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

(WT/DS291, 292, and 293)

Comments of the United States on Suggested Questions for Scientific or Technical Experts

August 16, 2004

1. The United States appreciates the opportunity at this stage of the proceeding to suggest specific questions which might be referred to experts for their consideration. As the United States has explained, however, it has not identified any dispositive issues upon which the advice of experts would be of assistance to the Panel in resolving this dispute. Up to this time, the defenses of the EC have been on legal and non-scientific factual grounds – that is, that the general and product-specific moratoria never in fact existed and cannot be "measures" under the SPS Agreement, and that the member State safeguard measures are, by definition, provisional measures under Article 5.7 of the SPS Agreement. As explained in the prior oral and written submissions of the United States, these defenses are without merit.

2. Although the United States has not identified any specific questions at this time, the United States will provide some general comments on the four issues identified by the Panel in its letter of 4 August 2004.

Issue No. 1

3. The Appellate Body has repeatedly found that the interpretation of the terms of the WTO Agreement are to be based on those terms' "ordinary meaning" in their context and in the light of the treaty's object and purpose. Accordingly, any reference works identified by experts, and any official documents of international organizations, would only be relevant to the extent that they shed light on the ordinary meaning of the terms of the SPS Agreement.

4. In addition, where the SPS Agreement specifically defines a term -- such as "risk assessment" -- that definition must control, and there is no need to look to dictionaries, reference works, or any other sources.

Issue No. 2

5. The United States has explained that in light of the general moratorium and product-specific moratoria adopted by the EC, no application was allowed to reach final approval, regardless of whether any particular delay in the processing of applications was justified or unjustified, and thus there is no need for the Panel to examine the basis for each and every delay. The United States, however, has not agreed that every delay and every information request made in processing individual applications was justified. Indeed, in many cases, applications were delayed without any outstanding request for information, or for any other reason – other than the EC's decision to adopt a moratorium on biotech approvals.

6. Although the EC has relied on product application histories, the EC has yet to provide the underlying documentation. Under the current schedule, the EC is to provide the additional information by September 3, 2004. Accordingly, the United States in its submission of 21 September 2004 may have additional comments on the matters covered under Issue No. 2.

Issue No. 3

7. With regard to Article 5.1 of the SPS Agreement, the EC has not yet identified any particular document that the EC would consider to be a risk assessment that might serve as a basis for any of the SPS safeguard measures. And, with regard to Article 5.7 of the SPS Agreement, the EC's own scientific committees have examined the bases put forward by the member States for each safeguard measure, and found sufficient scientific evidence to conclude that the member State concerns were without merit.[1] Moreover, up to this time the EC has not even *attempted* to explain why relevant scientific evidence is insufficient, or how any safeguard measure might be based on available pertinent information. Scientific experts can provide advice on specific scientific questions, but they cannot be called upon to develop their own arguments as to why a safeguard measure is consistent or inconsistent with the obligations under the SPS Agreement.

8. In addition, as noted in the 10 August 2004 letter of the United States, Issue No. 3(B) involves a legal conclusion on one of the fundamental obligations under the SPS Agreement, and one which is central to this dispute. Experts can provide a panel with vital perspectives, information, and advice on scientific and technical issues, but have no role in advising on the application of the legal standards in the covered agreements to the facts at hand. The United States therefore understands that the experts would not be asked to opine on Issue No. 3(B) itself, but only to provide scientific and technical advice on the facts the Panel is to consider in making this determination.

9. The EC has requested in its letter of 10 August 2004 that the Panel add Annex 3 of the Cartagena Protocol (also known as the Biosafety Protocol) to the list in Issue 3(A). The United States would note its opposition to the consideration of the Biosafety Protocol as relevant to substantive consideration of the issues raised in this dispute. As is the case with the CBD,[2] the SPS Committee has not identified the Biosafety Protocol as a standard setting organization under Annex A of the SPS Agreement."[3]

Issue No. 4

10. Issue 4(c) appears to be addressed to the U.S. claim under Article 5.5 of the SPS Agreement. Up to this time, however, the EC – other than arguing that the moratoria never existed – has not presented any defense to the U.S. Article 5.5 claim. Thus, the EC has not disputed that biotech processing aids and the biotech products covered in this dispute are appropriate for comparison under Article 5.5. Again, scientific experts can provide advice on

[1] *See* First U.S. Submission, Section III.F, and exhibits cited therein.

[2] *See* U.S. Letter of 10 August 2004.

[3] In addition, the Biosafety Protocol is not a pertinent source of law for purposes of interpreting the SPS Agreement. *See* Rebuttal Submission of the United States of July 19, 2004, at para. 16-26.

specific scientific questions, but they cannot be called upon to develop their own arguments as to why a particular provision of the SPS Agreement applies or does not apply to a specific measure.