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

(WT/DS291, 292, and 293)

Executive Summary of the Rebuttal Submission of the United States

July 29, 2004

I. INTRODUCTION

1. The United States in its first submission showed that the EC's moratorium on biotech approvals (both across-the-board, and with respect to individual pending product applications), as well as the member State product-specific bans, are inconsistent with the EC's fundamental obligations under the WTO Agreement. The EC's response to these clear showings of breaches of its WTO obligations have been remarkable: the EC has failed to address the central issues. With regard to the moratoria, the EC's only defense is that no such measures ever existed. In taking this position, the EC asks the Panel to ignore the statements, and indeed actions, of the EC's political-level decisionmakers. The EC makes this argument even though it has informed the Panel that there indeed is a key political component in the EC approval system. By asking the Panel to find that the moratoria never existed, the EC is requesting that the Panel adopt – solely for the purpose of this dispute and based only on the assertions of the EC representative in this dispute – a factual finding that is directly contrary to reality as understood throughout the EC and the worldwide agricultural trade community. In so requesting, the EC would seek to undermine the credibility of the WTO dispute settlement system.

2. Instead of acknowledging the reality of the moratorium and then attempting to justify it under the legal standards set out in the *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement), the EC has submitted a substantial volume of communications between member States and applicants for biotech approvals. None of this information, however, is inconsistent with the fundamental reality that the EC had adopted moratoria on biotech approvals. To the contrary, staff-level information exchanges regarding product applications are entirely consistent with a moratorium adopted on a political level, under which no product was allowed to reach final approval. Moreover, the very information that the EC has submitted confirms that certain member States simply were not going to allow final approvals, regardless of the underlying science.

3. With regard to the member States measures, the EC has asserted that there "may" be scientific bases for the product bans, but to date the EC has failed to identify any of them. This is understandable, since the EC's own scientific committees have reviewed the products and have found that they meet the requirements of the EC biotech approval system.

II. THE EC'S STATEMENT OF FACTS IS MISLEADING

A. The EC's Statement on the Purported Risks of Biotech Products is Misleading

4. Even though the EC's factual presentation on biotechnology is not tied to the legal issues in this disputes, the United States would like to note that the EC's statements regarding the purported risks of biotechnology are fundamentally misleading. Contrary to the EC assertion, there has, in fact, been consensus over the types of risks potentially posed by agricultural biotechnology products since the late 1980's. The consensus among international experts is that, qualitatively, the types of risks potentially posed by products of modern biotechnology are essentially the same as those posed by similar products produced through other, more traditional technologies.

5. In other words, the types of risks that regulators assess for foods produced through biotechnology are qualitatively the same as for foods produced through other methodologies—for example, the production of toxins, significant changes in composition, and the presence of food allergens. Similarly, the types of environmental risks – for example, the production of plant pests, and effects on beneficial non-target organisms – are not qualitatively different between biotechnology and non-biotechnology agricultural products.

6. In 1986, the OECD Ad Hoc Group on Safety and Regulations in Biotechnology concluded that any potential environmental impacts of recombinant DNA organisms are "expected to be similar to effects that have been observed with introductions of naturally occurring species or selected species used for

agricultural applications." In 1987 the U.S. National Academy of Sciences (NAS) published a white paper that stated that the risks posed by biotech organisms are the "same in kind" as those associated with organisms that have been modified through other techniques.

7. In 1993, the OECD, through work commissioned by the Group of National Experts on Safety in Biotechnology, concluded that the risks potentially posed by plants produced through modern biotechnology should be approached within the context of the potential risks of plants produced through traditional plant breeding. While the OECD and NAS may have been the earliest scientific bodies to come to these conclusions, the same conclusion has been reached by other international scientific organizations and national scientific advisory bodies. In 1996, a joint FAO/WHO expert consultation on biotechnology and food safety concluded that "Food safety considerations regarding organisms produced by techniques that change the heritable traits of an organism, such as rDNA technology, are basically of the same nature as those that might arise from other ways of altering the genome of an organism, such as conventional breeding." The Royal Society of the United Kingdom came to essentially the same conclusion that "as with genetic modification, conventional plant breeding technology (which can involve chemical or radiation-induced mutagenesis or cross-species hybridization) might also cause rearrangements of the genome, and therefore might also cause the activation of previously unknown toxins, anti-nutrients or allergens."

8. The scientific advisory bodies of the European Union have also confirmed the conclusion that, for both food and environmental risks, plants produced through modern biotechnology do not present new or novel risks. In 2003, the Scientific Steering Committee of the European Commission acknowledged that both the Scientific Committee on Plants and the Scientific Committee on Food have concluded in their published risk assessment that for the "GM crops" reviewed no new safety issues to humans or the environment have been presented. The Scientific Steering Committee also stated that the "published review of data do not indicate the GM crops presently in cultivation pose any more risks for humans, animals and the environment than do their conventional counterparts."

9. The level of scientific uncertainty claimed by the EC to exist around the risks posed by biotechnology products is both inconsistent with the history of the international discussion of this issue and with the actions of individual government regulatory authorities. In its 2003 report, the International Council for Science (ICSU) concluded after a synthesis of more than 50 independent scientific reviews that there is "convergence of science" that "Presently available genetically modified foods are safe to eat. GM foods presently on the market have been assessed for any risks of increased allergenicity, toxicity, or other risks to human health, using internationally agreed food safety standards. … This is the consensus view of several reports by national and international agencies."

10. In addition, government regulatory authorities with experience in regulating plants produced through modern biotechnology routinely use a case-by-case approach. For example, the United States, Canada, the EC, Japan, Australia, and South Africa have completed risk assessments on plants produced through biotechnology – essentially addressing the same types of risk assessment end points on a case-by-case basis. The foundation for this case-by-case approach to the regulation of biotechnology plants is the widely held scientific consensus that: 1) the risks potentially associated with biotech plants are essentially the same as those of plants produced by other techniques and 2) the assessment of risk should not focus on the methodology used in the breeding process but rather on the results of that process; *i.e.*, on the characteristics of the product itself.

11. To further illustrate the scientific consensus surrounding the types of risks potentially posed by biotech plants, both the Codex Alimentarius and the International Plant Protection Convention have adopted guidances that provide recommendations on the type of data that should be considered when conducting safety assessments for biotech plants. Both of these standard setting bodies were able to conclude these guidelines because of the already existing consensus on the types of risk issues that should be addressed in the risk assessment for biotech plants.

12. If scientific uncertainty concerning the risks of biotech plants had been as great as claimed by the EC, it is unlikely that any of these products would have successfully completed the regulatory process in any country. The assertion that the complexities—and uncertainties—of assessing the risks of the biotech plants currently in the EC system are far greater than non-biotech products is not born out by experience.

B. Neither the Biosafety Protocol nor the Precautionary Approach Serves as a Defense to the EC in this Dispute

13. The only way other sources of international law could be pertinent to this dispute is if, under Article 3.2 of the DSU, those other sources of law would assist the Panel in "clarifying the existing provisions of the [covered] agreements in accordance with customary rules of interpretation of public international law." But the EC has not identified how the Biosafety Protocol or a "precautionary principle" would be of relevance to interpreting any particular provision of the WTO Agreement.

14. Moreover, in the *EC – Hormones* dispute, the Appellate Body examined at length nearly identical arguments presented by the EC regarding the relationship between a purported "precautionary principle" and the SPS Agreement. The EC has not presented, and cannot argue, that any different results should apply here. Thus, even if a precautionary principle were considered a relevant rule of international law under Article 31(3) of the Vienna Convention, it would be useful only for interpreting particular treaty terms, and could not override any part of the SPS Agreement. So, for example, the notion of precaution could not excuse the EC from complying with the requirement under Article 5.1 that SPS measures be based on risk assessments. In addition, Article 5.7 of the SPS Agreement already allows for the EC to adopt a precautionary approach to regulating biotech products.

15. Just as the Appellate Body found it unnecessary and imprudent to make a finding on the status of the precautionary principle in international law, this Panel also should have no need to address this theoretical issue. Nonetheless, the United States notes that it strongly disagrees that "precaution" has become a rule of international law. In particular, the "precautionary principle" cannot be considered a general principle or norm of international law because it does not have a single, agreed formulation. In fact, quite the opposite is true: the concept of precaution has many permutations across a number of different factors. Thus, the United States considers precaution to be an "approach," rather than a "principle" of international law.

16. Moreover, if – as the United States submits – precaution is not a principle of international law, then it is *a fortiori* not a rule of customary international law. Customary international law is a binding rule that results from: 1) a general, consistent, extensive, virtually uniform practice of States; 2) followed by them from a sense of legal obligation. Precaution does not fulfill any of these requirements. Precaution cannot be considered a "rule" because it has no clear content and therefore cannot be said to provide any authoritative guide for a State's conduct. Second, it cannot be said to reflect the practice of States, as it cannot even be uniformly defined by those who espouse it. Third, given that precaution cannot even be defined and, therefore, could not possibly be a legal norm, one could not argue that States follow it from a sense of legal obligation.

17. For the purposes of interpreting the WTO Agreement in accordance with the principles in Article 31(3) of the Vienna Convention, the United States also strongly disagrees with any notion that the Biosafety Protocol is a rule of international law. To be relevant under Article 31(3), the international rule must be "applicable in the relations between the parties." In this case, however, the Biosafety Protocol is not applicable to relations between the United States and the EC, because the United States is not a party to the Biosafety Protocol.

18. Finally, the United States would not agree that the Panel would need to look to the Biosafety Protocol in interpreting the WTO Agreement even in a dispute between WTO Members that were both parties to the Protocol. The Protocol has a clear and unequivocal statement that it does not change the rights

and obligations under any existing international agreement. In addition, the EC does not argue that any provision of the Protocol is in any way inconsistent with the EC's full compliance with its WTO obligations.

C. The EC's Description of Its Biotech Approval Regime is Inaccurate

19. In describing the "EC Regulatory Framework," the EC conveniently leaves out a number of mandatory procedural steps, omits several deadlines by which specific action is required, and implies that the Commission has discretion – which the legislation does not grant – not to act on product notifications. But an accurate presentation of the EC system is important, because this serves as the baseline for understanding that the EC's delays under the moratorium are inconsistent with the EC's own laws. The inconsistency of the EC's moratorium with the underlying biotech approval legislation further highlights that the delays resulting from the moratorium are undue.

III. THE SPS AGREEMENT APPLIES TO ALL MEASURES IN THIS DISPUTE

20. In its first submission, the EC argues at length, and in the hypothetical, that the EC might adopt measures with respect to one or more biotech products that are not covered within the scope of the SPS Agreement. But, once again, the EC discussion is not linked to any of the legal issues in this dispute.

21. The pertinent question is whether the measures that the EC has actually adopted, and that are covered in this dispute's terms of reference, are within the scope of the SPS Agreement. But the EC does not even appear to contest this fundamental point. First, the EC has not disputed that both its Novel Foods regulation and Deliberate Release directive are covered within the scope of the SPS Agreement. Furthermore, with respect to the member State measures, the EC acknowledges that each of the member State measures was adopted for "some reasons" that fall within the scope of the SPS Agreement.

22. The EC's agreement that its measures were adopted for "some reasons" covered within the scope of the SPS Agreement is more than sufficient to bring those measures within the scope of that Agreement. SPS Agreement Annex A makes clear that "any measure" applied to protect against one of the enumerated risks falls within the scope the SPS Agreement. The Annex does not state that the measure needs to be exclusively applied to protect against only the enumerated risks. In fact, in the *EC – Hormones* dispute, the EC directive was not solely adopted to address alleged affects on human health. To the contrary, as the Appellate Body explained, the EC was also motivated to adopt its Hormones Directive by the perceived need to harmonize beef regulations in order to prevent distortions in the conditions of competition between producers in various EC member States. The harmonization of product standards is a goal expressed in the *Agreement on Technical Barriers to Trade.* Yet, despite the variety of rationales, all parties in the *EC – Hormones* dispute agreed that the Hormones Directive fell within the scope of the SPS Agreement.

23. The detailed EC discussion purporting to classify various alleged risks of biotech products as within or without the scope of the SPS Agreement is not tied to the legal issues in this dispute and is thus hypothetical. Nonetheless, the United States has responded to these arguments in an attachment to its rebuttal submission, and notes that the EC's analysis would result in an overly narrow scope of the measures intended to be covered by the SPS Agreement.

IV. GENERAL MORATORIUM VIOLATES THE SPS AGREEMENT

24. The EC's discussion of the general moratorium is remarkable in that it is concerned solely with whether or not the general moratorium qualifies as a "measure" under the SPS Agreement. Should the Panel find, as the complainants all submit, that the general moratorium is indeed a measure under the SPS Agreement, the EC has not contested that the general moratorium is inconsistent with the EC's obligations under the WTO Agreement. Indeed, in its answers to Panel's questions, the EC concedes that there was no overall risk assessment for biotech products that could serve as a basis for the general moratorium.

25. The evidence that the general moratorium exists is overwhelming. In addition to the evidence that the United States cited in its first submission and opening statement, official documents of the European Parliament also confirm the existence of the moratorium. For example, a February 2001 parliamentary Report: "Observes that the existing de facto moratorium particularly harms small and medium sized enterprises which, unlike multinational corporations, are often unable to perform their research work in countries outside the EU"; "Welcomes the agreement reached between Council and Parliament in the conciliation committee on the amendment of the directive on the release of genetically modified organisms and the assurances given by the Commission in that connection with regard to labeling and traceability, and considers that a clear framework now exists for the release of genetically modified organisms in Europe which will ensure maximum consumer protection and environmental protection, and that it would therefore not be justified to continue the de facto moratorium on the release of GMOs"; and notes that "Under this system approval takes an unacceptably long time. . . . [N]o authorisations have been approved under this directive since October 1998. This demonstrates a lack of mutual recognition between Member States and a de facto moratorium on all development. It calls into question the political will in Europe to support this industry."

26. More recently, a March 2003 resolution introduced in the European Parliament acknowledges the moratorium: "whereas, in view of the risks which GMOs represent, there are no grounds for lifting the de facto moratorium on GMO authorisation, especially since no labeling and tracing system has been introduced and no assessment has been carried out of the impact which GMOs may have on organic/conventional farming." The same resolution then goes on to urge the continuance of the moratorium pending the launch of "a broad public debate."

27. The EC presents three arguments in its first submission as to why this Panel should nonetheless find that there is no general moratorium. First, the EC argues that it cannot be "legally affected" by "casual statements of any of its numerous representatives." But the complainants are not relying on "casual statements of numerous representatives"; the statement cited by complainants are statements made by the EC's highest officials, by its member States, and by its official bodies. Moreover, the EC itself concedes, as it must, that such statements can be considered as evidence of the existence of a measure.

28. Second, the EC argues that even if the EC did adopt a general moratorium on approvals of biotech products, such a moratorium is legally precluded from qualifying as a "measure" under the SPS Agreement. The EC's argument, however, is based on two panel reports that are inapposite to this dispute. The United States does not contend that the EC's suspension of its approval process constituted a "practice" as described in the *US - Steel Plate* and *US - Export Restraints* reports cited by the EC. Although the EC's measure was not adopted in a transparent manner and officially published as a formal law, decree or regulation, the EC's decision to indefinitely suspend its approval procedures falls within the SPS definition of a measure and blocks biotech approvals just as effectively as would a written amendment to EC legislation.

29. Third, the EC claims that the application histories for certain products covered in the U.S. panel request disprove the existence of the moratorium. To the contrary, the information submitted by the EC is entirely consistent with the EC's imposition of a general moratorium. First, the information submitted by the EC confirms that there were in fact no approvals of biotech products between October 1998 and the establishment of the Panel's terms of reference in August 2003. Second, not only do the product histories confirm that no product was submitted for final approval, many of the product histories – as described below – illustrate just how the moratorium operated.

V. PRODUCT-SPECIFIC MORATORIA VIOLATE THE SPS AGREEMENT

30. The primary basis for the EC's denial of the product-specific moratoria is the vague statement that "what has happened in many of these applications is that, at different stages of the procedure, requests for

additional information have been put to applicants." The EC ignores, however, that product histories exhibiting requests for information are entirely consistent with the existence of a general and product-specific moratoria. The United States has not claimed that each and every application stopped all progress beginning in 1998. To the contrary, the moratorium was a decision by the EC not to move products to a final decision in the approval process. Certain progress in the process, short of final decision, is not the least bit inconsistent with a moratorium on final approvals.

31. Moreover, the EC product histories provide further, compelling evidence of the existence of both a general and product-specific moratoria. First, a number of applications – particularly those nearing the final stage of approval – exhibit lengthy, unwarranted delays, unrelated to any requests for additional information. Second, a number of product histories contain statements from member States acknowledging – in writing – that regardless of any scientific issues regarding the particular application at issue, the member State simply was not going to vote for approval unless and until the EC had adopted new forms of legislation. Such statements illustrate that, contrary to the EC assertions, the moratorium applied to each and every application, regardless of whether or not particular regulators had particular questions about individual applications.

A. Examples of Applications which Faced Lengthy Delays, Without Any Pending Requests for Information

32. *Oil-Seed Rape MS1, RF1 and Oil-Seed Rape, MS1, RF2*: In these two cases, France never allowed the product to be placed on the market, and thus these products in fact were never approved for cultivation, import, and marketing in the EC. In Question 99, the Panel asked the EC to confirm that France withheld its consent. The EC responded "Yes." The EC then goes on to argue that, nonetheless, an individual "can directly assert his or her right by directly relying on the Community law in question." This excuse is entirely unpersuasive. The EC does not assert that either of these products is in fact on the market in the EC; that EC Customs officials – in France or elsewhere – would admit either of these oil-seed products without the final step (the French consent) in the approval process; or that any biotech applicant has ever successfully asserted this right. Nor does the EC even attempt to explain what mechanism – such as a legal challenge – might be used to assert this right, or explain how a product can be considered approved if additional legal proceedings are required to allow the product to be placed on the market.

33. *BT-Cotton*: In February 1999 the regulatory committee did not approve the application by a qualified majority vote. Under the EC's own rules, an application that fails to achieve a qualified majority of votes in the regulatory committee must be submitted to the EC Council for an additional vote, and such submission must be made, to quote Article 21 of the EC Directive, "without delay." But, the EC's own chronology states that the next action is nearly three months later, in May 1999. And the action taken is not, as required under EC legislation, the submission of the application to the EC Council. Instead, the chronology states: "Launching of Inter-Service Consultation on draft Council Decision." This term, and this step, is not provided for under the EC's regulations. The chronology is then blank until July of 2001.

34. *Roundup Ready Cotton*: In February 1999, the Roundup Ready cotton application, like Bt cotton, did not receive a qualified majority vote in the the regulatory committee. Like for Bt cotton, the next step in the EC chronology is the "Launching of Inter-Service Consultation on draft Council Decision" in May 1999. There is no further entry in the chronology until January 2003, which is more than two and one-half years later. Again, this is another example of a major delay that was not caused, as the EC claims, by a pending request to the applicant for additional information.

35. *Oilseed rape tolerant for glufosinate-ammonium*: According to the EC chronology, this product received a favorable opinion from the scientific committee on plants in November 2000. Under the EC's approval system, the next step should have been to submit the application for approval by the EC's Regulatory Committee. But the EC chronology shows that no action was taken on the application until

November 2002, a full 2-year delay. This 2-year gap belies the EC's assertions that under its supposed "interim approach," it was moving ahead on processing applications in advance of the entry-into-force of 2001/18.

36. *Maize BT-11*: In the chronology of BT-11, there is no action on the application for 2 years after a favorable opinion of the Scientific Committee on Plants in November 2000. The next entry, an "evaluation of updates by the lead CA" in October 2002, is unexplained and unsupported by any exhibit or attachment.

B. Product Histories in Which Member States Acknowledge Opposition to Approval Regardless of the Merits of the Individual Application

37. The exhibits accompanying the product histories provide numerous examples in which member States noted in writing that they would oppose approvals 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. These statements by member States stand in stark contrast to the EC's argument that it had adopted an "interim approach" under which final approvals were to be granted prior to the adoption of new legislation. They also directly contradict the EC's arguments that the delays with respect to individual products were justified by fact-specific considerations unique to the individual products, such as conflicting science, or delays on the part of applicants.

38. *Novel Food and Feed Regulation.* Some member States have used the implementation of new food and feed regulations (which did not become effective until April 2004) as an excuse for halting this process. Pioneer/Dow's Bt corn application: The Austrian Federal Ministry of Health and Women notes in its letter to the EU's DG XI, dated 24 October 2003, that any registration of Pioneer/Dow's product "should also take into consideration the two new EU regulations concerning traceability and genetically modified food and feed which will enter into force in April 2004." Roundup Ready corn (NK603): In a letter from the Austrian Federal Ministry for Social Affairs and Generations to the EU's DG XI regarding Monsanto's application for Roundup Ready corn (NK603), the Ministry cites several scientific concerns, but states that "Irrespective of the above mentioned scientific objections raised, Austria is of the opinion, that products shall not be placed on the market before the new regulations concerning genetically modified food and feed as well as on traceability and labeling of GMOs will enter into force." Syngenta's Bt11 biotech sweet corn: On 10 August 2000, the French authorities cited the yet to be implemented food and feed regulations as a reason for withholding support for Bt11, choosing to disregard comprehensive scientific findings and instead continue the moratorium on biotech reviews.

39. *Traceability and Labeling Legislation.* Member States opposed to re-starting the review process for biotech crops also used the proposed new traceability and labeling regulations (which also did not become effective until April 2004) as a reason for continuing the moratorium. Syngenta's Bt-11 biotech sweet corn: several member State competent authorities statements clearly require that the new traceability and labeling regulations be in place prior to the lifting of the moratorium on biotech reviews and approvals. The German competent authority's objections, dated September 26, 2003, provided that "In accordance with the French position, the German CA is of the opinion that no consent should be given until both regulations are in force. In particular, the regulation on traceability and labeling of GMOs will provide for additional transparency and the possibility of choice for consumers." Likewise, Denmark, in late September 2003 stated that its support for Bt-11 was contingent on the implementation of the new traceability and labeling regulations. In doing so, it reminded the EC authority of the March 2001 declaration of six member States (the "March 2001 declaration") reaffirming the moratorium until traceability and labeling rules, as well as a system for environmental liability, are adopted. Again in February 2004, the Danish competent authority writes: "Furthermore, Denmark finds that approval for placing on the market cannot take place before the regulation on traceability and labeling is fully into force." Oilseed rape (GT-73): The Danish, Italian, Austrian and Belgian competent authorities all cite the need for traceability and labeling regulations to be in place before

they will support the approval of any biotech crops. The Austrian competent authority wrote: "As a matter of principle, this product should not be placed on the market before the entry into force of the Regulation of the European Parliament and of the Council concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC." Roundup Ready corn (GA21): Denmark acknowledged that "the assessment of the health and nutritional aspects of this application gives Denmark no reason to object to the approval of the GA21 maize nor to products derived from the maize." However, "in spite of the favourable assessment . . . , Denmark will submit a reasoned objection to the approval of the genetically modified GA21 maize, reference being made to the statement submitted by this country and four other member states at the Environmental Council on 24 and 25 June 1999 [declaring a suspension of new GMO authorizations until labeling and traceability rules are adopted]." Bt-11 sweet corn: Denmark states that "[w]ith regard to the issue of food safety as such, Denmark sees no problem in allowing the Bt11 maize for food purposes . . . Apart from this however, Denmark will refer to the Declaration concerning the suspension of new GMO authorisations made by five member States (France, Greece, Italy, Luxembourg, and Denmark) at the Environmental Council of 24 and 25 June 1999. With reference to this Declaration, Denmark therefore wishes to submit a reasoned objection concerning the Bt11 maize."

40. *Co-Existence and Environmental Liability Legislation.* Several member States have used the lack of coexistence and environmental liability laws as a reason to continue the moratorium. Such rules have no bearing on decisions or assessments regarding the environment or human or animal health or safety, and a desire for such rules cannot justify delay. Otherwise, a Member could always say it would like a better regulatory regime in other aspects and delay approvals indefinitely, rendering the SPS "undue delay" discipline meaningless. Glufosinate tolerant and Bt resistant (Bt-11) corn: The Austrian competent authority states: "As this product is in particular destined for cultivation in all countries of the European Union, Austria – apart from the need for further information – raises an objection against the putting of this product on the market, as long as all conditions for coexistence with GMO-free cultivation methods are not cleared in a sound legal way." Belgium makes the same objection for the same product: "Belgium is of the opinion that the placing on the market of this product should not be granted before a coexistence regulation is not yet entered into force." Denmark once again cites the March 2001 declaration of six member States reaffirming the moratorium until traceability and labeling rules, as well as a system for environmental liability, are adopted. Roundup Ready oilseed rape GT73: Austria objected to Roundup Ready oilseed rape GT73, as a "matter of principle," requiring that "further issues concerning liability and the coexistence of genetically modified, conventional and organic crops remain to be resolved." Also, on March 24, 2003, Denmark objected, citing the March 2001 declaration. Pioneer/Dow AgroSciences Bt corn (Cry1F 1507): The Austrian CA, as late as October 17, 2003, objected to the placing on the market of Pioneer/Dow AgroSciences Bt corn (Cry1F 1507), citing coexistence. The specific reasons cited by the CA are generally economic in nature, rather than issues of environmental safety: "Import, processing and cultivation of GM 1507 maize will result in the presence of adventitious and/or technically unavoidable GMO traces in non GMO maize. Although maize has limited capabilities to survive, disseminate or outcross, this may lead to effects on the implementation of co-existence of different agricultural systems (with or without GMO). As long as the conditions for co-existence are not clarified on the EU level, Austria holds the opinion that no consent for the placing on the market of 1507 maize should be given." Roundup Ready corn (NK603): Austria states that not only should biotech product approvals continue to be suspended until feed and traceability and labeling legislation becomes effective, but also, that no biotech products may be placed on the market without coexistence rules: "In addition the issue of co-existence of genetically modified, conventional and organic farming is at the moment under discussion and has to be resolved." Denmark also objects, again citing to the March 2001 declaration.

C. The EC Product Histories Are Incomplete

41. The EC relies almost exclusively on its product histories to support its claim that – despite the statements and actions of EC officials – there were in fact no general or product-specific moratoria. But the EC product histories are incomplete in three important ways. First, the product histories do not cover any products that were withdrawn prior to establishment of the Panel. These failed product applications are direct, compelling evidence of the existence of a general moratorium. In its first submission, the United States noted that applications under both the environmental release and novel food legislations had been indefinitely delayed by the general moratorium and consequently withdrawn, and gave nine specific examples. The EC has failed to provide any chronologies for these products.

42. The EC's product histories are also incomplete in that the EC has not provided the underlying documentation for each step in the process. Instead, in selecting what exhibits to provide to the Panel, the EC has picked and chosen among the various chronological entries.

43. Finally, the product histories are incomplete in that they do not include every step in the product histories. Although only the applicants and the EC have access to all correspondence, the United States has learned that at least some of the product histories are missing significant entries. For example, the application history for Fodder Beet A5/15 excludes a reference to at least one significant document. In particular, at a point in the process where the applicant believed that it had complied with all outstanding information requests, the chronology omits a letter from the lead competent authority to the applicant, stating that: "Since we met the new directive [2001/18] has been adopted and as you probably already know Denmark and five other member states have confirmed their opinion on suspending new authorizations for cultivation and marketing until effective provisions concerning complete traceability which guarantees reliable labeling has been adopted."

VI. MEMBER STATE MEASURES VIOLATE THE SPS AGREEMENT

44. The nine measures imposed by six member States are sanitary or phytosanitary measures which are not "based on" "risk assessment[s]" as required by Article 5.1 of the SPS Agreement. Although each of the six member States that have imposed bans on approved biotech products offered reasons for their measures – though unjustified according to the scientific committees – none of the member States put forth a "risk assessment" as defined in Annex A, paragraph 4. In response to the Panel's question (No. 107) on this issue, the EC claimed that "the Member States have made their own assessments and further risk assessments may be forthcoming" (emphasis added). The United States submits that, in fact, no such risk assessments supporting the member State measures have been provided.

45. In particular, the EC has provided on their second CD-ROM a folder titled "Safeguard Measures," in which the EC purports to provide EC member State justifications for the member State measures. A review of the documents confirms that none of the member State bans is based on a risk assessment.

46. In fact, the only risk assessments put forth for the banned products are the positive scientific assessments rendered by member States to which the products were submitted, and then by the EC's own scientific committees. In the case of each member State ban, these favorable assessments were reaffirmed when the scientific committees considered and rejected the information provided by the member States. Thus, the member State measures do not bear a "rational relationship" to the EC's positive risk assessments, and are not "based on" a risk assessment, in violation of SPS Articles 5.1 and 2.2.

47. The EC's argument in defense is that each of the member State measures falls within the scope of Article 5.7 of the SPS Agreement. But the EC does not specify how Article 5.7 might apply. Its only argument is that under the terms of the EC legislation, the member State measures are labeled as

"provisional." The mere label of a measure, however, is most certainly not sufficient to bring it within the scope of Article 5.7.

48. Before turning to the specific criteria of Article 5.7, the United States would note that the EC is incorrect in claiming that the United States was obliged to include an explicit Article 5.7 argument in its first submission. This argument fundamentally misunderstands the structure of the SPS Agreement. The United States in its first submission most certainly did explain that the member State measures are inconsistent with SPS Article 2.2, and this necessarily means that the United States submits that Article 5.7 does not apply. In other words, Article 5.7 provides not the basis for a claim of an alleged breach of a WTO obligation, but acts as a defense to shield measures that would otherwise violate Articles 2.2 and 5.1. As explained by the Appellate Body in *Japan – Agricultural Products II*, "Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence."

49. In *Japan – Agricultural Products II*, as well as in *Japan – Apples*, another dispute in which Article 5.7 was considered, the Respondent invoked the provision to defend the challenged measure against alleged violations of Articles 2.2 and 5.1. The Complainant (the United States in both cases) did not assert Article 5.7 as an independent claim in either dispute, nor did the Panels suggest that the Complainant should have invoked Article 5.7. Indeed, the United States is not aware of any dispute in which the Complainant has based a claim on the Respondent's violation of Article 5.7.

50. The EC member State measures do not meet any of the four criteria set out in Article 5.7. First, the scientific evidence with respect to the products subject to the member State measures is not "insufficient". Scientific evidence is "insufficient," according to the Appellate Body, if it "does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement." Here, the evidence is plainly sufficient to perform a risk assessment, because the EC itself has conducted positive risk assessments for each product subject to a member State measure.

51. Second, the member State bans were not adopted on the basis of "available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members." As the United States noted in its First Written Submission, the relevant Scientific Committee in the EC reviewed each of the member State bans and concluded in each case that the information provided by the member State did not warrant any change in the Scientific Committee's earlier favorable risk assessment. Thus, the EC's own scientific committees have confirmed that the member State measures are not based on "available pertinent information."

52. Third, the member States have not sought "to obtain the additional information necessary for a more objective assessment of risk." In fact, there is no information in the record that the Member States have sought to perform any risk assessments that would support their bans. To the contrary, as noted above, the EC's additional CD of documents contains no new information that could constitute an assessment of the risks by the member States.

53. Fourth and finally, neither the member States nor the European Commission has reviewed the import and marketing bans within a reasonable period of time. When asked by the Panel whether the member State measures were "reviewed within a reasonable period of time," the EC answered, without providing any evidence or elaboration, that the "measures are constantly subject to review." The conclusory statement that a measure is "constantly subject to review" does not come close to meeting the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption.