European Communities – Measures Affecting the Approval and Marketing of Biotech Products

(WT/DS291, 292, and 293)

Supplementary Rebuttal Submission of the United States

November 15, 2004

TABLE OF CONTENTS

I. Introduction

1. Subsequent to the filing of the Parties' rebuttal submissions, the EC has submitted over 2,800 documents filling five CD's that provide additional information on 40 application histories of products affected by the EC's moratorium on the approval of biotech products. The Panel also has informed the parties of its decision to seek the advice of scientific experts. The United States appreciates this opportunity to submit this supplementary rebuttal submission responding to the voluminous new materials submitted by the EC at this late stage in the proceedings, and to suggest additional questions that the Panel should pose to scientific experts.[1]

2. In its prior submissions, the United States has shown that the EC adopted general and product-specific moratoria, and that these moratoria are not consistent with its obligations under the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement"). The United States has also explained how the member State measures are not based on a risk assessment or otherwise consistent with the EC's SPS obligations.

3. In its rebuttal submission, the EC makes a number of legal or other arguments – most of which the United States has previously addressed in its prior oral and written submissions. In Part II below, the United States will address the arguments in the EC's second submission that appear to be new or substantially restated from prior EC submissions.

4. The EC has not, however, even attempted to explain how the moratorium is consistent with its SPS obligations. Rather, the EC's core defense remains that despite the fact that the moratorium was widely and openly acknowledged by EC member States and EC officials, no moratorium in fact ever existed. The EC attempts to support this position through the submission of the CDs containing documents related to the processing of applications, and through brief narratives describing the processing of pending applications.

5. As the United States has explained in its previous submissions, the evidence of the existence of the moratorium is overwhelming, and it is not necessary to engage in a detailed and exhaustive review of each application to reach the conclusion that the moratorium existed. Moreover, the mere fact that certain applications made some progress through the approval process, or that some of the delays may not have been unjustified, most certainly does not disprove the existence of the moratorium. The moratorium was a political-level decision not to allow any product to reach the final stage of approval; it was entirely consistent with that decision for EC regulators to allow certain applications to make some progress – short of final approval – through the approval process.

6. Nonetheless, the United States notes that the application histories submitted by the EC do not support the EC's view that the moratorium never existed. Rather, the chronologies provide numerous examples of how the moratorium operated to prevent decisions being reached on the

[1] The United States suggested questions to experts are contained in Annex I to this submission.

different product applications and in different stages in the approval process. In several cases, as pointed out in prior U.S. submissions, applications were completely ignored either at the member State or the Commission level for years. In others, member States lodged baseless objections and requests for information that unduly delayed various applications. The EC documents further show that the only risk assessments for the products at issue were those conducted by the lead competent authority and the EC's scientific committee, and that the results from those risk assessments neither conflicted with each other nor otherwise justified failing to reach a decision on the products.

7. In Part III below, the United States will show that the EC has failed to explain away numerous delays in the processing of various applications. In Part IV below, the United States will show that many member State requests for additional information were not based on legitimate scientific concerns, and thus that the delays resulting from those requests were not justified.

II. The EC's Second Submission Fails to Raise Any Meritorious Arguments in Support of its Positions

8. As noted above, although the EC's defense mostly relies on its product histories and associated documents, the EC's Second Submission does make some other new, or substantially restated, arguments. As described in this Part, those arguments are without merit.[2]

A. The EC's Concept of "Mootness" is not Relevant to this Dispute

9. As the United States explained in its answers to the Panel's first set of questions, the concept of "mootness" that the EC has articulated is not of relevance to this dispute. The Panel's terms of reference under the DSU are "[t]o examine . . . the matter referred to the DSB" in the request for the establishment of the Panel. In this case, those matters are the general and product specific moratoria and the member State safeguard measures as they existed in August 2003. The United States is not aware of, and the EC has not identified, any panel that, absent an agreement of the parties, has declined to examine a measure that was in force when its terms of reference were set. To the contrary, past GATT and WTO panels have examined and made findings on measures even if they were discontinued during the panel's work.[3] As the panel wrote in the *India – Autos* dispute:[4]

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[2] The United States also notes that the EC's Second Submission contains additional discussion on the scope of the risks covered in the SPS Agreement. Because the Panel has now sought expert advice on the definition of certain terms used do describe the scope of the SPS Agreement, the United States, as appropriate, will address these arguments in further written or oral submissions, taking into account any relevant expert advice on these issues.

[3] As discussed below, the United States also strongly disagrees with the EC's implication that it has terminated the general moratorium.

[4] Report of the Panel, *India – Measures Affecting the Automotive Sector*, WT/DS146/R, WT/DS175/R, para. 7.26.

> A WTO panel is generally competent to consider measures in existence at the time of its establishment. This power is not necessarily adversely affected simply because a measure under review may have been subsequently removed or rendered less effective. Panels in the past have examined discontinued measures where there was no agreement of the parties to discontinue the proceedings.[5]

10. Thus, consistent with the requirements of the DSU, the practice has been for panels to make findings and conclusions with respect to the measures that the complainant identified in its request for establishment of a panel.

11. The EC in its rebuttal submission has two responses, both of which are entirely without merit.

12. First, the EC argues that "Remarkably, the Complainants have made no attempt to explain why WTO Panels are prevented from applying a legal principle that is recognised in jurisdictions around the world and commonly applied by international tribunals, including the International Court of Justice." The EC makes no attempt at defining precisely what "legal principle" of mootness the EC claims that the WTO should adopt; the EC fails to explain why the GATT and WTO panels cited above have in fact considered terminated measures, and the EC makes no attempt to explain how such a principle would be consistent with the text of the DSU. In short, what is "remarkable" is that the EC criticizes the respondents for relying on the text of the DSU and on past GATT and WTO practice.[6]

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[5] Id., para. 7.26. The Panel also drafted a helpful footnote summarizing past practice on this issue: "See for instance the Panel Report on US – Wool Shirts and Blouses, WT/DS33/R, adopted on 23 May 1997, as upheld by the Appellate Body Report, para. 6.2 (DSR 1997:I, 343), where the measure was withdrawn following the issuance of the interim report, and the panel nonetheless issued a complete report. See also the Panel Report on Indonesia – Autos where the panel proceeded with its examination of the claims despite a notification in the course of the proceedings by the respondent that the programme in issue had expired: "(…) In any event, taking into account our terms of reference, and noting that any revocation of a challenged measure could be relevant to the implementation stage of the dispute settlement process, we consider that is appropriate for us to make findings in respect of the National Car Programme. In this connection, we note that in previous GATT/WTO cases, where a measure included in the terms of reference was otherwise terminated or amended after the commencement of the panel proceedings, panels have nevertheless made findings in respect of such a measures" (WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R, para. 14.9, DSR 1998:VI, 2201). As mentioned by that panel, there have also been such instances of continued proceedings despite expiry or partial disappearance of the measures at issue under the GATT: see for instance EEC –Apples I (Chile) (BISD 27S/98) paras 2.2 and 2.4; United States – Prohibition of Imports of Tuna and Tuna Products from Canada (BISD 29S/91), paras. 2.8, 4.2 and 4.3, where despite some evolution in the measures in the course of the proceedings and encouragement from the Panel to reach a mutually agreed solution, there was no agreement among the parties that such a solution had been found and the panel issued a complete report." *Id.*, para. 7.26 n. 313.

[6] The United States further notes that if the EC intends to imply that the International Court of Justice is *precluded* from examining a terminated measure, then the EC is misrepresenting ICJ practice. The Court has stated that subsequent events may "render an application without object," but the ICJ has further elaborated that such mootness determinations apply where adjudication would be "devoid of any purpose." Case Concerning the Northern Cameroons, Preliminary Objections, Judgment, I.C.J. Reports 1963, p 38. Also noteworthy is the fact that

13. Second, the EC tries to confuse the issue by addressing yet another question: namely, whether a Panel issuing findings on a terminated measure should also recommend that the DSB request the defending Member bring its measure into conformity with WTO rules. Plainly, under that same consistent GATT and WTO practice, panels do issue such recommendations. Furthermore, DSU Article 19.1 specifically provides that "where a panel ... concludes that a measure is inconsistent with a covered agreement, *it shall recommend* that the Member concerned bring the measure into conformity with that agreement."[7] While the EC cites the *U.S. – Customs Bonding* dispute as an example to the contrary, that dispute in fact involved an entirely different situation: the measure at issue in that dispute had ceased to exist *before the date of the request for establishment of the panel*.[8]

14. Moreover, this is not a case in which the measure at issue has terminated. As explained below in the discussion of the progress of the BT-11 and NK603 applications, the United States certainly does not agree that two token product approvals – made only after substantial delays and pursuant to Commission decisions after failures by both the Regulatory Committee and Council to take decisions – suffice to signal that the EC has begun to process other outstanding applications without undue delay, as required by the EC's SPS Agreement obligations.

15. As the United States explained at the first substantive meeting, it is particularly important for the United States, and for the WTO rules-based system as a whole, that the Panel in this dispute comply with past practice and issue findings on the EC's moratorium as of August 2003. All but two of the products caught up in the moratorium remain unapproved. Biotech product approvals remain a controversial political issue in the EC, and the recent expansion of the EC from 15 to 25 member States has not simplified the situation. In addition, as noted in the U.S. Second Submission, a number of EC member States believe that yet additional legislation must

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although the EC cites to the Case Concerning Questions of Interpretation and Application of the 1971 Montreal Convention Arising from the Aerial Incident at Lockerbie, Preliminary Objections, Judgment, I.C.J. Reports 1998, p. 131, para. 46, the Court in that case *declined* to apply mootness to the objection presented. Similarly, the EC's discussion of "mootness" principles under United States domestic law is simplistic and misleading. For example, U.S. law contains a well-known exception for disputes involving matters that are "capable of repetition, yet evading review." *See, e.g,, Norman* v. *Reed,* 502 U.S. 279 (1992). That doctrine provides that a terminated measure should be examined by a court if, for example, there is "reason to expect the same parties to generate a similar future controversy." *Id.*

[7] DSU Article 19.1 (emphasis added, footnote omitted).

[8] Report of the Appellate Body in *United States - Import Measures on Certain Products from the European Communities*, WT/DS165/AB/R, adopted 10 January 2001 ("*U.S.-Import Measures*"), para. 79. Nor does the *India – Autos* report help the EC here. That panel's reasoning on this issue was the subject of severe criticism by both India and the United States (*see Minutes of the Meeting of the Dispute Settlement Body Held on 5 April 2002*, WT/DSB/M/122, paras. 12, 15-17). It was also the subject on an Indian appeal (withdrawn and therefore not decided). The United States shared many of India's concerns and considered that the panel had failed to properly analyze its responsibilities under DSU Article 19.1. The United States also noted that the panel had failed to realize that its report would establish the rulings and recommendations with which India had to comply; whether or not India had effectively already done so was a matter for the future. As the *Indonesia Autos* panel had noted (in paragraph 14.9 of its report), a revocation (or other elimination or amendment) of a challenged measure was particularly relevant at the implementation stage of dispute settlement.

be adopted before the granting of new biotech product approvals.[9] And, although the EC has now approved two corn varieties for import and consumption, *the EC has yet to approve under 2001/18 a single biotech product for planting in the EC.* Accordingly, if the Panel were to depart from the DSU and past practice and apply the EC's concept of mootness, the possibility is substantial that the EC – once freed from the pressure of this ongoing proceeding – would halt all further approvals. It is thus of great import that the Panel issue a finding that the EC's politically-based moratorium is not consistent with WTO rules.

B. The EC Again Fails to Provide Any Argument Rebutting the Widely Known Fact That the EC Has Adopted a General Moratorium

16. In its second submission, the EC presents a number of arguments why– despite the widespread acknowledgment by EC officials of the imposition of a general moratorium – the Panel should nonetheless find that no moratorium ever existed. The EC's arguments in fact lend further support to the existence of the moratorium.

17. First, the EC defines a moratorium as existing where "the process of decision-making is temporarily stopped."[10] The EC then argues that no moratorium existed, because some applications continued to make some progress through the EC's elaborate approval procedures. This is a straw-man argument, and simply dispensed with. As the United States explained clearly in its first submission: "Particular product applications might make some progress, in fits and starts, through the EC approval system, but the EC has failed to allow any new biotech product to move to final approval since October 1998."[11] Thus, the United States has never claimed that *all* processing stopped; rather that the EC adopted a decision to ensure that no product ever proceeded to the stage of final approval.

18. Second, the EC relies on its adoption of a so-called "interim approach," under which the Commission "sought to anticipate the new Community legislation."[12] Upon examination, however, the EC's reliance on the "interim approach" in fact supports the existence of the moratorium.

19. On the one hand, the EC explains that:

> 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

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[9] Second U.S. Submission, Section V.B.3 (discussing statements of member State to the effect that approvals should be delayed pending adoption of possible Co-Existence and Environmental Liability Legislation).

[10] Second EC Submission, para. 290.

[11] First U.S. Submission, para. 2 (emphasis added). See also U.S. Panel Request ("In particular, the EC has blocked in the approval process under EC legislation all applications for placing biotech products on the market, and has not considered any application for final approval.")

[12] Second EC Submission, para. 292.

> achieve results in the approval procedures despite the transitional period of legislative changes.[13]

On the other hand, the EC describes the interim approach as follows:

> "The last Commission orientation debate on GMOs took place on 12 July 2000. On that occasion, the Commission agreed on an 'interim approach' for relaunching the authorisations of GMOs, entailing the anticipation of the key provisions (labelling, traceability, monitoring etc) of the forthcoming new environmental legislation. The new requirements would be incorporated into the individual authorisations of GMOs granted under existing legislation. In addition, it was agreed that a package of new measures on GMOs, namely on GM food and feed and on labelling and traceability of GMOs be proposed by the Commission by autumn 2000."[14]

Taken together, the EC is representing that under the interim approach, "new requirements" would be incorporated into individual applications; but that this decision was not "adopted in any form" and was "merely a practice that was followed on the basis of a political intent "

20. The EC's own description of the "interim approach" confirms a fundamental position of the United States: that the EC, "on the basis of political intent," made a decision to apply its biotech legislation in a manner that differed substantially from the text of the legislation.

21. The question is then precisely what change EC political-level decision-makers made in the operation of the legislation – a decision only to change the requirements for approval (as the EC claims solely for the purpose of this dispute settlement proceeding), or a decision to change requirements and to adopt a moratorium on final approvals (as EC member States and political-level decision makers widely acknowledged). And, once it is understood, as the EC acknowledges, that the EC would feel free to depart from its legislation by changing the approval requirements, it is not at all hard to understand that the EC might also decide to delay its final decisions based on the same political considerations. And in fact, the evidence – including the failure of any application to move to final approval for over 5 years, and the many lengthy and unwarranted delays in processing individual applications – overwhelmingly shows that the EC did in fact decide to apply a moratorium.

22. The EC's "interim approach" argument provides yet further support for the existence of a moratorium. The EC states that the "interim approach" would involve applying requirements of unenacted legislation. Those requirements, however, would not be finalized for at least three years after the EC's purported adopted of an interim approach in 2000.[15] Particularly in light of

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[13] EC Answers to Questions, para. 35.

[14] GMOs: Commission takes stock of progress (28 January 2004) (Canada Ex. 33).

[15] As noted above, the interim approach included application of the traceability and labelling and GM food and feed legislation. These were not adopted until 1993, and did not enter into force until April 1994.

the EC's admittedly politically-based approval system, it is not credible to believe that the EC would decide to depart from the face of its approval legislation by adopting new requirements on an extra-legal basis, while at the same time allowing products to move to final approval when the contents of those new requirements were not yet decided upon. As the United States noted at the first substantive hearing, it is no mere coincidence that the EC's first biotech approval in over five years occurred in May 2004 – less than one month after entry into force of the EC's new traceability and labeling and GM food and feed legislation.

23. Third, the EC now tries to explain away the numerous official acknowledgments of the moratorium by claiming that "all these statements refer to or comment on a fact which the European Community does not contest, i.e. that there have not been any market authorisations for a given period of time other than the market authorisations granted pursuant to the simplified procedure under the Novel Foods Regulation."[16] This assertion, however, is wrong. "All these statements" by EC officials do not refer simply to the fact that no biotech products reached final decision. To the contrary, the statements uniformly refer to the existence of a "moratorium." And, as the EC itself informs the panel, a "moratorium" "may be defined as 'a postponement or deliberate temporary suspension of some activity.'"[17] The United States submits that EC officials used the term "moratorium" because it precisely fits the situation: namely, that the EC had decided not to allow any biotech product application to move to final approval.

C. The EC's Theory of "Mixed Delays" is Meritless

24. In discussing the analysis of the term "undue delay" under Annex C of the SPS Agreement, the EC's second submission advances a novel theory of "mixed delays."[18] This theory is illogical and not supported by the text of the SPS Agreement. As the United States explained in a prior submission, as long as the approval procedure is within the scope of the SPS Agreement (and the EC apparently agrees that its Novel Foods regulation and Deliberate Release directive are within the scope of the SPS Agreement), the Member has an obligation to undertake and complete that procedure without undue delay, regardless of whether the delay is due to the consideration of risks outside the scope of the SPS agreement or, indeed, is due to any other consideration.[19]

25. First, the SPS Agreement provides that Members "shall ensure [that] procedures to check and ensure the fulfillment of [SPS] measures . . . are undertaken and completed without undue delay.[20] Nothing in the text of the SPS Agreement suggests, as the EC contends, that a Member is excused from this obligation if the delay stems from a consideration outside the scope of the SPS Agreement.

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[16] Second EC Submission, para. 294.
[17] Second EC Submission, para. 289 (quoting The New Shorter Oxford English Dictionary).
[18] Second EC Submission, paras. 261-267.
[19] U.S. Answers to Questions, para. 73.
[20] SPS Agreement, Annex C(1)(A).

26. The EC has instead invented an entirely new approach to applying the obligations of the WTO agreements. According to the EC's approach, a provision does not need to provide for an exception or derogation in order not to apply; instead, a separate, entirely unrelated obligation of a different WTO agreement can serve as an exception to that obligation. According to the EC, as long as a Member can show that its measure is not inconsistent with a different obligation, then that lack of inconsistency with one provision can excuse the inconsistency with another provision. This rather remarkable approach has even more surprises. According to the EC, unless the United States can prove that the EC moratorium is inconsistent with the *Agreement on Technical Barriers to Trade* (the "TBT Agreement"), then the United States is unable to prove its claim under the SPS Agreement. Apparently the EC would reverse the usual rule of treaty interpretation that there is no conflict between two obligations if satisfying one of them (for example the stricter one) would also satisfy the other.[21] Instead, for the EC, where two obligations apply, only the lesser of the obligations matters. Furthermore, in this dispute the EC has not answered the question of how both the SPS and TBT Agreements could apply to the same measure given the texts of Article 1.5 of the TBT Agreement ("The provisions of this Agreement do not apply to [SPS] measures as defined in Annex A of the [SPS Agreement]") and Article 1.4 of the SPS Agreement ("Nothing in this Agreement shall affect the rights of Members under the [TBT Agreement] with respect to measures not within the scope of this Agreement.") .

27. Moreover, the EC's argument, if taken to its logical conclusion, would severely undermine the "undue delay" obligation in Annex C. For example, take a case in which a WTO Member delayed an SPS approval procedure for years – for arbitrary reasons, or to protect a domestic producer. Under the EC's suggested interpretation, the Member would not be in violation of the SPS Agreement, because the delay did not arise from the evaluation of a risk enumerated in the SPS Agreement. Surely, in such circumstances, the drafters of the SPS Agreement did not intend to excuse a Member from its obligation under Annex C to undertake and complete approval procedures without undue delay.

D. The EC Has no Basis for Its Argument that the Panel Should Depart from the Definition of "Risk Assessment" set out in the Agreement

28. The EC – first in its Answers to the Panel Questions, and then in its Rebuttal Submission – spends considerable time addressing the definition of "risk assessment" for purposes of analysis under the SPS Agreement.[22] Presumably, the EC believes that a departure from the definition set out in the SPS Agreement is somehow supportive of its measures. As an initial matter, the United States notes that no issue in this dispute would appear to turn on the definition of "risk assessment." In particular, the EC has not even attempted to identify any risk assessments that might support the general moratorium, the product-specific moratoria, or the

[21] *See, e.g.,* Report of the Panel, *Turkey – Restrictions on Imports of Textile and Clothing Products*, WT/DS34/R (31 May 1999), para. 9.94 ("There is a conflict when two (or more) treaty instruments contain obligations which cannot be complied with simultaneously. . . . Incompatibility of contents is an essential condition of conflict". (Citing 7 Encyclopædia of Public International Law)).

[22] EC Second Submission, paras. 21-26; EC Answers to Questions, paras. 5-14.

member States safeguard measures.[23] In any event, the definition of "risk assessment" is clearly set out in Annex A.4 of the SPS Agreement, and that definition is dispositive. The EC's discussion of alternative definitions of "risk assessment" is without merit, and should be disregarded.

E. The EC Continues Not To Present A Serious Defense of its Member State Measures

29. As the United States has explained, each of the products subject to the member State safeguard measures have received positive risk assessments from the EC's own scientific committees, and those same committees have considered and rejected the scientific arguments advanced by the member States in support of the measures. In these circumstances, the member State measures cannot be considered to be based on a risk assessment. Nor can the measures fall within the scope of Article 5.7 since, *inter alia*, in light of the *positive* risk assessments, the scientific evidence cannot be considered insufficient, nor can the measures be supported by available pertinent information.

30. In its Second Submission, the EC again fails to point to any contrary risk assessments, nor does it attempt to explain how Article 5.7 applies in light of the full scientific evaluations of these products by the EC's own scientific committees. Instead, the EC's only argument on the application of 5.7 is the specious claim that "All the Complainants originally stated that the Member State measures are provisional measures."[24]

31. The only new material in the EC Second Submission addressed to the member State measures is an exhibit titled "Table summarising the position in relation to the Member State measures, as set out in the first written submission of the European Communities." The table, which purports to show the various reasons why the member States adopted each safeguard measure, should be given no weight by the Panel. It is not supported by any footnotes or any other references, and it appears to be nothing more than an *ex post facto* attempt to justify those measures.

32. Even if the new table could be considered to have some evidentiary value, it does not begin to show how the safeguard measures might be consistent with the SPS Agreement. For example, the table provides no citations to any "available pertinent information" that might be

[23] In fact, the EC apparently concedes that no risk assessment supports the general moratorium. The EC notes that if the Panel does find the existence of a general moratorium, the Panel should jump to the issue of the applicability of SPS Article 5.7, because the moratorium "would have to be considered to be of a provisional nature applied for reasons of insufficiency of scientific evidence." Second EC Submission, para. 305. The EC does not even venture to explain, however, how the scientific evidence could be insufficient when many of the products subject to the moratorium *have already* received positive risk assessments from the EC's own scientific committees.

[24] Second EC Submission, para. 317. The only reason complainants associated the word "provisional" with the safeguard measures is that this term is used in the EC legislation. As the United States explained in its Oral Statement (paras. 55-56), thefour-part test for the applicabilty of Article 5.7 is well-established, and the label given to describe a measure can in no way bring that measure within the scope of Article 5.7.

used as part of an argument under Article 5.7, nor does the table explain how scientific evidence might be sufficient when the EC has issued affirmative risk assessments for each product. The United States does note, however, that the table indicates that each measure was adopted for at least one type of risk that the EC agrees is within the scope of the SPS Agreement. So, once again,[25] the EC is not disputing that each member State safeguard measure falls within the scope of the SPS Agreement.

III. The EC Cannot Explain Away the Gaps in Its Product Chronologies

33. Once the EC had made a political-level decision to adopt a moratorium on biotech approvals, EC regulators understandably were in no hurry to process pending biotech product applications. As a result, applicants were faced with extensive and unwarranted delays. In its prior submissions, the United States provided examples of applications in which the delay was in the form of significant and unwarranted periods of inactivity, during which EC regulators simply made no progress in processing the applications.[26]

34. In its second submission, the EC provides brief and conclusory narratives concerning some, but not all, relevant biotech product applications.[27] Those narratives were submitted prior to the EC's submission, at the Panel's request, of a more complete set of product application documents, and thus do not refer to the more complete record currently before the Panel. Moreover, the EC's narratives are in many cases misleading. An examination of the actual documents in the application histories confirm that many products were subjected to undue delays in the form of lengthy periods of inactivity.

35. In the following paragraphs, the United States will present examples of how the actual documents in the application histories confirm the existence of such unwarranted delays in processing applications.[28]

A. EC Exhibit 69: Glufosinate tolerant and insect resistant (Bt-11) corn

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[25] In its First Submission, the EC had previously noted that "each of the Member State measures was adopted for some reasons that fall with the SPS Agreement, and some reasons that do not fall within the SPS Agreement." First EC Submission, para. 578.

[26] *See* Second U.S. Submission Section V.A; *see also* U.S. Answers to Questions, para. 71 and Annex I.

[27] EC Second Submission, paras. 162-246. The EC did not provide narratives for two relevant classes of applications. First, the EC – claiming mootness – has not attempted to explain the lengthy delays in the application histories for products that were withdrawn after the date of the establishment of this Panel in August 2003. As explained above in Section II.A, however, the EC is wrong as a matter of law in claiming that U.S. claims covering such products are moot. Second, the EC has failed to explain the lengthy delays in product applications that were withdrawn prior to the time of Panel establishment. The failure of the EC to process these product applications without undue delay, however, serves as important, additional evidence of the existence of the moratorium.

[28] The United States continues to review the extensive documentation submitted by the EC, most recently in September, and reserves the right to comment on additional product histories in its future submissions. The United States also understands that Canada will address in its supplementary rebuttal the lengthy delays in the oilseed rape product application histories.

36. Although the Scientific Committee on Plants (SCP) issued a favorable opinion on the application for Bt-11 corn under Directive 90/220 on November 30, 2000, the application was never approved.[29] The favorable SCP opinion *stood for nearly 2 years* with no Commission action on the application.[30] The next entry on the EC's chronology, October 9, 2002, is an email from the French Competent Authority (CA) to the Commission requesting a list of applications and the results of SCP examinations.[31] The applicant was required to submit an updated notification under Directive 2001/18 on January 15, 2003, given the Commission's failure to submit the application for a final decision under Directive 90/220.

37. In the narrative in its second submission, the EC attempts to explain away this 2 year gap by asserting that "the Scientific Committee recommended a monitoring plan, and the proposal by the applicant remains unsettled."[32] The actual documents, however, reveal that this assertion is untrue. The opinion did not identify any missing information or other deficiency in the application. To the contrary, the SCP stated without qualification that:

> "the Committee is of the opinion that there is no evidence to indicate that the placing on the market for cultivation purposes of the maize line Bt-11 and varieties derived from this line by conventional crossing with maize lines other than genetically modified ones, is likely to cause adverse effects on human health and the environment."[33]

The *only monitoring plan* referred to in the SCP opinion is an Insect Resistance Management (IRM) plan, which was favorably assessed. The SCP never recommended any changes to the applicant's proposed IRM plan.

38. The only other mention of monitoring was with respect to changes in field populations of non-target insects. The SCP concluded that Bt toxins have been applied widely as pesticides for many years without detected changes in field populations of non-target insects. The SCP also noted that monitoring could, nevertheless, *provide confirmation* that commercialization had not caused adverse effects on the environment.[34] The SCP did not request a monitoring plan on non-target insects, nor did it note any deficiency in the application. The SCP simply advised that after commercialization, field scale surveillance of insect populations should be performed. Moreover, nothing in the record indicates that EC regulators ever approached the applicant either to identify a problem, or to request additions to the application.

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[29] EC Exhibit 69, attachment 83.

[30] *Id.*

[31] EC Exhibit 69, attachment 87.

[32] EC Second Written Submission, para. 194

[33] EC Exhibit 69, attachment 83, section 4.

[34] "The SCP advises that insect populations in representative GM and similar non-GM maize crops should be monitored to provide reassurance that there are no effects on predators and parasitoids at an extended field scale. The SCP wishes to see the results." EC Exhibit 69, attachment 83.

39. Thus, to claim, as the EC has done, that an unresolved monitoring plan was the cause of the two year delay is false. Once the SCP issued its favorable opinion in November 2000, the Commission should have submitted the application to the Regulatory Committee without delay. But, the Commission never did. The two-year delay was, simply, the result of the moratorium.

B. EC Exhibit 65: Bt cotton (531)

40. The application for Bt cotton (531) under Directive 90/220 suffered a 3-year period of inactivity by EC regulators. In its narrative, the EC inaccurately recounts critical facts in an attempt to rationalize this unwarranted 3-year delay.

41. In this case, the SCP had issued a favorable opinion on July 14, 1998.[35] On February 22, 1999, the Regulatory Committee failed to reach a qualified majority either to accept or to reject the petition. Under 90/220, the Commission should have proceeded to submit a draft decision to the Council. But instead, the next entry in the EC's chronology is on May 7, 1999, "Launching of inter-service consultation on draft Council decision."[36] After that, the application was completely ignored by the Commission. Ultimately, the applicant submitted an updated notification on January 16, 2003.

42. The EC justification of this 3 ½ year gap is baseless. The EC claims in its second submission, inter alia, that "on 22 . . . February 1999 the Regulatory Committee failed to reach a qualified majority because a number of Member States maintained objections. These related, in particular, to the presence of an antibiotic resistance gene used as marker within the GM construct, the possible non-target effects on beneficial insects, and the sufficiency of the monitoring plan to analyse indirect effects of Bt cotton, for example on the food web. These are all legitimate scientific concerns. They cannot be ignored or brushed off without detailed consideration."[37]

43. That certain member States objected at the Regulatory Committee does not justify the EC's refusal to act on the application. Indeed, the EC's legislative framework provides a specific avenue for further action where the Regulatory Committee is unable to come to a decision: the Commission is to forward the application to the Council "without delay" for a decision.[38] In this case, that avenue was ignored. The EC's failure to follow its own procedures illustrates the operation of the moratorium.

44. Moreover, nothing in the record indicates that the applicant was ever requested to submit additional information to address the member State objections, nor that the basis of these objections was ever even notified to the applicant. To the contrary, the SCP had concluded that

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[35] EC Exhibit 65, attachment 47.

[36] EC Exhibit 65, attachment 60.

[37] EC Second Written Submission, para. 179.

[38] Directive 90/220/EEC, Article 21 ("If the measures envisaged are not in accordance with the opinion of the [Regulatory] 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) (Ex. US-25).

there was "no evidence to indicate that the placing on the market of line IPC 531 (expressing a B.t.k. toxin) with the purpose to be used as any other cotton is likely to cause adverse effects on human health and on the environment."[39] This conclusion necessarily includes the implicit conclusion by the SCP that the data provided by the applicant was sufficient and that no additional data was required to finalize its risk assessment.

45. Furthermore, nothing in the record indicates why the member States objected despite the SCP opinion that addressed the very issues covered in the objections. And , nothing in the record indicates that the EC undertook any process whatsoever to resolve the member State concerns. To the contrary, the "Interservice Consultations" were a bureaucratic black hole, in which the BT Cotton application fell and was never to receive further consideration until the enactment of new legislation.

46. It should also be noted that not only does the EC's defense of its failure to act after the Regulatory Committee meeting lack merit, it relies on an inaccurate account of the facts. The EC incorrectly implies that the concerns raised by "a number of Member States" in the Regulatory Committee had not already been the subject of "detailed consideration." In fact, all of the objections the EC lists were the subject of detailed scientific consideration in the SCP's positive opinion in July 1998.[40] The SCP specifically considered the "antibiotic resistance gene used as marker within the GM construct, the possible non-target effects on beneficial insects, and the sufficiency of the monitoring plan."[41] Neither the member States in their statements before the Regulatory Committee, nor the EC in its second submission, identified specific inadequacies in the SCP review.

47. The EC's second submission also incorrectly states that "[a]fter the no vote in the Regulatory Committee, Monsanto finally provided the required additional information on 25 July 2001, i.e. 29 months later, and the translation of the material provided was not made available until 18 February 2002, i.e. nearly 7 months later."[42] First, there was no "no vote" in the Regulatory Committee. Any vote, including a "no vote," would have required a qualified majority in favor or against the product, neither of which were achieved.

48. Second, and more importantly, the applicant was not responding to any request from the EC, but, on its own initiative, provided additional information to the lead CA as, not surprisingly, the state of scientific knowledge had advanced since the first submission of the application more than four years before. The new information related to molecular characterisation, safety assessment and analysis of flanking regions. This information was submitted as part of the applicant's commitment to stewardship and initiatives to provide

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[39] EC Exhibit 65, attachment 47, para. 7.1.

[40] Indeed, according to the documents provided by the EC, most member States provided no explanation or justification for why they did not support the application. Only Austria and the UK submitted statements that expressed concerns listed above. EC Exhibit 65, attachment 59.

[41] EC Exhibit 65, attachment 47, paras 6.3.3. (safety to non-target organisms), 6.2.1. (marker gene), 6.3.4. (monitoring).

[42] EC Second Written Submission, para. 180.

additional relevant new information as it becomes available.[43] To state that "additional information" had been required or requested as a result of the Regulatory Committee vote is not true.[44]

49. In sum, the EC has provided no justification for the Regulatory Committee's failure to reach a qualified majority or for the Commission's subsequent refusal to submit a decision on the application to the Council for a decision. As the EC's own chronology shows, for nearly 4 years, from May 7, 1999, after the launch of inter-service consultations on the draft Council decision, until February 12, 2003 when the lead CA finally circulated the SNIF to the Commission, the application was totally ignored by the Commission and lead CA. The only activity during that time was the applicant's struggle to maintain the relevance of its application by submitting additional and updated information as the years passed under the moratorium. The EC's attempt to cast the blame for this gap on the applicant is baseless.

50. Finally, the EC also implies that the applicant failed to provide an adequate monitoring plan under Directive 90/220, and claims that the applicant still does not have one under Directive 2001/18.[45] The implication is flatly wrong. The applicant had submitted an IRM plan as part of its product stewardship, which was deemed "adequate" by the EC's own SCP back in 1998.[46] With regard to the EC's claim that the applicant's monitoring plan is "insufficient" under Directive 2001/18, the fact that there are continuing discussions is wholly irrelevant to explain the 3 ½ year delay that occurred under Directive 90/220. Again, that the application is being discussed at the "staff-level" under Directive 2001/18 – in this case at an arguably delayed pace and on questionable grounds[47] - is entirely consistent with a moratorium adopted on a political level.

51. As of this time, the application has still not been approved. It has been 8 years since the application for Bt cotton (531) was first submitted in 1996. When the application reached the

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[43] Letter from Dr. Clemence to the Office of the USTR (Ex. US-137).

[44] The EC's implication that the applicant was somehow "tardy" in supplying translations of this voluntary, additional information is misleading. First, the information was not required. Second, the information was originally provided in English, one of the official languages of the EU, and, as a practical matter, English language submissions are the versions that are forwarded to the other member States and the Commission. Therefore, any time the applicant used to provide a Spanish translation should not count as a "delay."

[45] EC Second Written Submission, para.181.

[46] EC Exhibit 65, attachment 47, para. 7.2.

[47] The applicant submitted its updated application to the lead CA on January 16, 2003 and provided a general surveillance plan in accordance with Directive 2001/18. It was not until October 2, 2003 that the lead CA finally contacted the applicant, almost 9 months after the updated notification had been submitted, requesting further information on the monitoring plan. (The EC's chronology incorrectly shows an entry after 6 ½ months described as "Letter of lead CA . . . requesting additional information relating to the monitoring plan," referencing attachment 64. Attachment 64 is a letter from the lead CA regarding two notifications, C/ES/97/01 (event 1445 glyphosate-resistant) and the application for Bt Cotton (event 531). The lead CA commented on the monitoring plan for C/ES/97/01, not for Bt cotton.) Most of what was requested, however, was duplicative or unjustified. For example, the lead CA requested information on the insect resistance monitoring/management plan, even though this information had already been provided in an earlier submission. EC Exhibit 65, attachment 14_SCI (includes both appendix VI and appendix VII, Resistance Management Strategies for Bollgard Cotton).

point where it should have been submitted to the Council for a final decision, the Commission failed to do so, leaving the applicant in limbo for 4 years. As this application aptly illustrates and as the United States has maintained throughout this proceeding - it is irrelevant whether certain applications progressed to various stages in the EC approval process. No matter what progress was made – in this case, progress to the point where there were two positive risk assessments from the lead CA and the EC's SCP – in the end, no application was submitted for a final decision under the moratorium.

C. EC Exhibit 91: Roundup Ready corn (GA21)

52. The application for Roundup Ready corn (GA21) under Regulation 257/98 provides another clear example of the functioning of the moratorium. As the United States has previously noted,[48] the application was delayed at the member State level for 10 months while the lead CA completed its risk assessment. It was delayed for 17 months at the Community level before the SCP rendered its positive opinion in February 2002. After the Scientific Committee on Food issued its positive opinion on February 27, 2002,[49] the Commission failed to forward a draft measure to the Regulatory Committee as is required to complete the approval process, resulting in further delay that has lasted until the new GM Food and Feed regulation was passed in September 2003.

53. According to the EC's own chronology, almost two months passed after the positive SCF opinion with no activity at all on this application. The applicant then sent a letter on April 23, 2002 to the Commission. In the letter, the applicant offered that "[t]o enable the authorization procedure under Regulation 258/97 to proceed immediately, . . . we propose that the scope of the authorization decision includes processed grain and all derived ingredients . . . but not unprocessed grain."[50] The reason for this proposal, as the applicant clarifies, is because the food use of unprocessed grains is also subject to Directive 90/220 and that "[as you are aware] progress under this Directive has been suspended for some time, with the result that GA21 maize grain has not yet been considered for consent."[51]

54. Despite the efforts of the applicant to remove any possible impediments, the Commission still failed to forward the application to the Regulatory Committee after the positive SCF opinion. Instead, as reflected in the minutes of a meeting on June 5, 2002 between the Commission and the applicant, the Commission noted that although the next step was to take a Community Decision, "[i]t is desirable that such a Decision would take into account in an appropriate manner the legislative developments with respect to the authorization of GM food and feed as well as the labeling of GM products."[52] In other words, the EC simply halted the processing of this application in anticipation of possible upcoming changes to its regulations, an

[48] Responses of the United States to the Questions by the Panel and the European Communities Posed in the context of the First Substantive Meeting with the parties, June 16, 2004, Appendix I.

[49] U.S. First Written Submission, para. 54 and fn.127.

[50] EC Exhibit 91, attachment 44.

[51] EC Exhibit 91, attachment 44.

[52] EC Exhibit 91, attachment 45, p. 1.

action entirely consistent with the moratorium which EC and member State officials had announced. Although both the new food and feed and traceability and labeling legislations would not enter into force until 2004, and although the applicant stated its preference to apply the labeling requirements currently in effect under Regulation 258/97, the Commission noted that "it is clear that it would be more difficult to obtain a favourable opinion by a majority of Member States in the Comitology procedure," if the applicant were not required to anticipate the new labeling requirements before the new legislation was adopted.[53] In other words, the applicant was required to wait until the requirements for labeling under pending legislation were finalized.

55. In its second submission, the EC does not attempt to defend the Commission's refusal to forward the application to the Regulatory Committee. Thus, the EC does not contest that the GA-21 application was subjected to an unwarranted delay after the positive opinion by the SCF.

56. In its second submission, the EC does address the 17 month SCF review and the 18 months at the member State level. But the EC's discussion is inaccurate.

57. The EC charges that the 17 months it took for the SCF to render its opinion was due to insufficient information in the application.[54] That allegation wrongly implies that the significant delay was caused by the applicant.

58. The truth is reflected in the EC's own chronology: The application was forwarded to the Commission on January 21, 2000. The official member State consultation period was over by April 2000. The Commission asked the SCF for an opinion on May 18, 2000. Eleven months later, the SCF contacted the applicant for the first time, asking for additional information.[55] Within less than one month, the applicant provided an answer to all questions.[56] The EC's chronology provides no explanation, other than a cryptic notation about "lack of time," for the further 11 months it took for the SCF to issue an opinion on February 27, 2002.[57]

59. The EC's justification of the 18 months at the member State level is similarly groundless. The EC claims the delay was the result of "the incompleteness of the dossier initially submitted . . . and to the need for additional scientific data."[58] In this particular case, the lead CA requested the applicant to perform a further study on compositional analysis. The request was made on February 24, 1999, and the applicant provided its response by October 26, 1999.[59] Thus, the total time between the first submission, July 24, 1998, and the lead CA's opinion, January 17,

[53] EC Exhibit 91, attachment 45, p. 2.
[54] EC Second Written Submission, para. 223.
[55] EC Exhibit 91, attachment 39.
[56] EC Exhibit 91, attachment 40.
[57] The current revised regulatory framework recognizes that a period of six months is an achievable timeframe for the EC's Scientific Authority (EFSA GMO Panel) to come to an opinion. Regulation (EC) No. 1829/2003, Article 6.1.
[58] EC Second Written Submission, para. 222.
[59] EC Exhibit 91, attachments 11, 14.

2000, was 18 months. Of those 18 months, 8 were used by the applicant to answer questions. Contrary to the EC assertions, the First U.S. Submission was correct in highlighting the 10 month delay.

60. It has now been over 2 years since the SCF issued its positive opinion in February 2002, and the Commission has yet to forward a draft measure to the Regulatory Committee. Despite these several years of inaction and delay in the EU regulatory process, the applicant continues to seek Novel Foods authorization for GA21.

D. EC Exhibits 78 and 85: Roundup Ready corn (GA21) (C/GB/97/M3/2) and (C/ES/98/01)

61. The EC did not discuss the deliberate release applications for Roundup Ready corn (GA21) under Directive 90/220 in its second submission, based on the EC's unilateral determination that the issues regarding these applications were moot. In response to the Panel's request for more complete information, the EC subsequently produced a chronology and supporting documentation for this and other withdrawn applications. These documents confirm that these applications in fact suffered extensive, undue delays. The EC's delaying tactics also significantly delayed the parallel novel foods application for Roundup Ready corn (GA21) under Regulation 257/98, as was noted in the discussion above.

62. The first application for GA21 under Directive 90/220, submitted in the UK in 1997 (C/GB/97/M3/2), was delayed at the member State level for 7 months. In February 1999, the Advisory Committee on Release into the Environment (ACRE) notified the applicant that it would forward the application to the Commission following some amendments to the application.[60] The EC's chronology omits the applicant's submission dated March 23, 1999 of the final and complete amended application, as agreed between the applicant and the lead CA, which was ready to be forwarded to the Commission as of that date.[61] The application, however, was delayed for more than seven months for no discernible reason before it was finally sent to the Commission on October 15, 1999. More than four months after the positive ACRE opinion, the applicant explicitly inquired about this delay in a letter dated July 8, 1999 to the Minister of the Environment, only to receive a reply back four months later, on November 2, 1999, noting, without explanation, that the application "had recently been forwarded" to the Commission.[62]

63. The EC's chronology gives the false impression that activity actually occurred on this application after April 1999 by referencing an ACRE meeting on September 16, 1999.[63] As the minutes to that meeting show, however, GA21 was not on the agenda and was not discussed. The entry creates the misleading impression that there was activity during this time period, when

[60] EC Exhibit 78 + 85, attachment 22.

[61] Letter from Dr. Alistair Clemence to Dr. Adrian Butt, 23 March 1999 (Ex. US-145).

[62] Letter from Colin Bird to Dr. Alistair Clemence, 2 November 1999 (Ex. US-146).

[63] EC Exhibit 078 + 085, attachment 24 "Meeting of the Advisory Committee on Release into the Environment (ACRE), minutes."

in fact there was none on the side of the lead CA. As described above, seven months of politically motivated inaction followed the lead CA's positive risk assessment, until, finally, the exact application as submitted by the applicant on March 23, 1999 was forwarded to the Commission without further discussion or amendment.

64. The second application for GA 21 under Directive 90/220 (C/ES/98/1) abruptly halted when it reached the Commission level. The application was filed in Spain on May 29, 1998.[64] The lead CA rendered a favorable opinion and forwarded the application to the Commission on May 11, 1999. Sixteen months after that, the SCP rendered a favorable opinion on September 22, 2000. At this point, however, all activity unexpectedly ceased at the Commission level. The Commission did not submit the application to the Regulatory Committee for a decision, and there was no action or communication by the Commission on this application for the next 3 years, up to the time the application was finally withdrawn by the applicant on September 15, 2003.

65. Indeed, the only activity that occurred after the SCP's positive opinion was efforts by the applicant to re-start the process. For instance, 3 months after the SCP opinion, the applicant voluntarily limited the scope of its application to import only and to exclude production due to commercial reasons, which the lead CA forwarded to the Commission on March 21, 2001.[65] Six more months passed, with no response from the Commission. The applicant then voluntarily offered to update the application (in the form of undertakings) to the requirements of the impending Directive 2001/18, even though the applicable Directive 90/220 would not be repealed until October 17, 2002, in the hopes of obtaining prompt approval.[66]

66. Despite the applicant's efforts to submit additional information to anticipate future EC requirements, the EC still failed to act on the application. The applicant sent these undertakings to the lead CA on September 21, 2001. Inexplicably, the lead CA waited 6 months before forwarding the applicant's undertakings to the Commission on March 18, 2002. The March 18 lead CA letter stated that "[w]ith the aim of completing the Maize line GA21 dossier that the Spanish Competent Authority . . . submitted to the Commission in May 1999, the following information is enclosed: [v]oluntary commitment (undertakings) . . . [and] additional documentation presented by Monsanto Company about molecular characterization, composition

[64] The prior application for GA21 under Directive 90/220 had been submitted to the UK for import, storage and processing on December 12, 1997. [EC Exhibit 85] That application was withdrawn on March 29, 2001. This Spanish notification had been subsequently filed and requested not only import, storage and processing, but cultivation as well. Because of unexpected commercial constraints, however, the applicant decided to remove the request for cultivation from the scope of the Spanish application and, given the duplication with the UK application, to withdraw the latter. [EC Exhibit 85, attachment 93]

[65] EC Exhibit 78, attachments 91, 92.

[66] EC Exhibit 78, attachments 94, 95.

analysis and the reply to all objections arisen from all Member States."[67] Even though the lead CA considered the application to be "complete," the Commission did nothing.

67. Given the failure of the Commission to act for 2 years after the favorable SCP opinion, the applicant was forced to submit an updated application under Directive 2001/18 on January 15, 2003. The applicant submitted all necessary supplementary information according to Directive 2001/18 to the Spanish CA on January 15, 2003, but no action was taken in the following eight months, either by the Spanish CA or the Commission, to move the product towards consideration by the Regulatory Committee. By that time, however, circumstances had changed sufficiently in the almost 5 ½ years since the application was first filed such that the commercial opportunity for import of this product and use for animal feed in the EU was lost. As the applicant explained in its withdrawal letter, a new Roundup Ready maize line, NK603, had progressed to a more advanced stage than GA21 maize in the Directive 2001/18 procedure. This situation, coupled with the new EU regulations on GM foods and feeds, and a change in commercial focus from GA21 to the replacement product, NK603 maize, rendered the former product superfluous.[68] In short, the moratorium caused a delay of such length that commercial conditions changed during the interim to such an extent that the product was no longer commercially viable.

68. The United States finally notes the documents provided by the EC for Exhibits 78 and 85 also contain additional examples of statements by member States that they would oppose approvals of biotech applications until some type of new legislation was adopted, even though under EC law any objection had to be based on the merits of the application. For example, on July 15, 1999, France lodged an objection to EC Exhibit 78, indicating that a European system for traceability of biotech products was a prerequisite for approving new products.[69] France raised a similar objection to the approval of EC Exhibit 85, the application for Roundup Ready corn (GA21) in the UK, citing the "[l]ack of a coherent Community-wide traceability system."[70] Denmark, too, objected to EC Exhibit 85, stating that "taking into account the declarations given by the 12 ministers at the Council meeting in June 1999 [declaring a suspension of new GMO authorizations until labeling and traceability rules are adopted] . . . Denmark finds that this notification falls under the same scope in substance and should be treated in line with the three draft decisions concerning C/DE/96/05, C/BE/96/01 and C/DK/97/01."[71] As the United States has noted in its second submission, such statements by member States undercut the EC's argument that delays were justified by specific, scientific considerations unique to the individual products.

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[67] EC Exhibit 78, attachment 96. It should be clarified that the lead CA actually forwarded two items on that date, the undertakings that the applicant had submitted to the lead CA on September 21, 2001 (EC Exhibit 78, attachments 97 and 95) and information on molecular characterization that the SCP had requested and which the applicant provided on July 4, 2000. (EC Exhibit 78, attachments 98 and 88) Thus, there was nothing new for the Commission to evaluate other than the applicant's voluntary undertakings.

[68] EC Exhibit 82, attachment 21 (letter withdrawing both EC Exhibit 82 and EC Exhibit 78).

[69] EC Exhibit 78, attachment 61.

[70] EC Exhibit 85, attachment 35.

[71] EC Exhibit 85, attachment 42.

E. EC Exhibits 82 and 94: MaisGuard x Roundup Ready (MON810 x GA21) corn

69. MaisGuard x Roundup Ready maize is produced by conventionally hybridizing two "parental" biotech products, MON810 and GA21. This type of product is sometimes referred to as a product with "stacked" traits. The EC claims in its second submission that "[t]he United States . . . acknowledges that the delays are caused by the applicant," citing the U.S. response to question 47 of the Panel, table in Annex I.[72] The entry for this product in the summary table, however, was most certainly not intended to indicate that delay was the fault of the applicant. Rather, the applicant recognized that the applications for MON810 x GA21 would not move forward as long as consideration of the applications for the single trait parent GA21 (discussed above in EC Exhibits 91and 78) remained suspended under the moratorium.

70. The interactions between the applications on MON 810 x GA21 and the applications for its parental single-trait lines and others stalled under the moratorium is not easily apparent from the chronologies for these exhibits. The applications for approval of MON810 x GA21 submitted under Directive 90/220 and Regulation 258/97 were "bridging" applications that referenced the detailed risk assessments undertaken on the parental biotech products, complemented with confirmatory safety and characterization data on the MON810 x GA21 hybrid. While MON810 maize was approved under Directive 90/220 in 1998[73] and was notified in 1998 on the basis of an opinion of substantial equivalence as required under Regulation 258/97 in 1998,[74] the submission under Regulation 258/97 for GA21 maize (EC Exhibit 91) remained under scientific review for years after the submission of the applications for MON810 x GA21. Therefore, progress on GA21 maize was a limiting step on MON810 x GA21's progress in the regulatory process. In fact, the formal end of the review of GA21 maize has still not been completed to date, as the approval of GA21 under Regulation 258/97 is yet to be granted (see above).

71. In short, it was pointless for the applicant to devote resources to pursue the applications for MON810 x GA21 when the approval of GA21's applications had been stalled for years under the moratorium. Thus, the delays in the applications for MON810 x GA21 and GA21 under Directive 2001/18 is a direct consequence of the delays in the application for GA21 under the moratorium. Because of the delay in GA21, that product, as well as MON810 x GA21, have been superseded by a second generation Roundup Ready corn product (NK603 maize and NK603 × MON 810 maize, respectively).[75]

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[72] EC Second Written Submission, para. 234.

[73] Commission Decision concerning the placing on the market of genetically modified maize (*zea mays* L. line MON 810) pursuant to Council Directive 90/220/EEC, (98/294/EC), April 22, 1998, Official Journal of the European Communities, L 131/32, May 5, 1998 (Ex. US-131).

[74] "Question and Answers on the Regulation of GMOs in the EU," MEMO/04/85, Brussels, April 15, 2004, Annex 3 (Ex. US-132).

[75] In addition, as discussed in Part IVof this submission, a number of unjustified questions were asked by the lead CA in both MON810 x GA21 applications that further exacerbated efforts to make any headway on these applications.

F. EC Exhibit 82: MaisGuard x Roundup Ready (MON810 x GA21) corn

72. The deliberate release application for MON810 x GA21 corn under Directive 90/220 was submitted in August 1999, but never reached the Commission level stage of review. As the EC's chronology shows, the lead CA requested further information on November 30, 1999.[76] The applicant responded in August 2001 to all requests, except for a scientifically unjustified study on the nutritional composition of milk from dairy cows fed this product.[77] The applicant provided translated documents 5 months later in January 2002. Thereafter, for over 1 ½ years, until the application was withdrawn, the only activity by the lead CA was a meeting held in April 2002.[78] No other activity occurred until the applicant volunteered to update the notification under Directive 2001/18 on January 16, 2003.[79] The applicant, however, subsequently withdrew the application on September 15, 2003, at the same time it withdrew the application for GA21 as the delays caused by the moratorium had rendered the applications for GA21 and MON810 x GA21 commercially obsolescent. (See above for GA21).[80]

G. EC Exhibit 94: MaisGuard x GA21 (MON810 x GA21) corn

73. The novel foods application for MON810 x GA21 under Regulation 257/98 shares a similar history to this product's deliberate release application. The application was submitted to the lead CA in February 2000. The lead CA requested additional information on July 17, 2000.[81] The applicant took 1½ years to respond, providing information in February 2002.[82] This lag reflected, in part, the lack of progress that had been made by the application for the parental line GA21. As noted above, the application for the single trait parent GA21 under Regulation 258/97 stalled at the Commission level after the Commission requested an opinion from the SCF on May 18, 2000 and then again after the final SCF opinion in February 2002. In fact, in its comments on the application for MON810 x GA21, Italy stated that "examination of the documentation relating to authorization [of MON810 x GA21] should only be carried out after the marketing of GA21 has been authorized."[83] The lag also reflected, in part, the need to respond to requests for information that were scientifically unjustified.[84]

74. To date, the application for MON810 x GA21 is still pending. Given the reliance of the submission for this product on progress of GA21, the applicant took the pragmatic option of focusing on addressing regulatory questions on GA21 in order to facilitate progress on MON 810

[76] EC Exhibit 82, attachment 8.

[77] EC Exhibit 82, attachments 9_SCI, 10_SCI, 11_SCI. The fact that this type of study is scientifically unjustified is discussed in Section III below.

[78] EC Exhibit 82, attachment 18.

[79] EC Exhibit 82, attachment 20.

[80] EC Exhibit 82, attachment 21.

[81] EC Exhibit 94, attachment 12.

[82] EC Exhibit 94, attachment 13.

[83] EC Exhibit 94, attachment 11.

[84] See further discussion in Section IV.B.3.c and IV.4.B.c of this submission.

x GA21. Nonetheless, the applicant has continued to pursue the necessary regulatory clearance for MON 810 x GA21 in the EU.[85]

H. EC Exhibit 66: Roundup Ready cotton (RRC1445)

75. The EC suspended the deliberate release application for Roundup Ready cotton (RRC1445) under Directive 90/220 for nearly four years – from February 1999 until the new legislation, 2001/18, took effect in January 2003.

76. The SCP issued a positive opinion on July 14, 1998, but the Regulatory Committee subsequently failed to reach a qualified majority on February 22, 1999.[86] Following the inaction at the Regulatory Committee, the Commission failed to submit a proposal to the Council. Consequently, the Commission took no further action on this application. Finally, nearly 4 years later, the applicant was forced to update its notification with the lead CA under Directive 2001/18 on January 16, 2003.

77. The EC's only defense of this 4-year gap is its statement that "the Regulatory Committee failed to reach a qualified majority because a number of Member States maintained objections. These related, in particular, to the long-term effects of herbicide tolerant crops on the environment, to the presence of an antibiotic resistance gene used as marker within the GM construct, residue-limits levels, and to the effects on biodiversity of changes in herbicide tolerant crop management."[87]

78. This observation, once again, misses the point. It fails to recognize that following the Regulatory Committee vote, Directive 90/220 obliged the Commission to refer the application to the Council for a decision "without delay," a step the Commission failed to take in this case.

79. The EC's second submission also incorrectly implies that the objections raised by member States had not been adequately addressed in the SCP. As the EC notes, however, the SCP had come to a positive conclusion in July 1998. And in fact, the SCP assessed the safety of the product at issue based on detailed scientific considerations. The SCP addressed antibiotic resistance marker genes,[88] toxicity to non-target organisms,[89] out-crossing from the transgenic plant,[90] and came to the conclusion that "there is no evidence to indicate that the placing on the

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[85] Note, for example, the notification for foods and feeds produced from MON 810 x GA21 in order to allow for continued access to the EU market of EU products that were lawfully placed on the market prior to entry into force of the new rules governing biotech products in the EU, according to articles 8 and 20 of the Regulation on GM Food and Feed (Reg No 1829/2003). This notification was listed in the EU Commission (DG-SANCO) register of notified existing products. *See* Admissible Notifications of Existing Products Received by the Commission Pursuant to Articles 8 and 20 of Regulation (EC) 1829/2003 on GM Food and Feed (Ex. US-133).

[86] EC Exhibit 66, attachment 57.

[87] EC Second Written Submission, para. 184.

[88] EC Exhibit 66, attachment 43, paras. 6.2.1 and 6.2.2.

[89] EC Exhibit 66, attachment 43, para. 6.3.3.

[90] EC Exhibit 66, attachment 43, para. 6.3.1.

market of line RRC 1445 (expressing the CP4 EPSPS enzyme) with the purpose to be used as any other cotton is likely to cause adverse effect on human health and the environment."[91] Thus none of these purported member State objections explains the failure of the EC to proceed with this application.

80. Moreover, none of the member States objecting at the Regulatory Committee offered any competing risk assessments or scientific evidence for such objections. Neither did the Commission nor the member States identify any specific inadequacies in the SCP review. Finally, nothing in the record indicates that the Commission communicated any scientific concerns to the applicant, or that the Commission identified to the applicant any shortcomings in the application.

81. In short, there was sufficient information for the Commission to forward a decision to the Council and for the Council to take a decision, whether positive or negative, on the application. Thus, the EC's statement in its second submission that "any delay ... is entirely legitimate and related to risk assessment and management considerations"[92] is flatly incorrect. Only the existence of the moratorium explains the failure of the EC to move this application forward after EC's scientists considered the issues raised by member States and rendered a positive assessment on the application.

I. EC Exhibit 64: Roundup Ready fodder beet (A5/15)

82. The deliberate release application for Roundup Ready fodder beet (A5/15) has been in the EU approval process for over 7 ½ years, having been submitted to the lead CA in February 1997. As explained below, this timing reflects extensive, undue delays resulting from the EC moratorium.

83. The SCP issued a positive opinion on June 23, 1998. The Regulatory Committee, however, did not meet on this application for over a year and a half and, even then, did not take a vote. Four months later, the Regulatory Committee met once again, on March 9, 2000, and once again, did not vote. (The EC provided no documents for this second meeting.) After that, the application remained in limbo and was never submitted to either the Regulatory Committee or to the Council. Over 4 ½ years after the SCP positive opinion and deadlock at the Commission level, the applicant was forced to re-submit its application under the new Directive 2001/18 on January 16, 2003.

84. Once again, the EC attempts in its second submission to defend the Commission's inaction by pointing to objections raised by member States. "These [objections] were based on issues such as insufficient data on the molecular analysis of the insert, on residues, on primary metabolites and on characteristics of intestinal animal microbial flora (data collected from feeding studies performed with GM fodder beets treated with glyphosate and its conventional

[91] EC Exhibit 66, attachment 43, para. 7.
[92] EC Second Written Submission, para. 185.

counterpart), monitoring strategy of gene dispersal in seed-producing countries and possible effects of herbicide residues on animal health."[93]

85. As in its defense of delays in other applications, the EC's constant reference to member State objections is a diversion. The SCP considered the existing scientific evidence and the information provided by the applicants sufficient to address the objections voiced by the member States,[94] concluding that "[t]he Committee, after examining and considering the existing information and data provided in the dossier against the background of available knowledge in the areas concerned, considers that there is no evidence indicating that the use of the fodder beet tolerant to glyphosate . . . is likely to cause any adverse effects on human health and the environment."[95] Similarly, when launching its "inter-service consultation" after the positive SCP opinion, the Commission noted in its proposed Decision that the Commission, "having examined each of the objections raised in the light of Directive 90/220/EEC, the information submitted . . . and the opinion of the Scientific Committee on Plants, has reached the conclusion that there is no reason to believe that there will be any adverse effects on human health or the environment from the placing on the market of the product."[96]

86. The SCP had also noted in its opinion "that the notifiers should establish a detailed code of practice and work closely with growers to ensure Good Agricultural Practice which should minimize the spread of herbicide tolerance."[97] Over the next 4 months, the applicant provided supplemental information on its surveillance plan and a code of practices,[98] in line with the Guidance Note which the SCP had formally approved on December 18, 1998.[99]

87. In its second submission, the EC further asserts that the Regulatory Committee did not reach a vote at its first meeting on October 29, 1999 "because of requests for outstanding additional information" and that the United States "fails to mention that some of these [member State] objections have intervened after the opinion of the Scientific Committee and that the matters which are still under discussion all relate to scientific and technical issues . . ."[100] Again, the EC description is a distortion, ignoring or miscasting important events in the chronology.

88. Contrary to the EC's assertion that there were outstanding requests for information, the opposite was true. The applicants had voluntarily provided additional information in an attempt to remove any possible remaining obstacle to a Regulatory Committee vote. During the 1½ years between when the SCP issued its opinion and when the Regulatory Committee finally met,

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[93] EC Second Written Submission, para. 176.

[94] As discussed below in section IV.B.7 of this submission, some objections raised by member States were baseless, e.g., the Italian request for "an evaluation of the composition and characteristics of the intestinal bacterial flora in animals treated." EC Exhibit 64, attachment 59.

[95] EC Exhibit 64, attachment 83, para. 7 (emphasis added).

[96] EC Exhibit 64, attachment 85 (emphasis added).

[97] EC Exhibit 64, attachment 83, para. 7.

[98] EC Exhibit 64, attachments 86, 87, 91.

[99] EC Exhibit 64, attachment 92, p. 2.

[100] EC Second Written Submission, para. 176.

the applicants had voluntarily provided the following information: 1) supplemental information on its surveillance plan and a codes of practice; (2) an additional digestibility sheep feeding study to respond to certain member States' concerns;[101] (3) information in response to requests of the UK and the Dutch competent authorities for data above and beyond what the SCP had considered necessary to conduct a safety assessment;[102] and (4) voluntary undertakings and commitments, again, above and beyond what was legally and scientifically necessary for the Commission to take a decision on the application, in the hopes of re-starting the approval process in the wake of the political agreement on the revision of Directive 90/220.[103]

89. The EC's chronology identifies this last effort by the applicants as the "interim approach." Instead of benefiting from these efforts, however, the applicant was effectively penalized at the first Regulatory Committee meeting, as "[t]he Member States stated that they were not now in a position to take a decision on the measures, in particular because of the further information submitted by the notifiers."[104] Thus, despite the SCP's positive opinion, and despite voluntarily providing information meant to address any remaining objections by concerned member States, the application still did not move forward.

90. The EC's other argument that some member States objected after the SCP opinion is irrelevant. The Regulatory Committee failed to come to a vote - twice. Whether that was because some member States objected to the application, despite the positive SCP opinion, is irrelevant to the EC's WTO obligation to make a decision without undue delay and for that decision to be science-based.[105] In this case, despite a positive opinion of the relevant scientific committee, member States failed to vote at the Regulatory Committee, and the Commission failed to forward a decision to the Council. As noted above, despite the applicants' best efforts under the "interim approach" to anticipate future legislation, in this case, almost 3 years before such legislation was actually passed and more than 4 years before pending applications were legally required to meet the new requirements, the moratorium prevented the application from progressing. Indeed, as discussed below, the moratorium's existence and its effect on this application are clearly discussed in the documents provided by the EC.

91. After working under the "interim approach" for a year, after submitting significant additional information, after revising their undertakings and commitments several times to address member States' comments, the applicants attempted to get a resolution of this matter on July 12, 2000, stating that they had fully addressed all objections raised by member States and requesting the lead CA "to inform all member States that the application was complete and

[101] EC Exhibit 64, attachments 88, 89.
[102] EC Exhibit 64, attachments 93, 95, 105.
[103] EC Exhibit 64, attachments 97, 99, 100, 101.
[104] EC Exhibit 64, attachment 106.
[105] Directive 90/220/EEC, Article 21 ("If the measures envisaged are not in accordance with the opinion of the [Regulatory] 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) (Ex. US-25).

subject to a Community decision."[106] Even then the EC ignored, for six months, the applicants' request. It was not until January 29, 2001 that the lead CA met with the applicants.

92. In that meeting, it was noted that even though the revised Directive 2001/18 was expected soon, "[h]aving the revised directive fully adopted will not be sufficient. The re-start of the regulatory process will depend on the willingness of the Commission to do it. It is commonly analysed that the Commission will not promote an Art 21 vote meeting, if there are no indications that the member-states are supporting the process and/or expected to vote positively. . . . Another key step for the member-states acceptance is the publication of Commission papers on traceability/labeling and liability that is expected by March 2001 (or later). These papers are very important because one of the reasons for the 5 member-states to start a moratorium was precisely labeling and traceability."[107] In response to the applicants' question when the lead CA would forward the supplementary data to the Commission and other member States, it was noted that such a "letter was foreseen to give a signal that the dossier is considered as complete and therefore ready for the next European regulatory steps. It is considered that it is too early because of the upcoming events", meaning (as described above) advancements in the process of developing additional legislation.[108]

93. Thus, despite a 4 year long application process, during which the applicant made numerous submissions to address issues raised by the member States, despite the absence of any outstanding requests for information or unaddressed scientific issues, and despite the SCP's positive opinion, the EC deemed it still "too early" for the EC to submit the application for a final decision. In short, the "interim approach" did not allow the application to move any closer to a decision; instead, it simply constituted another way for the EC to describe its moratorium on approvals.

J. EC Exhibit 76: Roundup Ready corn (NK603)

94. The NK603 deliberate release application was submitted in January 2000, and finally approved – atlthough provisionally to a GM food and feed approval – in July 2004. Contrary to the EC's assertion, the processing of this application was delayed by the moratorium, and its ultimate approval does not signal the end of the moratorium

95. In its answers to the Panel questions, the United States noted that the EC had delayed action on the application for Roundup Ready corn (NK603) under Directive 90/220 for 12 months at the member State level.[109] The EC attempts to rebut the delay at the member State level by claiming that the notification the applicant submitted in August 2000 "was incomplete

[106] EC Exhibit 64, attachment 119.

[107] EC Exhibit 64, attachment 120 (applicants' confirmatory letter to lead CA, summing up the discussion of a meeting between the applicant and the lead CA that took place on January 29, 2001) (emphasis added).

[108] EC Exhibit 64, attachment 120.

[109] Responses of the United States to the Questions by the Panel and the European Communities Posed in the context of the First Substantive Meeting with the parties, June 16, 2004, Appendix I.

and therefore not considered as received until January 2001."[110] The U.S. calculations, however, are already based on the date of receipt suggested by the EC.

96. The EC's other main justification of the delay is its claim that 44 days after the application was submitted, the clock was stopped "because the Scientific Committee of the lead Competent Authority requested additional information on issues such as molecular characterisation, nutritional composition, and environmental impact."[111] While it is correct that the clock stopped on several occasions during the 90 day period - as foreseen under the EC's regulatory system - the complainants are still correct in their calculation of the length of the review, having taken into account each occasion on which the clock stopped and was re-started by the applicant responding to the questions of the lead CA.[112]

97. The EC incorrectly asserts in its second submission that the application has proceeded smoothly under Directive 2001/18 and that several member States have, nonetheless, maintained objections based on their own risk assessments.[113]

[110] EC Second Written Submission, para. 216.

[111] EC Second Written Submission, para. 216.

[112] Although the EC points to different lengths in the delay calculated by Argentina and the United States, both complainants are correct in their calculations. The United States is correct for the following reason: With the complete submission by the applicant dated December 20, 2000 and the lead CA opinion dated January 14, 2003, the total time elapsed was 25 months. The delay incurred due to time taken by the applicant to respond to the lead CA's questions was 13 months (see table below). As correctly described by the United States, the lead CA took the remaining 12 months instead of 90 days, as prescribed in the EC's regulatory system, to reach a decision. See Directive 90/220/EEC, Article 6.2. Argentina is also correct for the following reason: By the time the Argentine rebuttal was submitted in July 2004, a total of 3 years and 8 months had elapsed for a process that was supposed to take about 5 to 15 months according to the EC's regulatory system.

		Clock "stopped"
Submission	4 Aug 2000	
Submission of Spanish version	20 Dec 2000	
Rapporteur question 1	15 Feb. 2001	
Applicant answer 1	5 Sep. 2001	6.5 months
Rapporteur question 2	10 Oct. 2001	
Applicant answer 2	28 Mar 2002	5 months
Rapporteur question 3	21 May 2002	
Applicant answer 3	19 Jun 2002	1 month
2001/18 submission	29 Aug 2002	
Rapporteur opinion	16 Jan 2003	
TOTAL time used for 90 day period	25 months	13 months

[113] EC Second Written Submission, para. 217.

98. The approval procedure, however, did not progress "smoothly," as the EC contends. The Regulatory Committee was unable to obtain a qualified majority vote.[114] None of the documents provided by the EC support the EC's claim that those member States who abstained or voted against the approval of the product in the Regulatory Committee did so on the basis of "their own risk assessments." Member States' objections and the applicant's answers to these were taken into consideration by EFSA in delivering its positive opinion on NK603,[115] and none of the member States questioned the validity of EFSA's favorable opinion. Nonetheless, despite EFSA's opinion, member States failed to vote accordingly, or to provide reasoned decisions for not voting in line with EFSA's opinion.

99. After the absence of a vote in the Regulatory Committee, the Commission forwarded the proposal to the Council. The Council similarly failed to reach a qualified majority vote on the proposal.[116] Subsequently, the Commission adopted a decision authorizing the import of NK603,[117] contingent on the approval of the parallel application for NK603 under the Regulation on Novel Foods and Food Ingredients, Regulation 258/97. (This application is discussed in the following section.)

100. The fact that certain member States failed to cast their votes in accordance with the EC's own scientific committee's conclusions shows that member States continue to act based on political considerations. In addition, that failure required that the product be subject to additional delays entailed in the further consideration by the Counsel and the Commission. Accordingly, this single deliberate release approval – the first since 1998 – cannot be considered to indicate that the EC will proceed to process all applications without undue delay, as required under the SPS Agreement.

K. EC Exhibit 96: Roundup Ready corn (NK603)

101. The Commission approved this GM food and feed application in October 2004. However, this application was still subject to undue delays, and its ultimate approval does not indicate an end to the moratorium.

102. In its answers to the Panel's questions, the United States noted that the EC delayed action on the application for Roundup Ready corn (NK603) under Regulation 258/97 for 14 ½ months

[114] EC Exhibit 76, attachment 72.

[115] According to the documents provided by the EC, only Austria provided an explanation for why it voted negatively at the Regulatory Committee stage. EC Exhibit 76, attachment 72. These objections, however, had previously been raised by Austria prior to the EFSA opinion. EC Exhibit 76, attachment 44. No other member State gave an explanation for its negative vote.

[116] EC Press Release, C/04/221, 2599th Council Meeting, Agriculture and Fisheries, Brussels, 19 July 2004., 11234/2/04 REV 2 (Presse 221) (Ex. US-134).

[117] EC Press Release, IP/04/957, July 19, 2004 (Ex. US-135).

at the member State level and that the Regulatory Committee, despite a positive risk assessment, failed to obtain a qualified majority vote on the application.[118]

103. The EC claims that the United States "ignores the fact that the 18 months spent at Member State level were due to the incompleteness of the dossier initially submitted by Monsanto and to the need for further data on molecular characterisation and compositional analysis."[119] The EC conveniently omits the fact that, out of the 18 months mentioned by the EC, only 3½ were used by the applicant to provide additional information (see table below). The lead CA used the remaining 14½ months instead of the 90 days foreseen by Regulation 258/97.[120]

		clock "stopped"
Submission	24 Apr 2001	
Rapporteur request	13 Dec 2001	
Applicant response	28 Mar 2002	3.5 months
Rapporteur opinion	5 Nov 2002	
TOTAL time used for 90 day period	18 months	

104. As with its parallel application under Directive 2001/18, the moratorium's influence can be clearly seen in the course of the application for NK603 under the novel foods regulation. The EFSA granted a favorable opinion for the placing on the market of foods and food ingredients derived from NK603 maize on November 25, 2003. Nevertheless, the Standing Committee on Food Chain and Animal Health was unable to deliver, by qualified majority, an opinion. A proposal was adopted by the Commission on June 24, 2004 and transmitted to the Council on July 13, which was similarly unable to reach a qualified majority on the proposal on July 19, 2004.[121] The Commission finally adopted a decision authorizing NK603 derived products on October 26, 2004.[122]

105. As the EFSA noted, "[i]n delivering its opinion the Panel considered the applications and additional information provided by the applicant and the specific questions and concerns raised

[118] Responses of the United States to the Questions by the Panel and the European Communities Posed in the context of the First Substantive Meeting with the parties, June 16, 2004, Appendix I.

[119] EC Second Written Submission, para. 238. The EC also alleged in its second written submission that the United States and Argentina calculated different lengths of the delay. Para. 337. Both the United States and Argentina, however, are correct in their calculations of delays. Argentina is correct since the time between the date the application was first submitted to the lead CA, April 24, 2001, and the date of the rebuttal, July 14, 2004, is a total of 3 years. The United States is correct since the total time between the first submission and the lead CA's opinion, November 5, 2002, was 18 months.

[120] Regulation (EC) 258/97, Article 6.

[121] EC Second Written Submission, para. 239.

[122] EC Press Release, IP/04/1305, Brussels, October 26, 2004 (Ex. US-136).

by the Member States."[123] No member States questioned the validity of the EFSA' opinion. Nevertheless, the Standing Committee on the Food Chain and Animal Health and the Council, which includes all member States, failed to come to a decision because a number of member States refused to decide based on the relevant scientific facts.[124] As with the parallel application under Directive 2001/18, the failure of certain member States to cast their votes in accordance with the EC's own scientific committee's conclusions – with the result that a decision had to be referred to the Council and then the Commission – reflects that member States continue to make decisions based on political considerations. The recent approval of this product – which is only the second approval (after BT-11 in May 2004) does not indicate that the EC will proceed to process all outstanding applications without undue delay.

L. EC Exhibit 62: Oilseed rape (FALCON GS40/90)

106. The application for oilseed rape (FALCON GS40/90) has been pending for over 8 ½ years. It was first submitted under Directive 90/220 on April 1, 1996. The lead CA forwarded it to the Commission on October 25, 1996. After member States objected during the review period, the Commission requested an SCP opinion on February 20, 1998. The SCP submitted its opinion to the Commission on May 19, 1998[125] and formally expressed a positive opinion on July 14, 1998. The Regulatory Committee did not meet until over a year later, on October 29, 1999, and, despite the positive opinion, failed to vote on the application. Four months later, on March 9, 2000, the Regulatory Committee met again, and again, failed to vote on the application.

107. The Commission never submitted a draft measure on the application to the Regulatory Committee again. The application remained in this indeterminate state at the Commission for almost 3 years after the second failed Regulatory Committee meeting, until the applicant finally had to submit an updated application under Directive 2001/18 on January 16, 2003.

108. Once again, the EC tries to defend this failure to decide by citing objections made by a member State during the Regulatory Committee vote. The EC claims in its second submission that the Regulatory Committee "did not vote because it came to the conclusion that further information was needed on the assessment of the effect of the newly expressed protein on the biogeochemical cycle and the food chain as well as the likelihood of spreading."[126] In support of that sentence, the EC cites in a footnote "[s]ee also the further questions raised during the Regulatory Meeting by the Italian Competent Authority . . . ."[127]

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[123] EC Exhibit 96, attachment 40, p. 1.

[124] The United States notes, in particular, that during the member State review period, the French authorities formally objected, citing their position on the necessity of establishing all legal and technical methods necessary to ensure traceability and labeling before authorizing any new GMO products and derivative products. EC Exhibit 96, attachment 27.

[125] EC Exhibit 62, attachment 18 (noting the SCP submitted its opinion to the Commission on May 19).

[126] EC Second Written Submission, para. 164.

[127] EC Second Written Submission, para. 164, footnote 80.

109. As the United States explained above, the fact that a member State may have objected at the Regulatory Committee does not excuse an endless delay. Under the EC's own legislation, the Commission was required to submit a decision, whether favorable or negative, to the Council in the absence of action by the Regulatory Committee.[128] Moreover, the SPS Agreement requires that the EC make a decision without undue delay and for that decision to be science-based. In this case, despite a positive opinion of the relevant scientific committee, member States failed to vote accordingly at the Regulatory Committee and the Commission failed to forward a decision to the Council.

110. One month after the first Regulatory Committee meeting, the applicant formally submitted an "update" to its notification that it claimed substantiated that the additional information and commitments provided by the applicant fully satisfied the criteria of the proposed revised Directive.[129] On March 9, 2000, the Regulatory Committee met again. Although the EC's chronology states that the failure to reach a vote was "due to further requests for information," the EC has failed to provide any document that confirms that statement. Instead, the record shows that the only request for information that could possibly have been made at that meeting was a request from Italy for "more information concerning the assessment of the effect of the genic [*sic*] product on the biogeochemical cycles and on food chain and on the spreading of the gene due to the possibility of crossing between the PGM and wild species."[130] Although Italy's request was not scientifically justified,[131] the applicant responded to the Italy's questions by November 30, 2000.[132]

111. In sum, in the 3 years after the Regulatory Committee failed to reach a vote for the second time until the applicant was forced to submit an updated application under Directive 2001/18, the Commission did not submit a decision to the Council on this application, for no other reason than the general moratorium

[128] Directive 90/220/EEC, Article 21 ("If the measures envisaged are not in accordance with the opinion of the [Regulatory] 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).

[129] EC Exhibit 62, attachment 88. On February 28, 2000, after discussion with various member State CAs, the applicant provide yet more information regarding its commitment on traceability and labelling as well as a commitment to a stepwise introduction. EC Exhibit 62, attachment 94.

[130] EC Exhibit 62, attachment 95 and EC Exhibit 63, attachment 88.

[131] See Section Iv.B.7 *infra*.

[132] EC Exhibit 62, attachment 97.

M. EC Exhibit 92: Bt-11 Sweet Corn

112. The novel food application for BT-11 Sweet corn was finally approved, under the GM Food and Feed directive that entered into force in April 2004, in May 2004. As discussed below, the history of this application confirms the delays resulting from the moratorium, and its ultimate approval does not indicate that the moratorium has finally ended.

113. In its responses to the Panel's questions posed on June 3, 2004, the EC attempts to justify delays in the processing of the BT-11 application by claiming that "[b]etween October and early December 2003 [after the SCF positive opinion], three new risks assessment were issued by the Member States, all of which conflicted with the SCF opinion. In particular: - the French one confirmed its earlier finding, i.e., further studies were needed on toxicity; - the Austrian scientific body issued a new risk assessment concluding that the risk of allergenicity and toxicity of Bt11 sweet maize has not been sufficiently addressed; - a Belgian risk assessment was issued raising issues on the molecular characterisation of the product. The Austrian study was also presented to EFSA which disagreed with its conclusions."[133]

114. The EC's contention is unsupported by the record. No risk assessments were submitted during that time period. According to the EC's own chronology, the only events that occurred between October to December 2003 were: the finalization of a method validation by the EC's Joint Research Center on October 2, 2003;[134] the applicant's agreement to making public the validation method on October 20, 2003[135]; a meeting of the Standing Committee on the Food Chain and Animal Health on November 10, 2003;[136] a comment from France on November 27, 2003;[137] the vote at the Regulatory Committee on December 8, 2003 (which did not reach a qualified majority);[138] and a November 20, 2003 letter from the applicant to the Commission releasing technical data.[139] None of these documents contain any purported risk assessments conducted by France, Austria, or Belgium.

115. Furthermore, no risk assessments were submitted at the November 10, 2003 meeting of the Standing Committee on the Food Chain and Animal Health.[140] The EC chronology correctly describes the entry on November 27, 2003[141] as a "comment" from France, not a risk assessment. Acknowledging that the protein toxicity studies conducted did not show any adverse effects in lab animals and that the studies with broilers and cows similarly did not demonstrate any adverse effects, the French food agency stated, nonetheless, that it was concerned. To eliminate the

[133] Responses by the European Communities to the questions posed by the Panel on the 3rd of June, 2004, Response to Question 1.

[134] EC Exhibit 92, attachment 66.

[135] No document available per the EC's chronology.

[136] EC Exhibit 92, attachment 67 (misdated in the EC chronology as November 8).

[137] EC Exhibit 92, attachment 69.

[138] EC Exhibit 92, attachment 70.

[139] EC Exhibit 92, attachment 68.

[140] EC Exhibit 92, attachment 67.

[141] EC Exhibit 92, attachment 69.

possibility of unintended effects, the French food agency recommended further compositional analysis and a long term feeding study of the Bt-11 sweet corn with chickens or pasture animals, but the agency did not provide or refer to any risk assessment.[142]

116. France also submitted a written declaration to its vote at the Regulatory Committee on December 8, 2003.[143] That also is not a risk assessment. Referring to France's early November comment, the declaration simply notes France's concern with possible unintended effects due to the metabolism of sweet corn since it has a different sugar metabolism from field corn and demands more information.

117. The only document in the October – December timeframe from Belgium is its written declaration accompanying its vote at the Regulatory Committee meeting on December 8, 2003.[144] The declaration is simply is a one paragraph cover letter noting Belgium's opposition due to concerns about the molecular characterization of the Bt 11 maize.

118. Austria, too, submitted a written declaration at the Regulatory Committee meeting.[145] This document similarly does not qualify as a risk assessment. The declaration simply lists perceived inadequacies in the data supplied and requests additional information, without providing scientific bases for these criticisms.

119. The EC's incorrect assertion that competing risk assessments existed should not divert attention away from the real cause of the delay in processing the application for Bt-11 sweet corn. When the application was first evaluated at the Commission level in 2000, member States objected on the basis of the general moratorium. For example, as recalled by Denmark's Agriculture and Fisheries Council, "[i]n August 2000, Denmark submitted an objection to the approval of Bt11 maize in respect of the novel food regulation with reference to the declaration approved by Denmark, France, Italy, Greece and Luxembourg on the suspension of new GMO licences (the moratorium declaration), which was made at the Council meeting (environment) on 24-25 June 1999. The objection included a reference to the fact that, pending the approval of a regulation that would guarantee the labelling and effective tracing of GMOs and products

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[142] The French comment does not "evaluate the potential for adverse effects on human or animal health" posed by the sweet corn's different sugar metabolism from field corn. The comment is concerned with unintended effects, theoretical risks not identified by any of the existing protein toxicity or animal studies conducted. As the Commission stated in its Proposal for a Council Decision of January 28, 2004, "[t]he concerns raised in the opinion of the "Agence française de sécurité sanitaire des aliments" (AFSSA) of 26 November 2003 do not bring any new scientific elements in addition to the initial assessment of sweet maize Bt11 carried out by the competent authorities of the Netherlands. In fact these concerns were also expressed in two AFSSA opinions of 21 July 2000 and 20 March 2001 and were duly considered by the Scientific Committee on Food (SCF) in its opinion of 17 April 2002, which confirmed the findings of the initial assessment that Bt11 sweet maize is as safe for human food use as conventional maize." EC Exhibit 92, attachment 77.

[143] EC Exhibit 92, attachment 72.

[144] EC Exhibit 92, attachment 73.

[145] EC Exhibit 92, attachment 71.

derived from them, the moratorium countries would block any new licences for the cultivation and marketing of GMOs."[146]

120. Similarly, both times when the Standing Committee on the Food Chain and Animal Health met on this application, it failed to obtain a qualified majority with certain member States objecting due to the proposed new traceability & labeling regulations (which did not become effective until April 2004).[147]

121. In short, it is clear from the EC's own chronology that irrespective of any other considerations, certain member States would not allow the application for Bt-11 sweet corn to reach a final decision – regardless of the underlying science - until revised legislation was in place.

IV. Many Member State Requests for Information Were Not Based on Legitimate Scientific Concerns

122. The chronologies do not show – as the EC claims – legitimate scientific grounds for each request for information, and for the resulting delays, in the application histories. Rather, many supposedly scientific questions are requests that seek to force applicants prove the complete absence of hypothetical risks, in disregard of the safety data provided in the application. A pattern of deliberate delaying tactics is also illustrated by other types of scientifically baseless objections or requests for information that would have no relevance to an evaluation of the product's safety.

A. Member State objections do not Illustrate Scientific Disagreement or Uncertainty

123. The EC implies in its submissions that there has been "scientific disagreement" and "other scientific opinions" that justified ignoring the EC's own scientific committees' risk assessments[148]; that "unresolved or new" scientific issues were raised[149]; that the "underlying science and the evolution of acceptable regulatory solutions . . . were and are still in a state of great flux."[150] Further, in its oral statements, the EC alleged that applications were delayed by "conflicting risk assessments."

124. These allegations are not borne out by the EC's own documents and chronologies. Instead, the record shows that none of the various member States' objections and requests for information qualify as competing risk assessments, "scientific disagreement" or "other scientific

[146] EC Exhibit 92, attachment 80 (emphasis added).

[147] EC Exhibit 92, attachment 67 ("Finally, several Member States questioned the opportunity to proceed with the authorization of this product in anticipation of the coming into application of Regulation (EC) 1829/2003 and 1830/2003."); attachment 71, attachment 74**,** attachment 75, attachment 76.

[148] EC Second Written Submission, para. 30.

[149] EC Second Written Submission, paras. 31, 32.

[150] EC First Written Submission, para. 9.

opinions" that would call into question the positive risk assessments conducted by the EC's own scientific committees. Annex A of the SPS Agreement provides that a risk assessment must either evaluate "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 [] the associated potential biological and economic consequences," or "the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins, or disease-causing organisms in food…or feedstuffs." None of the objections made by the member States met the SPS definition of risk assessments. The objections were vague and general; did not identify and evaluate any specific risks posed; and were not supported by any scientific evidence that provided a basis for presuming a potential risk existed. Nor could the generic, vague statements in the member State objections and requests for information be considered "conflicting scientific opinion" of any weight that might counter the evidence presented in the product applications or in the risk assessments conducted by the lead Competent Authority or EC-wide scientific committees that demonstrated the safety of the products.

B. Various Member State Objections Relate Solely to Inappropriate "Theoretical Risks"

125. "[T]heoretical uncertainty is not the kind of risk, which under Article 5.1, is to be assessed" under the Agreements.[151] Yet the objections and related requests for additional information raised by member States were often based on just such theoretical risks. As discussed in more detail in the sections below, these objections were not based on legitimate scientific grounds and failed to reflect the substantial evidence that existed for each application establishing the product's safety. Instead, given the nature of the products and the information already provided, these objections and requests for additional information were unwarranted.

126. This fixation on theoretical risks and their refutation is yet another manifestation of the general moratorium. For example, France objected to the approval of Bt Cry 1F corn [exhibit 74], stating numerous times that additional animal studies were necessary "to prove the absence of risk," even though the existing data [*e.g.*, acute protein toxicity studies; compositional analyses] showed that no food safety risks could reasonably be anticipated. While few member States were as explicit, this approach underlies many of the member States requests for further data.

127. Yet, such proof is unattainable. "[U]ncertainty [] always remains since science can never provide absolute certainty that a substance will not ever have adverse health effects."[152] It is not possible for a risk assessment to evaluate every risk that a product might theoretically pose. It can, however, provide information that allows decision makers to make reasoned judgments about the risks it is reasonable to assume a product may present, based on the product's

[151] Report of the Appellate Body, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para. 186 ("EC Hormones").

[152] EC Hormones, para. 186.

characteristics. Accordingly, these member State objections and requests for additional data are not the kind that could be used to justify a delay in an approval procedure under Annex C of the SPS Agreement.

1. General background

128. To evaluate the safety of biotech products, two general categories of issues are examined: the safety of the new substance (typically, a protein) produced as a result of the inserted DNA, and whether the inserted DNA causes any other changes to the product. In evaluating the safety of the introduced substance, standard laboratory tests are conducted to characterize the potential toxicity of the introduced substance. These analyses include: **i**nformation regarding the original source of the inserted genetic material, with particular emphasis on known adverse health effects associated with the source (for example, toxicity or allergenicity); data and information regarding the function and specificity of the introduced protein(s); comparisons between the order (sequence) of amino acids (the building blocks of proteins) and those of known allergens or toxins ("sequence similarity" or "homology"); and the stability of the introduced protein(s) under simulated mamamalian digestion conditions. The second category of issues is addressed, in part, by comparisons made between the engineered product and a conventionally derived comparable product, to determine whether the composition or characteristics of the product has significantly and materially changed (*i.e.*, in a manner that could have some relevance to the product's safety characteristics). Analyses compare the spectrum of key components; for example, carbohydrates, proteins, and fatty acids, amino acid and vitamin content, as well as naturally-occurring toxicants, antinutrients, [153] and allergens. Because foods are generally characterized by a wide, natural variation in composition and nutritional value, the comparison should take into account the normal biological range established for non-engineered, commercially available products. Thus, the relevant considerations are whether the analyses demonstrate: (1) that the key components of the engineered product fall within the normal biological range of the non-engineered product; and (2) if any of the key components fall outside of the normal range, whether that deviation has any implications for human or animal safety.[154]

129. In addition, bioengineered plants are routinely characterized at the molecular level as part of the safety assessment for cultivation and use as food and feed. This analysis characterizes the introduced genetic material and its expression in the plant.

130. The stability of the transferred genetic material and the demonstration of the Mendelian inheritance of the introduced genetic material are important safety considerations. The general applicability of a safety assessment for a bioengineered plant depends on demonstrating the stability of the insertion and consistent expression of the new genetic material during the first generations over which the plant is propagated. If a bioengineered plant were to exhibit unintended compositional or other phenotypic changes in other tests, such as compositional

[153] An anti-nutrient is a chemical in food that prevents the absorption of nutrients.

[154] "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants," para. 44, CAC/GL 45-2003, CODEX ALIMENTARIUS (Ex. US-138).

analyses or field trials, molecular characterization might provide information useful in explaining the origin of those changes.[155]

131. Field tests also provide information on a number of issues. Such tests are designed primarily to examine whether the bioengineered plant exhibits the intended characteristics.[156] In addition, tests enable the identification of any plant that may have gained weedy characteristics atypical of the parent variety and any unusual susceptibility to pests or to diseases. If there are compatible species that may interbreed with the engineered crop, any potential consequences of such crosses, such as increased weediness of the intercrossing progeny, as well as any management techniques to minimize the possibility of such outcrossing are identified.

132. Finally, a number of issues relating to any potential environmental effects would also be typically evaluated, such as effects on other organisms in the ecosystem. This would also include information on indirect impacts, such as those on farming production methods, or other effects on commodities produced from the new product.

133. The results of these data, taken together, inform the overall assessment, and each can bear on the interpretation of other study results. Unexpected or anomalous results may suggest the need for an additional study.[157] By contrast, where all of the data consistently provide no indication of adverse effects, and there is no specific indication that the data submitted are inadequate, there is generally no reason to expect that any remaining risk has gone undetected, and that further studies are warranted.

2. Requests for chronic toxicity tests, when acute studies show no effects

134. One example of requests for additional information intended solely to disprove hypothetical risks is the insistence that applicants conduct additional, long-term or repeat dose (chronic) tests to prove the lack of the toxicity of the protein. For all of the products at issue in this dispute, the results of the acute toxicity tests and the homology comparisons provide no indication for any concern and do not indicate the need for additional testing.

135. All of the products at issue in this dispute are plants that have been engineered to produce one or more well-characterized proteins. Except for allergens, toxins, and anti-nutrients, proteins are not associated with any adverse health effects.[158] These proteins behave like any

[155] National Research Council, 1989, "Field Testing Genetically Modified Organisms," p. 60 (Ex. US-139).

[156] Generally, any new plant varieties would be screened as early as possible in the development process to identify substantial undesirable changes in a large number of parameters, and plants with visible alterations are eliminated from future product development.

[157] "Strategies for Assessing the Safety of Foods produced by Biotechnology," Report of Joint FAO/WHO Consultation, World Health Organization, Geneva 1991, section 4.3.1 (Ex. US-14); "Safety aspects of genetically modified foods of plant origin," Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, World Health Organization, Geneva, (May 29 – June 2, 2000), section 4.2.2 (Ex. US-141).

[158] Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety, Rome, Italy, 20 September to 4 October 1996, section 5, "Products that are substantially equivalent to existing foods or food components except for defined differences," 3rd paragraph (Ex. US-140).

other dietary protein, which when ingested are digested and used as nutrients or excreted. Further, there is no evidence that they bind specifically to mammalian tissues, or that they can cause the kinds of adverse health effects associated with other types of chemicals--*e.g.*, teratogenicity, mutagenicity, or carcinogenicity. Consequently these proteins would not be expected to cause such effects and generally should not be evaluated in the same manner as other chemicals. Rather, to determine the safety of the protein, it would typically be sufficient to demonstrate the lack of amino acid sequence similarity (homology) to known protein toxins or allergens, and that the proteins degrade rapidly under simulated mammalian digestion conditions.[159] In addition, dietary exposures would be evaluated by testing the purified protein at high doses in a short-term, single-dose (acute) test to ensure a lack of mammalian effects.[160]

136. For the most part, proteins that would be expected to be toxic to mammals should express toxicity when tested at the high doses required in the acute oral test.[161] While there are examples of proteins known to have longer-term effects in mammalian species, none of the proteins at issue in these applications are similar to these proteins.

137. The data submitted on all of the products at issue in this dispute indicate that the inserted proteins are rapidly degraded (within 2-30 minutes) to smaller non-toxic peptides and amino acids in mammalian gastric juices. As previously noted, these degradation products become nutrients. There is no evidence that they specifically bind to or accumulate in mammalian tissues. Nor is there any reason to think that the basic physiological processes of the mammalian digestive system would change under the circumstances of multiple or repeated long-term exposures, and thereby make these proteins toxic. Consequently, in the absence of any indication of concern in the acute toxicity tests, and in the absence of a structural relationship between the protein and any toxins, allergens or other proteins established to have longer-term toxicity, no further testing would normally be considered scientifically necessary to characterize any potential risks from the protein.

138. Thus, in the absence of any identified potential hazard or deficiency in the data discussed above, the request for chronic toxicity tests can only be interpreted as a demand to disprove a theoretical risk—that, for some unknown reason, and contrary to all available data, the protein will behave differently than all other proteins in the diet. Such requests are insufficient under the SPS agreement to justify the resultant delay in the EC's approval process.

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[159] Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety, Rome, Italy, 20 September to 4 October 1996, section 5, "Products that are substantially equivalent to existing foods or food components except for defined differences," 3rd paragraph (Ex. US-140).; "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants," para. 38, CAC/GL 45-2003, CODEX ALIMENTARIUS (Ex. US-138).

[160] Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety, Rome, Italy, 20 September to 4 October 1996, section 5, "Products that are substantially equivalent to existing foods or food components except for defined differences," 3rd paragraph (Ex. US-140).

[161] OECD Consensus Document on General Information Concerning the Genes and their Enzymes that Confer Tolerance to Phosphinothricin Herbicide OECD 1999 ("When proteins are toxic, they are known to act via acute mechanisms and at very low dose levels," citing (Sjoblad, et.al, 1991)) [EC Exhibit 75, attachment 106].

a. Roundup Ready Corn Exhibit 76 and 96

139. Austria filed an objection on the application for Roundup Ready maize NK603 on the grounds that not only acute but also subchronic, mutagenic, reproductive and ecotoxic effects of the protein (EPSPS) should be studied. [Exhibit 76, attachment 44] Austria raised the same objection on the application for Roundup Ready corn (NK603), for food and feed under Regulation 258/97. [Exhibit 96, attachment 33, p. 29] However, in both cases Austria wholly failed discuss the results of the acute studies, or provide an explanation of why the proteins in this product would behave differently than all available data indicate is likely. [Exhibit 76, attachment 44; Exhibit 96, attachment 33, p. 29]

140. Given that EPSPS proteins are commonly found in a wide variety of food sources which have a long history of safe use, the available information regarding the enzyme function of the protein, lack of homology to toxic proteins based on bioinformatics searches, and lack of acute oral toxicity when administered to mice at high doses, the additional toxicological testing for the EPSPS protein that Austria demanded is unfounded and unreasonable. Such testing exceeds Codex Alimentarius guidelines,[162] as well as the EC's own Scientific Committee Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed (March 2003)[163], as the applicant pointed out to Austria. [Exhibit 76, attachment 61, page 35]

b. Roundup Ready (GA21) corn-Exhibit 91

141. On April 18, 2000, Greece raised several objections, relating to the need for additional data, with respect to the GA21 novel food application submitted under Regulation 258/97. Among these was the absence of long-term toxicity testing on the EPSPS protein. Although Greece acknowledged that the acute studies conducted in mice "did not reveal any adverse effects or clinical observations," the member State argued that "there are no data from long-term toxicity tests" to demonstrate the safety of the product [Attachment 29, p.2]. Given the results of the acute study, the fact that no long-term toxicity tests had been conducted is insufficient to support a need for further testing. This is particularly true, given that all of the other submitted data also showed no indication of any adverse effects. Greece identified no product attribute or study result that offers any reason to believe that the protein will not behave as all available information indicates is likely. Rather, the requests merely seeks further evidence to disprove a speculative risk.

3. Request for multiple whole food studies

142. Another example of requests to disprove hypothetical risks involves whole food studies. Many member States requested that applicants conduct multiple studies in which animals are fed with the biotech food for a period of several weeks. The general purpose of whole food studies

[162] "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants," paras. 37, 38, CAC/GL 45-2003, CODEX ALIMENTARIUS (Ex. US-138).

[163] Ex. US-113.

is to confirm that the introduction of the desired trait has not unintentionally caused the plant to produce a toxicant or a modified amount of a particular nutrient or anti-nutrient (either significantly more or less), which might result in some significant dietary impact. As previously noted**,** one of the primary factors considered in evaluating the safety of biotech foods is whether the inserted DNA causes any changes other than the intended production of the new substance. To address this issue, the composition and characteristics of the biotech food are compared with its conventional counterpart, with emphasis on changes in the levels of significant nutrients and naturally occurring toxicants and anti-nutrients.

143. For a number of reasons, the requests for multiple whole food studies in different species are unfounded. As a general matter, international consensus documents do not recommend the routine use of whole food studies.[164] Rather, these documents indicate that such studies are not generally necessary in the absence of some indication for concern in the other data, such as in the acute toxicity tests or compositional analyses. Nonetheless, for all of the products at issue in this dispute, at least one whole food study was submitted as part of the application. In every case, the initial whole food study indicated no adverse effects.

144. Based on the submitted safety data, as well as the scientific knowledge accumulated from experience with these products, there is no reason to believe that the results of the second – or in some cases third or fourth – whole food would differ in any way relevant to the safety of the product. For all of these products, the results of compositional analyses indicate no reason to believe that any component of the product could cause a food safety risk. Further, these results are uniformly confirmed by the results of the first feeding study. Nor did the member States identify either a deficiency in the first study or a compelling reason why a second animal species might be more susceptible to a particular food component. Consequently, there is no reason to believe that any remaining issue relevant to the safety of the food that has gone undetected. The requests for such studies can only be considered, therefore, at best, an exercise in disproving speculative risks, and at worst, an attempt to merely cause delay.

a. Bt Cry 1F corn (1507) (Exhibits 74 and 75)

145. At the Community level, several member States objected to the application for Bt corn CRY1F (1507) (notified 11/23/2000), based in part on requests for further whole food studies. For instance, France made several requests for further information stating that based on the data presented "it was not possible to make a statement on the absence of risk to public health."

[164] "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants," para. 11, CAC/GL 45-2003, CODEX ALIMENTARIUS (Ex. US-138); "Strategies for Assessing the Safety of Foods produced by Biotechnology," Report of Joint FAO/WHO Consultation, World Health Organization, Geneva 1991, section 4.3.1; "Strategies for Assessing the Safety of Foods produced by Biotechnology," Report of Joint FAO/WHO Consultation, World Health Organization, Geneva 1991, section 4.3.1 (ex. US-14); "Safety aspects of genetically modified foods of plant origin," Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, World Health Organization, Geneva, (May 29 – June 2, 2000), section 4.2.2 (Ex. US-141).

Exhibit 74, attachment 96). Despite the fact that all of the data the applicant had submitted - acute toxicity tests demonstrating the safety of the novel protein, compositional analyses indicating no significant differences in the corn, and separate whole food studies on broiler chickens and ruminant dairy cattle – indicated no adverse effects, France demanded an additional feeding study with whole food sprayed with herbicide.[165] As an initial matter, the objection wholly fails to address the previously submitted data, providing neither a concern about the studies themselves, nor any explanation of why the previous study results provide any plausible scientific basis to expect that carrying out an additional evaluation will yield a different result, or other information that could significantly affect the assessment of the product's risks.

146. In addition, given that the design of the study conducted on broiler chickens is significantly more sensitive than any similar feeding study conducted with cattle, any adverse effects would have been expected to have been identified in the studies already conducted. The broiler chicken is widely accepted as a highly sensitive model in feeding studies. In 42 days, the broilers grow from 40 g to over 2000 g while consuming maize in high concentrations in the diet (50 to 70%). Their growth rate is highly dependent on the nutritional composition and quality of the diet. In addition, due to the number of experimental units (that is, the broiler chickens) that can be incorporated in the study design, small changes in grain or protein quality are more likely to be detected. On the other hand, ruminants, such as cattle, have a more hostile gut environment (including microbial protein degradation in the rumen) than non-ruminants and are, therefore, less likely to reveal differences in feed or nutrient quality. As a result of their efficient digestive processes, lower quality feed can be broken down or utilized, and therefore, any low-level effects from a difference in feed or nutrient quality would not be detected. Given these considerations, broiler chickens are the livestock animal of choice for evaluating nutritional equivalence, particularly for maize.

147. Italy, too, objected and requested additional whole food studies in ruminants (dairy cattle and/or sheep), without identifying any inadequacies in the broiler study provided with the initial submission or providing any rationale why another ruminant study was necessary [Exhibit 74, attachment 100]. Austria also demanded more whole food studies to evaluate toxicity, without any discussion of the results of the previous studies. [Exhibit 74, attachment 101]. Given the lack of any justification for these requests, the delay resulting from these requests must be considered undue under the SPS Agreement.

b. Roundup Ready Corn (GA21) Exhibits 78/85

148. On August 9, 1999, Denmark objected to this application, submitted pursuant to Directive 90/220, on the grounds that additional whole food studies in cattle and pigs were necessary to complete its evaluation of the application. [Attachment 67]. Austria also objected

[165] France also requested toxicity studies on the herbicide, which are not relevant to the evaluation of this product, but instead, to the approval of the herbicide under Directive 91/414/EEC. Similarly, Denmark requested data on the level of glypohsate residues in milk, which would not be relevant to this application, but to the approval of the herbicide under Directive 91/414/EEC.

to this application based on an asserted need for additional whole-food animal feeding studies: "The chicken broiler performance study should be complemented by feeding studies with representative animals which are normally fed with maize." [Exhibit 78 & 85 b, attachment 40, p. 2]. Italy as well, objected on identical grounds, arguing that "the evaluation of the environmental and feed aspects of this dossier can only be completed with…feeding studies with representative animals (i.e., ruminants) which are normally fed with maize." (Attachment 72).

149. None of the member States discussed the results of the previously submitted studies in relation to this request, including the broiler chicken study, submitted as part of the original application. As previously noted, there is no reason to believe, based on the compositional analyses and the first feeding study, that there is any safety issue that was not resolved. While it is true that Denmark asked to review the results of the chicken study, rather than merely the summary, the fact that they failed to review the results of the first study before asking for additional studies indicates that it was not any concerns about study deficiencies or results that formed the basis for the request. It is worth noting in this context that the SCP concluded that "there is no evidence to indicate that placing on the market of the modified maize line (*Zea mays* GA21) with tolerance to glyphosate herbicide is likely to cause any adverse effects on human health and the environment," without any feeding studies but the previously submitted broiler chicken study. [Attachment 90, p. 9] As discussed above, given that the study protocol for the broiler chicken feeding study is the most sensitive, and therefore, most likely to identify any effects of concern, some further explanation of the basis for these objections would be necessary to justify the refusal to forward this application to a vote. Moreover, Austria's objection does not specify which animals should be tested, nor how many such studies would be necessary. Consequently, particularly in light of the SCP opinion on this issue, none of the member State objections were warranted and the resultant delay was not justified.

c. MaisGuard (MON 810) x RoundupReady (GA21) Exhibits 82 and 94

150. On November 30, 1999, the lead CA requested that the applicant provide several additional studies to support the application for this product, submitted under Directive 90/220. [Exhibit 82, attachment 8] The lead CA specified that an additional whole food study needed to be conducted "with the genetically modified hybrid (treated and not treated with glyphosate) [and] compared with corresponding studies using the parental lines and non modified maize." [Attachment 8]. However, the request failed to provide any explanation of the reason it believed the additional feeding study on the hybrid would provide information that could not be determined from the feeding studies and compositional analyses previously submitted on both the parent lines, as well as the compositional data submitted on the hybrid.

151. Substantial data that had been submitted to demonstrate the safety of this product (as well as the feed safety of both transgenic parents).[166] Specifically, the applicant had previously provided a broiler chicken study [Exhibit 94, Attachment 13, pp. 25-29] as well as other feeding

[166] See infra at Section IV.B.4 for additional discussion of this request.

studies [Exhibit 78, attachment 26; Exhibit 91, Attachment 12, pp. 5-10]. In the light of the studies already provided, the request for the additional study cannot be considered to be scientifically justified.

152. Similarly, after considering the information supplied in the application for MaisGuard (MON 810) x RoundupReady (GA21) corn, notified under Regulation 258/97, the lead CA (the Netherlands) requested an additional whole food study in mice [EC Exhibit 94, attachment 12]. The rationale offered for this request was the need to address hypothetical concerns that unknown pieces of DNA could be scattered over the genome. While small random DNA insertions may not all be detected by molecular characterization, the mere presence of such insertions is not a safety concern in itself. Although some insertions could conceivably affect food safety, the impact of any such insertions can be determined by evaluating the compositional analyses of the plant as well as its agronomic performance. If both analyses indicate no unexpected changes, there is no basis on which to hypothesize a food safety concern for food from the plant. In this case, such assessments had been performed on each of the parental lines, MON 810 and GA21, and no unexpected changes were observed. At no time did the member State provide any explanation of the reason it believed that the compositional analyses or feeding studies previously submitted on both the parent lines, as well as the compositional analyses submitted on the hybrid, did not adequately address this issue.

153. As requested, the applicant analyzed the composition of the MaisGuard (MON 810) x RoundupReady (GA21) corn. Consistent with the previously submitted studies, the composition of MaisGuard (MON 810) x RoundupReady (GA21) corn was found to be comparable to that of the parental lines (MaisGuard corn (MON 810) and Roundup Ready corn (GA21)) and other commercial maize varieties. In addition to performing 90 day feeding studies in rats using MaisGuard (MON810) or RoundupReady (GA21) maize, the applicant also performed a broiler chicken feeding study using grain from MaisGuard (MON 810) x RoundupReady (GA21) corn. The study revealed no phenotypic adverse effects in broiler chickens fed MaisGuard (MON 810) x RoundupReady (GA21) corn .

154. Given all of the data that had been submitted on both parent lines, the requests for yet further studies lacked any scientific basis. One parent line (Mon 810) had been granted approval based on positive risk assessments by the lead CA and the SCP, both of which had considered the safety of the food from these plants.[167] The other parent line had received both a positive assessment from the CA of Spain, as well as a positive opinion from the SCP on the safety of consumption of the product. [EC Exhibit 91, Attachment 43] Accordingly, these objections cannot serve to justify the EC's failure to reach a decision on this application.

d. Roundup Ready corn (GA21) - Exhibit 91

[167] European Commission Decision of 22 April 1998, concerning the placing on the market of genetically modified maize (Zea mays L. line MON 810), pursuant to Council Directive 90/220/EEC (Ex. US-131).

155. On April 18, 2000, Italy, Austria, and Greece objected to the application for Roundup Ready corn (GA21), on the grounds that additional whole-food feeding studies needed to be conducted in several animals. (attachments 18, 25, and 29, respectively). However, none of the member States addressed the results of two feeding studies that had been submitted in 1998 as part of the original application under Novel Foods/Regulation No. 258/97. Both the rat feeding study and the broiler chicken study showed no adverse effects. [EC Exhibit 91, Attachment 43]

156. Italy demanded that feeding studies be conducted in dairy and beef cattle, as well as in pigs, without providing any explanation of the basis for this request. (attachment 18). By contrast, neither Austria nor Greece's objections provided any specific request for a particular number of studies or with a particular target species. None of the member States called into question the compositional analyses or addressed in any way the results of the previously submitted feeding studies. Indeed, Greece made its request notwithstanding its acknowledgment that "[d]ata of compositional and nutritional analyses of grain and forage samples are considered as adequate and support the substantial equivalence of the composition of the GA21 transgenic line with the non-transgenic control, as well as to maize varieties in commerce. Data concerning the secondary metabolite levels were also satisfactory regarding the examined parameters." (Attachment 29, p.2). Moreover the SCF opinion had already concluded that the data submitted, including the two whole food studies, were "sufficient for evaluation." [attachment 43, pp. 11-12] The SCF further cited these studies in support of its ultimate conclusion that "from the point of view of consumer health, maize grain from maize line GA21 and derived products…are as safe as grain and derived products from conventional maize lines." [attachment 43, pp. 11-12]. Accordingly, none of these objections offers an adequate basis under the SPS agreement for delaying a decision on the application in order to conduct additional whole food studies.

e. Bt-11 x Glufosinate Tolerant Sweet Corn-Exhibit 92

157. As it had in the application for Bt corn CRY1F (1507), Austria demanded additional long-term animal feeding studies for sweet corn in the application for glufosinate tolerant and Bt-11 sweet corn filed under Regulation 258/97. Austria argued that the toxicological assessment related only to Bt-11 field corn, and that consequently additional feeding studies in sweet corn were warranted. [Exhibit 92, attachment 25] France also objected, requesting that additional whole food studies be conducted with the sweet corn. [Exhibit 92, Attachment 23] Given the results of the compositional analyses, and the fact that feeding studies conducted on Bt-11 in field corn had been provided,[168] there is no general scientific basis for requesting additional feeding studies in sweet corn. The key difference between sweet and field corn is that sweet corn has a higher amount of natural sugars. There is no reason to believe that this fact alone would render the results of the safety assessments conducted on the field corn inapplicable to this product.[169]

[168] The applicant had referenced the whole food feeding studies it had performed on Bt-11 field corn on page 6 of 9 submitted November 28, 1998 at the beginning of Section 4: Additional Data. The EC did not provide the original submission by Novartis on April 6th, 1998 for processed products of sweet corn.

[169] See infra at Section IV.B.4 for additional discussion of this objection.

158. Greece also demanded that the applicant conduct additional whole food studies on this product, that would take "into account the synergistic effects of these proteins with the rest [of the] ingredients of the whole product." This demand was made even though the applicant had performed simulated digestibility studies, and acute toxicity tests, which Greece acknowledged "showed not a single adverse effect in the dosage tested." [Exhibit 92, attachment 28] Given that the applicant had also conducted data base searches for homology to known allergens and toxicants, and found none, there is no reason to believe that these proteins would behave any differently than any other protein, would spontaneously develop new or different toxic properties, or would otherwise interact with other components of the food. Although Greece discussed the submitted data, it did not identify, with any specificity, any deficiencies in that data. Moreover, Greece's stated concerns would not be addressed by the additional tests requested. Instead, the member State merely noted that "the *in vitro* methodology to study degradability of Btk and PAT proteins can be improved," but failed to specify how.

f. Roundup Ready Corn, Exhibit 96

159. After submission of the application on April 24, 2001, the lead CA requested an additional whole food feeding study in mice or rats, to address concerns about the presence of unintended DNA fragments that the company had identified as part of their molecular characterization data. [Attachment 7, pp. 1-2] The lead CA stated that "the presence of additional unintended modifications cannot be excluded with sufficient certainty" [Attachment 7, pp. 1-2] The mere fact, however, that an additional insert is present does not necessarily mean that the product presents an additional risk. Rather, the determination turns on the results of all of the other data and information provided by the applicant, which the member State failed to address in their request. If the results of those tests raise questions, then further examination would be warranted. But in this case, the applicant had conducted compositional analysis and a broiler chicken whole food study with the product containing the additional insert, and in these circumstances would have detected any resulting changes relevant to food safety. The applicant nevertheless conducted the requested test, which identified no adverse effects.

160. A year later, Austria objected that the information provided was insufficient, demanding that studies on "the whole transgenic plant, including its products, should be subjected to a thorough toxicological examination so as to detect any secondary effects." [Attachment 22]. Even though the 90 day rat study demonstrated no effects, providing yet further confirmation of the results from all of the other previously submitted data, including compositional analysis and a broiler chicken feeding study, Austria objected that *yet additional* whole food studies in catfish and dairy cattle were necessary. However, neither inadequacies nor food safety hazards were identified from the previously submitted data, nor was any general scientific rationale provided to justify the request.

4. Insistence That Safety of the Hybrid Product Be Proven Independent of the Data on the Parent

161. Another example of demands by the EC that applicants disprove merely theoretical risks are repeated demands that separate assessments be conducted for each hybrid plant produced through conventional breeding from a previously evaluated biotech product. In these cases, member States requested additional evaluations without having a plausible scientific reason that the risk profile of the hybrid plant would be altered by breeding such that the existing safety data on the parents should be discounted. The products at issue were created by crossing (breeding) varieties of the same species. Both varieties are themselves used in food, and therefore are extremely unlikely to introduce traits that have not been in food before (with the exception of the single trait introduced through genetic engineering, for which adequate safety data had already been provided). In addition, plant lines used for such crosses generally have been subject to extensive backcrossing and field testing to ensure genetic stability (including the absence of additional DNA segments inserted at other sites in a plant chromosome that could potentially disrupt the normal expression of other plant genes). Finally, because the plant lines are closely related to each other, crosses between them are no more likely to be subject to unintended changes than conventional breeding between non-biotech plants.

162. A further consideration is that modern crop breeding relies on a knowledge base that has been developed over the last 50 years through breeding programs.[170] Hybrid seed typically goes through at least 10 generations of breeding effort prior to the release of seed suitable for farmer cultivation. As a result, modern cultivars of major commercial crops are predictable in almost all aspects of performance (yield, disease resistance, maturity, etc.). The products at issue in this dispute use these hybrids and also employ the same methods of seed production. Consequently, any significant discrepancy that might theoretically arise from this cross would be expected to be detected in the field tests. The request for data on each hybrid corn developed also ignores all of the information about the safety of these plants that has been derived from the established processes in hybrid development, and their history of use. Thus, the mere fact that a product is the result of cross-breeding is insufficient to justify the need for additional studies to confirm the results of the existing data on the parents.

a. Bt-11 Corn - Exhibits 69 & 92

163. Austria objected in 1999 to the deliberate release application for insect-resistant (Bt-11) corn at the Community level, citing the fact that the notification included not only field corn but also sweet corn. [Exhibit 69, attachment 64] Austria demanded that "an analysis of the whole spectrum of key nutrients (carbohydrate- and fatty acids-spectrum, protein fraction, amino acids, vitamin content), possible anti-nutrients as well as toxins . . . be carried out." The applicant had provided a full battery of safety data on the product in field corn, including compositional analyses and feeding studies, demonstrating the equivalence between the biotech product and conventional corn. [Attachments 27, 28, and 29] This conclusion was also supported by the safety assessment performed by the lead CA. [Attachment 31] Thus, the mere fact that the notification also included the production of a sweet corn product produced through conventional

[170] OECD, 1993, "Safety Considerations for Biotechnology: Scale-Up of Crop Plants," pp.14-16 (Ex. US-142).

breeding is insufficient to justify this request. As previously noted, the key difference between sweet and field corn is that sweet corn has a higher amount of natural sugars. There is no reason to believe that this fact alone would make the cross between the field and sweet corn more likely to produce unintended compositional or nutritional changes than any other cross between non-biotech plants, or otherwise render the results of the safety assessments conducted on the field corn inapplicable. The SCP concluded that

> "The Committee is of the opinion that there is no evidence to indicate that the placing on the market for cultivation purposes of maize line Bt-11 and varieties derived from this line by conventional crosses between Bt-11 line and maize lines other than genetically modified ones is likely to cause adverse effects on human health and the environment.
>
> The notifier has submitted a package of relevant information on grain and silage nutritional values and has carried out relevant feeding trials with target animals. Data from these studies provide no indication of risks associated with the cultivation of these GM maize lines."

[Attachment 83].

164. Austria raised a similar objection in the novel foods application for Bt-11 in sweet corn, filed under Regulation 258/97, arguing that additional compositional and safety data were necessary to establish the equivalence between Bt-11 sweet corn and Bt-11 field corn. [Exhibit 92, Attachment 25]. Austria summarily rejected the applicant's reliance on the risk assessments conducted by the lead CA and the SCP on Bt-11 field corn, on the grounds that this evidence "cannot be considered adequate since sweet maize and field maize have different component spectrums." [Exhibit 92, attachment 25] The SCP, in its opinion above, discounted this argument.

165. The UK expressed comparable concerns with respect to the same application. [Exhibit 92, attachment 22] Even though the applicant had conducted studies on the expression of the modified protein in field maize and even though the UK acknowledged that "it is accepted that the protein [in sweet maize] is the same as in the field maize," the UK nevertheless objected on the grounds that studies relating to the expression of the introduced genes be provided on sweet corn were necessary. No further explanation for discounting the data submitted on the parental field corn is offered.

166. Greece also raised a similar objection to this application. Although acknowledging that the nutritional data provided on both the Bt11 field maize and Bt11 sweet maize revealed only slight compositional differences given the large natural variations exhibited in hybrids, Greece required "analyses for all the parameters (especially for amino acids, fatty acids, anti-nutrients and secondary plant substances) for both the Bt11 sweet maize and Bt11 field maize. [EC Exhibit 92, attachment 28]. Neither of these objections identify any unique property about the product that would make the product behave differently than all of the data indicates is likely.

Nor do they provide any other scientific justification for rejecting the results of the safety data conducted on the parent field corn. Indeed, the SCF noted that "the distinction between the results for the sweet maize and field maize is not relevant to the assessment as long as the appropriate corresponding non-modified maize is used as control." [EC Exhibit 92, attachment 53, section 3.10]

b. Bt Cry 1F corn - Exhibit 74 & 75

167. Austria objected to the application for Bt corn CRY1F (1507) (notified 11/23/2000), claiming that the studies on Bt corn CRY1F (1507) were insufficient to assess the risks from all its subsequent progeny because safety studies were necessary for all subsequent products. [Exhibit 74, attachments 101, 128] No further justification or explanation was provided. As discussed above, there is no general scientific rationale that would support requiring separate risk assessments for each hybrid of an approved parent line. Nor did Austria raise any concern with the existing safety data. This objection, therefore, cannot serve to justify any consequent delay in processing this application.

c. Bt Cry 1ab x Roundup Ready Corn--Exhibits 82 & 94

168. In the application for MaisGuard (MON 810) / RoundupReady (GA21) corn, the lead CA insisted on molecular characterization of the MON 810 x GA21 line without regard to the previous data that had been submitted on the parental lines (Exhibit 94, Attachment 12). This request for additional information disregarded substantial analyses showing that expression of each introduced trait in the hybrid was identical to the corresponding single-trait parental line.

169. Similarly, the lead CA requested further information on the levels of EPSPS protein expressed in the hybrid lines, based on concern that EPSPS expression levels were slightly higher in the hybrid lines than in the parental lines. Such information is not relevant to assessing the risks given the known safety information about the EPSPS protein.[171] The lead CA also requested unnecessary comparisons of compositional data between the new hybrid and non-transgenic control lines. The data submitted in the application (Exhibit 94, Attachment 2] analyzed the new hybrid in comparison to the transgenic parental lines (1) MaisGuard maize line MON 810 and (2) Roundup Ready maize line GA21. As cited in the application [EC Exhibit 94, attachment 2, p. 46], the transgenic parental lines had already been shown to be substantially equivalent to non-genetically modified maize except for the introduced traits. Therefore, a demonstration that the new hybrid line did not differ in compositional analysis from either transgenic parental line is also a demonstration that the new hybrid line does not differ from the non-transgenic control lines (when a=b and a=c, then b=c).

[171] LA Harrison, MR Bailey, MR Naylor, JE Ream, BG Hammond, DL Nida, BL Burnette, TE Nickson, TA Mitsky, ML Taylor, RL Fuchs, and SR Padgette. The Expressed Protein in Glyphosate-Tolerant Soybean, 5-Enolypyruvylshikimate-3-Phosphate Synthase from Agrobacterium sp. Strain CP4, Is Rapidly Digested in Vitro and Is Not Toxic to Acutely Gavaged Mice. Journal of Nutrition 126:728-740, 1996 (Ex. US-143). .

170. In the same letter, the member State also requested an additional feeding study to resolve concerns about hypothetical unknown pieces of DNA that could be scattered over the genome. [Exhibit 94, Attachment 12] As previously noted, the mere presence of any such insertions would not be a safety concern in itself. If there is no evidence of unexpected change in either the compositional analysis of food from the plant, or in the agronomic performance of the plant, there is no basis on which to hypothesize a food safety concern for food from the plant. In this case, such assessments had been performed on each of the parental lines, MON 810 and GA21 and no unexpected changes were observed. Given the lack of any scientific basis to expect that the traits introduced into MON 810 and GA21 would interact with each other, once the parental lines have been determined to be safe, they may be conventionally bred with other varieties with the expectation that unintended effects resulting from the conventional breeding of these plants would be no more likely than unintended effects resulting from the conventional breeding of two non-genetically engineered plants. Such techniques have been used over decades to safely develop new maize varieties, yet such varieties have not commonly been subject to the level of analysis requested by the lead CA.

171. Nonetheless, the applicant analyzed the composition of the MaisGuard (MON 810) x RoundupReady (GA21) corn. The composition of MaisGuard (MON 810) x RoundupReady (GA21) corn was found to be comparable to that of the parental lines (MaisGuard corn (MON 810) and Roundup Ready corn (GA21)) and other commercial maize varieties. [EC Exhibit 82, Attachment 5] The applicant also had previously submitted several whole food feeding studies, including a 90 day feeding study in rats using MaisGuard (MON810) or RoundupReady (GA21) maize, and a broiler chicken feeding study using grain from MaisGuard (MON 810) x RoundupReady (GA21) corn. None of these studies revealed any adverse effects in broiler chickens fed MaisGuard (MON 810) x RoundupReady (GA21) corn. [EC Exhibit 82, Attachment 9].

172. In response to the dossier submitted under Regulation 258/97, applying for food and feed approval, the UK also insisted that the applicant provide extensive characterization of the new hybrid, rather than simply relying on the analyses previously carried out on the transgenic parental lines (EC94-attachment 10). The UK acknowledged that it had previously reviewed both parental lines, but offered no explanation for why it believed that, in this particular instance, it needed data to confirm that "the expression of the introduced genes in the parental lines will be identical when combined in one hybrid." [Exhibit 94; Attachment 10]. As part of this request, the UK requested molecular characterization to "confirm[] the absence of antibiotic resistance markers and have details regarding the homology between the two constructs introduced as a result of the crosses." Id. Given that neither parent contained an antibiotic marker gene, there is absolutely no scientific basis for theorizing that cross-breeding between the two products would somehow introduce such a gene. The lead CA had previously made the same request for additional molecular characterization, noting that they "were not convinced that the introduced traits in the new hybrid are identical to the traits in the parental lines MON 810 and GA21." (Exhibit 94; Attachment 12). Neither Member state, however, offered any scientific basis for why the cross would have altered the traits, or otherwise addressed the relevant data that the

applicant had provided on this point. The applicant had previously established the stability of the inserts for both of the parental lines, separately, demonstrating that the traits would remain stable in subsequent hybrid offspring. [EC Exhibit 94, Attachment 2, Section V] In the absence of any indication of concern with respect to this data, there is no explanation for why additional data was necessary to demonstrate the safety of this hybrid, as opposed to other hybrids.

173. Similarly, in reviewing the notification for this product submitted under 90/220, Spain requested additional feeding studies on the hybrid line for this product, without taking into consideration previous feeding studies carried out for both transgenic parental lines [EC Exhibit 82, Attachment 8]. The request, however, fails to articulate any reason that additional feeding studies might be needed, given that studies provided on the transgenic parental lines did not raise any concerns. Spain also requested "Mendelian segregation studies of the hybrid in order to verify the stability of both events jointly" [EC Exhibit 82, Attachment 8]. There is no logical basis for this request, which implies some interaction between the MON 810 and GA21 events. The company had already shown the stability of these transformation events in each parental line. The insertions, having been shown to be stable in the parental lines, would be no more likely to be affected by crossing than any other gene already present in either parent.

5. Vague Requests for Data on Environmental Effects

174. Another category of unwarranted information requests relate to the concerns expressed regarding various vague, potential environmental effects, which, upon examination, amount to yet additional requests to disprove wholly speculative risks. One primary example of these are concerns about potential changes to biogeochemical processes. This is a concern that bioengineered plants might alter essential environmental functions such as nutrient cycling associated with microbes or other organisms. Several nutrient cycles depend on microbial functions, such as Nitrobacter and Nitrosomonas species for the nitrogen cycle and Desulfovibrio and Desulfomaculatum species for the sulfur cycle. For a number of reasons, these are risks that, based on what is generally known about the issue and the products, are so unlikely as to be purely theoretical.

175. The available information does not indicate that any of these bioengineered plants present any potential for disrupting these cycles. The attributes of these products are such that there is no general scientific reason to expect that they would cause such effects; for example, the modification is not intended to function in a manner that affects these cycles. In addition, there is generally a duplication of function between many microbial groups, such that even in the unlikely event that there was a measurable effect on a particular group, it would have no effect on any global biogeochemical process. Moreover, given the immense variation in levels of biogeochemical processes due to such agricultural practices as cultivation, fertilization and no-till, it is difficult to envision that, absent a truly massive change, any variation in biogeochemical processes that could be linked to the biotech plant could be determined to be significant. Any change of such a magnitude should have been discerned as part of the field trials. Absent any

indication of unusual activity in the field trials, there is no reason to believe that positing such risks is anything more than mere speculation.

a. Bt–11 corn Exhibit 69

176. In the application for glufosinate tolerant and insect-resistant (Bt-11) corn (filed under Directive 90/220 on May 28, 1996), despite a favorable lead CA opinion, various member States objected to the application, citing various vague, environmental concerns. Among the several objections Italy raised with respect to this application was the need for additional data to resolve alleged potential effects of the Bt plant on "biogeochemistry," noting that increased lignin content might lead to slower degradation of the plant material, and required additional study. [Exhibit 69, attachment 112, 154] The research paper cited by Italy in EC Exhibit 69, Attachment 154 does not identify the significance of any potential effects and in fact suggests that lower biodegradation could potentially lead to beneficial effects such as increased soil organic matter, improved soil structure, reduced soil erosion and decreased evolution of CO2. (Saxena and Stotzky 2003). Moreover, given the SCP's specific finding that "[r]isks to soil organisms and soil function through degradation of modified plant material and contamination of groundwater are considered to be extremely low," it is difficult to see how this objection could fairly serve as adequate justification for failing to reach a decision on this product. [Attachment 83]

177. Sweden objected simply that "more information is needed on the ecological effects on other organisms than the target organism (the cornborer)," without identifying any deficiencies in the data the applicant had provided, or otherwise identifying any basis for this criticism. [Exhibit 69 attachment 58] The applicant had submitted substantial data to demonstrate the low likelihood of any non-target effects, including studies on honeybees, ladybeetles, lacewings, and insidious flowerbugs, as well as on two bird species. [EC Exhibit 69, Attachments 8, 9, 10, 11, 12, 83]. Data on potential secondary effects on predatory insects was also submitted. [EC

Exhibit 69, attachments 10, 11, 12, 83]. This kind of vague objection and request for unspecified information is unwarranted in light of all of the pertinent data already presented in the applicant's submission.

178. Based on the submitted data, the SCP issued a favorable opinion on November 30, 2000, finding that "there is no evidence to indicate that the placing on the market for cultivation purposes [of this product] is likely to cause adverse effects on…the environment." [Attachment 83]. In addition, following two more years of complete inactivity, the application was re-submitted under Directive 2001/18 and obtained another positive risk assessment from the lead CA. [EC Exhibit 69, attachments 94, 95]. Accordingly, these objections cannot support a finding that any resulting delay was legitimate.

b. Bt Cry 1F corn--Exhibit 74 and 75

179. Austria objected to the application for Bt corn CRY1F (1507) for import and processing under Directive 90/220 (notified 11/23/2000), on the grounds that insufficient information had provided to evaluate the product's impact on non-target organisms. [Exhibit 74, attachment 101]. The member State first criticized the submitted applicant's studies evaluating non-target effects on the ground that they were carried out with an isolated protein, which the member State argued was "not convincing proof of the harmlessness of the whole genetically modified plant itself." [Exhibit 74, attachment 101]. Austria also cited the need for additional information to address "provisional" research on Cry1Ab proteins and the Bt-corn/cotton leafworm/green lacewing tritrophic interaction. [Exhibit 74, attachment 101].

180. The concern raised is entirely theoretical for this product, given that it is not intended to be grown. It is based on a series of highly improbable and hypothetical events, with no relation to realistic conditions of use of the product. In order for the issue Austria raises to be a viable concern, it must be assumed that the corn would spill during transport, and would establish and spread to such an extent that effects on predator species would occur. While some corn seed may spill during transport, as a general matter, modern commercial corn does not persist in the environment. As the SCP noted in evaluating the potential for gene transfer from the cultivation of Bt-11 corn, "The risk of genetic escape from modified crop plants will be limited by poor dispersal and the absence of sexually-compatible plants either of the same or different species. Zea mays is not an invasive crop but is a weak competitor with limited powers of dispersal….The risk of volunteer maize plants surviving is considered to be remote." [Exhibit 69, Attachment 83]. Consequently, Austria's objection provides no justification for delaying a decision on this application.

c. Roundup Ready Corn (GA21)-- Exhibit 78/85

181. Italy raised a number of objections to the application for GA21 corn, based on the need for additional information to address several vague environmental concerns. Specifically, the member State argued that additional information was necessary on the "effects due to the dissemination (soil, water, air) of the herbicide and its influence on the biodiversity and the biochemical process." [Exhibit EC 78/85, attachment 72]. Italy also requested that the applicant generate information on "the possible variations in soil microflora and fertility due to the foreseeable increased selective activity of this herbicide." Finally, Italy requested additional data on "the relationship between the GMP and the food chain." [Exhibit EC 78/85, attachment 72]. These requests in no way address the substantial amount of environmental safety data submitted by the applicant. Moreover, the Italian CA does not specify what studies the applicant needed to conduct, does not identify any possible risk, nor even explain which organism(s) or biochemical processes may be of concern. [Exhibit EC 78/85, attachment 72]. In the absence of such guidance, these requests are effectively unlimited and endless. It is notable that despite the absence of the data requested by Italy, the SCP was able to render opinions on the issues raised in this objection. [Attachment 90] Specifically, the SCP concluded that

> The probability of horizontal gene flow from plants to micro-organisms is considered to be extremely small, as noted in section 4.4.1. EPSPS genes are naturally present in soil microflora….Risks to soil organisms and related functions through degradation of modified plant material and contamination of groundwater are considered to be extremely low….The Committee, after examining the information and data provided in the dossier, and using available background knowledge underpinning the areas concerned, considers that there is no evidence to indicate that [this product] is likely to cause adverse effects…on the environment."

[Attachment 90].

6. Requests for studies to demonstrate that feeding animals biotech food does not alter the composition of the food derived from the animal.

182. A further example of requests related to unfounded and theoretical risk are requests for additional studies to provide confirmation that biotech animal feeds do not alter the composition of the food derived from animals consuming the feed. Where the compositional analyses demonstrate that the nutritional makeup of the feed falls within the normal biological range of variation that has been established for non-engineered, commercially available feeds, there is no general scientific reason to expect that any effects on milk or meat would occur. In addition, where it has been shown that the introduced protein is rapidly degraded or excreted, like any other dietary proteins, there is no scientific basis on which to speculate that these proteins would accumulate in meat or milk. Where a whole food study has been performed to confirm the results of the compositional analysis, and the study provides no indication of adverse effects or unexpected results, such concerns are wholly speculative.[172]

a. Bt (Mon810) x Roundup Ready Corn--Exhibit 82

183. In the notification for MaisGuard (MON 810) x RoundupReady (GA21) corn, Spain requested "information on nutritional composition in milk from this maize" (Fax of November 30, 1999, Attachment 8). Given the demonstrated safety of corn in feed, generally, as well as the substantial data submitted to support the feed safety of both transgenic parents, there is no scientific basis to suggest a concern. One of the parental lines (Mon 810) was approved by the EC several years prior to this submission, and the feed safety was established as part of that process. In addition, as part of its original submission, the applicant had relied on substantial compositional analyses on the other parent (GA21), as well as feeding studies. [EC Exhibit 82,

[172] In fact, studies of this issue have been conducted, and have confirmed that biotech animal feeds do not alter the composition of the food derived from the animals consuming the feed. *See, e.g.,* L. Cromwell, M. D. Lindemann, J. H. Randolph, G. R. Parker, R. D. Coffey, K. M. Laurent, C. L. Armstrong, W. B. Mikel, E. P. Stanisiewski, and G. F. Hartnell, *Soybean meal from Roundup Ready or conventional soybeans in diets for growing-finishing swine1,2,3G*., J. Anim. Sci. 2002. 80:708–715 (Ex. US-144); A. R. Castillo, M. R. Gallardo, M. Maciel, J. M. Giordano, G. A. Conti, M. C. Gaggiotti, O. Quaino, C. Gianni, and G. F. Hartnell, Effects of Feeding Rations with Genetically Modified Whole Cottonseed to Lactating Holstein Cows, J. Dairy Sci. 87:1778 (2004) (Ex. US-144).

attachments 2, 5]. None of these studies identified anything that would provide any basis for the concern raised by the member State.[173]

b. Roundup Ready Corn (GA21)--Exhibit 91

184. In the notification for Roundup Ready Corn (GA21), Italy objected that the applicant needed to "produce documents showing that feeding animals on a diet containing modified maize does not lead to alterations in the composition of the foodstuffs derived from them for human consumption." [Attachment 18]. As part of its submission, the applicant had submitted a whole food study conducted with broiler chickens. [Attachment 40, Appendix II]. No adverse effects were observed. Moreover, the compositional analyses submitted as part of the original submission demonstrated that the engineered corn fell within the normal compositional ranges of traditionally bred corn. As a consequence of these results, there is no reason to believe that the corn would, for some unknown reason, and contrary to all existing data, suddenly behave differently when ingested by animals. Yet the Italian objection did not question the results of these studies, or otherwise address the previously submitted data. Also, in February 2002, the SCP issued a favorable opinion for this product, finding that "[t]he data on the chemical composition of the two transgenic lines LH and DK derived from GA21 allow the Committee to conclude that they are substantially equivalent to non-transgenic lines." [EC Exhibit 91, Attachment 43]

7. Objections Wholly without Scientific Merit

185. In several instances, member States asked for additional studies that would yield information that would have no relevance in assessing the safety of the product at issue.

a. Bt-11 Corn Exhibit 69

186. In the application for glufosinate tolerant and insect resistant (Bt-11) corn, Italy objected at the Community level based on concerns of the potential weediness of the corn. Italy's assertion, for which there is absolutely no scientific basis, was that "[m]aize seed can remain viable in solid up to 24 months at warm temperatures therefore maize Bt11 . . . represents a potential weediness for some Mediterranean areas." [Exhibit 69, attachment 112] This is entirely specious. Commercial maize has never been considered a weed. Corn is grown throughout the world without any report that it is a serious weed. Although maize seed can regerminate in a subsequent season, maize has been so intensively domesticated, particularly with regard to the inability of its seeds to shatter from the cob, that it does not persist in the environment without human intervention (i.e., cultivation in an agricultural setting). It also

[173] Conducting the dairy cattle feeding study involved considerable cost and delay to the applicant. Such a test would require the applicant to obtain approval for further experimental plantings to generate sufficient maize for the feeding study; employ external consultants to undertake the required study; grow maize for the feeding study in the 2000 season; harvest, transport and ensile the maize under rigorous experimental conditions; undertake the cow-feeding phase; analyse the milk samples; and produce all reports to the Standards of Good Laboratory Practice.

possesses few of the characteristics of plants that are notable as successful weeds, in that it is easily controlled by herbicides or mechanical means. Moreover, the Italian objection was already addressed by the SCP, which concluded that "Zea mays is not an invasive crop but is a weak competitor with limited powers of dispersal. . . . The risk of volunteer maize plants surviving is considered to be remote." [Exhibit 69, Attachment 83].[174]

b. Bt Cry 1F--Exhibits 74 and 75

187. Belgium objected to the application for Bt corn CRY1F (1507) (notified 11/23/2000) at the Community level, inter alia, requesting additional Northern blot data on the mature kernel, despite the fact that the applicant had already measured protein levels in the mature kernel (the measure most relevant to food safety) and had performed a Northern analysis of the developing kernel. [EC Exhibit 74, attachments 95, 132] (Northern blots give information on synthesis of messenger RNAs, which are used as templates for the synthesis of new proteins.) Given the fact that the mature kernel stays essentially dormant until germination begins (which means that there is little or no messenger RNA synthesis); does not have significantly different protein levels from the developing kernel; and that an analysis was already done on the developing kernel, a request for additional data on the mature kernel would not provide any new information relevant to a safety assessment.

188. Italy too objected to the Bt corn CRY1F (1507) application and demanded, without providing any rationale, a proteomic analysis.[175] [EC Exhibit 74, attachments 100, 131] This technique is not standardized or validated and would generate a great deal of information for which no baseline exists against which to evaluate the data. Consequently, the information would be of no use in reaching a determination on the safety of the product.

189. Similarly, Austria cited as another reason for additional whole food feeding studies the need to show no allergenic effects. Again, for the reasons stated above, such a request for additional whole food studies is without scientific basis. [EC Exhibit 74, attachment 101]

c. Roundup Ready Corn (GA21) Exhibit 76

190. In September of 2001, the lead CA for NK603 stated that PCR[176] should be used to detect small DNA insertions because PCR provides a greater degree of sensitivity. These requests are reiterated in a fax in October 2001. The stated concern is that the random small insertions could cause some unintended effect if they inserted into or near a gene rather than in non-coding/non-regulatory regions of the genome. However, the information obtained from this analysis would not provide information relevant to the safety assessment for this product. The plant's genome

[174] Moreover, as far back as 1986, the OECD noted, "the chances of introducing 'weediness' into a crop by rDNA techniques is far less likely than the introduction of such a characteristics by conventional plant breeding methods, in which weeds are often used as a source of genetic material for desirable traits such as disease and insect resistance." OECD, Recombinant DNA Safety Considerations," p. 30 (Ex. US-110).

[175] A proteomic analysis provides the expression patterns of all of the proteins in an organism.

[176] Polymerase chain reaction – a methodology used to identify specific small fragments of DNA.

was screened for unintended insertions by Southern blotting, which is the accepted method of detecting such fragments. In addition, the behavior of the plant in the field and compositional analysis did not indicate any substantial changes that would suggest genetic disruption caused by undetected random insertions. Finally, standard breeding techniques in corn mean that most or all hypothetical random inserts should be lost from the commercial variety. Given all these considerations, use of some PCR-based method to detect additional fragments potentially too small to be seen by a Southern is scientifically unjustified.

191. An additional example of unjustified requests are requests that the GA21 applicant conduct additional allergenicity testing. Austria, for example, raised numerous objections to the assessment of allergy risks in the Roundup Ready maize NK 603. [EC Exhibit 76, attachment 44] It claimed that the standard databank analysis for sequence similarity to known allergens that had been carried out was insufficient confirmation of the lack or absence of a possible allergenic component. It also considered the digestion studies that had been carried out insufficient, of themselves, to prove that the protein has no allergenicity. Although neither test alone can rule out possible allergenicity, current scientific practice uses a "weight of the evidence" approach that would consider the results of these tests, as well as information on the original source of the inserted genetic material, to assess allergenicity, just as the application had done. Austria's objection thus ignores the generally accepted scientific approach to assessing allergenicity. Austria instead referred to an internal Austrian study for additional recommended steps for the assessment of potential allergenicity, including mice studies using the genetically modified plant and the parent plant. Austria's proposed tests, however, lack any scientific foundation. "There are currently no validated animal models of food allergy that could be used to assess a protein's potential to become a food allergen if it has had no previous dietary exposure."[177] Consequently, it is not surprising that the Austria's objection fails to sufficiently define what the applicant is to do, or – even if the applicant were able to perform these tests -- how the data generated from such tests could be interpreted. In addition, Austria's desired but undefined allergy testing is a departure from the international consensus on sufficient testing for allergenicity.[178]

192. Similarly, France objects to this product application on the grounds that more research needs to be performed on allergenicity assessment of proteins. [Exhibit 76, attachment 19] However, scientific knowledge about allergenicity is sufficient to perform a risk assessment for this product, and France did not point to any scientific basis that would indicate that the specific product at issue was even potentially allergenic. It did not identify any deficiencies in the data submitted in the application. And it did not propose an alternative scientific approach to test for allergenicity. Accordingly, no scientific basis existed for France's objection. Moreover, EFSA issued a positive opinion, finding that the product posed no significant risk of allergenicity.

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[177] Organisation for Economic Co-operation and Development "Report of the Task Force for the Safety of Novel Foods and Feeds", para. 115 (May 2000).

[178] ; "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants," ANNEX-Assessment of Possible Allergenicity, CAC/GL 45-2003, CODEX ALIMENTARIUS (Ex. US-138).

d. Roundup Ready Corn – Exhibit 76

193. Austria objected to the safety assessment of Roundup Ready maize NK 603, in part, because it was concerned about conformation of the CP4 EPSPS L214P protein, which Austria claimed was an unexpected effect that necessitated that the risk assessment "should particularly be looked into." [Exhibit 76, attachment 11]. The specific "additional information" is not specified. [Exhibit 76, attachment 11]. Moreover, Austria's concern was already addressed by the extensive information contained in the applicant's original submission to the lead CA. This information included several types of studies on the CP4 EPSPS L214P protein itself as well as knowledge gained from extensive study of other EPSPS proteins.

194. Italy also objected to this application, demanding proteomic analysis to assess the possible differences between line NK603 and the recipient.[179] [EC Exhibit 76, attachment 61, page 13.]. The member State offered no basis whatsoever to justify its request for a test that, as discussed previously, is neither standardized, nor scientifically validated. Without a framework for interpretation, any resulting information would be of no use in reaching a determination on the safety of the product, and cannot provide a sufficient basis for a delay in processing the application.

e. Bt Corn-Cry 1F-Exhibits 74 & 75

195. In the application for Bt corn CRY1F (1507) (notified 11/23/2000), the lead CA on 12/13/2001 rejected compositional data from field trials that had been conducted in France, Italy and Chile, on the grounds that these locations were insufficiently representative of locations exporting corn to the EU. (Exhibit 74, attachment 52, question 12). The member State instead requested that the applicant conduct additional field trials for two consecutive growing seasons from additional locations within the EU. However, no explanation was provided for the conclusion that the locations were "insufficiently representative."

196. Such data would generally be considered "representative" and relevant compositional data for evaluating corn that might be imported into the EU. In the absence of some further explanation, such as an anomaly in the submitted data, the only explanation for the request would appear to be the resulting two year delay caused by the time it would take for the applicant to generate the data.

V. Conclusion

197. The EC's adoption of a moratorium on biotech approvals is widely acknowledged by EC officials and is proven by the actions of the EC in delaying the processing of applications and in failing to reach any final decisions from October 1998 up through the time of the establishment of the Panel. This conclusion does not require an extensive examination or analysis of the 2,800 technical documents submitted by the EC. Nonetheless, as explained in this supplementary

[179] Italy's objection was omitted from the chronology

rebuttal, an examination of those documents in fact further confirms that the EC adopted a moratorium on biotech approvals. In addition, even after two written submissions and a three-day substantive meeting, the EC has not begun to provide a scientific justification for the member State safeguard measures. Accordingly, for all the reasons set forth above and in the prior oral and written submissions of the United States in this dispute, the United States submits that the Panel should find that the EC measures covered in the U.S. panel request are inconsistent with the obligations of the European Communities under the SPS Agreement and the GATT 1994.

ANNEX I

Suggested Questions for Submission to Scientific Experts

I. If no adverse effects are identified in the acute toxicity tests with purified protein, and if the protein does not have characteristics of proteins known to have adverse effects (e.g., it does not share significant amino acid homology with such proteins, its biological function is not associated with adverse effects, it is rapidly digestible, and it is not derived from an organism known to be toxic, allergenic or otherwise harmful), is there any basis to expect that a long-term or repeat dose study would identify an adverse effect that had not been identified in the previous studies?

Please address this matter in the context of the discussion of EC Exhibits 76, 91, and 96 in Part IV of the U.S. Supplementary Rebuttal.

II. Is there any basis to expect that a second animal whole food study would identify any adverse effect that had not previously been identified, when neither the first (well-conducted) whole food study nor compositional and nutritional analyses and protein safety tests, showed any adverse health risks, and agronomic performance tests showed no unexpected agronomic properties?

Please address this matter in the context of the discussion of EC Exhibits 74, 75, 78/85, 82, 91, 92, 94, and 96 in Part IV of the U.S. Supplementary Rebuttal.

III. Is there any basis to expect that a second animal whole food study would identify any adverse effect caused by small random DNA insertions when neither the first (well-conducted) whole food study nor compositional and nutritional analyses and protein safety tests, showed any adverse health risks, and agronomic performance tests showed no unexpected agronomic properties?

Please address this matter in the context of the discussion of EC Exhibits 94 and 96.in Part IV of the U.S. Supplementary Rebuttal.

IV. Hybrid Safety

a. With respect to the hybrid corn products at issue in this dispute, if the safety of the biotech parent plants has been established, is there any basis to expect that this data would not be relevant to assessing the safety of any progeny produced through conventional breeding?

Please address this matter in the context of the discussion of EC Exhibits 74, 75, 82, 94, 69, 92 in Part IV of the U.S. Supplementary Rebuttal.

b. With respect to the hybrid corn products at issue in this dispute, is there any basis to expect that conducting the same safety analyses on the progeny would identify any adverse effect that had not previously been identified by the studies on the parents, when the introduced traits are not expected to interact and the agronomic performance of the progeny indicate no unintended effects?

Please address this matter in the context of the discussion of EC Exhibits 74, 75, 82, 94, 69, 92 in Part IV of the U.S. Supplementary Rebuttal.

V. Is there any basis to expect that feeding animals with any of the products at issue in this dispute would alter the composition or safety of food derived from these animals (e.g., meat or milk), in light of the data demonstrating that the introduced protein in those products is not toxic, is rapidly degraded, and that the product's composition falls within the natural ranges for the crop?

Please address this matter in the context of the discussion of EC Exhibits 82 and 91 in Part IV of the U.S. Supplementary Rebuttal.

EXHIBIT LIST

US-131 Commission Decision concerning the placing on the market of genetically modified maize (*zea mays* L. line MON 810) pursuant to Council Directive 90/220/EEC, (98/294/EC), April 22, 1998, Official Journal of the European Communities, L 131/32, May 5, 1998

US-132 Question and Answers on the Regulation of GMOs in the EU," MEMO/04/85, Brussels, April 15, 2004

US-133 Admissible Notifications of Existing Products Received by the Commission Pursuant to Articles 8 and 20 of Regulation (EC) 1829/2003 on GM Food and Feed

US-134 EC Press Release, C/04/221, 2599th Council Meeting, Agriculture and Fisheries, Brussels, 19 July 2004., 11234/2/04 REV 2 (Presse 221)

US-135 EC Press Release, IP/04/957, July 19, 2004

US-136 EC Press Release, IP/04/1305, Brussels, October 26, 2004

US-137 Letter from Dr. Clemence to the Office of the USTR, 11 November 2004

US-138 "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants," para. 44, CAC/GL 45-2003, CODEX ALIMENTARIUS

US-139 National Research Council, "Field Testing Genetically Modified Organisms" (1989), Chapter 5

US-140 Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety, Rome, Italy, 30 September to 4 October 1996

US-141 "Safety aspects of genetically modified foods of plant origin," Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, World Health Organization, Geneva, (May 29 – June 2, 2000)

US-142 OECD, "Safety Considerations for Biotechnology: Scale-Up of Crop Plants" (1993)

US-143 LA Harrison, MR Bailey, MR Naylor, JE Ream, BG Hammond, DL Nida, BL Burnette, TE Nickson, TA Mitsky, ML Taylor, RL Fuchs, and SR Padgette. The Expressed Protein in Glyphosate-Tolerant Soybean, 5-Enolypyruvylshikimate-3-Phosphate Synthase from Agrobacterium sp. Strain CP4, Is Rapidly Digested in Vitro and Is Not Toxic to Acutely Gavaged Mice. Journal of Nutrition 126:728-740, 1996

US-144 A. R. Castillo, M. R. Gallardo, M. Maciel, J. M. Giordano, G. A. Conti, M. C. Gaggiotti, O. Quaino, C. Gianni, and G. F. Hartnell, "Effects of Feeding Rations with

Genetically Modified Whole Cottonseed to Lactating Holstein Cows," J. Dairy Sci. 87:1778 (2004);

and

L. Cromwell, M. D. Lindemann, J. H. Randolph, G. R. Parker, R. D. Coffey, K. M. Laurent, C. L. Armstrong, W. B. Mikel, E. P. Stanisiewski, and G. F. Hartnell, "Soybean meal from Roundup Ready or conventional soybeans in diets for growing-finishing swine1,2,3G", J. Anim. Sci. 2002. 80:708–715

US-145 Letter from Dr. Alistair Clemence to Dr. Adrian Butt, 23 March 1999

US-146 Letter from Colin Bird to Dr. Alistair Clemence, 2 November 1999