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

(WT/DS291, 292, and 293)

Executive Summary of the
U.S. Opening Statement on Legal Issues
at the Second Substantive Meeting
(Delivered February 22, 2005)

March 23, 2005

1. Since the first 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.

Developments Since the First Substantive Meeting

2. The EC's submissions 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."

3. 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. Although no further confirmation is needed, the United States is providing one further official acknowledgment of the moratorium. The United States does so only because the EC in this dispute has claimed ignorance of the moratorium, and has asked the complainants to explain it. The exhibit, from a French Government website, asks and answer the question, "What is the de facto moratorium on GMOs?" The United States suggests that if the EC wants a definition of the moratorium, the EC should refer to this exhibit, which describes the moratorium, at least in the view of the Government of France.

4. 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.

5. The EC in its first submission attempted to rebut the U.S. *prima facie* case by arguing that any and all delays were the result of legitimate scientific questions, and by relying on 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.

6. 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.

7. 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.

8. 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 explained that the partial product dossiers provided by the EC did not, as the EC had asserted, contain competing risk assessments. 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. 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. 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.

9. 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.

10. 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. The U.S. third submission also provided over 20 examples where the questions by EC regulators were not required for assessing risks.

11. 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.

12. In sum, 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.

Burden of Proof

13. 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.

14. The EC argues 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. The United States does not contend, as the EC argument implies, that the EC suspended all processing of applications, nor does the United States 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.

15. 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, including 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. What the EC really objects to is that the EC, as opposed to the complainants, provided the documents in the product application histories. The United States, however, did not need the application histories to prove its *prima facie* case. It was the EC itself that chose to rely on the application histories in the EC's attempt to rebut that *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

16. 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."

17. The EC continues not to provide a serious defense of the member State safeguard measures. Since the first substantive meeting, the only new development regarding the safeguard

measures is that the Panel posed some questions to experts on the safeguards, and certain experts responded to those questions.

18. 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. With regard to environmental effects, 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. These views of the experts on environmental issues, however, have very little significance for the resolution of this dispute, and certainly cannot suffice to bring the safeguard measures within the scope of Article 5.7.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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. 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.

24. 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

25. 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. As the United States explained it its second and third submissions, 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. Nonetheless, the United States 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 current status of the EC moratorium should be of considerable relevance to an understanding of the EC's motivations, and to an objective assessment of the facts.

26. The United States refers the Panel to U.S. Exhibit 148, which is an article describing the latest state of play in the political maneuverings that lie at the heart of the moratorium. The excerpt illustrates and supports the following points.

27. 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.

28. Second, the application described in the article (GA21) is for food use. The product received a positive opinion from the Scientific Committee on Food three years ago, 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.

29. 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.