be said that such statements amounted to "product characteristics".

112. With reference to para. 336 of Canada's first written submission, does the European Communities agree that the term "like" in Article 2.1 of the TBT Agreement has the same meaning and scope as the term "like" in Article III:4 of the GATT 1994?

366. No. As the Appellate Body has said a number of times:

> … there can be no one precise and absolute definition of what is "like". The concept of "likeness" is a relative one that evokes the image of an accordion. The accordion of "likeness" stretches and squeezes in different places as different provisions of the *WTO Agreement* are applied. *The width of the accordion in any one of those places must be determined by the particular provision in which the term "like" is*

encountered as well as by the context and the circumstances that prevail in any given case to which that provision may apply.[100]

367. The Appellate Body has also cautioned the automatic transposition of the interpretation of "likeness" under the first sentence of Article III:2 to other provisions where the phrase "like products" is used.[101] The same obviously applies to the automatic transposition of the concept between other WTO provisions.

368. Although it is not possible to say in the abstract whether the term "like" in Article 2.1 of the *TBT Agreement* has the same *meaning* as the term "like" in Article III:4 of the GATT 1994, it is, in the view of the European Communities clear that it cannot have the same *scope.* As explained in the first written submission of the European Communities, Article 2.1 of the *TBT Agreement* can only apply to differences in treatment between products that are covered by the technical regulation in question. Thus the *scope* of the term "like product" in Article 2.1 of the *TBT Agreement* must be limited by the scope of the products covered by the technical regulation under consideration.

113. With reference to para. 359 of Canada's first written submission, does the European Communities agree that it is appropriate to interpret the term "necessary" in Article 5.1.2 of the TBT Agreement by reference to the three factors referred to by Canada?

369. No. Article 5.1.2 *TBT Agreement* is concerned with conformity assessment procedures, but taking what is in the technical regulation or standard as a given. The word "necessary" essentially refers to the relationship between the conformity assessment procedure and the technical regulation or standard, rather than to the content of the technical regulation or standard itself.

370. Thus, in the first bullet point Canada refers to "the relative importance of the common interests or values that the measure is intended to protect". The "common interests or values" that it is intended to protect will generally be apparent from the technical regulation or standard, rather than the conformity assessment procedure.

371. The same is true of the relationship between the measure and the end pursued (Canada's second bullet point).

372. The effects on international trade (Canada's third bullet point) are referred to expressly in the first sentence of Article 5.1.2 *TBT Agreement*. The second sentence of Article 5.1.2 *TBT Agreement* begins with the words "this means". Consequently, it is not a case of interpreting the word "necessary" by reference to the effects on international trade, but the converse. Whether or not the conformity assessment procedures create unnecessary obstacles to international trade is to be assessed, *inter alia*, by reference to whether or not the conformity assessment procedures are more strict than "necessary" to give the importing Member adequate confidence that products conform with the relevant technical regulation or standard.

114. Could the European Communities give examples of situations where, in its view, conformity assessment procedures would be "applied more strictly than is necessary", contrary to the requirements of Article 5.1.2 of the TBT Agreement?

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[100] Quoted from Appellate Body report in European Communities – Asbestos, para 89 where the Appellate Body was quoting from its report in *Japan –Alcoholic* Beverages, para 114.

[101] *Japan –Alcoholic* Beverages, para 113.

373. The European Communities would offer the following example.

374. A technical regulation lays down product characteristics for electrical plugs, requiring them to contain a fuse. The intention is to protect human life and property. The conformity assessment procedure requires any plug manufacturer wishing to sell plugs in the territory of the importing Member to obtain prior authorisation. It is clear from the technical regulation that this requires, at least, the submission to the authorising authorities of all the technical details and documents, together with a physical sample of the plug containing the fuse. Up to this point, we assume that there would be no breach of Article 5.1.2 *TBT Agreement*.

375. Next, the authorising authority decides that every single physical plug to be imported to the Member's territory will each have to be physically brought to the (unique) premises of the authorising authority, where it will be opened and inspected in order to verify that it does indeed contain the required fuse. Each plug will then receive a certificate of conformity, and then, and only then, each plug can be sold.

376. We may reasonably assume that this approach is stricter than necessary to give the importing Member adequate confidence that the plugs conform to the technical regulation. Since plugs are mass produced, it is very likely that the final product will exhibit a high degree of homogeneity, so a sample should be sufficient. When fuses blow, they have to be replaced anyway. If a plug requiring a fuse were sold without a fuse, it is unlikely to be a commercial success. The threat of withdrawal of authorisation in case of a finding of non-conformity following a complaint should provide sufficient incentive for the importer to comply. The cost of bringing each individual plug to the premises of the authorising authority before onward distribution is probably prohibitive, and would effectively make any imports non-commercial.

377. The requirement is not expressly provided for in the technical regulation, so it is not the conformity assessment procedure that is, as such, too strict. Rather, the decision on whether or not to proceed in this way is left, in the municipal jurisdiction, to the authorising authority. The problem is therefore that the conformity assessment procedure is being applied (by the authorising authority) more strictly than necessary to give the importing Member an adequate degree of confidence that the imported plugs will contain fuses.

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

378. The text, context and object and purpose of these provisions being different, the European Communities would not assert that the two phrases mean the same thing in all cases. Rather, the European Communities would take the view that the acceptable period of time would depend on all the circumstances. In particular, some issues, by their own nature, may require more time. This may typically be the case for environmental or biodiversity or ecosystem type issues, which may be both unusually complex, and which may require the passage of time (the seasons), at least when it comes to field testing.

116. With reference to para. 480 of the EC first written submission, is it the European Communities' position that the procedural time-limits set out in domestic legislation are not relevant to an assessment of whether a particular delay is undue? If so, how can this position be

reconciled with the provision of Annex C(1)(b) which requires, inter alia, that the standard processing period of each procedure be published?

379. As stated in the above referenced paragraph, the European Communities is of the view that the procedural time-limits set out in domestic legislation are not relevant to an assessment of whether a particular delay is undue. If the drafters of the *SPS Agreement* had wanted to directly enforce time-limits laid down in domestic legislation, they would have drafted the obligations contained in Annex C(1)(a) and (1)(b) in a different manner. They could have stated, for example, that delays are undue if they exceed the time-limits laid down in the relevant domestic legislation. Equally they could have required, not that a *standard* processing period, but that the processing period *tout court* be published.

380. Indeed, by referring to a "standard" processing period in Annex C(1)(b) the drafters implied that time-limits for specific procedures in the application of SPS measures are not and cannot be set in stone. Standard time-limits are based on the assumption that a process runs smoothly and does not encounter unforeseen obstacles. Unforeseen obstacles, by definition, cannot be planned nor predicted, which is why standard time-limits at least in complex assessment procedures usually are not of a binding nature in the sense that exceeding them would automatically entail undue delay (and much less entail an automatic decision). Accordingly, exceeding the "standard" time-limit published pursuant to Annex C(1)(b) of the *SPS Agreement* does also not automatically result in "undue" delays under Annex C(1)(a).

381. In the specific case of assessment procedures for GMOs experience has shown that a number of risk assessment or risk management aspects are not fully defined and subject to constant evolution of the background scientific debate. Applicants as well as competent authorities have to adjust to these constant developments which not seldomly means that additional information is (spontaneously) submitted by the applicant or is requested by the competent authority. This is the case in all regulatory regimes on GMOs including those of the Complainants.[102] The present EC GMO legislation takes this fact into account and provides that the clock is stopped if (reasoned) requests for additional information.[103]

117. With reference to para. 482 of the EC first written submission, why is a delay caused by risk considerations which do not fall within the scope of Annex A of the SPS Agreement not relevant to a determination of whether said delay is inconsistent with Annex C(1)(a) of the SPS Agreement? Is it not inevitable that the approval procedure conducted pursuant to the provisions of the SPS Agreement would be delayed as a result of the aforementioned cause?

382. The European Communities does not state that delays for reasons outside the scope of the *SPS Agreement* are always irrelevant to determining whether or not there is an inconsistency with the *SPS Agreement*.

383. The European Communities recalls its position that since the *SPS Agreement* applies to measures which pursue certain objectives – objectives of prevent certain risks – a measure that pursues other objectives as well as SPS objectives must be viewed as two separate measures. This applies to approval procedures as much as to other SPS measures.

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[102] The European Communities refers to the examples provided in para. 489 in its first written submission.

[103] See Article 14(4) and 15(1) of Directive 2001/18. See also Article 6(7) and 13(6) of Directive 2001/18.

384. The case of delays is somewhat more complex. As the European Communities has explained, delays may be considered "measures" for the purposes of dispute settlement where there is an obligation that is applicable to delay or inaction. That does not actually make the delay an "SPS measure", which are defined in Annex A.1, but rather a measure subject to an SPS obligation.

385. The reasons why a given period of time has elapsed may relate to SPS objectives or to other objectives (such as, for example, objectives that would cause a resulting measure to fall under the *TBT Agreement*).

386. The European Communities considers that in these circumstances, as a first step, any reasons for the time that has elapsed that relate to non-SPS objectives should be identified, and the elapsed time specifically attributable to those reasons should be measured against what is acceptable under the WTO provisions applicable to it.

387. The reason for this is that an approval procedure pursuing both SPS and non-SPS objectives must be considered for WTO purposes as an SPS approval procedure to the extent that it pursues SPS objectives and a non-SPS approval system for the rest. Delays in the non-SPS approval system are simply not subject to the disciplines of Annex C but to whatever other WTO provision may be applicable.

388. In the present case it is a fact that the approval procedure set up under the EC GMO legislation is designed to address both SPS concerns and non SPS concerns. The Complainants have not challenged this linkage. Because of the linkage, an approval procedure may be held up both for reasons relating to objectives coming under the *SPS Agreement* and for reasons relating to objectives outside the *SPS Agreement*. To the extent that delays occur for reasons relating to objectives outside the *SPS Agreement* these delays cannot automatically be held to be "undue," at least where the reasons form part of the approval procedure as designed (and not challenged by the Complainants).

389. To the extent the reasons relate to objectives coming outside the *SPS Agreement* and the resulting measure would come under the *TBT Agreement*, the corresponding delays could be assessed under Article 5.1.2 of the *TBT Agreement.* The European Communities submits that such a delay cannot be considered undue under the *SPS Agreement* unless it would be considered unjustified under the *TBT Agreement*.

118. Assume for the sake of argument that an approval procedure in respect of an application for the approval of a particular biotech product is governed by the provisions of the SPS Agreement and the TBT Agreement, consistent with the European Communities' views as set out at para. 441 of its first written submission. Assume further that there is a delay in the processing of the application concerned and that the delay is caused by risk considerations which do not fall within the scope of Annex A of the SPS Agreement. Finally, assume that the delay is not inconsistent with relevant provisions of the SPS Agreement but is inconsistent with the provisions of the TBT Agreement. What is the legal position? Would a panel need to find that the Member concerned has breached its WTO obligations in respect of the conduct of the relevant approval procedure?

390. As explained in the reply to question 117, because there is but one authorisation procedure which comes both under the *SPS Agreement* and the *TBT* (or other relevant) *Agreement(s)*, the assessment of delays under the relevant provisions of these agreements may be linked. In concrete terms, this means that TBT (or other non SPS) considerations may become relevant for the assessment of "undue delays" in Annex C(1)(a). To the extent that the "TBT delays" are not unjustified they cannot be considered "undue" under the *SPS Agreement*.

391. Regarding the hypothetical scenario proposed in question 118, the European Communities would note that if the delay is *exclusively* caused by risk considerations coming under another agreement than the *SPS Agreement* and is found to be inconsistent with that agreement, the finding would also affect the assessment of "undue delays" under the *SPS Agreement* as the SPS part of the authorisation procedure would have come to an end if it was not because of the non-SPS risks.