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

**Responses of the United States to Questions from the Panel after the Second Substantive Meeting**

**October 18, 2006**

## A. Questions to the all the Parties:

Q1. *With reference to the statement by the European Communities, inter alia in para. 12 of the EC reply to Question 3 of the United States, do the parties consider that a Panel is entitled to address "systemic claims" or issues related to "systemic obligations" and, if so, to what extent?*

1. As noted in U.S. Question 3 to the European Communities ("EC"), "systemic" and "direct" are terms used by the EC to describe its claims against the United States.[1] Each of the EC's "in conjunction with" claims, through which it seeks to recast several provisions of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU"), are couched as "systemic", while the EC claim of a U.S. breach of DSU Article 22.8 (in and of itself) is described by the EC as a "direct claim." Neither of these terms appears in the DSU, nor are they part of customary rules of interpretation of public international law, as reflected in Articles 31 and 32 of the Vienna Convention on the Law of Treaties.

2. The question is not one of whether the EC has characterized one of its claims as "systemic" or "direct." Indeed, it is unclear what, exactly, the EC means when it uses these terms, other than to indicate in the case of a "systemic" claim that it is unable to identify a particular obligation in a specific provision of the DSU which the United States had allegedly breached. Rather, it is the role of the Panel to examine the actual obligations set out in the DSU as it is currently drafted, and to analyze the arguments of the United States and the EC in light of those obligations. Any EC claim must be grounded in the actual text of the DSU. As the United States has argued in several of its previous submissions, the EC claims which it terms "systemic" merely reflect how the EC would like to see the DSU redrafted, at least for purposes of this dispute. Through its "systemic" claims, the EC seeks license to depart from the agreed text of the DSU so as to insinuate new obligations into several provisions of the DSU. The United States has demonstrated that there is no basis for finding a U.S. breach of these so-called "systemic" obligations.

Q2. *With reference to the US rebuttal, para. 27, do the parties consider that a measure that does not comply with the requirements of Article 5.7 SPS would automatically be in breach of Article 2.2 SPS, or Article 5.1 SPS, or both?*

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[1] U.S. Questions to the EC, Question 3.

3. Article 5.7 applies "[i]n cases where relevant scientific evidence is insufficient" to perform a risk assessment.[2] Accordingly, an analysis under Article 5.7 presupposes that there is, or may be, a breach of Article 5.1 or Article 2.2; otherwise, it would not be necessary for the Member maintaining a measure to assert that the requirements of Article 5.7 have been met.

4. In original proceedings brought against a measure, the question of whether the requirements of Article 5.7 have been met might arise in response to a claim that a measure is inconsistent with Article 2.2 or Article 5.1. In such a proceeding, the complaining party would have the burden of establishing a breach of Article 2.2 and/or Article 5.1. It would not be sufficient for the complaining party to demonstrate that the requirements of Article 5.7 have not been met in order "automatically" to establish a breach of Articles 2.2 and 5.1. For example, where there is sufficient scientific evidence to perform a risk assessment, a Member may not provisionally adopt a measure pursuant to Article 5.7. However, this is a separate question from whether a risk assessment within the meaning of Article 5.1 has actually been performed.[3]

5. In this dispute, the Dispute Settlement Body ("DSB") has already ruled that the EC import bans on meat from cattle treated with the five hormones (for which the EC now asserts that the conditions of Article 5.7 have been met) breach Article 5.1. The EC does not claim to have performed a risk assessment consistent with Article 5.1. Against that background, the question in this dispute is whether the EC has established, in pursuing its claim under Article 22.8, that the EC has provided a solution to the nullification or impairment caused by the breach of Article 5.1 because the conditions of Article 5.7 have been met. Since the Article 5.7 conditions have not been met, the EC has not demonstrated that it has provided a solution to the nullification and impairment found by the DSB. In that sense, the failure to meet the requirements of Article 5.7 "automatically" leads to the conclusion that the Article 5.1 breach found by the DSB has not been removed.

Q3. *When and how was each of the following documents made available to Canada and the United States? Please answer independently for each of the documents mentioned below:*

*(i) 1999 Opinion;*
*(ii) 2000 Opinion;*
*(iii) 2002 Opinion;*
*(iv) each of the "17 studies".*

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[2] Appellate Body Report, *Japan – Apples*, para. 179.

[3] At the same time, the United States recognizes that a responding Member would likely only have raised Article 5.7 in the context where the responding Member does not claim to have performed a risk assessment meeting the requirements of Article 5.1 or that there is sufficient scientific evidence for purposes of Article 2.2. In that situation, there would appear to be no dispute that there would be a breach of Article 5.1 or 2.2 if the requirements of Article 5.7 are not met, and in that sense the breach of Article 5.1 or 2.2 would be "automatic."

6. As noted in the U.S. response to Panel Question 49 after the first substantive meeting, the EC contacted the United States in 1999 to inform relevant U.S. regulatory agencies of its completion of the 1999 Opinion on the six hormones at issue in the *EC – Hormones* dispute. At that time, the U.S. Food and Drug Administration ("FDA") and Department of Agriculture ("USDA") reviewed the documents put forward by the EC. The response to those documents is contained in Exhibit US-21. The United States and the EC then met during the summer of 1999 to discuss the results of the EC's 1999 Opinion.

7. We have been unable to locate any records indicating that the EC provided 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 record of a requested discussion or conference on the scientific underpinnings of the EC's ban once it asserted in the fall of 2003 that it had developed a risk assessment and brought its measure into conformity with DSB recommendations and rulings.

8. 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. However, the EC did not provide any information on its 2000 Review or 2002 Opinion, nor did it present any information on the scientific conclusions and analyses it viewed as supporting its amended ban. A copy of this presentation may be found in Exhibit US-22.

9. The United States sent the EC an SPS Article 5.8 request in the fall of 2004, to which the EC responded on May 19, 2005. A copy of the Article 5.8 request and the EC's response may be found at Exhibit US-23. The EC's response contained internet links for the 2000 Review and 2002 Opinion.

10. At no point in time prior to the initiation of this dispute was the United States in possession of all of the "17 Studies" ostensibly underpinning the EC's "risk assessment." These materials were not provided by the EC in its response to the U.S. Article 5.8 request and were produced in a piecemeal fashion throughout these proceedings. We have discussed the EC's failure to produce these studies in detail in the U.S. Rebuttal Submission (paras. 19-22) and have chronicled the (lack of) availability of these studies in Table 1 to that Submission.

> Q4. *Has the European Communities assessed in a systematic manner the existence and level of risks from failure to observe good veterinary practices with respect to the administration of oestradiol 17ß as a growth promoting hormone to cattle, in particular in the United States' and Canada's markets? If so, please indicate where this assessment is to be found in the evidence provided to the Panel.*

11. The EC has not assessed the existence and level of risks from failure to observe good veterinary practices with respect to the administration of estradiol 17ß as a growth promoting hormone to cattle in the United States. In fact, the EC has not even seriously argued in the course of these proceedings that it has done so.

12. As noted by the United States in several of its submissions, the EC presented a number of unrealistic misuse scenarios. However, the actual occurrence of these scenarios in U.S. feedlots is purely speculative and unsupported by evidence.[4] For example, in its 1999 Opinion, from pages 30-31 (§ 3.3), the EC presents several hypothetical misuse scenarios but fails to assess the probability that any of these scenarios would occur. The EC postulates that ears from cattle containing growth promoting implants will enter the human food supply. When the United States asked whether the EC had provided any evidence that this has ever occurred or would ever occur, the experts (Drs. Boobis and De Brabander) noted that there was no such evidence. The EC also concludes that there is a risk that a black market will exist in the United States for estradiol 17β. (1999 Opinion, § 3.3.3). However, the only evidence on the record regarding the existence of a black market demonstrates that such a market exists in the EC, where use of the hormone as a growth promoter has been banned. Not only does the EC fail to provide evidence of or assess the potential for misuse in its 1999 Opinion, even if one were to assume misuse, the EC has failed to provide any evidence that violative residue levels would result except in the most extreme overdosing circumstances.[5]

13. In its Exhibit EC-73, the EC discusses several hypothetical misuse scenarios but similarly fails to assess, in any meaningful way, the likelihood of the occurrence of any of these scenarios in U.S. feedlots. For example, the EC asserts that "stacking" of implants (*i.e.*, treatment with more than one dose of an implant at the same time) is commonplace in the United States.[6] However, the evidence cited by the EC to support this argument – a guidance document from the University of Nebraska – does not stand for this conclusion. This fact was confirmed by the author of the guidance cited by the EC.[7] Further, the EC fails to examine the actual workings of the U.S. food safety system both in this document and in each of the three Opinions comprising its "risk assessment." The United States has discussed the actual workings of the U.S. food safety system at length and has demonstrated that the EC's speculation that a risk of failure exists is not based on any evaluation of any evidence.[8]

14. It is essential to recall the views of the scientific experts on the issue of whether or not the EC has indeed assessed the risk of a failure to meet GVPs. Dr. Boisseau noted that "as the [EC] did not conduct any quantitative risk assessment for growth promoters, it is not possible to say that the scientific evidence referred to by the [EC] assesses the risk to human health from residues resulting from these misuses/abuses."[9] Dr. Boobis agreed, stating: "[t]here was no attempt to evaluate the risks from the resultant exposures on misuse or abuse, either in the papers cited or by the SCVPH (2002) in their evaluation of these studies. Indeed, the SCVPH (2002)

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[4] The United States discusses the EC's failure to assess the risk of misuse (or failure to satisfy good veterinary practices) at length in its Rebuttal Submission (pages 21-30) and its Oral Statement at the Second Substantive Meeting (Expert Issues) (paras. 60-67).

[5] *See* U.S. Rebuttal Submission (pages 21-30); Dr. Boobis' Response to Panel Question 62.

[6] Exhibit EC-73.

[7] *See* Letter from Dr. Dee Griffin, Exhibit US-28; U.S. Rebuttal Submission, paras. 60-63.

[8] *See* U.S. Rebuttal Submission, para. 55; U.S. Comments on the Experts' Responses, paras. 105-106.

[9] Dr. Boisseau Responses (Question 48), p. 24.

simply noted that '[t]herefore, these data have to be considered in any quantitative exposure assessment exercise', without undertaking such an exercise."[10] While Dr. De Brabander appears to disagree with Drs. Boobis and Boisseau, his responses fail to indicate whether or not he is of the opinion that the EC actually assessed the risk of misuse, and in several instances his opinions are simply based on anecdotal information and policy considerations, rather than scientific evidence or citations to the EC's purported risk assessments.[11]

15. Finally, it is necessary to recall that, even if one assumed that the EC actually assessed the risk of a failure to meet GVPs, the scientific evidence put forward by the EC indicates that violative residues in meat would only occur as a result of that failure in the most extreme circumstances. Dr. Boobis provides a thorough review of the EC's materials in his response to Panel Question 62 (at pages 50-52). The United States has also reviewed these EC materials and commented on their failure to demonstrate violative residues except for in the most unrealistic scenarios.[12]

Q5. *In its comments on comments of the United States and Canada on experts replies to the Panel questions (in particular Question 13), the European Communities indicates that oestradiol 17ß might be a "weak genotoxin" (para. 44). At what doses is genotoxicity observable in vivo? How are these doses comparable to those found in meat from cattle treated with growth promoting hormones? How would this assertion affect the identification of adverse effects and the evaluation of potential occurrence of these effects from consumption of meat from cattle treated with oestradiol 17ß for growth promotion purposes?*

16. To date, the EC has presented only one study (out of 127 Exhibits) which addresses genotoxicity of estradiol 17 *in vivo*.[13] In Exhibit EC-125, rats were treated with 5 milligrams of estradiol 17 . This dose of estradiol 17 resulted in a two-fold increase in the number of mutations in mammary tissue. However, as discussed in the meeting with the experts, the results of this study are highly questionable for a number of reasons, and the doses involved in the study

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[10] Dr. Boobis Responses (Question 48), p. 42. *See* Dr. Boobis Responses (Question 62), p. 52 ("the data generated by the EU research in question do not provide any indication that it is not possible to conduct a risk assessment of the hormones used as growth promoters.")

[11] *See*, *e.g.*, U.S. Comments on the Responses of the Experts, para. 107.

[12] *See* U.S. Comments on the Experts' Responses, Section C.6; U.S. Rebuttal Submission, Section II.B.4.

[13] In paragraph 43 of its Comments on the US and Canada's Comments on the Experts' Replies, the EC claims to have "sufficient and constantly growing evidence from studies in vivo that show the direct genotoxicity of oestradiol 17 and its catechol metabolites...". However, U.S. review of the studies listed in paragraph 43 reveals that only one, EC-125, demonstrated genotoxicity of estradiol 17 *in vivo* (and only then at irrelevant doses) while the other studies were performed only with catechol metabolites. This fact was confirmed by Dr. Metzler, member of the EC delegation, at the meeting with the experts on September 28, 2006. The distinction between estradiol 17 and its catechol metabolites is important because the EC has presented no evidence to show that the catechol metabolites are present *in vivo* at levels comparable to those which produce genotoxic effects *in vitro*. Moreover, the EC has presented no evidence to show that consumption of estradiol 17 residues in beef affects the production of catechol metabolites whatsoever.

are not comparable to residue levels found in meat from cattle treated with estradiol for growth promotion purposes.[14] Indeed, the doses are exponentially greater than those necessary to elicit biological or endocrine effects (in other words, they are well above the hormonal threshold).

17. To compare the dose of estradiol 17 used in EC-125 to levels found in meat from cattle treated with growth promoting hormones, it is necessary to examine the dose relative to body weight. A laboratory rat weighs approximately 250 grams. Therefore, the dosage administered to the rats in EC-125 was 5 milligrams/250 grams, or 20 milligrams/kilogram. If a human (average weight of 70 kg.) were treated with an equivalent dose of estradiol 17 , the dose would be 1400 mg (20 milligrams/kilogram x 70 kg). This dose is exponentially greater than residue levels found in meat from cattle treated with estradiol for growth promotion purposes. According to JECFA,[15] a conservative estimate of the amount of estradiol 17 in a 250 gram serving of meat from treated cattle is between 15 and 25 nanograms, or 0.000015-0.000025 milligrams. In other words, in relative terms, the dose administered to the rats in the EC's study (Exhibit EC-125) is more than 50 million times greater than the amount of estradiol residues consumed by humans in meat from treated cattle.

18. Therefore, the dose of estradiol 17 administered to rats in EC-125 was astronomically higher than that derived from eating a serving of beef from treated cattle. The difference is even greater when one takes into account the different routes of administration of estradiol 17 . The rats in the study were treated estradiol 17 via subcutaneous implants, which results in very high bioavailability. In contrast, only a small percentage ($\leq$ 10%) of orally-ingested estradiol 17 is bioavailable due to rapid metabolism in the liver and small intestine. So, not only was the dose exponentially greater in the rat study but the dose was much more bioavailable than would be the case from consuming residues in meat. For these reasons, this study is not relevant to the purported risk to human health associated with eating meat from cattle treated with growth-promoting hormones.

## B. Questions to the United States and Canada:

Q17. *What legal procedures were used in your respective domestic legal systems to adopt the suspensions of obligations at issue? Would the same legal procedures apply to their abrogation?*

19. Under the U.S. legal system, the applicable authorities and procedures are set out in Sections 301-309 of the Trade Act of 1974, as amended (codified at 19 U.S.C. 2411-2419) (commonly referred to as "Section 301").

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[14] *See* paragraphs 27-29 of U.S. Oral Statement at the Second Substantive Meeting (Expert Issues).

[15] *See* "Evaluation of certain veterinary drug residues in food", Fifty-Second Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report Series: 893 (2000) ("52nd JECFA Report"), p. 83. (Exhibit US-5).

20. Suspension of obligations: On July 12, 1999, the arbitrator determined that the level of nullification and impairment suffered by the United States in this dispute was $116.8 million per year, and that the United States was entitled to suspend the application of tariff concessions up to that amount. On July 26, the DSB authorized the United States to suspend the application of tariff concessions in this amount. In accordance with the arbitrator's report and DSB authorization, the USTR determined that appropriate action under Section 301 in response to the EC's failure to comply with the DSB recommendations and rulings was to suspend the application of tariff concessions and increase tariffs on a specific list of EC products with an annual trade value of $116.8 million. The USTR then published a *Federal Register* notice announcing the suspension of concessions in the form of increased duties on specific products of the EC.

21. Termination of Suspension: Section 301 provides that the USTR may terminate an action previously taken under Section 301 if, *inter alia*, the DSB adopts a report finding that the rights of the United States under the trade agreement are not being denied. Section 301 requires USTR to consult prior to terminating any action. Upon making such a determination, USTR would publish a notice in the *Federal Register* announcing the termination of the suspension of concessions and the restoration of regular MFN rates of duties on the affected products.

Q18. *Would you consider that, for the purpose of the DSU, Directive 2003/74/EC should be viewed as a new measure or as the continuation of the previous measure found to be inconsistent with the WTO Agreement, since it still imposes a ban?*

22. Since the United States is not the complaining party, there is no challenge to an EC measure in this dispute as such. Rather, the question is whether the EC has demonstrated, within the meaning of Article 22.8 of the DSU, that the EC has removed its WTO-inconsistent measures or has provided a solution to the nullification or impairment.[16] If the EC has simply continued its WTO-inconsistent measure, then there would be no solution to the nullification or impairment. If the EC has not demonstrated that it has solved the nullification or impairment through a new or revised measure, then the EC has not met its burden under Article 22.8. Accordingly, the United States has not argued that the EC's amended bans are or are not new measures for purposes of the DSU. Rather, we view the pertinent question to be whether or not the EC's bans in fact bring it into conformity with the DSB recommendations and rulings in the *Hormones* dispute. If there were a DSB finding that the EC has complied by basing its permanent ban on estradiol on a risk assessment within the meaning of SPS Article 5.1 and satisfying the four cumulative conditions of SPS Article 5.7 for its provisional bans on the other five hormones, then there would no longer be a basis to apply the suspension of concessions or other obligations. This would be the case whether the EC's ban was a new measure or a continuation (albeit with modification) of the previous measure.

[16] No party has argued that the third prong of the Article 22.8 test is involved here – reaching a mutually satisfactory solution.

## C. Questions to the United States:

Q19. *Does the United States argue a violation of Article 5.2 and of Article 5.6 SPS? In other words, do you expect the Panel to issue findings regarding the compliance of Directive 2003/74/EC with those provisions? What is the purpose of the reference to Article 2.2 SPS in para. 27 of the US rebuttal submission?*

23. As the responding party, the United States has not made any claims of an EC breach of its WTO obligations. The EC, as the complaining party, is responsible for bringing such claims and satisfying its burden of proof for each claim. One of the EC claims in this dispute is that the United States has breached its obligations under DSU Article 22.8, which sets out the conditions under which a Member suspending concessions or other obligations must cease to apply the suspension against another Member. In order to satisfy its claim under DSU Article 22.8, the EC must demonstrate that it has either removed the WTO inconsistent measure(s) or that it has provided a solution to the nullification and impairment of benefits.

24. The EC clearly has not removed its import bans nor has it claimed to have done so. Therefore, in order to satisfy its burden in this proceeding, the EC must demonstrate that it has brought its measure into conformity with the DSB recommendations and rulings in the *Hormones* dispute. Those recommendations and rulings include findings of EC breaches of SPS Articles 5.1 and 3.3. The EC argues it has satisfied the DSB recommendations and rulings by basing its permanent ban for estradiol on a risk assessment and satisfying the four conditions of SPS Article 5.7 for the other five hormones in lieu of a risk assessment. These arguments call for findings as to whether or not the EC has in fact demonstrated that it has brought itself into conformity with the DSB's recommendations and rulings, as these findings are integral to the EC's Article 22.8 claim.

25. The reference to SPS Article 2.2 in paragraph 27 of the U.S. Rebuttal Submission was made in the context of describing how SPS Article 5.7 functions as a qualified, temporary exemption under the SPS Agreement. The reference was not intended to elicit a finding of a breach of SPS Article 2.2. Rather, the appropriate finding would be that the EC, in failing to satisfy the conditions of Article 5.7, has not solved the nullification and impairment of benefits arising from its failure to base its measures relating to the five other hormones on a risk assessment within the meaning of SPS Article 5.1. The EC concedes that it has not based these measures on such an assessment; therefore, the EC has not brought its measures into conformity with the DSB recommendations and rulings.

26. The United States believes that a finding of compliance or non-compliance with the requirements of SPS Article 5.2 would be appropriate as part of the Panel's analysis of whether the EC has based its measure on a risk assessment within the meaning of SPS Article 5.1. Article 5.2 requires that risk assessments take into account certain elements, including available scientific evidence; relevant processes and production methods; and relevant inspection, sampling and testing methods. Article 5.2 is not mutually exclusive of SPS Article 5.1; rather, it

sets out the specific components of the risk assessment on which Members are required to base their measures for purposes of SPS Article 5.1. If the EC has not satisfied the requirements of Article 5.2, it has not conducted a risk assessment, as appropriate to the circumstances. Its measure (permanent ban on estradiol) therefore cannot be based on a risk assessment within the meaning of SPS Article 5.1.

Q20. *Could the United States clarify whether its arguments regarding a violation of Article 3.3 SPS apply only in relation to the definitive ban on oestradiol 17 ß or whether they apply also in relation to the provisional ban imposed on the other five hormones?*

27. U.S. arguments regarding a violation of SPS Article 3.3 apply in relation to each of the EC bans on meat from cattle treated with growth promoting hormones for which international standards exist. In other words, U.S. arguments relate to each of the hormones at issue except for melengestrol acetate ("MGA"), for which JECFA has conducted a risk assessment, set an ADI and proposed an MRL, but for which Codex has not adopted an MRL. SPS Article 3.3 requires that Members base their measures on international standards where they exist and only permits Members to diverge from such standards if there is a scientific justification for doing so. For purposes of this dispute, that scientific justification could have taken the form of a properly conducted risk assessment for estradiol or satisfying the four conditions of Article 5.7 for testosterone, progesterone, zeranol and trenbolone acetate. The United States has demonstrated that the EC has failed to provide such a justification.

28. The United States has demonstrated that the EC has failed to satisfy the conditions of Article 5.7 for its provisional ban on MGA because, among other things, there is sufficient scientific evidence to conduct a risk assessment for MGA and the EC has not based its provisional ban on MGA on available pertinent information. The United States has also demonstrated that the EC failed to satisfy the conditions of Article 5.7 for the other four provisionally banned hormones (testosterone, progesterone, zeranol, and trenbolone acetate).