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

(WT/DS291, 292, and 293)

Response of the United States
to the Request for a Preliminary Ruling
Submitted by the European Communities

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TABLE OF CONTENTS

I. INTRODUCTION

1. The European Communities ("EC") offers no basis for its request for a preliminary ruling ("EC Request") that the U.S. panel request in this dispute fails to meet the requirements of Article 6.2 of the *Understanding on the Rules and Procedures Governing the Settlement of Disputes* ("DSU"). To the contrary, as required by Article 6.2, the U.S. panel request properly "identif[ies] the specific measures at issue and provide[s] a brief summary of the legal basis of the complaint sufficient to present the problem clearly."

2. First, the U.S. panel request clearly specifies the specific measures in dispute, and the EC presents no basis for any other finding. Second, the EC has asked this Panel to insert into Article 6.2 a requirement not actually present in the text of the provision, namely that the United States summarize the specific legal arguments to be presented in the first U.S. submission. The Appellate Body in *EC Bananas*[1] has already rejected the suggestion (made, then as now, by the EC) that a complaining party must summarize its legal arguments in the panel request, and this Panel should do so as well.

II. STATEMENT OF FACTS

3. On May 13, 2003, the United States requested formal dispute settlement consultations with the EC. The consultation request explained:

> "Since October 1998, the EC has applied a moratorium on the approval of biotech products. The EC has suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system. A number of applications for placing biotech products on the market have been blocked in the approval process under EC legislation[FN1] and have never been considered for final approval. The approvals moratorium has restricted imports of agricultural and food products from the United States.
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> "Moreover, the member States maintain a number of national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC. The national marketing and import bans have restricted imports of agricultural and food products from the United States.
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> "The measures affecting biotech products in the EC include:
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> (1) the suspension by the EC of consideration of applications for, or granting of, approval of biotech products;

[1] Report of the Appellate Body, *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, WT/DS27/AB/R, adopted September 25, 1997 ("*EC Bananas*").

> (2) the failure by the EC to consider for approval applications for the biotech products mentioned in Annexes IA and IB to this request; and
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> (3) national marketing and import bans maintained by member States, as described in Annex II to this request.
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> "[FN1] Directive 2001/18, O.J. L 106 17.4.2001, p. 1 (and its predecessor, Directive 90/220, O.J. L 117, 8.5.1990, p. 15, as amended by Directive 94/15, O.J. L 103, 22.4.1994, p. 20 and Directive 97/35, O.J. L 169, 27.6.1997, p. 72); and Regulation 258/97, O.J. L 043, 14.2.1997, p. 1."[2]

The consultation request then noted that these measures appeared to be inconsistent with the EC's obligations under specified provisions of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement"), the *Agreement on Agriculture* ("Agriculture Agreement"), the *Agreement on Technical Barriers to Trade* ("TBT Agreement") and the *General Agreement on Tariffs and Trade 1994* ("GATT 1994").

4. The reference in the consultation request to a "moratorium" on biotech approvals followed numerous public statements by EC officials acknowledging the existence of this *de facto* measure. In June 2000, for example, European Commissioner for Health and Consumer Protection, David Byrne, stated that the reluctance of member States to approve the placing on the market of new biotech products "has resulted in a complete standstill in the current authorisations and a de facto moratorium on the commercial release of GMOs."[3] And, for example, at a press conference in October 2001, a press report described the comments of European Environment Commissioner Margot Wallström as follows: "After admitting that no end was in sight for the moratorium, which she said was an illegal, illogical, and otherwise arbitrary line in sand, Wallström also accused the member states of abandoning their legislative responsibility and leaving the European biotechnology industry in the dark."[4]

5. The United States consulted with the EC on June 19, 2003. At no time during the consultations did the EC suggest it did not understand the legal basis for the U.S. complaint. Instead of explaining when the moratorium would be lifted or how a moratorium on the approval of biotech products might be consistent with the EC's obligations under the WTO Agreement, the EC simply denied that the moratorium existed. Accordingly, the consultations failed to resolve the dispute.

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[2] WT/DS291/1.

[3] "Biotechnology: Building Consumer Acceptance," Speech by David Byrne, European Commissioner for Health and Consumer Protection, European Business Summit, June 10, 2000, at 3 (Exhibit US-1).

[4] "EU Moratorium on GMOs Could Last Until Traceability, Labeling Regime in Place," at A-8 (Exhibit US-2).

6. Consequently, on August 7, 2003, the United States requested the establishment of a panel. The panel request specified the measures that are the subject to this dispute as follows:

> "Since October 1998, the European Communities ("EC") has applied a moratorium on the approval of products of agricultural biotechnology ("biotech products"). Pursuant to the moratorium, the EC has suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system. In particular, the EC has blocked in the approval process under EC legislation all applications for placing biotech products on the market, and has not considered any application for final approval. The approvals moratorium has restricted imports of agricultural and food products from the United States.
>
> "In addition, EC member States maintain a number of national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC. The national marketing and import bans have restricted imports of agricultural and food products from the United States.
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> "The measures affecting biotech products covered in this panel request are:
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> > (1) as described above, the suspension by the EC of consideration of applications for, or granting of, approval of biotech products;
> >
> > (2) as described above, the failure by the EC to consider for approval applications for the biotech products mentioned in Annexes I and II to this request; and
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> > (3) national marketing and import bans maintained by member States, as described in Annex III to this request."[5]

7. The Dispute Settlement Body ("DSB") considered the U.S. panel request, along with similar requests from Canada and Argentina, at its meetings held on August 18 and August 29, 2003. At neither of those DSB meetings did the EC state any concerns that the Complainants' panel requests were inconsistent with Article 6.2 of the DSU. This panel was established at the August 29, 2003 meeting of the DSB.

[5] WT/DS291/23 (footnote omitted). The EC makes no claim that the U.S. panel request does not identify the national marketing and import bans described in subparagraph (3) above.

III. THE REQUIREMENTS OF DSU ARTICLE 6.2

8. Article 6.2 of the DSU requires, in relevant part, that a request for the establishment of a panel:

> identify the specific measures at issue and provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly.

9. The EC Request contains a number of quotations from Appellate Body and panel reports, in particular from *Korea Dairy*[6] and *EC Bananas,* that explain this provision and emphasize its role and importance in dispute settlement. It has entirely missed, however, one aspect of these reports which is critical to the issue now before this Panel: the key distinction between *claims* – which must be included in the panel request – and the *arguments* in support of those claims – which need not be included. As the Appellate Body explained in *EC Bananas*:

> In our view, there is a significant difference between the *claims* identified in the request for the establishment of a panel, which establish the panel's terms of reference under Article 7 of the DSU, and the *arguments* supporting those claims, which are set out and progressively clarified in the first written submissions, the rebuttal submissions and the first and second panel meetings with the parties.[7]

10. Furthermore, the Appellate Body in *EC Bananas* made clear that a panel request may adequately state a claim if the request simply cites the pertinent provision of the WTO agreement:

> We accept the Panel's view that it was sufficient for the Complaining Parties to list the provisions of the specific agreements alleged to have been violated without setting out detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements.[8]

11. The Appellate Body confirmed this reading in *Korea Dairy*. In that dispute, the problem with the panel request was that it cited too broadly to Article XIX of the GATT 1994 and various articles of the *Agreement on Safeguards*, all of which contained numerous sub-articles, so that it was difficult to determine which specific obligations in those provisions were at issue.[9] The U.S.

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[6] Report of the Appellate Body, *Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products*, WT/DS98/AB/R, adopted January 12, 2000 ("*Korea Dairy*").

[7] *EC Bananas*, para. 141.

[8] *Id.*

[9] The Appellate Body explained:

> In the present case, we note that the European Communities' request for a panel, after identifying the Korean safeguard measure at issue, listed Articles 2, 4, 5 and 12 of the Agreement on Safeguards and Article XIX of the GATT 1994. Article XIX of the GATT 1994 has three sections

panel request in this dispute, by contrast, cites to specific provisions of the WTO agreements at issue, and cannot be said to suffer a similar defect.

12. The EC also fails to note that *even if* a panel request is insufficiently detailed "to present the problem clearly," the Panel is not automatically deprived of jurisdiction over the matter. Rather, the Appellate Body has found that a panel must examine, based on the "particular circumstances of the case," whether the defect has prejudiced the ability of the responding party to defend itself. As the Appellate Body explained in *Korea Dairy*:

> In assessing whether the European Communities' request met the requirements of Article 6.2 of the DSU, we consider that, in view of the particular circumstances of this case and in line with the letter and spirit of Article 6.2, the European Communities' request should have been more detailed. However, Korea failed to demonstrate to us that the mere listing of the articles asserted to have been violated has prejudiced its ability to defend itself in the course of the Panel proceedings. Korea did assert that it had sustained prejudice, but offered no supporting particulars in its appellant's submission nor at the oral hearing. We, therefore, deny Korea's appeal relating to the consistency of the European Communities' request for the establishment of a panel with Article 6.2 of the DSU.[10]

Therefore, in evaluating claims regarding whether a panel request "presents the problem clearly," a Panel must consider the particular circumstances of the case, including whether the defending party has been prejudiced.

13. The EC asserts that the U.S. panel request neither (1) identifies the specific measures at issue, nor (2) provides a brief summary of the legal basis of the complaint sufficient to present the problem clearly, and that the EC therefore cannot "start preparing its defence in any meaningful way." As detailed in the sections that follow, the EC is wrong on all counts.

> and a total of five paragraphs, each of which has at least one distinct obligation. Articles 2, 4, 5 and 12 of the Agreement on Safeguards also have multiple paragraphs, most of which have at least one distinct obligation. The Agreement on Safeguards in fact addresses a complex multi-phased process from the initiation of an investigation, through evaluation of a number of factors, determination of serious injury and causation thereof, to the adoption of a definitive safeguard measure. Every phase must meet with certain legal requirements and comply with the legal standards set out in that Agreement.

Korea Dairy, para. 129.

[10] *Id.,* para. 131.

IV. THE EC'S ASSERTION THAT THE U.S. PANEL REQUEST DOES NOT IDENTIFY THE "SPECIFIC MEASURES AT ISSUE" IS INCORRECT

14. The EC appears to have two concerns with the identification of the measures subject to this dispute. Neither of these concerns has merit.

15. First, the EC claims that, "It is, in particular, the reference [in the panel request] to an alleged 'suspension' that remains entirely in the dark."[11] Even without any context, and on the plain language of the panel request, it is difficult to see how the concept of a "suspension" of the consideration and granting of biotech approvals is at all ambiguous. But in light of well-known statements of EC officials acknowledging the existence of a *de facto* moratorium, the EC's claim that it is "in the dark" on the meaning of a "suspension" is not credible.

16. Along, these same lines, the EC poses the following question:

> "Is there supposed to be a decision or some other kind of normative or executive act, perhaps a moratorium legislation of the kind New Zealand had, by which the European Communities has proceeded to 'suspend'?"

Although the United States is unaware of any single executive decree or legislative act through which the moratorium has been implemented, such decree or act would be within the scope of the covered measures. Where the EC in this dispute denies the existence of a moratorium – a moratorium nonetheless acknowledged by its own officials – it cannot in turn try to profit from its lack of transparency by arguing that the Complainants have not identified the moratorium with sufficient specificity.

17. Second, the EC claims that the U.S. panel request is fatally flawed because it uses both the phrase "a suspension of consideration" and "a failure to consider." The EC does not explain why these two different wordings introduce any ambiguity concerning the measures subject to the request. Moreover, in the context of the panel request, the reason for using these two different wordings is quite clear.

18. The first phrase – suspension of consideration – is used to describe the EC's across-the-board moratorium affecting all biotech products:

> "(1) as described above, the suspension by the EC of consideration of applications for, or granting of, approval of biotech products."

The second phrase – failure to consider – is used to describe the EC's conduct as it affects the specific products identified in the annexes to the Panel Request:

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[11] EC request, para. 22.

> "(2) as described above, the failure by the EC to consider for approval applications for the biotech products mentioned in Annexes I and II to this request."

These are simply two different wordings for the same concept -- the word "suspension" fits better with the EC's conduct as it affects all biotech applications, while the phrase "failure to consider" fits better with specific applications. The EC does not and cannot explain how these different wordings amount to a failure to identify the specific measures at issue.

19. For the above reasons, the EC has presented no reason for finding that the U.S. panel request does not meet the requirement of Article 6.2 to identify the specific measures at issue.

V. CONTRARY TO THE EC'S ALLEGATIONS, THE U.S. PANEL REQUEST PROVIDES A BRIEF SUMMARY OF THE LEGAL BASIS OF THE COMPLAINT SUFFICIENT TO PRESENT THE PROBLEM CLEARLY

20. The U.S. panel request, which lists the specific provisions of the SPS Agreement, TBT Agreement, Agriculture Agreement, and GATT 1994 alleged to be violated, provides a brief summary of the legal basis of the complaint sufficient to present the problem clearly, as required by Article 6.2.

21. The Appellate Body has made clear on several occasions that a panel request may adequately summarize the legal basis of the complaint under Article 6.2 by simply citing the pertinent provisions of the WTO Agreement.[12] The EC cites *Korea Dairy*, in which the Appellate Body stated that there may be circumstances in which a "listing of treaty articles would not satisfy the standard of Article 6.2."[13] But in that proceeding the articles cited had multiple paragraphs, many of which had their own distinct obligations: for instance, the panel request cited Article XIX of the GATT 1994, containing three sections and five paragraphs, each with at least one distinct obligation, and Article 12 of the Safeguards Agreement, which spans two pages and contains 11 paragraphs.[14]

22. By contrast, the U.S. panel request in this dispute lists specific provisions of the SPS Agreement, TBT Agreement, Agriculture Agreement, and the GATT 1994. Where an article consisted of more than one paragraph, the U.S. panel request specifically identified the particular paragraph number. Moreover, where a paragraph has subparagraphs, in most cases the panel

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[12] *E.g., EC Bananas*, para. 141; *Korea Dairy*, para 124.

[13] *Korea Dairy*, para. 124.

[14] Id.

request goes on to specify the specific subparagraphs.[15] Unlike in the case of *Korea Dairy*, there are no circumstances in this dispute that would render citation to the relevant specific provision of the WTO agreement insufficient under Article 6.2.

23. Previous panels and the Appellate Body have been very careful to distinguish between the claims that must be made in a panel request under Article 6.2 -- *i.e.*, the brief summary of the legal *basis* for the complaint sufficient to present the problem clearly -- and the *arguments* supporting those claims. The claims must be set forth in the panel request. The arguments do not. As the Appellate Body stated in *EC Bananas:*

> We accept the Panel's view that it was sufficient for the Complaining Parties to list the provisions of the specific agreements alleged to have been violated without setting out detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements. In our view, there is a significant difference between the *claims* identified in the request for the establishment of a panel, which establish the panel's terms of reference under Article 7 of the DSU, and the *arguments* supporting those claims, which are set out and progressively clarified in the first written submissions, the rebuttal submissions and the first and second panel meetings with the parties.[16]

24. In this dispute, the EC is not faulting the United States for failing to set out the legal *basis* for the complaint. It is faulting the United States, incorrectly, for not including its *arguments* in support of that basis.

25. The EC presents two lines of argument why in this case the U.S. panel request must have gone beyond listing the claims, to also include the arguments in support of those claims.

26. First, the EC counts up the number of provisions listed by the United States, and proposes that this number is somehow too high to be covered by the provision actually found in the text of the DSU, namely that a panel request that specifies the claims is in compliance with DSU Article 6.2.

27. As an initial matter, the United States notes that it does not agree with the EC's count of the number of obligations covered in the U.S. panel request. For example, the EC argues that SPS Agreement Article 7 includes two separate obligations. The second Article 7 obligation, however, is to comply with the obligations in SPS Agreement Annex B, and the U.S. panel request specifies the specific provisions of Annex B alleged to be violated. Accordingly, the EC

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[15] The only exceptions are SPS Agreement Annex B(5), and TBT Agreement Articles 2.9 and 5.6, each of which contain four subparagraphs establishing related transparency obligations. The specific subparagraphs were not identified because the United States considers the EC measures to be inconsistent with each one.

[16] *EC Bananas*, para. 141.

engages in double-counting by counting both the general obligation to comply with Annex B, and also the specific provisions of Annex B listed in the U.S. panel request.

28. Moreover, the simple reason that the U.S. panel request covers a number of obligations is that the EC's decision to adopt, without transparency, a *de facto* moratorium on the approvals of important agricultural products understandably results in a violation of several provisions of the WTO Agreement. Article 6.2 of the DSU does not impose an entirely different standard on a panel request on the basis that the defending party has engaged in multiple violations of the WTO Agreement.

29. In addition, other than pointing to the number of obligations covered by the U.S. panel request, the EC does not explain how it is confused, or in any way prejudiced, by the panel request. Surely, the EC cannot claim, for example, that it fails to understand (and thus is unable to begin to defend itself against) the proposition that a general moratorium on the approval of biotech products might violate the obligation in Article 5.1 of the SPS Agreement that SPS measures must be based on risk assessments. Nor, for example, can the EC claim not to understand (and thus not to be able to begin to defend itself against) the proposition that a 5-year moratorium would be inconsistent with the requirement in Annex C(1)(a) of the SPS Agreement to undertake and complete procedures to ensure the fulfilment of SPS measures "without undue delay."

30. Finally, the EC itself acknowledges that "several of those provisions [cited in the panel requests] are either mutually exclusive – such as those contained in the SPS and in the TBT Agreements – or subordinated – such as those of the GATT 1994 in relation to the ones contained in the other agreements."[17] In the consultations and at the meetings of the DSB, the United States has made clear that it considers the moratorium to be an SPS measure. The EC, however, has refused to even acknowledge the existence of the moratorium, much less to acknowledge that the moratorium falls within the scope of the SPS Agreement. It is for this reason that the Complainants in their panel requests have been required to cite both SPS provisions and the corresponding provisions of the TBT Agreement. In these circumstances, it is difficult to understand how the EC could claim any confusion or prejudice from citing provisions of both the SPS and TBT Agreement.

31. Second, the EC suggests that the "common practice" is for panel requests to go beyond stating the claims to laying out the arguments in support of those claims. The EC does not, however, even begin to explain how a "practice" could alter the textual requirements of DSU Article 6.2, nor does it attempt to reconcile its suggestion with the fact that the panel request in *EC Bananas*[18] (which the Appellate Body considered to have been consistent with Article 6.2) did not set out the complaining parties' arguments in support of their claims. Furthermore, the

[17] EC Request, para. 40.

[18] WT/DS27/6.

EC gives no real basis for its assertion of a "practice"; it mentions exactly three panel requests, when in fact, as of October 31, 2003, there had been **119** panels established.[19] Certainly, citation to panel requests in such a tiny fraction of cases would not be sufficient to establish a "practice" of any kind.[20]

32. In short, the EC has not presented any reasons why the U.S. panel request, which clearly specifies the claims in this dispute, should be found inconsistent with the requirements of Article 6.2 of the DSU.

VI. THE U.S. PANEL REQUEST DOES NOT PREJUDICE THE ABILITY OF THE EC TO DEFEND ITSELF

33. In *Korea Dairy*, the Appellate Body denied Korea's Article 6.2 claim *in toto* because, although it had asserted prejudice, Korea offered no supporting particulars.[21] The EC does assert that it is prejudiced by the U.S. panel request, but only in the vaguest and most conclusory manner.

34. The EC's only explanation of its alleged prejudice is that:

> "[T]he lack of specificity of the identification of the measures at issue, coupled with the mere listing of an elevated number of provisions and the absence of co-relation between the two, has so far prevented the European Communities from starting preparing its defence in any meaningful way."[22]

This argument, however, is nothing more than a restatement of its argument, refuted above, that the request is insufficiently detailed with respect to actual arguments to support the legal basis of the complaint. In light of the Appellate Body's reasoning in *Korea Dairy*, such a mere restatement is plainly insufficient to establish prejudice. If lack of detail in the panel request automatically meant "prejudice", there would be no need for a "prejudice" analysis.

35. Moreover, the United States finds it hard to accept that the EC has not already begun to "prepare its defense in a meaningful way." To be specific, is the EC arguing that it has not already begun to develop explanations of why it denies the existence of a moratorium despite the

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[19] *Statistical Information on Recourse to WTO Dispute Settlement Procedures (1 January 1995 – 31 October 2003): Background Note by the Secretariat*, Job(03)/225, circulated 11 December 2003, part III(A).

[20] The United States notes that the EC has in any event not followed any such "practice: itself; see, e.g., the panel request in *United States – Anti-dumping Act of 1916*, WT/DS136/2, in which the EC did nothing more than provide citations to, and cursory paraphrases of, provisions of the WTO Agreement.

[21] *Korea Dairy*, para 131.

[22] EC Request, para. 50.

statements of EC officials to the contrary; of why no new biotech products have been approved for over 5 years if there has been no moratorium; and of how such a moratorium is consistent with the substantive, procedural and transparency obligations of the SPS Agreement? The EC in its ruling request does not make such claims, and, indeed, could not credibly do so.

36. Accordingly, even if the EC had succeeded in demonstrating that the U.S. panel request does not meet the requirements of DSU Article 6.2, which it has not, the EC has offered nothing to suggest that it has been prejudiced.

VII. THE EC FAILED TO RAISE ITS ARTICLE 6.2 CONCERNS AT THE EARLIEST POSSIBLE OPPORTUNITY

37. Finally, the EC fails to recognize that procedural objections must be raised at the earliest possible opportunity, and not for the first time in a ruling request filed after the composition of the panel.[23] In the FSC dispute, the United States requested a preliminary ruling that a claim be dismissed because of an inadequacy in the consultation request. The panel rejected that request, and the Appellate Body upheld that rejection, stating,

> It seems to us that, by engaging in consultations on three separate occasions, and not even raising objections in the DSB meetings at which the request for establishment of a panel was on the agenda, the United States acted as if it had accepted the establishment of the panel in this dispute, as well as the consultations preceding such establishment. In the circumstances, the United States cannot now, in our view, assert that the European Communities' claims . . should have been dismissed.[24]

38. Likewise, at no time prior to the composition of this Panel did the EC so much as intimate that it considered the panel request in any way deficient, waiting until after the panel was composed to offer its objection. In upholding the panel's rejection of the U.S. request for a preliminary ruling in FSC under very similar circumstances, the Appellate Body stated, "The procedural rules of the WTO dispute settlement system are designed to promote, not the development of litigation techniques, but simply the fair, prompt and effective resolution of trade disputes."[25] This Panel should reject the EC's effort to avoid the fair, prompt and effective resolution of this dispute through its groundless – and untimely – objections to the U.S. panel request.

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[23] Report of the Appellate Body, *United States – Tax Treatment for "Foreign Sales Corporations"*, WT/DS108/AB/R, adopted March 20, 2000, para. 165 ("*FSC*").

[24] *Id.*

[25] *Id.*, para. 166.

VIII. CONCLUSION

39. For the reasons stated above, the EC's arguments in support of its request for a preliminary ruling that the U.S. panel request does not meet the requirements of Article 6.2 are without merit. Accordingly, the Panel should reject that request.

EXHIBIT LIST

US-1 "Biotechnology: Building Consumer Acceptance," Speech by David Byrne, European Commissioner for Health and Consumer Protection, European Business Summit, June 10, 2000

US-2 "EU Moratorium on GMOs Could Last Until Traceability, Labeling Regime in Place," BNA Daily Report for Executives, October 30, 2001