United States – Continued Suspension of Obligations in the *EC – Hormones* Dispute

Responses of the United States to Panel Questions

October 3, 2005

A. Questions to the United States:

Q38. *Could the United States explain how a Member which claims it has complied with recommendations and rulings of the DSB in a given case and which wants the measures applied against it to be withdrawn should act in a situation where, as in the present case, the Member suspending concessions or other obligations believes that it has made no determination as to the continued existence of a nullification or impairment and considers that the former has not established that there is a disagreement, within the meaning of Article 21.5 of the DSU? Other than through Article 21.5, is there any other manner whereby the EC can seek to obtain a multilateral determination on whether or not its compliance measure has removed the WTO inconsistency?*

1. The first and easiest way to resolve a situation of a claim of compliance after DSB authorization to suspend concessions is for "the Member concerned" (*i.e.*, the implementing Member) to work informally with the complaining party to assure it of compliance or to work out a mutually satisfactory solution. One would expect that in such a situation the Member concerned would have significant incentives to approach promptly the Member applying the suspension of concessions or other obligations[1] (the "suspending Member"), provide sufficient evidence and explanation, and respond to any questions of the suspending Member, to demonstrate that the Member concerned had complied. If the Member concerned provides the evidence and explanation sufficient to permit the suspending Member to understand how the Member concerned has complied, then the Member concerned could secure a prompt end to the measures applying the suspension of concessions or other obligations at the same time saving all parties the time and resources necessary for formal dispute settlement.

2. Here, the EC has done little to help the United States ascertain whether the EC has complied with the DSB recommendations and rulings and has provided little in the way of

[1] The United States understands the term "apply the suspension of concessions or other obligations" as used in Article 22.8 of the DSU to be shorthand for the somewhat complicated circumstance where the DSB authorizes a Member to suspend concessions or other obligations, the Member does so, and the Member applies measures that would not otherwise be consistent with a covered agreement. The United States is aware, as question 41 from the Panel indicates, that a Member is not obligated to suspend concessions or other obligations even though the DSB has so authorized the Member, nor is the Member obligated to apply measures that reflect this suspension of concessions or other obligations. One example where a Member could suspend a concession but not apply measures that reflect this suspension would be where the Member continues to apply a tariff rate equal to or less than the bound rate even though the Member has suspended the tariff binding.

explanation or evidence concerning the EC's claim of compliance. We leave it to the Panel to consider why that may be.

3. Alternatively, the Member concerned could consult with the suspending Member to reach a mutually agreeable solution, thereby satisfying the third condition of Article 22.8. This solution could then be notified to the DSB.

4. If informal consultations fail to allow the suspending Member to understand whether the Member concerned has complied and fail to yield a mutually satisfactory solution, and the Member concerned wishes to continue to pursue the matter, there a number of alternatives short of seeking a formal multilateral determination available to the Member concerned, including use of good offices. However, if the Member claiming compliance chooses to seek a formal multilateral determination, one obvious option (under the current text of the DSU) is to pursue a claim under DSU Article 22.8 against the ongoing suspension of concessions. The EC has demonstrated that this is possible by virtue of the fact that it has made such a claim in this proceeding. Article 22.8 specifically contemplates the conditions under which suspension of concessions may no longer be applied, and therefore appears to be a logical choice and avenue for determining whether or not a Member may continue to do so. An Article 22.8 analysis would include a determination of whether a "compliance measure" indeed removes the WTO-inconsistent measure or provides a solution to nullification or impairment.

> Q39. *Having regard to the terms of Article 22.8 , could the United States comment on the EC claim that the United States maintains, with respect to a new measure (Directive 2003/74/EC), suspensions of concessions authorized in relation to the old measure (i.e. that found to be incompatible by the original EC-Hormones panels and the Appellate Body)?*

5. There is no basis for the EC's claim. The EC has provided no evidence in support of that claim, and its allegation is not correct. The United States is applying the authorized suspension of concessions or other obligations because the DSB authorized it to do so after finding that the EC had not complied with the DSB's recommendations and rulings. If there were a DSB finding that the EC has complied, then obviously there would no longer be a basis to apply the suspension of concessions or other obligations. It is incorrect to claim that the United States is applying the suspension of concessions or other obligations "with respect to a new measure" just because the United States continues to apply multilaterally authorized suspension of concessions or other obligations on a date after the EC unilaterally announced its compliance. This is the classic *post hoc, ergo propter hoc* (after, therefore because) fallacy. Furthermore, nothing about the U.S. measures applying the suspension of concessions changed after the EC unilaterally claimed compliance. In other words, it is not as though the United States altered its measures to respond to the EC's claim of compliance; indeed, these measures were adopted in 1999, long before the EC's announcement, and so cannot be "with respect to" the EC's "new measure".

Q40. *Having due regard to the statement of the United States in paragraph 96 of its first written submission, could the United States elaborate on the reasons why following the EC approach would "unsustainably create an endless loop of litigation and nullify the right of complaining parties to suspend concessions for non compliances" (US first submission, paras. 2 and 9), with respect to the present dispute and the options which the United States believes were available and should have been used by the EC?*

6. Under the EC's approach, when the Member concerned announces its compliance in a post-suspension setting, the complaining party would be obligated to resort to an Article 21.5 compliance proceeding. Upon completion of the compliance review, if the panel finds no compliance, the Member concerned could nevertheless prevent the complaining party from resuming[2] its suspension of concessions by again announcing compliance, thereby again forcing the complaining party to initiate another round of litigation. If the complaining party fails to initiate Article 21.5 proceedings and continues to apply its suspension of concessions, according to the EC's interpretation, it could be found to be in breach of several DSU and other covered agreement obligations, including DSU Article 22.8, for failing to cease to apply a suspension of concessions in the face of the unilateral declaration of compliance, and Article 23.2(a), for having made a unilateral determination of the "new" measure's WTO-consistency. This cycle could continue indefinitely (hence the "endless loop" metaphor) with no relief for the complaining party despite successive findings that the Member concerned has not complied. As an example of how this theory might work in practice, the EC, after being found in this panel proceeding not to have complied, could announce that it now is imposing its ban on estradiol 17β as a provisional measure justified under Article 5.7 of the SPS Agreement, and that it believes that its studies do in fact amount to risk assessments for the other five hormones as well, and so again declare its compliance. At that point, the cycle would begin anew.

7. Furthermore, under the EC's proposed approach, it would appear that the ability of the suspending Member to review a "new" measure and prepare any claims, arguments or opinions on that measure before initiating Article 21.5 proceedings would be severely limited. Pursuant to the EC's interpretation, the suspending Member must reach a conclusion on the Member concerned's measure within an undefined and unspecified "reasonable timeframe".[3] It is impossible to tell under the EC's theory when one would infer a determination by the suspending Member. After a day? A week? A year?

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[2] The same problem of an endless loop of litigation would arise where the complaining party has not yet suspended concessions, perhaps because the arbitration under Article 22 of the DSU has not yet concluded. Repeated claims of compliance would, under the EC's proposed approach, require the complaining party to engage in repeated panel proceedings, thus preventing the complaining party from ever being able to apply a suspension of concessions or other obligations.

[3] *See*, *e.g.*, Oral Statement by the European Communities in the First Substantive Meeting, para. 63.

Q41. *The United States argues that it has made no "determination", within the meaning of Article 23.2(a) of the DSU, with respect to the EC measure notified to the DSB. However, one may argue that, even with the authorization of the DSB, the Member concerned is not obligated to impose the retaliatory measures or to maintain them. In addition, Article 22.8 provides that the suspension of concessions "shall only be applied until such time as the measure found to be inconsistent... has been removed". In that context, could the United States explain to what extent maintaining the suspension of concessions or other obligations – whether justified or not – is not a "determination", when the other party has made a notification of implementation to the DSB?*

8. There is no basis to assume that the continued suspension of concessions is based on a U.S. position concerning the EC's notification to the DSB. Members submit notifications on various measures (*e.g.*, subsidies, SPS measures, TBT measures) all the time to various WTO bodies. The fact that a Member may not have taken any action at a given point in time in response to these notifications does not indicate that a Member has made any "determination" concerning another Member's notification. Governments take time to reach conclusions; it is neither accurate nor appropriate to impute a "determination" from inaction (such as not changing the application of the suspension of concessions or other obligations).

9. As noted by the panel in *Section 301*, a determination must be sufficiently "firm" and "immutable."[4] The definition of determination emphasizes that a Member's decision must be final and formal. It does not, as argued by the EC, contemplate an "implicit" determination. While the United States would not hazard to set out strict parameters for what actions might constitute a determination, it is clear that internal deliberations of a WTO Member do not and cannot. Were it otherwise, Members would not be able to engage in internal debates and discussions as to whether recourse to dispute settlement would be fruitful. This interpretation is supported by the careful choice of words in the DSU generally, such as "considers" in DSU Article 3.3 and "disagreement" in DSU Article 21.5. Had the drafters of the DSU intended to capture internal deliberations in the prohibition set out in DSU Article 23.2(a), there are ample, less-formal or firm terms that they could have used to do so. In addition, a "determination" for purposes of DSU Article 23.2(a) is only made "in such cases", in other words, where a Member is seeking redress for a violation (DSU Article 23.1). As we have indicated in our written and oral submissions to the Panel, the United States was not seeking recourse for a violation in connection with the EC's claim of compliance; we had already sought and obtained redress for the EC's import ban.

10. Finally, analysis of the text of Article 23.2(a) indicates that WTO Members did not agree on an obligation to affirmatively make a determination concerning the consistency with a covered

[4] Panel Report, *United States – Sections 301-310 of the Trade Act of 1974*, WT/DS152/R, adopted 27 January 2000 ("*Section 301*"), fn. 657.

agreement of another Member's measure, let alone agree on a deadline by which such a determination must be made. Rather, in Article 23.2(a) they agreed on an obligation not to make a determination. The implications of the EC's position are therefore quite ironic. Pursuant to the EC's interpretation of Article 23.2(a), Article 23.2(a) would be converted from a prohibition on making determinations into an obligation to make them – a Member would in effect be required to make a determination upon learning of an implementing Member's declaration of compliance, and to do so within some unspecified time frame.

Q42. *With reference to paragraphs 181-190 of the first written submission of the United States, does the United States consider that there would be a risk of delaying the resolution of the dispute if the Member suspending concessions refused to have recourse to Article 21.5 of the DSU or any other means of multilateral determination of compliance?*

11. We believe that it is not "delaying resolution of the dispute" to have the Member concerned, if it does not want to await the conclusion of the review by the suspending Member of its claim of compliance, challenge the measures implementing the suspension of concessions. Furthermore, it is not "delaying resolution of this dispute" in the post-suspension setting to refrain from initiating an Article 21.5 compliance panel if there is no obligation to do so nor a time limitation for when such a proceeding must be brought. It is no more a "delay" in resolving the dispute for the Member concerned to have recourse to panel proceedings than it was a "delay" for the suspending Member to have had recourse to panel proceedings in the first place to challenge the measure that is the subject of the DSB's recommendations and rulings. It would seem odd to read the DSU as saying that a Member that has already been found to be in breach of a covered agreement and that has maintained that breach past the end of the reasonable period of time should have a right to proceedings that are more expedited than the Member who has been suffering nullification and impairment during that entire time period.

B. Questions to Canada and the United States:

Q43. *Do Canada and the United States agree with the European Communities' statement in paragraph 32 of its first written submission that the specific forms described in paragraph 2 [of Article 23 of the DSU] do not exhaust the list of prohibited unilateral actions and its reference to the Panel Report in US - Section 301 Trade Act? Why?*

12. While textually there is merit in reading DSU Article 23.1 as a general rule that covers more than the three "specific and clearly-defined"[5] forms of conduct in Article 23.2, it is difficult to envisage exactly what behavior or actions Article 23.1 could cover other than what is

[5] Appellate Body Report, *U.S. – Import Measures on Certain Products from the European Communities*, AB-2000-9, WT/DS165/AB/R, adopted 10 January 2001, para. 111.

described in Article 23.2. What is clear, however, is that the suspension of concessions or other obligations pursuant to DSB authorization, absent a multilateral finding that the conditions in Article 22.8 are met, neither "violate[s] the general obligation in Article 23.1" nor constitutes any one of the "instances specifically singled out in Article 23.2."[6]

Q44. *Do Canada and the United States agree with the European Communities that whenever there is a violation of Article 23.2 of the DSU, there is always a violation of Article 23.1?*

13. In light of the connection between the two provisions, including the phrase "in such cases" in the chapeau of Article 23.2, it would appear that when a Member breaches the specific provisions of Article 23.2, it also consequentially breaches the general rule set out in DSU Article 23.1. Any analysis of a violation of Article 23.2 would be contingent on whether the basic conditions of Article 23.1 have been met, such as whether the Member accused of a violation of Article 23.2 is indeed "seek[ing] the redress of a violation." As we have demonstrated, this proceeding does not present a situation where the United States is seeking redress of a violation within the meaning of Article 23.

Q45. *Do Canada and the United States consider that the European Communities could have, as the party having to comply, effectively made a recourse to Article 21.5, in the light of the recourse to Article 21.5 by the European Communities in the EC - Bananas III case? If yes, and in light of Article 6 of the DSU, who would be the complainant, and what would be the complaint?*

14. The EC demonstrated in the *Bananas (21.5)* dispute, over U.S. objections, that a responding Member can indeed have recourse to an Article 21.5 proceeding. U.S. objections at the time went to some of the same questions posed by the Panel. While the EC would be the "complaining" party since it is requesting the establishment of the panel, and the EC in its panel request would specify the terms of reference (subject to Article 7 of the DSU and the limitations in Article 21.5), Article 21.5 does not specify who would be the "responding" party. However, the EC, having established in *Bananas (21.5)* that Members claiming compliance are able to have recourse to Article 21.5, is hardly in a position now to say that it is unable to have recourse to Article 21.5. Presumably it was because of the disadvantages of Article 21.5 that the EC chose to have recourse to normal panel proceedings in this instance, and there is nothing wrong or improper about such recourse.

15. Relating to U.S. objections to the Article 21.5 proceeding in the *Bananas* dispute, and the United States not being a party in that proceeding, we would note that, in that dispute, the EC's measure taken to comply was already being evaluated by the arbitrator in an earlier-commenced Article 22.6 proceeding – indeed, by the same individuals comprising the Article 21.5

[6] *See* EC First Written Submission, para. 32.

compliance panel. Therefore, there was no need for the United States to be a part of an Article 21.5 proceeding, filed later, which would simply be reviewing the same question of the WTO-consistency of the EC's measure.

Q46. *Presuming that Canada and the United States are interested in a prompt resolution of this dispute, why have they not initiated the expedited procedure of Article 21.5 to challenge the EC implementing legislation as they do in these proceedings?*

16. As we have noted, the United States is indeed interested in a prompt resolution of this dispute. Our cattle and meat processing industry would very much like to have the import ban on its products lifted so that it may resume trade with the EC. They have been denied access to the European market since the 1980s. We have been in talks with the EC over the course of the last few years in hopes of achieving resolution of the dispute. Because these exchanges would qualify as settlement negotiations, the United States would view their content as confidential. However, the United States can assure the Panel that it has been in contact with the EC on this issue.

17. However, the United States does not believe that it was or is under an obligation to initiate Article 21.5 proceedings once the EC declared its own compliance with DSB recommendations and rulings in the *Hormones* dispute. As the United States has argued in its written submissions and statements to the Panel, Article 21.5 does not obligate a Member duly authorized to suspend concessions or other obligations to initiate a proceeding, nor does it contain a time limitation for when a suspending Member must initiate such a proceeding.

Q47. *With reference to the European Communities' statement in paragraph 62 of its oral presentation, could Canada and the United States confirm whether, and explain why, the implementation of the EC - Hormones case has "practically not been on the DSB agenda since July 1999"?*

18. Implementation of the *EC – Hormones* dispute has (practically) not appeared on the DSB agenda since July 1999. The reason for its absence is simple – the EC has not submitted a status report on the dispute during this period. The EC followed the same approach in the *Bananas* dispute, ceasing its status reports and only resuming reports at the specific request of another of the complaining parties in the dispute. The United States would also note that the status reports of the EC in the *Hormones* dispute were of little benefit in updating the DSB on the status of the EC's implementation - the status reports were unchanging for the period before the EC stopped providing them.

19. The United States has been seeking a resolution of the *Hormones* dispute with the EC for some time. Such a resolution would have obviated the need for a status report. That resolution has appeared imminent for most of that time. However, the EC can hardly claim that it could deprive the DSB of its obligation to keep the dispute under surveillance by the EC's failure to

provide a status report. The United States also notes that Article 21.6 would permit any Member to raise the issue of implementation at any time with the DSB – there is no time limitation on the DSB's surveillance. Furthermore, the text of Article 22.8 indicates that DSB surveillance continues once a Member has been authorized to suspend concessions, stressing that "the DSB shall continue to keep under surveillance the implementation of adopted recommendations or rulings", in situations where "concessions or other obligations have been suspended but the [DSB] recommendations . . . have not been implemented."

Q48. *The European Communities states in paragraph 44 of its oral statement that "a 'determination' ... need not be pinned down to a specific statement in a specific form, it is the whole conduct a WTO Member is displaying that needs to be looked at". Why would this not be the case here? If the sum of US and Canadian statements, actions and arguments are not a unilateral determination of violation, isn't it at least evidence of their disagreement with the European Communities within the meaning of Article 21.5?*

20. As noted in our first written submission, we do not believe that there was a "disagreement" within the meaning of Article 21.5 of the DSU as of the date of the EC's consultation and panel requests. While the United States had not been able to say that it shares the EC's view on the scientific evidence and Opinions ostensibly supporting its ban, it also had not yet disagreed with it. We have been interested in examining these materials. However, we would emphasize that even if there were a "disagreement" between the United States and the EC, Article 21.5 contains no obligation for a suspending Member such as the United States to initiate an Article 21.5 compliance proceeding, nor does it set a time limitation for when such a proceeding must be brought.

21. As for what might constitute a "determination" for purposes of DSU Article 23.2(a), we submit that this has to be something more than the continued exercise of DSB authorization. Article 23.2(a) is unique in the covered agreements. In context, given the referral in Articles 23.1 and 23.2(a) to following DSU procedures, it seems clear that the type of "determination" at issue is the type that would result from dispute settlement. Dispute settlement does not result in "implied" or "imputed" determinations from the conduct of a panel or the Appellate Body, but explicit findings. This interpretation is supported by the definition and interpretation of "determination," which denotes a significant degree of firmness, immutability and finality.

Q49. *Can the United States and Canada explain whether they provided answers to the European Communities' requests for information on scientific studies made by the European Communities? If not, why?*

22. The United States has provided answers to EC requests for information on both: (i) the EC 1999 Opinion and (ii) studies that formed the basis of U.S. regulatory decisions approving the use of the six hormones for growth promotion purposes.

23. The EC contacted the United States in 1999 to inform relevant regulatory agencies of its completion of a 1999 Opinion on the six hormones at issue in the *EC – Hormones* dispute. At that time, the U.S. Food and Drug Administration and Department of Agriculture reviewed the documents put forward by the EC. The response to those documents has been attached as Exhibit US-21.

24. The United States and the EC then met during the summer of 1999 to discuss the results of the EC's 1999 Opinion. At that point, the EC had made no claim of compliance regarding its import ban.

25. We have been unable to locate any records indicating that the EC put forward its 2000 Review or 2002 Opinion to U.S. authorities for a similar review, or that it requested a scientific conference or discussions on the conclusions of those documents similar to those held in 1999. Similarly, we have no records of a requested discussion or conference on the scientific underpinnings of the EC's ban once it claimed that it had developed a risk assessment and brought its measure into conformity with DSB recommendations and rulings in the fall of 2003.

26. The United States and the EC held a video conference in the fall of 2003, during which the EC provided a brief PowerPoint presentation summarizing its amended ban, but did not provide any information on its 2002 Opinion, nor did it present any information on the scientific conclusions and analyses it viewed as supporting its amended ban. We have attached a copy of this presentation as Exhibit US-22.

27. Regarding U.S. responses to EC requests for scientific data on the six hormones, our recollection is that, in a 1999 meeting concerning analytical chemistry methods, the EC requested access to U.S. Food and Drug Administration administrative records relating to approvals of the six hormones.

28. We indicated to the EC at the time that the United States government is unable to release the entire record supporting such approvals, as portions of the record (such as formulations and processes) are treated as trade secrets under U.S. law.[7] However, we noted that we do disclose data summaries so that interested parties may examine the basis for approvals, including study methodologies and results. To our knowledge, the EC has not pursued access to these data summaries.

29. We informed the EC at the time that the monographs underpinning the Joint FAO/WHO Expert Committee on Food Additives ("JECFA") reports on the six hormones contained as much if not more information on the hormones than would be found in our records, and suggested that the EC consult these monographs.

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[7] The scientists advising the panel in the original dispute confirmed that these types of studies are proprietary and remain confidential. *See* paragraph 8.255 of the Panel Report.

C. Questions to all parties:

Q50. *Could each party provide the Panel with a detailed account of the efforts it has made to solve this dispute since the notification by the European Communities of its implementing measure in 2003?*

30. The United States has been involved in talks aimed at resolving this dispute both before and after the EC's notification of its amended ban in the fall of 2003. These talks qualify as settlement negotiations, and as such the United States would view the content of the negotiations as confidential. However, we can assure the panel that we have been in contact with the EC on this issue. In addition, the EC and the United States held a video conference in the fall of 2003, and the United States filed its SPS Article 5.8 request for more information on the EC's amended ban in December, 2004.

Q51. *Having regard to the first claim of the European Communities, in a post-retaliation phase, if a suspension of concessions is consistent with Article 22.8, can it nevertheless be inconsistent with Article 23 of the DSU? Under what circumstances? Please elaborate.*

31. In a post-suspension scenario, it is difficult to see how a Member could be found in breach of Article 23 if it is suspending concessions in a manner consistent with Article 22.8. Consistency with the terms of Article 22.8 means that there has been no compliance (no removal of the measure, no provision of a solution, or no mutually agreeable solution), such that the suspension of concessions remains authorized by the DSB. By continuing to apply that authorization to suspend concessions, a Member would not be seeking redress for some new breach within the meaning of Article 23.

Q52. *In the US - FSC case, the European Communities suspended the application of its suspension of concessions and then initiated an Article 21.5 procedure because it considered that the US implementing legislation was inconsistent, inter alia, with the SCM Agreement. Please give your views on whether it would also be possible to request the establishment of an Article 21.5 panel while continuing to apply the suspension of concessions pending the outcome of the Article 21.5 procedure?*

32. It would theoretically be possible to request the establishment of an Article 21.5 panel while continuing to apply the suspension of concessions pending the outcome of the Article 21.5 process. Nothing in the text of Article 21.5 would prohibit this scenario.

33. However, we would note that, under the EC's current interpretation of Article 22.8 of the DSU, it is difficult to see the scope for an Article 21.5 proceeding. For the EC, the Member concerned may satisfy the requirements of Article 22.8 through a simple declaration of its own compliance. A suspending Member therefore would be in breach of Article 22.8 by continuing to apply the suspension of concessions, irrespective of whether there was an Article 21.5 process.

By continuing to apply the suspension of concessions pending the outcome of an Article 21.5 compliance panel, the suspending Member runs afoul of the EC's interpretation of Article 22.8, *i.e.*, that upon hearing a claim of compliance, a suspending Member must cease to apply the suspension pursuant to Article 22.8.

Q53. *Are the parties of the view that, in the absence of a challenge by the implementing party against the continued suspension of concessions, such suspension can continue for an indefinite period of time, even though they are supposed to be only temporary. If not, what provision of the DSU can serve as a legal basis for preventing the suspension of concessions for an indefinite period of time?*

34. The answer to the Panel's first question would appear to be largely in the hands of the Member concerned and what steps that Member has taken to satisfy the DSB recommendations and rulings, and could change on a case-by-case basis. For example, the parties have all noted that, pursuant to Article 22.8, the duration of suspension of concessions is intended to be temporary. However, by temporary, the DSU means that the suspension of concessions must be lifted when the Member concerned has satisfied the conditions of Article 22.8, *i.e.*, that it has removed the offending measure or provided a solution to the nullification or impairment. The satisfaction of the conditions set out in Article 22.8 marks the point in time when suspension of concessions may no longer be applied, and satisfaction of those conditions can be determined either through agreement between the parties, or by multilateral proceedings. As we have noted, in this instance, the EC has done little to help the United States ascertain whether the EC has complied with the DSB recommendations and rulings.[8]

35. Article 22.8 specifies the end point for any application of the suspension of concessions or other obligations. Satisfaction of the terms of Article 22.8 does not always, however, involve recourse to dispute settlement. One of the conditions set out in the text of Article 22.8 for when suspension of concessions must be lifted is that the parties have reached a "mutually satisfactory solution". Presumably, neither party would have to seek recourse to dispute settlement in the event of such a solution, and the parties could resolve the dispute by notifying their solution to the DSB.

Q54. *Could the parties provide the Panel with their understanding of the meaning of the term "measure" in Article 19.1 of the DSU and of the term "measures taken to comply with the recommendations and rulings [of the DSB]" in Article 21.5 of the DSU? More particularly, do the parties consider that a measure taking, e.g., the form of a ban remains the same measure, irrespective of the change in supporting legislation, as long as it is a ban? If not, what makes a "measure taken to comply" different from the measure which had to be brought into conformity?*

[8] *See*, *e.g.*, EC PowerPoint presentation. (Exhibit US-22).

36. An Article 21.5 proceeding would examine a new and different measure than the one that is the subject of the DSB recommendations and rulings, by the simple fact that a measure found to be inconsistent could not, at the same time, be one taken to comply. The issue of what constitutes the new and different measure cannot be discussed as a general matter, but depends very much on the particular situation – for example, in the SPS context a ban could remain the same but the Member could now have a risk assessment and so the ban would be a "different measure" in that sense. In the context of this dispute, the "measure taken to comply" could encompass the conversion of portions of the ban into "provisional" measures, as well as the fact that the EC claims to have based its measure on a new "risk assessment", rather than a change in the text of the ban itself.

Q55. *When does the legal effect of the DSB authorization lapse and by what procedures? Where parties disagree on the consistency of a notified implementing measure effected after the DSU retaliation authorization, does the DSU authorization lapse at the time when (i) the DSB makes a decision of compliance with respect to the implementing measure, or (ii) the implementing measure is in actual compliance regardless of whether the DSB has made a determination of compliance or not, or (iii) the Member concerned notifies its implementing measure to the DSB and declares its compliance, or (iv) the DSB makes a specific determination to terminate its previous retaliation authorization?*

37. Article 22.8 specifies that the application of the suspension of concessions or other obligations is to stop when the conditions specified therein have been satisfied. There are two basic ways to ascertain whether those conditions have been satisfied. Either the parties can reach agreement, or the DSB can make the determination. Where parties disagree on whether the Member concerned has complied, a DSB determination would be needed (scenario (i)). Regarding scenario (ii), if the complaining party agreed that there was compliance, then yes, the conditions in Article 22.8 would be satisfied and there would be no need for a DSB determination. The parties could simply notify their agreement and mark the end of the dispute in a communication to the DSB. However, absent such agreement, there would be no way to confirm whether or not there is compliance with DSB recommendations and rulings in the absence of a DSB determination. Scenario (iii) does not work for all the reasons we have discussed in our written and oral statements. Regarding scenario (iv), we would note that while there is no mechanism other than positive consensus to achieve scenario (iv), we would not rule out a determination by positive consensus. However, this seems unlikely since, if the parties agree on compliance, then they would accept that the authorization no longer has effect.

Q56. *Article 21.5 of the DSU provides that where there is a "disagreement as to the existence or consistency with a covered agreement of measures taken to comply with ... such dispute shall be decided through recourse to these dispute settlement procedures." Since Article 21.5 provides that "such dispute shall be decided*

through recourse to [the DSU]", would the parties consider that either of them has an obligation to refer the matter to the DSB under Article 21.5? If yes, why?

38. As we have noted in both written and oral statements to the Panel, the DSU, including Article 21.5, does not specify in this post-suspension of concessions setting the particular procedures a Member either should take, or is obligated to take, in order to determine whether the Member concerned has satisfied the conditions of Article 22.8.

39. The DSU leaves it open to the parties to choose one of various means to proceed, including bilateral consultations, use of good offices, conciliation and mediation under Article 5 of the DSU, recourse to DSU Article 21.5, recourse to normal panel proceedings (as is the case with the current proceeding), and arbitration under Article 25 of the DSU. The EC would instead remove all alternatives except Article 21.5 proceedings and would read into Article 21.5 an (unspecified) deadline that is not there. The EC would also read into Article 21.5 a requirement that the complaining party and only the complaining party invoke Article 21.5, despite the fact that when it was convenient for the EC, it has itself demonstrated that an implementing Member may invoke Article 21.5.

40. By inserting an obligation to initiate compliance proceedings in this post-suspension scenario into Article 21.5's text, complaining parties could be forced to split proceedings between an Article 21.5 compliance panel and a regular panel in scenarios where, for instance, the Member concerned has both taken measures to comply as well as other related measures that may undo the effects of the measure taken to comply (for example, where a Member repealed an illegal quota but had already raised tariffs above its bound level - the repeal could be a measure taken to comply while the earlier tariff increase may not be considered to be one). There is no reason why the complaining party should not be able to seek review of both in a regular panel proceeding.

Q57. *How would you distinguish between expressing "disagreement" over the WTO compatibility of a measure taken to comply with recommendations and rulings adopted by the DSB for the purpose of deciding whether or not to start an Article 21.5 procedure and a unilateral "determination" of WTO compatibility of such a measure?*

41. This question demonstrates the basic catch in the EC argument. The EC has suggested that the United States should be required to invoke Article 21.5. The EC has never hinted that if the United States had so invoked Article 21.5, that indication would have been in breach of Article 23 because it would have amounted to a "determination" contrary to Article 23.2(a). The United States agrees that had the United States, as the EC wanted, brought a 21.5 proceeding against the EC import ban, that "disagreement" would not have equated to a "determination" for DSU Article 23 purposes, any more so than the original decision to resort to dispute settlement. The EC cannot have it both ways. Either a "disagreement" for purposes of Article 21.5 cannot be inferred to involve a "determination" contrary to Article 23, or else the EC is saying the

suspending Member is in an impossible situation. It must breach Article 23 either through not invoking Article 21.5 or through invoking Article 21.5.

42. As we have noted in our first written submission, we do not believe that a disagreement existed within the meaning of Article 21.5, as the United States was still in the course of evaluating the materials put forward by the EC in support of its ban. We therefore do not believe that our actions rose to the level of a "quarrel" or a "refusal to accord or agree" with the EC. In light of the definition of "disagreement", which does not indicate the same finality or firmness of an Article 23.2(a) "determination", if there is no "disagreement" between the parties, there is certainly no "determination" as to the WTO-consistency of a measure.

Q58. *In a situation where an Article 21.5 panel, requested to examine the compatibility of an implementing measure, finds that only partial compliance has been achieved, what is the procedure available to the original complainant:*

(a) *Can it continue to apply the suspension of concessions initially authorized by the DSB?*
(b) *Does it need to request a new authorization?*
(c) *Can the implementing party object to the level of suspension and request an Article 22.6 arbitration to determine a new level of suspension of concessions?*

43. These important questions are the subject of negotiations in the DSU review precisely because Members recognize that many of them are not addressed by the current text of the DSU. As we have noted in several instances, this proceeding is not the place to address these questions because, among other things, this proceeding does not present these questions.

Q59. *Is Article 23 of the DSU applicable to a suspension of concessions under a previous authorization of the DSB and in the absence of a new DSB decision of termination of the previous authorization?*

44. The United States does not exclude the possible application of Article 23 of the DSU in every "post-suspension situation." DSU Article 23 could apply, for example, where a suspending Member declares that a measure taken to comply is inconsistent with a covered agreement, that this inconsistency increases the level of nullification or impairment, and as a result of this perceived new inconsistency, the Member then increases the level of the suspension of concessions without recourse to the procedures of the DSU.

45. However, in this dispute the United States is not seeking redress for any new breach of a covered agreement, but rather continues to apply the suspension of concessions or other obligations already authorized by the DSB. In other words, the United States followed the procedures of the DSU, as required by Article 23. The EC's declaration of compliance did not automatically "undo" the following of those procedures or mean that the United States

automatically is now seeking redress for the EC's measures that the EC has claimed to bring it into compliance.

Q60. *Having regard to the US reference to the DSU negotiations in footnote 202 of its first written submission, could the parties indicate which proposals have been made in that context that would represent amendments to the current text of Articles 21.5, 22.8, 23.1 and 23.2(a) of the DSU?*

46. The United States raised the issue of DSU review in the footnote of its first written submission to highlight the fact that the DSU, as currently written, does not prescribe a particular procedure or approach for how Members must or should proceed in the post-suspension of concessions setting. In attempts to clarify and improve the text of the DSU, several Members have proposed amendments to its text.[9] We are left, for purposes of WTO dispute settlement, with the text of the DSU as written, not as Members, through findings in dispute settlement, would attempt to have it rewritten. Any claims of breach of the provisions of the DSU must be based, and findings premised, on the actual text of the DSU.

Q61. *How does the principle of good faith affect the allocation of burden of proof in these two disputes? What kind of presumption should be made by the Panel if/when applying this principle? Does the application of this principle under the circumstances of the present disputes lead to the conclusion that the EC's implementing measure shall not be presumed WTO-inconsistent? Or, should the conclusion be that the US and Canadian measures of suspension of obligations shall not be presumed to be inconsistent with the DSU? Please elaborate on why one specific conclusion is preferable than the other in your view.*

47. This proceeding does not mark the first time that the EC has argued that there is a presumption of good faith. In the *EC – Bananas (21.5)* proceeding, the EC argued, as in this proceeding, that its measures taken to comply were "presumed to conform with WTO rules unless their conformity has been duly challenged under the appropriate DSU procedures." The panel disagreed, highlighting that there is simply no basis in the WTO Agreement for the EC's argument that it is presumed compliant with its obligations absent a finding against its measures. Similarly, there is no presumption of compliance for the EC's amended ban in this proceeding.

48. There is no presumption of compliance or good faith in WTO dispute settlement that attaches to measures taken by WTO Members. Such a presumption is not found in the text of the DSU, nor is it found in the covered agreements, in the light of relevant provisions of which panels are charged with examining a matter under DSU Article 7.1. The findings of that

[9] A compilation of several of these proposals may be found in the document JOB(03)/10 Rev. 4. Proposals introduced after this compilation document was prepared include JOB(05)/71 (European Communities and Japan), JOB(05)/47 (European Communities and Japan), and JOB(04)/52 (Argentina, Brazil, Canada, India, New Zealand, and Norway).

evaluation then form the basis of the DSB recommendations and rulings, which "cannot add to or diminish the rights and obligations provided in the covered agreements" pursuant to DSU Article 3.2.

49. While DSU Article 3.10 uses the term "good faith", it does not do so in a manner indicating that a presumption of good faith attaches to measures taken by Members. Article 3.10 provides, in relevant part, as follows: "It is understood . . . that, if a dispute arises, all Members will engage in these procedures in good faith in an effort to resolve the dispute." Article 3.10 is not a general incorporation of "good faith" principles of public international law, whatever the precise contours of those might be. On the one hand, Article 3.10 is an understanding, not an obligation. On the other, Article 3.10 simply notes that, when a dispute has been initiated, Members will make best efforts to resolve it. It makes no reference whatsoever to a presumption of good faith which attaches to Member's measures, making them "presumed compliant" or WTO-consistent.

50. Indeed, presumptions *per se* are not applicable in WTO dispute settlement. The only concept that comes close to resembling a presumption in dispute settlement is that the complaining party bears the burden of proof in making its *prima facie* case of the WTO inconsistency of another Member's measure. Rather than a presumption of good faith in dispute settlement, this instead is testament to the fact that there is no presumption of bad faith that attaches to measures taken by a WTO Member.

51. It is unclear why, indeed, such a presumption or principle is necessary, or should be added or inserted into the already clear text of the covered agreements. The established rules of burden of proof in dispute settlement already ensure that a complaining party establish its *prima facie* case, thereby obviating any need for such a presumption.

52. The EC, in its written submission, failed to demonstrate that such a presumption exists in WTO dispute settlement. It cites to dicta in the *Hormones (22.6)* proceeding,[10] but when the arbitrator's statement is viewed in context, it becomes clear that it was simply discussing relevant burdens of proof in WTO dispute settlement, noting that once a Member has claimed WTO-inconsistency of a measure in a dispute, it must prove that this is indeed the case. Indeed, the statement falls squarely under the bold header "**BURDEN OF PROOF**".[11] The arbitrator's dialogue is unexceptional – it is simply a discussion on the need to make a *prima facie* case before another Member's measure can be found to be WTO-inconsistent.

53. Two other disputes cited by the EC, *Canada – Aircraft (21.5)* and *Chile – Alcoholic Beverages,* do not mention a presumption of good faith whatsoever. Rather, they state that there

[10] *See* EC First Written Submission, para. 88.

[11] *See* Decision by the Arbitrators, *European Communities – Measures Concerning Meat and Meat Products (Hormones) – Original Complaint by the United States – Recourse to Arbitration by the European Communities Under Article 22.6 of the DSU*, WT/DS26/ARB, adopted 16 July 1999, at paras. B.8 – B.9.

is no presumption of bad faith in WTO dispute settlement.[12] The United States does not disagree that, in WTO dispute settlement, the initial burden rests with the complaining party alleging a WTO violation. Yet, the EC appears to believe that the concept of good faith would operate only in favor of the EC, by affirmatively demonstrating that all of the steps and actions it has taken are WTO-consistent, and it either believes that no other Member would be able to avail itself of the concept of good faith, or ignores the fact that, if such a presumption existed, it would apply with respect to the United States as the responding party in these proceedings. In these proceedings, the EC, as the complaining party, bears the burden of proving its *prima facie* case against the United States. The EC has failed to satisfy this burden because it has not demonstrated removal of its WTO-inconsistent measure or that it has provided a solution to U.S. nullification or impairment within the meaning of Article 22.8.

54. In addition, the EC cites an ICJ opinion discussing good faith.[13] However, nowhere in the covered agreements is this presumption or principle discussed. As a panel established under Article 6 of the DSU, this Panel is charged under its terms of reference (DSU Article 7.1) with examining this matter "in light of the relevant provisions in [the covered agreements]". The relevant provisions of the DSU and the SPS Agreement do not contain a presumption of good faith in dispute settlement.

Q62. *Do you agree with the view that (i) if an original complaining party initiates an Article 21.5 dispute challenging the consistency of an implementing measure, that party shall bear the burden to prove that the implementing measure is WTO-inconsistent during the compliance procedure, and that (ii) if an original defending party initiates an Article 21.5 dispute claiming the WTO-consistency of its measure, that original defending party shall bear the burden of establishing the consistency of its implementing measure as a complaining party to the Article 21.5 dispute? Please elaborate on your response.*

55. The United States agrees that if an original complaining party initiates an Article 21.5 proceeding challenging the existence or consistency of an implementing measure, it bears the burden of proving the WTO-inconsistency of the measure. This onus on that complaining party is a function of the rules of burden of proof in WTO dispute settlement. Were it otherwise, a complaining party could simply allege that a measure was WTO-inconsistent and obtain a finding to that effect without mounting any case or adducing any evidence of the inconsistency whatsoever.

56. There are certainly disadvantages for an original responding Member invoking an Article 21.5 compliance proceeding. This perhaps explains why the EC has not done so here, although those difficulties were not an obstacle to the EC invoking Article 21.5 as the Member concerned

[12] *See* EC First Written Submission, paras. 89-90.
[13] *See* EC First Written Submission, para. 87.

in the *Bananas* dispute. For example, it is difficult for a Member to have to demonstrate the negative – that there is no inconsistency. However, considering the current text of the DSU and the rules of burden of proof in WTO dispute settlement, an original responding Member would have to make a *prima facie* showing of the WTO-consistency of its measure – a showing that would then have to be rebutted by the original complaining party. As noted in our closing statement at the first substantive meeting, adducing sufficient evidence to make a *prima facie* case of consistency is by no means an insurmountable task. For instance, considering the issues in this dispute, such a case might involve putting forward facts and arguments in support of claims that the EC's amended ban is based on a risk assessment within the meaning of SPS Article 5.1, and a legitimate provisional ban within the meaning of the four cumulative elements of SPS Article 5.7.

Q63. *Would the parties consider that the principle rebus sic stantibus, could apply to a decision of the DSB (see, inter alia, para. 26 of Canada's oral presentation regarding the legal status of DSB decisions)? In its oral comments on Canada's oral presentation, the EC stated that there is no hierarchy in customary international law, the principle of good faith in this case, and a treaty language, the DSB authorization in the current dispute. Could the parties provide evidence that the EC statement is or is not supported by international jurisprudence?*

57. The United States is not completely sure what the Panel had in mind by "the principle *rebus sic stantibus*". The United States is familiar with the use of the term *rebus sic stantibus* as a treaty law doctrine that addresses a fundamental change of circumstances which has occurred with regard to those existing at the time of the conclusion of a treaty, and which was not foreseen by the parties. Article 62(1) of the Vienna Convention on the Law of Treaties provides: "A fundamental change of circumstances may not be invoked as a ground for terminating or withdrawing from a treaty unless: (a) the existence of those circumstances constituted an essential basis of the consent of the parties to be bound by the treaty; and (b) the effect of the change is radically to transform the extent of obligations still to be performed under the treaty." With this background, the United States would like to make the following observations.

58. First, public international law principles (assuming that in its question the Panel had such a principle in mind) are not directly applicable in WTO dispute settlement. Instead, Article 1.1, Appendix 1, and Article 3.2 of the DSU reflect a very conscious choice on the part of WTO Members to limit the use of international law in WTO dispute settlement proceedings to customary rules of treaty interpretation.

59. Second, the United States considers that the doctrine of *rebus sic stantibus*, as described in paragraph 57 above, would not apply directly in WTO dispute settlement, and that even if it were to apply it could not be invoked on the facts of this proceeding.

60. Third, to the extent that the Panel is inquiring whether and how a DSB authorization to suspend concessions can be affected by changes in circumstances after the date of that

authorization, the United States notes that Members addressed those concerns in the text of the DSU itself: DSU Article 22.8 sets out the conditions pursuant to which a WTO Member may no longer apply the suspension of concessions authorized by the DSB.

61. As to the hierarchy of customary international law, international principles and treaty language, the United States would note that the EC's claims against the United States and Canada constitute two separate disputes. In our dispute, we have not advanced the argument to which the EC was reacting.

> Q64. *If the Panel were not able to reach a conclusion on the first claim of the European Communities under DSU Article 23, do you think the Panel should proceed to examine the second claim of violation of Article 22.8 of the DSU?*

62. We have noted on several occasions that an analysis under Article 22.8 of whether the EC has either removed the WTO-inconsistent measure or provided a solution to the nullification or impairment is a logical avenue for resolving the claims raised in this proceeding. For this reason, we think that it is appropriate for the Panel to proceed to an analysis of the EC's Part II claim in the event that it cannot reach a conclusion on the EC's claim under DSU Article 23. However, it is unclear if the EC is pursuing its claim under DSU Article 22.8.

63. Furthermore, the United States emphasizes that as part of its apparent strategy in this proceeding, the EC chose to adduce nothing more than simple assertions of its own compliance in support of its Part II Article 22.8 claim – perhaps because it was the "if and only if" portion of its claims against the United States. We have demonstrated that the EC failed to present evidence sufficient to make its *prima facie* case on this claim, and have also noted that the window of opportunity for the EC to supplement that evidence is effectively shut pursuant to paragraph 13 of the Panel's Working Procedures. Paragraph 13 provides that:

> [t]he parties shall submit all factual evidence to the Panel no later than during the first substantive meeting, except with respect to evidence necessary for purposes of rebuttals, and answers and comments to questions. Exceptions to this procedure will be granted upon a showing of good cause. In such cases, the other parties shall be accorded a period of time for comment, as appropriate.

It is difficult to envision how a complaining party could show good cause for putting forward evidence to make its *prima facie* case for the first time after the first substantive meeting.

> Q65. *Canada and the United States have argued that the EC measure taken to comply with the recommendations and rulings of the DSB in the Hormones case are incompatible with Article 5.1 and 5.7 of the SPS Agreement. However, the European Communities does not make any reference to these provisions, either in its request for establishment of the panel, or in its first written submission. Do the parties believe that the Panel has, nonetheless, jurisdiction to review the*

compatibility of the EC implementing measure with Articles 3.3, 5.1 and 5.7 of the SPS Agreement? On what legal basis should the Panel consider itself entitled/not entitled to address the arguments of Canada and the United States in relation to the SPS Agreement?

64. The United States has argued that the EC's amended ban is neither based on a risk assessment for purposes of Article 5.1 of the SPS Agreement, nor a provisional measure within the meaning of SPS Article 5.7. Pursuant to DSU Article 7, a panel's standard terms of reference include the provisions referred to by the responding party. Those standard terms of reference provide that a panel is to "examine, in light of the relevant provisions in (name of the covered agreement(s) cited by the parties to the dispute)" – the use of the plural "parties" makes it clear that it is not just the provisions cited by the complaining party to which a panel may look.[14] The United States has argued that it was the EC's burden, in making its *prima facie* case of a U.S. breach of DSU Article 22.8, to demonstrate that it has implemented the DSB's recommendations and rulings in order to establish that it had satisfied the requirements of Article 22.8. Such a demonstration is integral to the EC's Article 22.8 claim against the United States, and an examination of the compatibility of the EC ban with SPS Articles 3.3, 5.1 and 5.7 is clearly within the purview or jurisdiction of this Panel. We have demonstrated that the EC has failed to make its *prima facie* case of a U.S. breach of Article 22.8 by failing to support its claim with anything more than simple assertions.

Q66. *In this particular case, would it be for the European Communities to prove the compatibility of its measure with Article 5.7 of the SPS Agreement because it applies certain aspects of that measure provisionally or would it be for Canada and the United States to demonstrate a violation of Article 5.7 because they consider that the EC measure is in breach of that provision? Could the parties discuss the application of the burden of proof in relation to Article 5.7 in light of the panels and Appellate Body findings with respect to that provision in Japan-Agricultural Products II and Japan - Apples?*

65. In this case, it would be for the EC to make a *prima facie* case of its measure's compatibility with SPS Article 5.7 as part of its DSU Article 22.8 claim against the United States (*i.e.*, that it has either removed the WTO-inconsistent measure or provided a solution to nullification or impairment). The EC alleges to have implemented the DSB's recommendations and rulings through the vehicle of a "provisional" measure within the meaning of Article 5.7.[15] Therefore, consistent with previous examinations of the Article as well as with previous applications of burden of proof in SPS disputes, the EC must demonstrate how the "provisional"

[14] If it were otherwise, a panel could not, for example, consider a provision that a responding party has cited as an affirmative defense if the complaining party did not include that provision in its panel request.

[15] *See* EC First Written Submission, paras. 17 (in which the EC asserts its compliance with DSB recommendations and rulings) and 137 *et seq*. (in which the EC asserts it compliance with DSB recommendations and rulings for purposes of its "Part II" Article 22.8 claim).

measure satisfies the cumulative elements set out in SPS Article 5.7. As highlighted in *Japan – Apples*, when a Member applies a ban it deems to be "provisional", and puts a sanitary or phytosanitary measure into effect that is not based on a risk assessment (as required by Article 5.1), the onus falls on that Member to demonstrate why it is justified in doing so.[16]

Q67. *Do the parties consider that Article 5.7 applies only when no risk assessment can be made at all or also when scientific evidence exists but is insufficiently specific?*

66. WTO Members are obligated to base their sanitary measures on a risk assessment, as appropriate to the circumstances.[17] As noted by the Appellate Body, this requirement is a specific application of SPS Article 2.2's requirement that Members ensure that any sanitary measures are, *inter alia*, "not maintained without sufficient scientific evidence."[18] In the course of conducting a risk assessment, a Member takes into account available scientific evidence in reaching its conclusions and in defining and evaluating the likelihood of a particular risk.[19]

67. Article 5.7 applies when a Member is unable to complete a risk assessment, as envisioned by Article 5.1 and paragraph 4 of Annex A to the SPS Agreement. One of the four conditions for provisionally adopting a sanitary measure pursuant to Article 5.7 is that the "scientific evidence is insufficient." As noted by the Appellate Body in Japan – Apples, "relevant scientific evidence" will be "insufficient" within the meaning of Article 5.7:

> if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement. Thus, the question is not whether there is sufficient evidence of a general nature or whether there is sufficient evidence related to a specific aspect of a [] problem, or a specific risk. The question is whether the relevant evidence, be it "general" or "specific", in the Panel's parlance, is sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.[20]

In other words, the relevant question is not the specificity of the evidence relating to the five hormones, but rather whether all the evidence relating to those hormones, *in toto*, permits the EC to conduct a risk assessment for those hormones.

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[16] *See* Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, AB-2003-4, WT/DS245/AB/R, adopted 10 December 2003 ("*Japan – Apples*"), para. 175. ("Japan relied on Article 5.7 only in the event that the Panel rejected Japan's view that 'sufficient scientific evidence' exists to maintain the measure within the meaning of Article 2.2. It is in this particular context that the Panel assigned the burden of proof to Japan to make a *prima facie* case in support of its position under Article 5.7.")

[17] *See* SPS Article 5.1.

[18] *See* Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, AB-1997-4, WT/DS26/AB/R, WT/DS48/AB/R, adopted 26 July 1999 ("*EC – Hormones*"), para. 180.

[19] *See* SPS Agreement, Annex A, para. 4.

[20] Appellate Body Report, *Japan – Apples*, para. 179. (Emphasis added).

68. The simple fact is that there is ample evidence to conduct a risk assessment on the five hormones – JECFA, the relevant international risk assessing body has done so, as have numerous individual national regulatory bodies. Any new studies developed by the EC, assuming that they indeed support the conclusions they are put forward in support of,[21] could be considered together with the extensive history of study of the five hormones in conducting a risk assessment as appropriate to the circumstances. In the case at hand, while any new studies could hypothetically affect the conclusion of the risk assessment, their existence would not make the scientific evidence "insufficient" for conducting such an assessment.

Q68. *Do all parties agree that the term "on the basis" in Article 5.7 of the SPS Agreement has the same meaning as "on the basis" in Article 5.1, i.e. that a "rational relationship" is required?*

69. The United States agrees that the phrase "on the basis of" in SPS Article 5.7 has the same meaning as "based on" in SPS Article 5.1. Indeed, the definition of "basis" cross-references the noun form of "base".[22] Therefore, if a measure is maintained "on the basis of [available pertinent information]" within the meaning of Article 5.7, that measure should bear a rational relationship to, or be sufficiently warranted by, the available pertinent information.

Q69. *During the EC - Hormones proceedings, the European Communities was of the view that "the scientific evidence concerning the need to regulate the use of hormones was in itself sufficient to justify its legislation and the European Communities did not need to rely on the exception provided for in Article 5.7 concerning cases where relevant scientific evidence was insufficient" (DS26/R/USA, para.4.239). Does this mean that "the evidence concerning the need to regulate the use of hormones generally" is different from the specific evidence concerning the health risk associated with the administration of hormones in animals for growth promotion purpose? Is there sufficient evidence concerning the latter?*

70. As the United States demonstrated in its first written submission, scientific evidence concerning the need to regulate the use of hormones generally is different from specific evidence concerning the health risk associated with consumption of meat and meat products from cattle

[21] *See* Panel Report, *Japan – Measures Affecting the Importation of Apples – Recourse to Article 21.5 of the DSU by the United States*, WT/DS245/RW, adopted 20 July 2005 ("*Japan – Apples (21.5)*"), para. 8.145 (noting that in order to complete a risk assessment appropriate to the circumstances within the meaning of SPS Article 5.1, the scientific evidence underpinning the risk assessment must support the conclusions reached in that risk assessment).

[22] *See* New Shorter Oxford English Dictionary (Brown, L. ed.) (1993), p. 188.

treated with hormones for growth promotion purposes, and there is sufficient evidence concerning the latter.[23]

71. A key principle of toxicology that helps to distinguish between general and specific instances of risk from substances in the diet is that risk is a function of both hazard (*i.e.*, toxicity) and exposure. For this reason, it is critical to consider the risk from use of hormones in meat and meat products for growth promotion according to good veterinary practices.

72. The EC does not consider whether consumer dietary exposure to hormone residues in meat and meat products from cattle is specifically a source of risk. Although the EC's hazard identification might indeed be relevant to general considerations regarding hormones (*e.g.*, that there can be circumstances such as those occurring under therapeutic administration of high doses, in which hormone use can cause harm), the EC fails to assess the specific risks at issue in this dispute because they do not consider the available evidence directly related to the expected doses from dietary exposures to hormones. In particular, the EC did not make use of relevant bioavailability data, and used unrealistic scenarios to calculate possible exposure estimates.

73. When conducting a risk assessment, results from laboratory and population studies are commonly used to identify a hazard and its biochemical mechanisms. Often, laboratory studies are performed, *e.g.*, using high doses of compound administered by injection into muscle. High doses are used to maximize the likelihood of observing a statistically significant change or the specific hypothesized adverse consequences. However, for the results of these kinds of high dose studies to be useful in estimating human health risks from an alternate exposure pathway, *e.g.*, oral ingestion, the results from the high dose studies must be evaluated in light of information on the uptake, distribution and elimination of the compound via that alternate pathway. It is only by taking such information into account that one can determine whether the compound of interest is biologically available in the body such that it can affect target tissues.

74. The EC's Opinions simply did not consider the significance of dosage and bioavailability of hormones by the oral route of exposure. For example, as noted in paragraph 156 and footnote 165 of our first written submission, when taken orally, estradiol 17ß is largely inactivated via the gastrointestinal tract and liver. This is one reason why, when estradiol 17ß is used in human oral therapies such as hormone replacement therapy, the daily dose has to be 500 to 20,000 times higher than what would be ingested through eating meat from treated animals (0.03-0.05 micrograms of estradiol 17ß per person per day, versus daily human dosages of 25-1000 micrograms in post-menopausal hormonal therapies). Similar points were made by JECFA in its 52nd report in 2000. For instance: "[e]stradiol is generally considered to be inactive when administered orally due to gastrointestinal and/or hepatic inactivation"[24]; "[p]rogesterone is largely inactive when administered by the oral route because of its low systemic

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[23] *See* U.S. First Written Submission, paras. 68, 69, 140 - 147, and 150 - 160.

[24] 52nd JECFA Report (2000), p. 45. (Exhibit US-5).

bioavailability"[25]; and "[t]estosterone is generally considered to be inactive when administered orally due to gastrointestinal and/or hepatic inactivation. Maintenance of physiological concentrations after injection is also difficult because of its rapid clearance."[26]

75. The EC's Opinions also employ highly unrealistic scenarios to support the assertion that there is "a considerable risk that highly contaminated meats could enter the food chain."[27] For example, the EC hypothesizes that: animals are implanted at or just before slaughter, despite the fact that implanting close to slaughter would serve no growth promotion purposes; the implants are incorrectly and illegally implanted into an edible part of the animal; the illegal implant sites are undetected during slaughter inspection, and the implants themselves are undetected during processing, retail handling and preparation; and the implants and surrounding tissue are processed and sold in single units such that single individuals are exposed to the full dose administered to a single cow.[28]

Q70. *Having regard to the statement of the United States in paragraphs 151-152 of the first US written submission, the Panel notes that Article 5.7 of the SPS Agreement talks about "available pertinent information" on the health risk. In the parties' views, does this mean that the "available pertinent information" under the circumstances of the current disputes refer to the information on risks associated with the consumption of meat from animals treated with hormones for growth promotion purposes according to good veterinary practice? Or, does it refer to the risk of the five hormones to human health generally?*

76. The U.S. does not consider it necessary for the Panel to address the question of what would constitute "available pertinent information" under Article 5.7 for purposes of this dispute because this is not a dispute in which relevant scientific evidence is insufficient for a risk assessment to be conducted.

77. In any event, the United States considers that in the context of this dispute, "available pertinent information" refers to "information on risks associated with the consumption of meat from animals treated with hormones for growth promotion purposes according to good veterinary practice" because this is the information that addresses the specific question about risks from consumption of meat treated with hormones for growth promotion purposes. Although current risk assessment principles call for evaluation of general evidence for possible harm (and risks) in

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[25] 52nd JECFA Report (2000), p. 79. (Exhibit US-5).

[26] 52nd JECFA Report (2000), p. 88. (Exhibit US-5).

[27] "Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on Review of previous SCVPH opinions of 30 April 1999 and 3 May 2000 on the potential risks to human health from hormone residues in bovine meat and meat products", 10 April 2002 ("2002 Opinion"), p. 21. (Exhibit US-1).

[28] *See*, *e.g.*, 2002 Opinion, p. 11-12; *see also* "Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health – Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products", 30 April 1999 ("1999 Opinion"), pp. 31-32. (Exhibit US-4).

the initial stage of a risk assessment (that is, the hazard identification stage), this does not excuse the failure by the EC to consider available pertinent information pertaining to the specific risk in question. Presently, the EC's failure to consider available pertinent information relevant to the assessment of actual human exposures from the hazard of concern (*i.e.*, hormones in meat) is not justified given the information available to the EC, including relevant international standards for the five hormones and their underpinning studies.

Q71. *Article 5.7 of the SPS Agreement requires that a Member review the measure within a reasonable period of time. In the parties' view, how long should this reasonable period of time be in this case? At which point of time should the calculation of the reasonable period of time start? Has the European Communities conducted such a review after the adoption of Directive 2003/74/EC in September 2003? What is the plan of the European Communities to conduct such review?*

78. The "reasonable period of time" contemplated in the fourth cumulative requirement of SPS Article 5.7 is not a fixed period, but rather reflects circumstances on a case-by-case basis.[29] In the *Varietals* dispute, in making its finding that Japan had not reviewed its measure within a reasonable period of time, the panel noted that Japan's import ban had been in place for "almost 30 years and, with respect to the specific products and pest at issue, for 20 years. During this period of time Japan has been in a position to obtain further information on varietal differences and their relevance to quarantine efficacy."[30] Similarly, the EC import ban on meat treated with the five hormones for growth promotion purposes has been in place for over fifteen years. As the United States has previously noted, there was sufficient scientific information enabling the EC to conduct a risk assessment well before it instituted its import ban, and in the original panel proceeding the EC insisted that it had sufficient scientific evidence to conduct a risk assessment and that Article 5.7 was not applicable.[31] These facts, plus the fact that other risk assessments on hormones have been completed during the fifteen years that the ban has been in place, are clear indications that the EC has had a reasonable period of time to conduct a review of its measure.

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[29] *See* Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, AB-1998-8, WT/DS76/AB/R, adopted 19 March 1999 ("*Japan – Varietals*"), para. 93. ("The second part of the second sentence of Article 5.7 stipulates that the Member adopting a provisional SPS measure shall 'review the … measure accordingly within a reasonable period of time.' In our view, what constitutes a 'reasonable period of time' has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure. In the present case, the Panel found that collecting the necessary additional information would be relatively easy. Although the obligation 'to review' the varietal testing requirement has only been in existence since 1 January 1995, we agree with the Panel that Japan has not reviewed its varietal testing requirement 'within a reasonable period of time'.") (Internal citations omitted).

[30] *See* Panel Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/R, adopted 19 March 1999 ("*Japan – Varietals*"), paras. 8.57-8.58.

[31] *See* Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, adopted 26 July 1999 ("*EC – Hormones*"), para. 4.239.

79. The Appellate Body noted that, in light of the fact that a "reasonable period of time" may vary on a case-by-case basis, one of the factors a panel should take into account in making this determination is the "difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure."[32] As we have noted, there is already a substantial body of evidence available for completing a risk assessment on the five "provisionally" banned hormones, placing into doubt what "additional information" whatsoever might be required to review the amended ban. In addition, taking into account the characteristics or severity of the "provisional" measure – an outright ban on U.S. meat and meat products treated with the five hormones – one could envision a relatively short "reasonable period" due to the extreme nature of the measure.

Q72. *Please explain what you understand to be the relationship between Article 3.1 and Article 5.7 of the SPS Agreement?*

80. WTO Members are required to (1) base their measures on a risk assessment pursuant to SPS Article 5.1, as well as (2) base their sanitary measures on international standards where they exist pursuant to SPS Article 3.1. In the event that a Member introduces a measure that achieves a "higher level of sanitary . . . protection than would be achieved by measures based on the relevant international standards" within the meaning of Article 3.3 of the SPS Agreement, it must have a scientific justification for doing so. The Appellate Body in the original *Hormones* dispute agreed with a panel finding that WTO Members are required by SPS Article 3.3 to satisfy the requirements of Article 5.1.

81. SPS Article 5.7, which deals with provisional measures, is an exception to Article 2.2's requirement that Members not maintain their measures without sufficient scientific evidence, and by extension Article 5.1's requirement that they base their measures on a risk assessment. While the United States believes that there can be situations in which there is insufficient scientific information for a Member to perform a risk assessment even when an international standard exists, the simple fact in this dispute is that international standards and a significant body of scientific studies exist on the risks posed by the five hormones. It would therefore be very difficult to demonstrate that the relevant conditions of Article 5.7 have been satisfied, *e.g.*, that there is insufficient scientific evidence concerning the hormones.

Q73. *Do you consider it possible that scientific evidence may be judged to be sufficient to undertake a risk assessment at a particular point in time, and yet considered to be insufficient for the same purpose several years later? Does the fact that a significant number of scientific studies have been undertaken with regard to these potential risks in the intervening years have any relevance for your response? Does the existence of international standards have any relevance? Please explain.*

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[32] *See* Appellate Body Report, *Japan – Varietals*, para. 93.

82. Although it is not the case here (*see* U.S. answer to Panel question 69), it is possible that, if scientific evidence is sufficient to conduct a proper risk assessment at one point in time, it will later be insufficient to conduct such an assessment. Such a situation might arise, for example, when evidence of a new pathway for a risk comes to light, but the data concerning that pathway, while sufficient to identify it, is not adequate to perform a risk assessment. International standards serve as an indicator that evidence is sufficient to conduct a risk assessment. However, because Members may be able to react more quickly to new information than international standard setting bodies, the existence of international standards is not dispositive under SPS Article 5.7.

Q74. *Assuming the Panel deems it necessary to determine whether the European Communities revised measure complies with certain provisions of the SPS Agreement, do the parties consider that the consultation of scientific experts would be necessary or only useful? What would be the issues on which experts should be consulted? To the extent feasible, should the Panel consult the experts consulted in the EC - Hormones case?*

83. We believe that the scientific issues in this dispute, as they were almost ten years ago, are clear, and that the EC's Opinions and the "new" studies on which they rely do not demonstrate any risk or justification for its import ban, and that therefore there is technically no need to consult experts in this proceeding. However, we recognize that the Panel, in a scientific dispute such as this, may wish to consult with experts on the scientific evidence in developing its analysis and making its findings, and we appreciate the Panel's discretion to do so.

84. In the event that the Panel chooses to consult scientific experts, the United States believes that scientific experts can provide a panel with vital perspectives, information and advice on technical issues.[33] At the same time, it is clear that a panel cannot delegate to experts the panel's central task of interpreting the covered agreements cited in a dispute. Experts may advise only on factual issues, not on the application of the legal standards in the covered agreements to the facts at hand. In terms of what those factual issues might be, we would expect the experts to examine, among other things, the EC's 17 studies and its Opinions.

85. As to whether the Panel should, to the extent feasible, consult with the scientific experts from the original *EC – Hormones* proceedings, we would note that the process by which the original experts were selected differed from that which evolved over the course of subsequent disputes. In the original proceedings, two of the experts were selected by the parties themselves, whereas under the current process, the panel selects the experts following consultation with the parties. We would suggest that the group of experts be selected pursuant to current practice, which would mean that the three experts selected by the original panel should be consulted.

[33] *See* Article 11.2 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* and Article 13 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes*.

TABLE OF EXHIBITS

Exhibit US-	Title of Exhibit
21	Letter dated June 17, 1999, from Jane E. Henney, M.D., Commissioner of Food and Drugs, to Mr. Horst Reichenbach, Director General, DG XXIV
22	EC PowerPoint presentation, Fall 2003