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

(WT/DS291, 292, and 293)

Executive Summary of the Supplementary Rebuttal Submission of the United States

December 3, 2004

I. Introduction

1. The EC has not 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 CDs containing documents related to the processing of applications, and through brief narratives describing the processing of pending applications.

2. However, 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.

3. 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 different product applications and in different stages in the approval process. In several cases, 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.

II. The EC's Second Submission Fails to Raise Any Meritorious Arguments

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

4. 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. As the panel wrote in the *India – Autos* dispute: "A WTO panel is generally competent to consider measures in existence at the time of its establishment. . . . Panels in the past have examined discontinued measures where there was no agreement of the parties to discontinue the proceedings."

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

7. Moreover, this is not a case in which the measure at issue has terminated. 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.

8. 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, a number of EC member States believe that yet additional legislation must be adopted before the granting of new biotech product approvals. 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.

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

9. 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.

10. First, the EC defines a moratorium as existing where "the process of decision-making is temporarily stopped." 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. 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.

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

12. 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 achieve results in the approval procedures despite the transitional period of legislative changes." On the other hand, the EC describes the interim approach as follows: "On [12 July 2000], 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." 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."

13. 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. 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.

14. In addition, 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. Particularly in light of 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. 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 legislation.

15. Third, the EC now tries to explain away the numerous official acknowledgments of the moratorium by claiming that "all these statements" refer simply to the fact that no biotech products reached final decision. To the contrary, the statements uniformly refer to the "moratorium." And, as the EC itself informs the panel, a "moratorium" "may be defined as 'a postponement or deliberate temporary suspension of some activity.'" 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

16. The EC's novel theory of "mixed delays" is illogical and not supported by the text of the SPS Agreement. 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." 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.

17. The EC has instead invented an entirely new approach to applying the obligations of the WTO agreements. According to the EC's approach, as long as a Member can show that its measure is not inconsistent with a different obligation (in this case obligations under the TBT Agreement), then that lack of inconsistency with one provision can excuse the inconsistency with another provision. 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. 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.") .

18. 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

19. The EC spends considerable time addressing the definition of "risk assessment" for purposes of analysis under the SPS Agreement. 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 member States safeguard measures. 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

20. 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. 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. Moreover, 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 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.

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

21. In its second submission, the EC provides brief and conclusory narratives concerning some, but not all, relevant biotech product applications. 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.

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

22. 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. In the narrative in its second submission, the EC attempts to explain away a 2-year gap following the SCP opinion by asserting that "the Scientific Committee recommended a monitoring plan, and the proposal by the applicant remains unsettled." The actual documents, however, reveal that this assertion is untrue. The opinion did not identify any missing information or other deficiency in the application.

B. EC Exhibit 65: Bt cotton (531)

23. The application for Bt cotton (531) under Directive 90/220 suffered a 3-year period of inactivity by EC regulators. The EC justification of this gap is baseless. 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. 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. Furthermore, nothing in the record indicates why the member States objected despite the SCP opinion that addressed the very issues covered in the objections. In sum, nothing in the record indicates that the EC undertook any process whatsoever to resolve the member State concerns.

24. The EC's second submission also incorrectly states that the applicant "finally provided . . . required additional information," which incorrectly implies that delays were due to outstanding data requests. The

applicant, however, 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.

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

25. The novel foods application for Roundup Ready corn (GA21) under Regulation was delayed at the member State level for 10 months while the lead CA completed its risk assessment, and then delayed for 17 months at the Community level before the SCF rendered its positive opinion in February 2002. The EC charges that the 17 months it took for the SCF to render its opinion was caused by the applicant. The truth is reflected in the EC's own chronology: 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. Within less than one month, the applicant provided an answer to all questions. 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.

26. After the SCF issued its positive opinion on February 27, 2002, 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 lasted until the new GM Food and Feed regulation was passed in September 2003. Almost two months passed after the positive SCF opinion in February 2002 with no activity at all on this application. The applicant then sent a letter on April 23, 2002 offering to narrow the scope of the application in order to facilitate the EC's evaluation. Despite the efforts of the applicant to remove any possible impediments, the Commission still failed to forward the application to the Regulatory Committee. Instead, 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." In other words, the EC simply halted the processing of this application in anticipation of possible upcoming changes to its regulations.

D. EC Exhibits 78 and 85: Roundup Ready corn (GA21)

27. 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.

28. The first application for GA21 under Directive 90/220, submitted in the UK in 1997, was delayed at the member State level for 7 months – from March to November 1999. 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. As the minutes to that meeting show, however, GA21 was not on the agenda and was not discussed.

29. The second application for GA 21 under Directive 90/220 abruptly halted when it reached the Commission level. 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.

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

30. MaisGuard x Roundup Ready maize is produced by conventionally hybridizing two "parental" biotech products, MON810 and GA21. Progress on GA21 maize was a limiting step on MON810 x GA21's progress in the regulatory process.

31. 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. The lead CA requested further information on November 30, 1999, and 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. 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.

32. The novel foods application for MON810 x GA21 under Regulation 257/98 shares a similar history. The application was submitted to the lead CA in February 2000. As noted above, the novel foods application for the single trait parent GA21 under Regulation 258/97 stalled at the Commission level. In its comments on the application for MON810 x GA21, Italy stated that "examination of the documentation relating to authorization should only be carried out after the marketing of GA21 has been authorized." To date, the application for MON810 x GA21 is still pending.

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

33. 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. 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." This observation 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. The EC's second submission also incorrectly implies that the objections raised by member States had not been adequately addressed in the SCP. In fact, the SCP assessed the safety of the product at issue based on detailed scientific considerations. 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.

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

34. 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. 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. 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.

35. The EC attempts in its second submission to defend the Commission's inaction by pointing to objections raised by member States. However, the SCP considered the existing scientific evidence and the information provided by the applicant to be sufficient to address the objections voiced by the member States. In addition, the EC's assertion that there were outstanding requests for information is not true. The applicant had voluntarily provided additional information in an attempt to remove any possible remaining obstacle to a Regulatory Committee vote. The actual reasons for the delay were stated in a January 2001 meeting with the applicant: "[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. . . ."

H. EC Exhibit 76 and 96: Roundup Ready corn (NK603)

36. The NK603 deliberate release application was submitted in January 2000, and finally approved – although provisionally to a GM food and feed approval – in July 2004. The Commission approved the GM food and feed application for NK603 in October 2004. Tthe processing of this application was delayed by the moratorium, and its ultimate approval does not signal the end of the moratorium

37. The approval procedure did not progress "smoothly," as the EC contends. For both the GM food and feed and the deliberate release applications, the Regulatory Committee was unable to obtain a qualified majority vote. 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 opinions on NK603, and none of the member States questioned the validity of EFSA's favorable opinions. The Council similarly failed to reach qualified majority vote on the proposals. 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.

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

38. The deliberate release application for oilseed rape (FALCON GS40/90) has been pending for over 8 ½ years. It was first submitted on April 1, 1996, and the lead CA forwarded it to the Commission on October 25, 1996. After member States objected during the review period, the SCP 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. 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, and the applicant responded to Italy's questions by November 30, 2000. The Commission never submitted a draft measure on the application to the Regulatory Committee again, and the application remained in this indeterminate state at the Commission for almost 3 years. The applicant finally had to submit an updated application under Directive 2001/18 on January 16, 2003.

J. EC Exhibit 92: Bt-11 Sweet Corn

39. 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. 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." The EC's contention is unsupported by the record. No risk assessments were submitted during that time period.

40. The EC's incorrect assertion that competing risk assessments existed should not divert attention away from the real cause of the delays. When the BT-11 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 derived from them, the moratorium countries would block any new licences for the cultivation and marketing of GMOs."

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

41. 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

42. 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 opinions" that would call into question the positive risk assessments conducted by the EC's own scientific committees. 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"

43. As the Appellate Body stated in *EC-Hormones,* "[T]heoretical uncertainty is not the kind of risk, which under Article 5.1, is to be assessed" under the Agreements. Yet the objections and related requests for additional information raised by member States were often based on just such theoretical risks, and 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, 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. Yet, such proof is unattainable. As the Appellate Body explained, "[U]ncertainty [] always remains since science can never provide absolute certainty that a substance will not ever have adverse health effects." 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 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. Requests for chronic toxicity tests, when acute studies show no effects

44. 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 chronic toxicity tests. 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. None of the proteins at issue in these applications are similar to proteins known to have longer-term effects in mammalian species. In addition, the data submitted on all of the products at issue in this dispute indicate that the inserted proteins are rapidly degraded in mammalian gastric juices. These degradation products become nutrients, and there is no evidence that they specifically

bind to or accumulate in mammalian tissues. 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. Thus, requests 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.

45. Unwarranted requests for chronic toxicity studies contributed to delays in the consideration of the following applications: Roundup Ready Corn (Exhibits 76 and 96) and Roundup Ready (GA21) Corn (Exhibit 91).

2. Request for multiple whole food studies

46. Another example of requests to disprove hypothetical risks involves whole food studies. As a general matter, international consensus documents do not recommend the routine use of whole food studies. Rather, these documents indicate that such studies are not generally necessary in the absence of some indication for concern in the other data. 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. 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.

47. Unwarranted requests for additional whole food studies contributed to delays in the consideration of the following applications: Bt Cry 1F corn (1507) (Exhibits 74 and 75), Roundup Ready Corn (GA21) (Exhibits 78 and 85); MaisGuard (MON 810) x RoundupReady (GA21) (Exhibits 82 and 94), Roundup Ready corn (GA21) (Exhibit 91), Bt-11 x Glufosinate Tolerant Sweet Corn (Exhibit 92), and Roundup Ready Corn (Exhibit 96).

3. Insistence That Safety of Hybrid Products Be Proven Independent of the Data on the Parent

48. 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. In addition, plant lines used for such crosses generally have been subject to extensive backcrossing and field testing to ensure genetic stability. 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.

49. 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. 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.

50. Unwarranted requests for additional studies of hybrid products contributed to delays in the consideration of the following applications: Bt-11 Corn (Exhibits 69 and 92), Bt Cry 1F corn (Exhibits 74 and 75), and Bt Cry 1ab x Roundup Ready Corn (Exhibits 82 and 94).

4. Vague Requests for Data on Environmental Effects

51. 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. 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. 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.

52. These types of vague and unwarranted requests for additional studies of environmental effects contributed to delays in the consideration of the following applications: Bt–11 corn (Exhibit 69), Bt Cry 1F corn (Exhibits 74 and 75), and Roundup Ready Corn (GA21) (Exhibits 78 and 85)

5. Requests for studies on the composition of the food derived from the animal.

53. 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.

54. Unwarranted requests for studies of the products of animals that consumed biotech feed contributed to delays in the consideration of the following applications: Bt (Mon810) x Roundup Ready Corn (Exhibit 82) and Roundup Ready Corn (GA21) (Exhibit 91).

6. Objections Wholly without Scientific Merit

55. In several instances, member States asked for other types of additional studies that would yield information that would have no relevance in assessing the safety of the product at issue. These include: Bt-11 Corn (Exhibit 69) – information on potential weediness of maize; Bt Cry 1F (Exhibits 74 and 75) – Northern blot data on mature kernels and proteomic analysis; Roundup Ready Corn (Exhibit 76) – PCR analysis, additional allergenicity testing, protein conformation, and proteomic analysis; Bt Corn-Cry 1F (Exhibits 74 & 75) – additional field trials.