UNITED STATES – CONTINUED SUSPENSION OF CONCESSIONS IN THE *EC – HORMONES* DISPUTE

EXECUTIVE SUMMARY OF THE ORAL STATEMENT OF THE UNITED STATES ON LEGAL ISSUES AT THE SECOND SUBSTANTIVE MEETING OF THE PANEL

October 13, 2006

1. Mr. Chairman, members of the Panel, last week's meeting with the scientific experts reinforced a fundamental point – that the European Communities ("EC") has failed to demonstrate that the conditions of Article 22.8 of the WTO's *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "DSU") for ending the Dispute Settlement Body ("DSB") -authorized suspension of concessions in the *Hormones* dispute have been met. To prevail on its claim that the United States has breached Article 22.8, the EC must demonstrate that it has either removed its WTO-inconsistent measures or provided a solution to the nullification or impairment suffered by the United States as a result of its ongoing bans on U.S. meat and meat products. The EC has done neither.

2. The EC could have satisfied its burden by demonstrating that its "amended" ban brought it into conformity with its obligations under the WTO *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement"). But it did not. The experts have provided valuable scientific and technical advice that confirms this fact. Their written and verbal responses demonstrate that the EC has failed to complete a risk assessment for estradiol or base its ban on a risk assessment within the meaning of SPS Article 5.1.

3. Similarly, the experts' responses confirm that the EC has not imposed provisional bans within the meaning of SPS Article 5.7. Before discussing the EC's failure to bring its measures into conformity with the SPS Agreement and DSB recommendations and rulings, and thereby satisfy the conditions of DSU Article 22.8, however, I would like to briefly touch on the other DSU claims raised by the EC in the course of these proceedings.

4. The Panel will recall that the EC initially alleged that the United States was breaching its WTO obligations by failing to meet the requirements of several provisions of the DSU – namely Articles 21.5, 22.8, 3.7 and several provisions of Article 23 read "in conjunction" with each other. The United States has demonstrated that the EC's DSU claims are merely a reflection of how the EC would like to see the DSU rewritten rather than based in the actual text of the DSU as written and agreed to by WTO Members. As noted by the Appellate Body, "[d]etermining what the rules and procedures of the DSU ought to be is not our responsibility nor the responsibility of panels; it is clearly the responsibility solely of the Members of the WTO."[1]

5. The EC alleges that its "provisional bans" on meat and meat products from cattle treated with the five other hormones (testosterone; progesterone; zeranol; trenbolone acetate; and

[1] Appellate Body Report, *EC – Certain Products*, para. 92. (Emphasis added).

melengestrol acetate) satisfy its obligations under SPS Article 5.7 and thereby bring it into conformity with the DSB recommendations and rulings that it must base its measures for these hormones on a risk assessment, as appropriate to the circumstances, within the meaning of Article 5.1 of the SPS Agreement.

6. Article 5.7 is a qualified exemption from Article 2.2 of the SPS Agreement which stipulates, among other things, that Members shall not maintain sanitary measures without sufficient scientific evidence "except as provided for in paragraph 7 of Article 5."[2] In light of the fact that "Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2" and that "Articles 2.2 and 5.1 should constantly be read together,"[3] it is clear that Article 5.7 is also a temporary exception from a Member's obligation to base its measure on a risk assessment within the meaning of Article 5.1. In order to qualify for this exception, however, the EC must demonstrate that it has satisfied the four cumulative conditions of Article 5.7.

7. The experts' written and oral comments confirm that the EC has failed to do so and thereby failed to demonstrate that it has brought its measures into conformity with DSB recommendations and rulings. As a result, the EC has not removed the WTO-inconsistencies of its measures or provided a solution of the nullification or impairment suffered by the United States within the meaning of DSU Article 22.8.

8. For example, the EC's bans on the other five hormones are not imposed in a situation where relevant scientific information relating to the hormones is insufficient within the meaning of SPS Article 5.7. As demonstrated by the United States and confirmed by the written and oral responses of the experts, there is more than sufficient scientific evidence to permit "performance of an adequate assessment of risks as required under Article 5.1"[4] for the five hormones.

9. In addition, the EC's bans on the other five hormones are not based on available pertinent information within the meaning of SPS Article 5.7. Its bans cannot be based on available pertinent information because none of that information suggests that meat and meat products from cattle treated with the five hormones for growth promotion purposes according to good veterinary practices pose a risk to consumers.

10. The EC alleges that its permanent ban on meat and meat products from cattle treated with estradiol for growth promotion purposes is based on a risk assessment within the meaning of Article 5.1 of the SPS Agreement.[5] In these proceedings we have examined what, exactly, constitutes a risk assessment for Article 5.1 purposes from several angles and have confirmed a few basic concepts regarding the necessary components of a risk assessment for estradiol. A risk assessment must identify adverse effects from the consumption of meat from cattle treated with

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[2] *See* Appellate Body Report, *Japan – Apples*, para. 170.
[3] Appellate Body Report, *EC – Hormones*, para. 180.
[4] Appellate Body Report, *Japan – Apples*, para. 179.
[5] *See, e.g.,* EC First Written Submission, para. 17.

estradiol and evaluate the potential occurrence of such effects,[6] and it must engage in four fundamental steps: hazard identification; hazard characterization; exposure assessment; and risk characterization.[7]

11. Rather than concluding that the EC's Opinions constitute a complete risk assessment, the experts' responses indicate that the EC has failed to progress beyond the first step of risk assessment, hazard identification. As noted by the United States, this stage of risk assessment addresses the simple question of what can possibly go wrong, not the likelihood of something going wrong.

12. The EC has also failed to base its permanent ban on meat and meat products from cattle treated with estradiol for growth promotion purposes on a risk assessment, as appropriate to the circumstances, within the meaning of SPS Article 5.1. In order for the EC's measure to be "based" on a risk assessment, its assessment (the Opinions) must sufficiently warrant or reasonably support its measure, a ban on meat and meat products from cattle treated with estradiol for growth promotion purposes. Yet, the EC's Opinions and their underlying studies simply identify theoretical risks from estradiol generally rather than the specific risk ostensibly addressed by the EC's measure.

13. The materials relied on by the EC focus on potential adverse effects from exposure to estradiol or estrogens generally rather than providing evidence of the specific risk from residues in meat from cattle treated with estradiol for growth promotion purposes. In its most recent set of exhibits, the EC has failed yet again to provide evidence of the specific risk allegedly posed by residues in meat from treated cattle.[8]

14. While the sort of scientific evidence of a general risk presented by the EC, of which the *U.S. Report on Carcinogens* it has referred to is a good example, may be handy for completing the hazard identification (first) component of a risk assessment, it is not evidence of the specific risk against which the EC purports to mitigate with its bans.

15. A measure banning the import of meat treated with estradiol for growth promotion purposes cannot be premised on the EC's failure to produce evidence of a risk from this product. This failure represents the very type of theoretical uncertainty that is "not the kind of risk which, under Article 5.1, is to be assessed."[9] As a result, the EC's Opinions fail to sufficiently warrant or reasonably support its measure.

16. This point is highlighted by the fact that so many of the studies relied on by the EC in its Opinions do not actually support the conclusions it has drawn from them. For instance, as discussed yesterday morning, the EC's Opinions reach conclusions on the genotoxicity, carcinogenicity and mutagenicity of estradiol that simply are unsupported by scientific evidence.

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[6] Panel Report, *EC – Hormones*, para. 8.98.

[7] *See* Codex Replies to Panel Questions, p. 6.

[8] *See* Exhibits EC-110 to EC-127, filed on July 12, 2006 in the EC Comments on U.S. Comments on the Responses of the Experts.

[9] Appellate Body Report, *EC – Hormones*, para. 167.

The experts have confirmed this point. The experts looked at the materials put forward by the EC in its attempt to produce evidence of the specific risk, yet have disagreed with the fundamental conclusions the EC draws from those materials. For example, the experts agreed that the scientific evidence did not support the conclusion that residue levels found in meat would be carcinogenic.

17. This is why, in yesterday's meeting, the United States made the point in the discussion of Appellate Body guidance from the original *Hormones* dispute that the Appellate Body's language on appropriate levels of protection was not necessarily relevant to the debate at hand. The point the United States made is that if there is no evidence of a risk from meat treated with estradiol for growth promotion purposes, it does not matter what level of protection the EC has set for itself. Its level of protection could be zero risk, no additional risk, negligible risk, or some risk – if the product in question is safe, all of these levels of protection are satisfied and there is no need to parse distinctions between them. Despite this fact, if the Panel wishes to delve deeper into this Appellate Body discussion, the United States would note that it provided additional guidance on the matter of appropriate levels of protection and existence of distinctions in those levels in its Report in the *Australia – Salmon* dispute beginning at page 42.

18. For these reasons, those set out in the U.S. submissions, and in light of the responses of the Panel's scientific experts, the EC has failed to conduct a risk assessment for estradiol and has failed to base its permanent import ban on meat and meat products from cattle treated with estradiol for growth promotion purposes on a risk assessment, as appropriate to the circumstances, within the meaning of Article 5.1 of the SPS Agreement.

19. Finally, by failing to base its permanent ban on meat from cattle treated with estradiol on a risk assessment within the meaning of SPS Article 5.1 or to satisfy the conditions of SPS Article 5.7 for its provisional bans on meat from cattle treated with the other five hormones, the EC has not brought its measures into conformity with its obligations under SPS Article 3.3. As a consequence, the EC has again failed to satisfy the conditions of DSU Article 22.8 because it has not removed the WTO-inconsistencies of its measure.

20. The EC's measures are not based on international standards, and must therefore be premised on a "scientific justification" or maintained "as a consequence of the level of . . . protection [the EC] determined to be appropriate in accordance with the relevant provisions of [Article 5 of the SPS Agreement]."[10] Because the EC's measures are neither based on a risk assessment nor satisfy the necessary conditions for a provisional ban as required by Article 5 of the SPS Agreement, they fail to satisfy its obligations under SPS Article 3.3.

21. In conclusion, the EC has failed to base its permanent ban on estradiol on a risk assessment within the meaning of Article 5.1 of the SPS Agreement or to satisfy the conditions of SPS Article 5.7 with its provisional ban on the other five hormones. As a consequence, the EC also fails to satisfy its obligations under Article 3.3 of the SPS Agreement. The experts'

[10] SPS Article 3.3.

responses and comments provide the necessary scientific underpinning for these conclusions, as well as the corresponding conclusion that the EC has not satisfied the conditions of DSU Article 22.8, the conditions by which the United States would have been obligated to cease to apply the suspension of concessions in the *Hormones* dispute to the EC.

22. For all the reasons discussed above and in its various submissions to the Panel, as well as the arguments raised by Canada in these proceedings, the United States respectfully requests the Panel to reject the EC's claims in their entirety.