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

(WT/DS291, 292, and 293)

U.S. Opening Statement at the Second Substantive Meeting

February 22, 2005

INTRODUCTION

1. Mr. Chairman, members of the Panel: Good morning.

2. The central issue in this case is that the EC announced and applied an across-the-board moratorium on biotech approvals. Under that moratorium, the EC allowed some products to make some progress through the lengthy EC approval procedures, but allowed no product to reach the point of final decision. The adoption of this nontransparent change in its regulatory procedures results in "undue delay" under Annex C of the SPS Agreement; is inconsistent with the EC's obligations to publish measures promptly and to keep applicants informed of the progress of applications; is not based on a risk assessment as required under Article 5.1; and results in arbitrary or unjustifiable discrimination in the EC's chosen levels of protection.

3. In addition to the moratorium, six EC member States have adopted marketing or import bans on biotech products that are approved by the European Communities. These member State product-specific bans, like the moratorium, are not based on scientific evidence and are thus inconsistent with the EC's obligations under the WTO Agreement.

4. Since our last substantive meeting, hundreds of pages have been written and many, many hours have been expended by all involved. But in terms of the development of the dispositive legal issues, the complainants' case has only been further confirmed and remarkably little else has changed. In particular, the central defense of the EC – despite the overwhelming evidence to the contrary – remains that the EC did not impose a moratorium. The EC still has not even attempted to rebut the complainants' arguments showing that the moratorium is inconsistent with the SPS Agreement. And likewise, the EC has still not attempted to explain how its member State safeguard measures could be consistent with the SPS Agreement.

Moratorium and Undue Delay

Developments Since the First Substantive Meeting

5. As noted, the EC's responses have provided additional confirmation of the complainants' case – even though the complainants' first submissions were more than sufficient and no additional confirmation was required. The confirmation has followed a consistent pattern: the EC has repeatedly submitted information supposedly in support of its positions, but each time the EC's information is both consistent with the existence of a moratorium, and indeed provide further support for complainants' contentions that the EC has adopted a moratorium and has failed to process applications without "undue delay."

6. The first U.S. submission provided overwhelming evidence that the EC adopted and maintained a moratorium under both its deliberate release and novel food directives. EC officials and bodies from across the range of EC institutions – the Commission, the Council, the Parliament, and member States – have acknowledged the existence of the moratorium. Giving just one example, Commissioner Byrne, when speaking to the member States in February 2003, said that "we must lift the moratorium."[1] Although no further confirmation is needed, we are attaching one further official acknowledgment of the moratorium. We do so only because the EC in this dispute has claimed ignorance of the moratorium, and has asked us to explain it. We will refer to Exhibit US-147. This exhibit is from a French Government website. The exhibit asks and answer the question, "What is the de facto moratorium on GMOs?". Hopefully it will save time as we go through the questions and answers this afternoon. Earlier, the EC stated that it wanted to ask the United States what the moratorium is. We would suggest that if the EC wants

[1] Exhibit US-37.

a definition, the EC should refer to this exhibit, which describes the moratorium, at least in the view of the Government of France. Indeed, as the United States has noted before, it is only in the context of this dispute that the EC denies the existence of the moratorium.

7. The first U.S. submission went on to explain that the moratorium was inconsistent with various provisions of the SPS Agreement: Articles 2.2, 2.3, 5.1, 5.5, 7, and 8 and Annexes B and C. Among other things, the United States explained that many of the product applications caught up in the moratorium had received positive risk assessments from the EC's own scientific committees. But then those applications failed to make further progress when the applications reached a political level – in particular, when the EC refused to submit the applications to a vote by member States in the EC's regulatory committee. The EC's adoption of a moratorium that did not allow any product to reach the final stage of the approval process is necessarily an "undue delay" under Annex C of the SPS Agreement. Moreover, the EC's own risk assessments were positive. Accordingly, the resulting delays must be "undue" under Annex C, and the moratorium must be found in breach of Article 2.2 – as not "based on scientific principles" and "maintained without sufficient scientific evidence" – and in violation of Article 5.1 – as not based on a risk assessment.

8. The EC in its first submission attempted to rebut the U.S. *prima facie* case by ignoring all of the EC's acknowledgments of the moratorium, arguing that any and all delays were the result of legitimate scientific questions, and asserting that in fact no moratorium ever existed. The EC claimed that this argument was supported by certain exhibits to its first submission. Those exhibits contained chronologies of the approval process for a number of products, along with only a small selection of the underlying documents cited in the chronologies.

9. As the United States explained at the first substantive meeting, the EC's chronologies were perfectly consistent with the existence of a moratorium. The chronologies showed some questions from regulators and some responses, and some progress, but at the end of the day no decisions were made. Moreover, certain chronologies contained lengthy, unjustified gaps – of over two years – for which no explanation other than the EC's adoption of a moratorium were plausible.

10. Also at the first meeting, the EC represented to the Panel that each of the member State objections and questions resulted from conflicting risk assessments, and thus that all delays were warranted to address outstanding scientific issues. When the Panel asked the EC to point out those risk assessments in the exhibits provided with the EC's first submission, the EC explained that such documents were held by the member States. In other words, the EC had made representations to the Panel about a set of documents even though – according to the EC – the Commission did not even have access to those documents and would need to request them from member States. The EC represented that a request under Article 13 would assist the Commission in obtaining the documents, and the Panel obliged by presenting such a request to the EC.

11. By late June, the EC provided additional documents from the dossiers, although the dossiers were still far from complete. In its second submission, the United States examined the partial product dossiers provided by the EC. Those documents did not, as the EC had asserted, contain competing risk assessments. Instead, the documents mainly consisted of more of the requests for information from member State officials, and more of the responses from applicants. As noted, the fact that application histories include questions and answers is completely consistent with the EC's adoption of a moratorium. And, the documents provided yet further

confirmation – though none was needed – that the EC had subjected applications to "undue delay" and had adopted a moratorium. Based on the new EC documents, the United States identified additional application histories – particularly those nearing the final stage of the decision-making process – that exhibited lengthy, unwarranted delays, unrelated to any requests for additional information.

12. In addition, a number of product histories contained specific statements from member States acknowledging the existence of the moratorium. In each case, the member States wrote that regardless of any scientific issues regarding the particular application at issue, the member State asking for more information was not going to vote for approval, unless and until the EC had adopted new forms of legislation. For example, in one application history, the Austrian competent authority wrote as follows:

> 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. 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.

13. The United States also noted in its second submission that the EC product histories, which the EC had relied upon in its defense, were still substantially incomplete. In August, the Panel requested that the EC complete the application histories that the EC had relied upon for its defense. As a result, an amended set of application histories was made available to the complaining parties and the Panel by the end of September.

14. As pointed out in the third U.S. submission, once again the EC's additional documentation did not include the competing risk assessments claimed by the EC, and the

documentation was fully consistent with the existence of a moratorium. And once again, upon examination, the documentation provided further evidence – although none was needed – of "undue delay" and the existence of the moratorium. The United States showed 13 examples of how underlying documents in the product chronologies confirmed the existence of unwarranted delays in processing applications.

15. The U.S. third submission also provided over 20 examples where the questions by EC regulators were not required for assessing risks. Those examples also provided yet further confirmation – although none was needed – for "undue delay" and the existence of the moratorium.

16. The process of consultation with experts followed. The experts' written and oral responses were consistent with the U.S. views, and the experts noted many types of questions which were scientifically unjustifed.

17. To date, those are the developments between the first substantive meeting and the current meeting concerning the dispositive legal issues with relation to the moratorium and undue delay. The documents submitted by the EC and the comments from the experts are entirely consistent with a political-level moratorium under which applications were allowed to make some progress but were never allowed to reach a final decision. Moreover, the documents illustrate many instances of unwarranted delays in the form either of inactivity by the EC or member State officials, or in the form of unjustifed requests for additional information.

18. The EC has thus failed to rebut the compelling evidence that the EC has adopted a moratorium and has subjected applications to "undue delay." Because the complainants have shown that the moratorium is not based on scientific evidence, as required by the SPS

Agreement, and the EC has not even attempted to rebut this showing, the Panel should find that the EC has breached its obligations under the SPS Agreement by adopting a moratorium.

Burden of Proof

19. Throughout this proceeding, the EC has placed great emphasis on the issue of the burden of proof – for example, the EC's third submission is devoted largely to this topic. This dispute, however, presents no difficult or unusual issues regarding burdens of proof.

20. The EC argues in its third submission that the United States has not met its burden of presenting a *prima facie* case because the U.S. first submission did not address "each and every delay" in the processing of each product covered in the U.S. panel request. This argument is baseless. The contention of the United States and the other complainants is that the EC adopted a moratorium that never allowed products to reach final approval. We do not contend, as the EC argument implies, that the EC suspended all processing of applications, nor do we contend that each and every one of the EC's delays were unwarranted. Thus, nothing in the theory of the U.S. case requires an examination of each and every delay for each and every product.

21. The EC also asserts that the EC, as opposed to the complainants, has provided most of the evidence in this dispute. This contention is untrue: the complainants have provided extensive evidence. For example, the U.S. first submission included over 100 exhibits in support of our showing that the EC had adopted a moratorium on biotech approvals, had subjected applications to undue delay, and that member States had adopted product-specific bans that were not based on scientific evidence. Those exhibits included positive risk assessments by EC scientific bodies, numerous statements by EC officials acknowledging the moratorium on biotech approvals, and copies of the relevant EC laws and member State safeguard measures.

22. What the EC is really complaining about is that the EC, as opposed to the complainants, provided the documents in the product application histories. There is no basis for that. The United States, Argentina, and Canada did not need the application histories to prove our *prima facie* case. It was the EC itself that chose to rely on the application histories in the EC's attempt to rebut plaintiffs' *prima facie* case. Having chosen to rely on the product application histories, the EC cannot complain when the complaining parties insist that this information must be complete, and that the EC not be permitted to rely on excerpts of information presented by the EC out of context for purposes of this dispute.

Member State Safeguards

23. With regard to the member State safeguard measures, the United States has explained that, in each case, the EC's own scientific committees had reached positive risk assessments, and had examined and rejected the reasons put forth by the member States for adopting the measures. Accordingly, these measures also were not "based on scientific principles" and were "maintained without sufficient scientific evidence," in violation of Article 2.2. The measures also were not "based on" a risk assessment, in violation of Article 5.1. Although the EC has since vaguely implied that the measures fall within the scope of Article 5.7, this provision cannot apply to the member State safeguard measures. The EC itself has completed positive risk assessments: therefore the scientific evidence cannot be considered "insufficient."

24. The EC continues not to provide a serious defense of the member State safeguard measures. The first EC submission relied on the specious argument that under the terms of the EC legislation, the member State measures are labeled as "provisional," and that the label of the measure was sufficient to meet the requirements of Article 5.7. The EC second submission

relied on a conclusory table which purported to show the various reasons why the member States adopted each safeguard measure. The table was not based on any evidence, and did not explain how any of the safeguard measures might possibly meet any one of the four elements of Article 5.7. The third EC submission did not include a single reference to the member State safeguard measures.

25. The only new development regarding the EC safeguard measures is that the Panel posed some questions to experts on the safeguards, and certain experts responded to those questions. With regard to food safety, the expert specializing in food safety found no validity to any of the rationales put forward by the member States.

26. With regard to environmental effects, however, experts specializing in environmental issues wrote that certain member States in certain instances may have had scientific concerns that were not adequately addressed in the EC's positive risk assessments. The question before us is what, if any, significance these expert views have in evaluating whether the member State safeguard measures are consistent with the SPS Agreement. The answer is that they have very little significance, and certainly cannot suffice to bring the safeguard measures within the scope of Article 5.7.

27. As the EC itself has stressed in its supplementary submission, the role of the experts is to provide views on scientific questions posed by the Panel; it is not the role of the experts to make the case for a disputing party. But the EC has never explained how Article 5.7 might apply to any of the member State safeguard measures. In particular, the EC has not described (1) why the member State believed that the relevant scientific evidence was insufficient to assess a risk, or even the specific risk that was of concern to the member State, (2) what available pertinent

information might serve as the basis for the safeguard measure, (3) whether the member State sought to obtain additional information necessary for an objective assessment of the risk; and (4) whether the member State reviewed the measure within a reasonable period of time.

28. The experts provided scientific opinions on some of the elements that might be relevant to an analysis under SPS Article 5.7, but those statements do not come close to a full analysis under Article 5.7. Moreover, even if the EC were to tried to build an Article 5.7 argument from the responses of the experts, the EC could not do so.

29. First, the safeguard measures are product bans, preventing cultivation, import and processing, and the use of the products as food. The experts' responses, however, entirely support the scientific findings of the EC scientific committees with respect to food safety. In addition, the experts' scientific concerns addressed cultivation, not import and processing. Thus, the experts' responses cannot serve as the basis for an argument that the safeguard measures fall under Article 5.7.

30. Second, the experts' responses cannot assist the EC in meeting the third and fourth requirements of Article 5.7. In particular, Article 5.7 requires Members adopting a provisional measure to seek to obtain additional information necessary for an objective assessment of the risk; and to review the measure within a reasonable period of time. There is no basis for finding that the member States adopting the safeguard measures sought the additional information necessary for an objective assessment. As the Appellate Body confirmed in the Japan-Varietals case, where a Member fails to seek additional information as required under Article 5.7, the measure cannot fall within the scope of the Article 5.7 analysis.

31. Third, even where the experts speak of risks associated with cultivation, the experts were left to speculate on the actual reason the member State had for adopting the measure. This is because the EC has not presented any specific explanations in its submissions, and because the member State documents do not explain the member State rationales in detail. The experts' speculations of the rationales of the member States cannot stand in the place of actual assertions by the EC concerning any purported scientific basis for its member State measures.

32. Fourth, and finally, in the event the Panel would engage in further analysis of environmental issues under Article 5.7, the United States notes that the same experts who disagreed with the risk assessments of the SCP also generally found that either (1) science has advanced since the date of the imposition of the measures so that a risk assessment is now possible, and (2) that management measures are available and that there would no longer be a scientific basis for a total ban on planting. In addition, the experts noted that in some cases studies could have been started as early as 1998 to address the member States' concern. Those opinions of the experts are summarized in Part II.C of the U.S. comments on the experts' responses.

Mootness

33. At the first substantive meeting, the EC argued that this dispute is moot because the EC had approved a single product – a sweet corn for food use – under the Food and Feed directive. In our second and third submissions, the United States addressed the issue of mootness, including the approval last fall of a second product. As we have explained, the concept of mootness is inconsistent with the text of the DSU and longstanding GATT and WTO practice. The measure

to be examined in this case is the moratorium at the time of Panel establishment, which is August 2003.

34. Nonetheless, in closing, I would like to point out recent developments illustrating that the moratorium is still very much alive. To be clear, whether or not the moratorium is maintained after August 2003 is not a legal issue before the Panel. But the following report should be of considerable relevance to an understanding of the EC's motivations, and to an objective assessment of the facts.

35. We would refer the Panel to U.S. Exhibit 148. This article describes the latest state of play in the political maneuverings that lie at the heart of the moratorium. The following excerpt is somewhat lengthy, and I apologize for that, but all of it is instructive:

> Health and Consumer Protection Commissioner Markos Kyprianou has questioned whether the commission should proceed with approving applications for GMO food products given that member states have yet to reach a qualified majority in favor of such applications. Kyprianou believes that it is "no use" forwarding applications for GMO food products to member states for a vote if they keep failing to reach a clear decision in favor or against such GMO products, an EU source said.
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> Specifically, Kyprianou has not forwarded the first GMO application for food that has come up under his tenure for a member states vote as was expected, the EU source said. The vote on Monsanto's GA21 corn was scheduled to take place in a regulatory committee on Jan. 25.
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> Before proceeding, Kyprianou intends to assess why member states are voting against or abstaining from voting on GMO applications.
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> This failure of member States to take a clear position in favor of or against a GMO application has led to a situation where applications have been kicked back to the commission. The last commission, which ended its tenure in October 2004, opted to approve several GMO applications, but previous commissions did not take that political risk even though they were entitled to do so under EU rules.

> Some sources have expressed doubts that any commission can continue to approve applications in light of a clear member state division and not face a political backlash . . . ."

36. This excerpt illustrates and supports the following points: First, even nearly a year after the April 2004 entry into force of the new tracing and labeling and GM food and feed directives, the EC must still fight a political battle to reach a decision on any biotech product. This undermines the EC's contentions that products were delayed because of the need for the new directives to enter into force.

37. Second, the application described above is for food use. The product received a positive opinion from the Scientific Committee on Food three years ago,[2] and yet the EC still fails to submit it to a vote of the member States in the Regulatory Committee. Since the approval is for food use, none of the environmental issues discussed at length by the EC in its most recent comments are relevant to the application. Yet, the political battle remains.

38. Third, the EC continues to ban a large range of products for reasons that are openly political – openly, that is, except in the meetings in this dispute. This is why it is so important to the complainants, and indeed for the rules-based trading system itself, for the Panel to find that the EC's moratorium is not consistent with WTO rules.

39. We will do our best to answer any questions of the Panel.

[2] *See* discussion of GA21 application under 258/97 (novel food) in paras. 52-60 of the U.S. Supplementary Rebuttal.