

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

(WT/DS291, 292, and 293)

**Executive Summary of
U.S. Opening Statement on Expert Issues
at the Second Substantive Meeting
(Delivered February 21, 2005)**

March 23, 2005

1. As the United States has repeatedly explained, the central issue in this case is that the EC adopted a 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.

2. The central, dispositive legal issues in this dispute – whether the EC adopted a moratorium, and whether that moratorium is consistent with the WTO Agreement – do not turn on any scientific issues. However, the United States does believe that the answers to certain scientific questions provide further confirmation of the fact that the EC adopted a moratorium. In particular, when an application is delayed until an applicant responds to a scientific question that is not required as a matter of science for completion of a risk assessment, the application has been unduly delayed. Moreover, this evidence must then be added to all of the other evidence confirming the existence of the moratorium.

3. In its third submission, the United States provided over 20 examples where the questions by member States and EC regulators were not required for assessing risks. As the United States addressed in its comments on the experts' responses, the experts' comments confirm that questions were not scientifically justified. In addition, in their testimony last week, the experts did not alter their conclusions on these issues. In short, the scientific issues, and the consultations with the experts, has further confirmed the existence of the moratorium and undue delay in the processing of biotech applications.

Evaluating Whether Particular Questions Were Scientifically Justified

4. As the United States has repeatedly explained, the resolution of this dispute does not turn on an examination of each and every member State objection. However, in the event the Panel makes findings on the member State objections examined by the scientists, the United States has three general comments on the issue of whether or not particular member State questions were required for assessing the risk of a product, and on how the Panel should evaluate the experts' views on this subject.

5. First, as a matter of legal interpretation of the SPS Agreement, certain objection must be considered as resulting in “undue delay” under Annex C. In particular, where a member fails to make a decision on a product until the applicant answers a question that is so vague and general as to be unanswerable must be considered “undue delay.” An example of such an unanswerable question would be “does the product have any adverse impact on any aspect of the environment,” where the regulator does not specify what impacts are of concern and what impacts would be considered adverse. In essence, such a question means that the regulator is putting an impossible burden on the applicant to prove the negative – in this example, to prove that there are no adverse impacts on any aspect of the environment. That burden is compounded by the fact that the regulator gives the applicant no guidance. Such types of questions necessarily result in endless delay, which in turn must be considered “undue.” Otherwise, a WTO Member could block all product approvals, indefinitely, by posing such vague and general questions. The views of the scientific experts may, however, be helpful in determining whether or not a question is so vague and indeterminate as to be unanswerable.

6. Second, in deciding whether a question contributes to undue delay, or was legitimately posed to assist in assessing risks, the entire factual context of this dispute must be considered. In

particular, in examining the objections, the fact that EC political-level officials and member States had announced a moratorium must always be kept in mind. In fact, unnecessary information requests often came from the same member States which had announced the moratorium. The United States submits that the Panel is entitled to employ its common-sense understanding of the entire situation in examining the facts of this case. Indeed, viewing all facts in context is simply part of making “an objective assessment of the matter before it,” as provided under DSU Article 11.

7. Third, and relatedly, the fact that an expert is of the view that there was a plausible scientific rationale for a question does not necessarily inform the Panel that the member State asking the question shared that rationale. In many cases, the objection did not specify why additional information was needed. Where the record provides no specific rationale for the question, the experts and the Panel are left to speculate. The experts, and very properly so, were not instructed to examine the member State objections in light of the entire factual context. In contrast, however, the United States submits that the Panel’s objective assessment of the facts should take account of the EC’s many announcements that it had imposed a moratorium on biotech approvals.

The EC’s Comments on the Experts’ Responses

8. The EC’s comments on the experts’ responses, although impressive in length, have very little, if any, relevance to dispositive legal issues. Three sections of the EC comments appear to be addressed to the moratorium and undue delay.

9. Part V of the EC comments addresses the experts’ responses to the Panel’s product-specific questions. The United States has the following general points on these EC comments.

10. Where one or more expert responded that a particular member State request for information was needed for a risk assessment of the products, the EC, understandably, supports those views. However, even if the EC’s and the experts’ characterization of such member State objections are accurate, the fact that some objections by EC regulators were not unwarranted is still consistent with the existence of the moratorium. The complainants have never claimed that each and every member State objection or request for information was unwarranted or resulted in undue delay.

11. Where one or more expert responded that a particular member State request for information was not needed for the assessment of risks, the EC, understandably, takes issue with those views. In fact, the experts believed that a substantial number of different types of questions, when considered in light of the totality of information available, were unnecessary for conducting a safety assessment. Those types included:

- questions related to the safety of the antibiotic resistance marker genes in these products;
- requests for additional molecular characterization data;

- requests for quantitative, event specific detection methods;
- requests for detailed information on environmental effects when the application sought approval only for import and processing, and not for planting;
- vague and open-ended requests for information on environmental effects;
- requests for chronic toxicity studies;
- requests for additional whole-food studies; and
- requests for studies on the composition of food produced from animals that consumed biotech feed.

12. At the experts' session, the EC directly challenged the experts on these issues. In the view of the United States, the experts were persuasive in defending their positions. Should the Panel decide it needs to make findings on those member State objections, based on all the evidence and explanations the United States has provided in its own submissions, the United States supports the views of the experts with regard to scientifically unjustified questions. Findings that such objections were not justified amounts to "undue delay" under Annex C of the SPS Agreement, and such findings serve as further confirmation of the existence of the moratorium.

13. Parts III and IV of the EC comments on the expert responses address "general and methodological issues" and the Panel's general questions. The theme of these comments are "complexity," "scientific uncertainty," and "evolving science." The EC elaboration on these themes is wildly overstated. But regardless of their accuracy or inaccuracy – the discussion of such broad themes has little or no role in the resolution of this case. To the extent such themes inform the evaluation of particular member State objections, the experts and parties have incorporated those themes in their comments on the particular objections. And, to the extent those themes do not relate to individual member State objections, they touch on no issue in this case.

14. The EC's general comments appear to be aimed toward the development of an argument that the moratorium falls within article 5.7 of the SPS Agreement. The EC's general discussion of themes such as "uncertainty," however, does not help the EC in the development of any argument under Article 5.7. In fact, Japan – the responding party in the Apples case – similarly relied on a general theme of uncertainty, and the Appellate Body firmly rejected it:

The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to "cases where relevant scientific evidence is insufficient", not to "scientific uncertainty". The two concepts are not interchangeable. Therefore, we are unable to endorse Japan's approach of interpreting Article 5.7 through the prism of "scientific uncertainty".

The Panel should do the same here with respect to the EC suggestion.

15. As noted, the EC discussion of uncertainties and risks associated with biotech products is wildly overstated. The United States addressed this matter comprehensively in Section II.A of its second submission. For example, the United States pointed out that the EC’s contentions in this case are inconsistent with its own public statements regarding biotech products. According to the EC’s Scientific Steering Committee, “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.”

16. In addition, the experts’ responses do not support the EC’s presentation on risks and uncertainties of biotech products. Regarding the potential for these products to present any human health effects, the advice from the experts – both in their written testimony, and during the discussions last week--identified no scientific issues that could justify the EC’s inability to determine whether the products met the EC’s level of protection. Rather, the advice confirmed that the totality of the information presented was generally sufficient to allow the EC to evaluate any potential adverse human health effects, even if in the abstract a scientist might have preferred more detailed molecular characterization, or more precise information on a particular point.

17. Furthermore, while the experts believed that issues relating to the evaluation of environmental effects were frequently more complex than those for food safety, the experts also presented various ways to analyze and resolve the issues the EC raised. For example, on issues relating to potential effects on non-target organisms, one expert confirmed that although the evaluation of potential effects on non-target organisms can be challenging because it is not possible to study all of the various species, systems, and biogeochemical cycles, several different methodologies to do so are available. The expert (Dr. Andow) mentioned two approaches, one using general environmental indicator species, and the other focusing on those non-target organisms that would be expected to be exposed in the agricultural environment where the crops would be grown. The fact that these methods have been available since 1999 calls into question the EC’s post-hoc justifications.

Advice from IO’s on Definitions

18. The EC asserts that its interpretations of terms used in the SPS Agreement are “effectively confirmed” by various organizations’ advice. However, the EC provides little or no explanation for its conclusion. In some cases, the EC has selectively relied on the advice provided, generally failing to acknowledge the advice on how such terms are typically construed and applied. For example, although the EC relies on the IPPC’s definition of a pest, the EC does not address the fact that ISPM 11, which was also cited by the IPPC, directly contradicts many of the arguments presented in the EC’s first written submission.

19. For other terms, the EC relies on artificial, and largely irrelevant, distinctions to support its claim. For example, the EC argues that the definition suggested for the term “additive” confirms that the GMO itself is not an additive. This argument is entirely beside the point. Whether the plant itself is an “additive” – a point the United States has never contested – in no way resolves the question of whether the genetic insert or construct in the product is properly considered as an “additive” within the meaning of the SPS Agreement. Applesauce that contains

food coloring is not itself considered to be a food additive, but it is indisputable that the food coloring contained in the applesauce falls within the definition of an additive in food. And, any measure applied to protect human health from risks arising from the food coloring in the applesauce would accordingly be considered an SPS measure.

20. The EC raises this same argument with respect to “contaminants,” “toxin,” and “disease.” Whether the organizations’ advice confirms that the biotech products are not themselves contaminants or toxins is utterly irrelevant to whether either the genetic inserts or the substances produced by the inserts are contaminants or toxins. Nor would advice that biotech products are not “diseases” resolve whether measures taken to address any risks that might be presented by the antibiotic marker genes could properly be characterized as a measure taken to address “risks arising from . . . disease-causing organisms.”