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

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

October 3, 2006

Introduction

1. At the outset, the United States would like to thank the Panel and the Secretariat for all their hard work in making the arrangements for today's meeting and last week's meetings with the scientific experts, and the cooperation of the parties. All of this hard work made it possible for so many people to attend from so many different countries and positions. We know that the open meetings provided valuable insight to the public concerning the Panel's professional and impartial conduct of these proceedings and the workings of the World Trade Organization ("WTO") dispute settlement process.

2. 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. The third scenario envisioned by DSU

Article 22.8, that "a mutually satisfactory solution is reached" between the parties, has clearly not been satisfied given where we find ourselves today.

3. 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.

4. 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.

DSU Articles 21.5, 22.8, 23, and 3.7

5. 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. In the words of the EC, the "case [was] about procedural violations."[1] The EC's allegation of a U.S. breach of Article 22.8 by itself was simply an "if but only if" claim set out in the second part of the EC's first written submission. According to the EC's theory, if the Panel did not agree with the intertwining "in conjunction with" procedural DSU claims set out in the

[1] EC First Written Submission, para. 24.

first part of its submission, the Panel should only then turn to an analysis of the WTO-consistency of the EC's "amended" ban.

6. 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."[2] Yet, through its claims of a U.S. breach of "Article 23.2(a), read in conjunction with Article 21.5 and Article 23.1 of the DSU" and a breach of "Article 23.1 of the DSU read in conjunction with Articles 22.8 and 3.7 of the DSU,"[3] the EC attempts to insinuate obligations into the text of the DSU that actually are not there. The EC made extremely vague and unspecific claims, but it seeks very specific findings of a U.S. breach of each individual DSU provision. The EC's position is untenable.

7. The United States addressed the EC's claims and arguments in great detail in its previous submissions to the Panel and will not repeat those arguments here. It bears noting, however, that regarding at least one of the EC's DSU claims, the alleged U.S. breach of Article 23.2(a), it has become progressively clearer in the course of these proceedings that the United States could not possibly have made a "determination" whether the EC's amended bans were in fact WTO-consistent by the time the EC initiated these proceedings in 2003.

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[2] Appellate Body Report, *EC – Certain Products*, para. 92. (Emphasis added).
[3] EC First Written Submission, para. 149.

8. In light of the EC's failure to provide the United States with all of the materials relevant to its measures, the United States was still in the course of reviewing the EC's bans and Opinions when the EC requested this Panel. It was the EC that bore the consequences of the delayed and piecemeal fashion in which it produced materials ostensibly underpinning its measures.[4] Indeed, the EC has continued to produce "new" materials in its attempt to demonstrate that its bans satisfy the obligations under the SPS Agreement as recently as last week's meeting with the experts.

9. The vast majority of these studies were never mentioned in its alleged risk assessments, most were published after the EC issued its final Opinion in 2002, and the EC submitted several of these studies with a blind-eye turned to deadlines set by the Panel for submission of new evidence. It is difficult to comprehend how the EC's choice to produce materials in this staggered fashion can then be construed as evidence of a "convenient 'lean-back-and-wait'"[5] stance on the part of the United States. In any event, as we have learned from the experts' comments, none of these piecemeal, *post hoc* materials support the EC's conclusion that it has brought its measures into conformity with its WTO obligations.

10. At the time of the alleged U.S. "determination," the United States was only in possession of the EC's Opinions – not these additional reams of material.[6] It is inconceivable that the United States could have reached a determination that the EC's "amended" ban was WTO-consistent based on these Opinions. At this point I think we can all agree that the EC itself did not deem it possible to demonstrate the WTO-consistency of its measures based on these

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[4] U.S. Rebuttal Submission, para. 22.
[5] *See, e.g.,* EC Rebuttal Submission, para. 31.
[6] *See*, *e.g.*, U.S. Rebuttal Submission, Table 1 ("Comments on the Availability of the 17 Studies").

Opinions alone. Yet, ironically, the EC's claim of a U.S. breach of DSU Article 23.2(a) "in conjunction" with several other provisions of the DSU would have obligated the United States to make such a determination upon learning of the EC's declaration of compliance back in 2003.[7] The EC admits as much, noting that "[t]here is nothing 'ironic' in this. Article 23 in conjunction with Article 22.8 of the DSU does oblige a retaliatory Member to take note of a compliance measure and to decide if the continued application of sanctions is still justified."[8]

11. In sum, by contrasting the EC's procedural DSU claims against the actual text of the DSU and the obligations contained therein, the United States has demonstrated that the EC failed to satisfy its burden of proof on its claims under DSU Articles 21.5, 23 and 3.7 read "in conjunction" with each other. Therefore, it is logical that the Panel, as it has done, turn to an analysis of the EC's Article 22.8 claim and determine whether the "amended" EC bans comport with its SPS Agreement obligations. The experts' responses and comments inform this analysis.

Article 22.8

12. The EC has failed to demonstrate that it has either removed the WTO-inconsistencies of its measures or provided a solution to the nullification or impairment suffered by the United States. It has therefore not demonstrated that the United States is or was obligated to cease applying the DSB-authorized suspension of concessions in the *Hormones* dispute within the meaning of Article 22.8.

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[7] U.S. Rebuttal Submission, para. 18.

[8] EC Rebuttal Submission, para. 34. (Emphasis added).

The EC's Assertion of its Own Compliance

13. Before engaging in the particulars of whether the EC's amended permanent and provisional bans satisfy its obligations under the SPS Agreement (and thereby DSB recommendations and rulings) and highlighting how the experts have confirmed that they do not, I would like to touch on an argument made by the EC concerning the burden of proof and DSU Article 22.8. The EC argues that a presumption of compliance should attach to its declaration that its "amended" measure is WTO-consistent and brings it into conformity with DSB recommendations and rulings.[9]

14. The United States has demonstrated that there is no such thing as a presumption of conformity that attaches to a Member's measure in WTO dispute settlement. A Member may not simply allege a WTO breach and satisfy its burden of proof as a complaining party through a declaration of its own compliance. The EC's attempt to do so goes well beyond the limits of any application of good faith in the DSU. Nowhere does the text of the DSU or relevant interpretation of the burden of proof in WTO dispute settlement indicate that good faith alone satisfies a complaining party's *prima facie* case. Indeed, in light of the number of deficiencies in the EC's Opinions highlighted last week by the experts, it is clear that while a Member may implement measures in good faith, the Member's state of mind could not demonstrate that those measures – in this case the EC's bans – actually satisfy the elements of Article 22.8. In other words, the EC could be acting in good faith, but still be wrong about the WTO-consistency or compliance of its amended measure.

[9] *See, e.g.,* EC Closing Statement, First Substantive Meeting, para. 5.

15. If anywhere, good faith would attach to the U.S. measures complained against by the EC in this dispute. And in any event, the written and oral responses of the experts confirm that the EC's "amended" bans fail to satisfy its obligations under the SPS Agreement.

The EC's provisional bans on the five other hormones fail to satisfy the conditions of SPS Article 5.7

16. 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 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.

17. 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."[10] 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,"[11] 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.

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[10] *See* Appellate Body Report, *Japan – Apples*, para. 170.
[11] Appellate Body Report, *EC – Hormones*, para. 180.

18. 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.

The EC does not impose its bans on the other five hormones in a situation where relevant scientific information relating to the hormones is insufficient within the meaning of SPS Article 5.7

19. 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"[12] for the five hormones.

20. Notwithstanding the quantity of materials put forward by the EC in its effort to demonstrate that evidence is insufficient to conduct a risk assessment, the quality of these materials, insofar as they fail to demonstrate that residues of any of the five hormones in meat from treated cattle pose a risk to consumers, is lacking. Neither the available materials comprising the 17 Studies, which are the materials ostensibly underpinning the EC's Opinions, nor the materials put forward by the EC in the course of these proceedings uncover any evidence of a new risk from the five provisionally banned hormones.

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

21. Indeed, in its Rebuttal Submission, the EC pointed to three new studies in particular as evidence of its assertion that "a number of significant scientific developments [have taken place] which, taken together with all other available evidence, indicate that it is not possible to undertake a definitive risk assessment for [the] five hormones."[13] The experts summarily dismissed the three studies submitted by the EC, noting that none of them demonstrated a risk from meat from cattle treated with hormones for growth promotion purposes.

22. Recall that nearly ten years ago, the EC argued that the evidence relating to these hormones was more than sufficient to conduct a risk assessment. Presumably, then, some new discovery or evidence of a new risk must have come to light in the intervening period such that the evidence available to conduct a risk assessment is no longer sufficient. One would expect that the materials put forward by the EC in these proceedings would demonstrate and highlight this insufficiency. The United States and the experts have failed to identify any such evidence. Indeed, the experts agree that the current body of scientific evidence is sufficient to conduct a risk assessment for testosterone, progesterone, zeranol, trenbolone acetate and melengestrol acetate.

The EC has not based its bans on the other five hormones on available pertinent information within the meaning of SPS Article 5.7

23. In addition, the EC's ban 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

[13] EC Rebuttal Submission, paras. 143-149.

from cattle treated with the five hormones for growth promotion purposes according to good veterinary practices pose a risk to consumers.

24. The EC fails to adduce any scientific material or pertinent information demonstrating such a risk. As a result, it fails to consider actual, available information pertaining to the specific risk in question. Such information includes relevant international standards for the five hormones and their underpinning studies, all of which indicate that hormone residues in meat from treated cattle are safe and could not serve as a basis for a ban on their use. The experts have confirmed this fact in their written and oral responses.

The EC has not completed a risk assessment for meat and meat products treated with estradiol 17β for growth promotion purposes

25. 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.[14] 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 estradiol and evaluate the potential occurrence of such effects,[15] and it must engage in four fundamental steps:

> first, hazard identification, in which biological, chemical or physical agents capable of causing adverse health effects are identified;

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[14] *See, e.g.,* EC First Written Submission, para. 17.
[15] Panel Report, *EC – Hormones*, para. 8.98.

second, hazard characterization, the evaluation of the nature of adverse effects associated with these agents, including a dose-response assessment;

third, exposure assessment, the evaluation of the likely consumer intake of these agents, including exposures from other relevant sources; and

fourth, risk characterization, the estimation of the occurrence and severity of potential adverse effects in a given population based on the hazard identification, hazard characterization and exposure assessment.[16]

26. The EC agrees that these steps are integral to a risk assessment.[17] Only through completion of these steps can the relevant risk – that from the consumption of residues in meat from cattle treated with hormones for growth promotion purposes – be properly assessed. The EC avers that its "risk assessment" satisfies every one of these steps.[18]

27. The United States and the scientific experts consulted by the Panel disagree. 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. It is a process that favors hypothetical, worst-case scenarios. The United States notes that this is essentially the same flaw that the DSB found with the EC's ban in the original *Hormones* dispute. The EC appears not to have taken the DSB recommendations and rulings there to heart.

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[16] *See* Codex Replies to Panel Questions, p. 6.
[17] EC 1999 Opinion, p. 70.
[18] *See* EC Comments on the Responses of the Experts (Question 14).

28. This is an appropriate time to discuss an issue raised by the EC in defense of its "risk assessment", namely that risk assessments may be either qualitative or quantitative. As we have noted, the EC's view of a "qualitative" risk assessment is apparently one devoid of form or scientific rigor. The scientific experts did not agree, noting that risk assessments of all types should possess four required steps unless certain specific conditions have been demonstrated. Their responses on the scientific evidence indicated that the EC had not provided evidence of those necessary conditions, namely that estradiol is genotoxic below a threshold or that it has been shown to be a DNA-mutagen. As is evident from last week's meetings, the experts agree that there is no evidence in support of either of these conclusions.

29. The EC appears to premise its view of qualitative risk assessments on *dicta* from the Appellate Body noting that there is no requirement in the SPS Agreement that risk assessments establish a minimum quantifiable magnitude or threshold level of degree of risk.[19] It is clear, taking into account the definition of risk characterization, that this is this final step of risk assessment to which the Appellate Body was referring. In other words, the final estimation of risk (risk characterization) need not establish a minimum quantifiable magnitude or threshold level of degree of risk.

30. This final estimation of risk, however, must still be premised on a properly conducted hazard identification, hazard characterization and exposure assessment. Otherwise, as noted earlier, the final estimation of risk may be greatly exaggerated. The EC reads the Appellate Body's language to cover the three earlier steps of risk assessment, but that is a misreading that does not relieve the EC from the constraints imposed by those steps. It is clear from the

[19] Appellate Body Report, *EC – Hormones*, paras. 186, 253(j).

Appellate Body's discussion that it did not absolve WTO Members from satisfying these steps in completing a risk assessment within the meaning of SPS Article 5.1.

31. These four criteria are fundamental elements of a risk assessment. They are elements elaborated by the original *Hormones* panel and to which the EC has stipulated yet failed to satisfy.[20] In fact, the EC has only satisfied the first step – hazard identification. As noted by the United States as early as its first written submission, there is no great challenge to completing this first step of risk assessment. The potential biological effects of hormones at high concentrations, some of which are adverse, are generally not in dispute in the scientific community.

32. Indeed, it is possible to identify hazards from countless substances that we consume every day. If WTO Members were permitted to stop their risk assessments at this step, without carrying through to the remaining three steps, trade in perfectly safe products would grind to a halt. In failing to conduct the hazard characterization, exposure assessment and risk characterization steps of risk assessment, the EC does not demonstrate or evaluate the relevant risk to human health from residues of hormones in meat from cattle treated for growth promotion purposes. As a consequence, the EC fails to satisfy the requirements of SPS Article 5.1, DSB recommendations and rulings relating to its bans and the conditions of DSU Article 22.8.

The EC has not based its permanent ban on meat and meat products from cattle treated with estradiol 17β on a risk assessment

33. 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

[20] *See, e.g.,* EC Comments on the Responses of the Experts (Question 14).

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.

34. Put another way, the EC's Opinions never move past a general hazard identification exercise to address the relevant risk that the EC's ban purports to mitigate against – that arising from the presence and consumption of residues present in meat resulting from the administration of estradiol to cattle for growth promotion purposes. In part, as discussed earlier, they fail to do so by neglecting to engage in the necessary analysis under the remaining three steps of risk assessment; in part they fail to do so because the studies and exhibits on which the EC relies in its "risk assessment" fail to demonstrate a risk from the consumption of estradiol residues at levels present in meat from cattle treated for growth promotion purposes. The additional materials submitted by the EC in the course of these proceedings have done nothing to bolster the conclusions set out in its Opinions and similarly fail to demonstrate a risk from the consumption of residues in meat from treated cattle.

35. 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.[21]

36. 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. The EC fails to adduce evidence demonstrating that meat from treated cattle poses a risk to consumers. The EC's statement yesterday confirmed this fact. Rather than trying to point to statements by the experts from last week's meetings that support its assertion of the presence of a risk assessment for estradiol, it instead resorted to attacking the impartiality of the Panel's experts. We have discussed the inappropriateness of this tactic in a previous submission to the Panel and noted the inclination of the EC to impugn an expert in one situation while mysteriously supporting his view when it aligned with theirs.[22] Rather than discussing how the reams of scientific materials it has produced over the last two years provide evidence of a specific risk from estradiol residues in meat from treated cattle, it shifted to a discussion of the general conclusions of the *U.S. Report on Carcinogens*.

37. 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,

[21] *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.

[22] *See* U.S. Comments on EC Comments on the Responses of the Experts, paras. 2-3.

under Article 5.1, is to be assessed."[23] As a result, the EC's Opinions fail to sufficiently warrant or reasonably support its measure.

38. In the absence of any evidence of the relevant, specific risk from meat treated with estradiol for growth promotion purposes, we find ourselves in a scenario quite similar to that in the original *Hormones* proceedings. The Panel may recall that in those proceedings the EC put forward a series of studies and reviews that it claimed formed a basis for its measure. These included the earlier version of the *1999 IARC Monograph* often cited by the EC in these proceedings. Upon review of these materials, however, the panel and Appellate Body noted that they:

> constitute[d] general studies which d[id] indeed show the existence of a general risk of cancer; but they d[id] not focus on and d[id] not address the particular kind of risk here at stake – the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes.[24]

39. In other words, while the EC had identified a hazard from the hormones generally, the very same hazard identified in the *1999 IARC Monograph* and the *U.S. Report on Carcinogens*, it failed to address the relevant, specific risk at issue – that from residues in meat from treated cattle. Remarkably, the EC's Opinions, developed in the shadow of this finding, suffer from this same fatal flaw in that they only succeed in demonstrating theoretical, general risks from

[23] Appellate Body Report, *EC – Hormones*, para. 167.
[24] Appellate Body Report, *EC – Hormones*, para. 200.

estradiol when it is administered at levels not relevant to those found in meat from treated cattle, or in ways not germane to the relevant risk pathway.

40. 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. 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.

41. 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. It's 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.

42. The scientific evidence cited in a risk assessment serves as the bedrock for the conclusions reached in the assessment upon which a Member's measure will ultimately be based. As such, the evidence must actually support those conclusions. A risk assessment purporting to demonstrate one thing when its underlying studies demonstrate another cannot be a risk assessment, as appropriate to the circumstances, within the meaning of SPS Article 5.1.[25]

43. In an effort to bolster its unsupported conclusions regarding the genotoxicity and carcinogenicity of residues in meat, the EC argues that the *11th U.S. Report on Carcinogens* and the *1999 IARC Monograph on Hormonal Contraception and Post-menopausal Therapy* support its decision to ban meat from hormone-treated cattle. The United States has demonstrated at length that these materials do not address the specific risk from hormones in beef, but rather reflect a scientific conclusion that is completely unexceptional: that estrogens generally, or estradiol at levels sufficient to cause a hormonal response, increase the risk of cancer. Dr. Boobis spoke to this issue last week and confirmed that this is the case.

44. For example, not only does the *U.S. Report on Carcinogens* discuss exposure to estrogen generally, it states in its introduction that the whole purpose of the *Report* is to provide information on hazard identification – that is, the first step of risk assessment – and that it "does not establish the exposure conditions that would pose cancer risks to individuals in their daily lives."[26] It speaks to a general risk, not a risk from residue levels found in meat from treated cattle. It is not evidence of the specific risk alleged by the EC.

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[25] Appellate Body Report, *Japan – Apples*, para. 8.145.

[26] 11th Report on Carcinogens, Introduction, p. 1 (Exhibit EC-101).

45. Similarly, while the *1999 IARC Monograph* draws conclusions on estrogens and estradiol generally, it is not evidence of the specific risk we are discussing today. Indeed, as quoted earlier, the original *Hormones* panel was aware of the general nature of the materials developed by IARC and the risks posed generally by hormones. The EC has not demonstrated anything different or new than was already known and analyzed by the original *Hormones* panel, JECFA, Codex, its own CVMP, IARC, the U.S. Report on Carcinogens, the U.K. Veterinary Products Committee, and numerous other national regulatory bodies. Despite this fact, the EC premised its ban in part on the conclusion that residue levels found in meat would cause cancer. The experts have confirmed that this conclusion is baseless.

46. 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.

The EC's permanent and provisional bans fail to satisfy the conditions of SPS Article 3.3

47. 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.

48. 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]."[27] 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.

Conclusion

49. 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' 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.

50. 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.

[27] SPS Article 3.3.