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

(WT/DS291, 292, and 293)

Comments of the United States on the EC's Final Position on Whether to Seek Advice from Scientific Experts

July 27, 2004

1. In its Final Position on Whether to Seek Advice from Scientific Experts, the European Communities reiterates its request that the Panel should seek advice from scientific experts. The EC's submission, however, fails to identify any dispositive issues upon which the advice of scientific experts would be of assistance to the Panel is resolving this dispute. In failing to identify any dispositive technical or scientific issues, the EC's Final Position serves as further confirmation that there would be no need or value in consulting with experts.

The EC's Earlier Suggested Terms of Reference Provide No Basis for Seeking Expert Advice

2. In its Final Position, the EC first notes that its suggested terms of reference, submitted earlier on June 4 and June 16, provides examples of "generic questions" that might be submitted to experts in this dispute.[1] Those suggested terms of reference, however, provide no basis for seeking consultation with experts.

3. In fact, the EC in its suggested terms of reference repeatedly emphasized that it was too early in the proceeding to identify definitively the issues that might be submitted to experts, and that it would be necessary to return to this question after the rebuttal submissions. In particular, the EC wrote:

> "The Communities consider that, in line with its first submission on this issue and some comments from the complainants, that it might be counterproductive to draft questions too early, and to request such advice before scientific and technical issues in dispute have been well identified. The Communities is therefore of the view that it is necessary to do so after the reception of the written rebuttal submissions of the Parties, where such issues in dispute will be identified." [2]
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> "The European Communities believes it is too early to address precisely and definitively all of the questions which might be put to the experts."[3]
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> "In order to assist the Panel in its reflections, the European Communities is however prepared to advance, by way of example, some technical and scientific questions that could potentially be put to experts (on the basis of the issues that presently appear to divide the parties)."[4]
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> The EC offers these examples in order to assist the discussion. It does not suggest that all of these are, or relate to, all of the scientific and technical issues in dispute,

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[1] Final Position of the European Communities on the Need to Seek Scientific or Technical Expert Advice, para 10 (July 22, 2004) (hereinafter "EC Final Position") (referring to the EC's suggested terms of reference submitted to the Panel on May 27, 2004 and June 16, 2004).

[2] Responses by the European Communities to the questions posed by the Panel on the 3rd of June, 2004, para. 44 (June 16, 2004) (emphasis added).

[3] *Id.*, para. 49 (emphasis added).

[4] *Id.*, para. 52 (emphasis added).

> or that answering all these questions are relevant to the resolution of the legal issues.[5]

4. Since the time that the EC first submitted its suggested terms of reference, the EC has provided a large volume of additional information, and the parties have responded to extensive questions from the Panel and have made their rebuttal submissions. If the EC believed that any of the "generic" questions in its suggested terms of reference warrant expert advice, it was incumbent on the EC to specify what those questions might be and how they might relate to the dispositive legal issues in this dispute. The EC, however, has failed to do so.

5. In addition, the United States in its submission of June 8, 2004 explained why the "generic" questions posed by the EC in its suggested terms of reference were inappropriate for expert advice.[6] In particular, the United States explained that under the text of the SPS Agreement, questions of "scientific uncertainty" are not appropriate for submission to scientific experts; the United States further explained that the findings of the Appellate Body in the *EC-Hormones* and *Japan-Apples* disputes confirm this point.[7] The relevant disciplines of the SPS Agreement provide that SPS measures must be based on risk assessments, that provisional measures may be taken under Section 5.7 only if the scientific evidence is "insufficient," and that approval procedures must be completed without "undue delay." Deciding whether the EC has complied with these obligations does not turn on the degree of "uncertainty" with regard to any particular scientific or technical issue.[8] The United States also explained that any issues regarding the definition of terms in the SPS Agreement are to be decided based on the ordinary meaning of those terms, and that submission of definitional issues to experts is entirely inappropriate.[9] The EC has not even attempted to respond to these fundamental points.

The Scope of the SPS Agreement is Not an Appropriate Issue for Expert Advice

6. After referring back to its earlier submission on examples of possible "generic questions" that might be submitted to experts, the EC gives a truly remarkable first specific reason for arguing that experts are required: the EC argues that they are needed to assist the Panel in determining a purely legal question – that is, the scope of the SPS Agreement. In particular, the EC argues that the Panel needs to consult experts on the definition of many of the individual words used in the Annex A definition of "sanitary or phytosanitary measure."[10] The Appellate Body, however, has repeatedly found that the interpretation of the terms of the WTO Agreement are to be addressed under the customary principles of treaty interpretation reflected in the *Vienna*

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[5] *Id.*, para. 57 (emphasis added).

[6] Preliminary Comments of the United States on the EC's Suggested Terms of Reference for Scientific and Technical Advice (June 8, 2004).

[7] *Id.*, para. 7.

[8] *Id.*, para. 7.

[9] *Id.*, para. 8.

[10] EC Final Position, paras. 13-17.

Convention on the Law of Treaties. And those principles require that the interpretation of treaty terms is to be based on those terms' "ordinary meaning" in their context and in the light of the treaty's object and purpose.

7. The EC has provided, and can provide, no basis for departing from this fundamental principle of treaty interpretation. Furthermore, the EC has cited to no dispute in which a panel has ever turned to experts for assistance in interpreting a provision of the WTO Agreement.

The Meaning of "Risk Assessment" is Not an Appropriate Issue for Expert Advice

8. The EC's suggested second reason for seeking expert advice is for assistance on determining the meaning of "risk assessment," as this term is used in the SPS Agreement.[11] This argument, just like the argument that expert advice is needed to decide on the scope of the SPS Agreement, is lacking in any foundation. Indeed, the SPS Agreement, in Annex A, defines the term "risk assessment." No experts are needed to locate this definition, or to interpret its plain meaning.

9. Most of the EC's comments on this point in fact have nothing to do with experts, but instead are an abstract legal argument regarding the significance of the positive risk assessments conducted by the EC's own scientific committees. In doing so, the EC discusses at length hypothetical distinctions between risk assessments and "risk management," a term which is not even in the SPS Agreement.[12] The EC's discussion, though incorrect as a legal matter, is based on a straw-man argument and is not even pertinent to the outcome of this dispute. In particular, the EC argues that the United States and the other complainants "assert, erroneously, that an opinion issued by those advisory committees exhausts the process described as 'risk assessment' provided for in the SPS Agreement." The EC provides no cite for this description of the U.S. claims in this dispute – and in fact, the EC's description is not correct.

10. Nowhere does a discipline in the SPS Agreement turn on the "exhaustion" of risk assessments. To the contrary, the United States has pointed to the EC's own risk assessments for two purposes. First, Article 5.1 requires that SPS measures be based on risk assessments. The United States has explained that the only risk assessments of which it is aware are the *positive* risk assessments of the EC's own scientific committees, and certainly the EC's moratorium on biotech approvals and the member State bans cannot be based on such positive assessments. And, the EC does not dispute that the EC's own risk assessments meet the definition of "risk assessment" under the SPS Agreement, and the EC does not dispute that those risk assessments are positive. The United States has not argued that no other risk assessments may be considered by the Panel. However, although the EC indicated to the Panel at the first substantive meeting

[11] EC Final Position, paras. 18-22.

[12] *See* Appellate Body Report in *EC-Hormones*, para. 181 ("We must stress, in this connection, that Article 5 and Annex A of the SPS Agreement speak of 'risk assessment' only and that the term 'risk management' is not to be found either in Article 5 or in any other provision of the SPS Agreement.").

that it would be submitting additional risk assessments that supported its measures, the EC has failed to explain what documents on its additional CD of information are (in its view) risk assessments under the SPS Agreement, and has not explained how any of those documents might be the basis under Article 5.1 for any of the EC's measures in this dispute.

11. Second, for a measure to fall within the scope of Article 5.7, it must meet four criteria, including that the scientific evidence is "insufficient", and that the measure is adopted on the basis of "available pertinent information." The United States has explained that the EC's own *positive* assessments are significant because they show both that scientific evidence is not insufficient for performing a risk assessment, and that the EC measures are not based on available pertinent information. Again, the United States has not argued that the EC is foreclosed from submitting additional risk assessments. The EC, however, has failed to identify any risk assessments that purportedly might serve as the basis for the measures at issue in this dispute.

A General Discussion of the Purported Risks of Biotech Products is Not an Appropriate Issue for Expert Advice

12. Third, the EC argues that the Panel should seek expert advice with regard to whether "[biotech] products, and the risks associated with them, are the same as or similar to conventional products and their associated risks."[13] Indeed, the United States in its rebuttal submission did explain that the EC's description of the purported risks of biotech products was overstated and misleading.[14] At the same time, however, the United States was very clear in explaining that no dispositive issue in this dispute turns on these abstract scientific questions.[15] In particular, regardless of the answer to abstract questions regarding the purported risks of biotech products, the EC is obligated to complete its approval procedures without "undue delay," and any SPS measure adopted by the EC must be based on a risk assessment.

An Examination of Whether Delays in the Processing of Individual Applications are "Undue" and Are Subject to Moratoria on Approvals Does Not Require Expert Advice

13. Although the EC's Final Position contains a section on the examination of the individual product histories, the EC seems to agree that the arguments of the United States regarding those

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[13] EC Final Position, para. 23.

[14] U.S. Rebuttal Submission, paras. 8-15.

[15] *Id.*, para. 8 ("As for most of its factual presentation, the EC does not describe how its assertions, even if true, would be relevant either to the legal issues in this dispute or to the products covered in this dispute. In particular, the EC does not claim, and indeed could not claim, that any of the scientific issues discussed in its background section justified either a general moratorium or the product-specific moratoria. Moreover, if the EC has scientific questions about biotechnology, those questions can be and should be addressed within the context of the EC's own approval system, and in a manner consistent with its WTO obligations. Indeed, this is how the EC approached scientific and technical issues for the biotech products that the EC approved prior to October 1998.")

histories do not raise scientific or technical issues that call for expert advice.[16] Instead, the EC argues that the United States has not met its burden of proving the existence of "undue delays," a general moratorium, or product-specific moratoria. Of course, the United States submits it has provided overwhelming evidence of the existence of undue delays and the moratoria, and the United States thus strongly disagrees with the EC contentions. But in any event, whether or not the United States has met its evidentiary burden does not call for expert advice.

An Examination of the Member State Measures Does Not Require Expert Advice

14. Finally, the EC argues that experts are required to determine whether the member State measures qualify as provisional measures under Article 5.7 of the SPS Agreement.[17] In particular, the EC argues that experts are needed to assist in assessing whether or not scientific evidence is insufficient with respect to three types of "concerns"[18] supposedly expressed by certain member States in relation to the products subject to the member State measures. As explained below, this argument is without merit.

15. As a preliminary matter, however, the United States would note that the EC's linkage of member State "concerns" to the member States measures is without any foundation in the record. In its rebuttal submission, the EC makes the following remarkable assertions:

> "The Panel asked the United States to explain its position in relation to the concerns cited by the Member States. The United States answered that question by reference to what it alleges 'the Member State measures cite' - which is something different. The United States thereby changed the terms of reference of the Panel's question . . . . *What is or is not expressly referred to in the Member State measures themselves is not the point.* Those measures are in some cases relatively succinct, as is often the case with provisional measures. The United States knows perfectly well that they do not contain more than a summary or indication of the issues."[19]

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[16] EC Final Position, para. 35 ("The European Communities submits that no scientific advice is needed to refute the United States' claim on the existence of a moratorium."). The EC also writes that the United States "does not challenge any other delays, and in particular, none of those caused by requests for information." *Id.* para. 34. The United States, however, has not agreed that every delay and every information request made in processing individual applications was justified. Rather, 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.

[17] EC Final Position, paras. 36-39.

[18] "Concerns" is the term used by the EC to describe the purported basis for the member State measures. The EC does not even claim that these concerns are in fact based on any scientific evidence whatsoever. *See* EC Second Submission, pages 101-02, and Exhibit EC-155.

[19] *Id.*, para. 312 (emphasis added).

The EC then attaches a table (Ex. EC-155) to its Second Submission purportedly showing the reasons for each of the member State measures. This table, however, *is unsupported by any references to any documents submitted in this dispute,* and in fact is unsupported by any references at all. The EC's table is thus nothing more than an *ex post facto* justification for the member State measures, and has no evidentiary value. Moreover, the United States submits that the reasons that the member States cite in their measure is precisely "the point" – other WTO Members or Panels could not even begin to evaluate these measures under the disciplines of the WTO Agreement without examining the reasons that the member States adopting them actually gave at the time of adoption.

16. The EC's argument that experts are needed to assist in examining whether the scientific evidence is "insufficient" with regard to these member State "concerns" is without merit for two reasons. First, for each member State measure, the EC's own scientific committees have examined the bases put forward by the member States, and found sufficient scientific evidence to conclude that the member State concerns were without merit.[20] Most recently, on July 23, 2004, two additional opinions of the European Food Safety Authority (EFSA) became publicly available. In these opinions, EFSA found that additional submissions by Austria and Greece in support of their respective safeguard measures provided no new scientific evidence that would in any way invalidate the EC's earlier, positive risk assessments.[21] Thus, there is no basis in the record for finding that the evidence is "insufficient" to evaluate the "concerns" raised by member States.

17. Second, experts are inappropriate in these circumstances because there is, in fact, no scientific or technical issue in dispute that might be submitted to the experts. In particular, not only is there no basis in the record for finding that the scientific evidence with regard to member State concerns is "insufficient," the EC has not even attempted to explain why the evidence is insufficient, nor even specifically *alleged* that the evidence is insufficient. In fact, given that EC-level approvals require EC member States to allow the products subject to the member State safeguards to be marketed everywhere else within the EC, the EC's failure to even make such an allegation is understandable. But in any event, where no disputing party even contends that the scientific evidence is insufficient to evaluate the member State "concerns," it would be inappropriate to convene a panel of experts to assist in the consideration of this issue.

Conclusion

18. By this point in this dispute, the EC has filed two lengthy submissions, a set of responses to the Panel's extensive questions, an additional CD of documents, and at least two submissions

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

[21] Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Austrian Invoke of Article 23 of Directive 2001/18/EC (adopted 8 July 2004) (Ex. US-129); Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Greek Invoke of Article 23 of Directive 2001/18/EC (adopted 8 July 2004) (Ex. US-130).

directed exclusively to the issue of scientific experts. Yet the EC has still failed to identify a single, specific scientific or technical issue that is dispositive to a legal issue in this dispute. The United States submits that the EC's failure to identify any such issues further confirms that to seek expert advice in this dispute is unnecessary, and that to do so would not only consume the parties' and the Panel's resources but would also prolong these proceedings unnecessarily.

EXHIBIT LIST

US-129	Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Austrian Invoke of Article 23 of Directive 2001/18/EC (adopted 8 July 2004)
US-130	Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Greek Invoke of Article 23 of Directive 2001/18/EC (adopted 8 July 2004)