

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

(WT/DS320)

First Written Submission of the United States of America

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I. INTRODUCTION

1. On July 26, 1999, the Dispute Settlement Body (“DSB”) authorized the United States to suspend concessions to the European Communities (“EC”) in the amount of \$116.8 million because the EC failed to implement the DSB’s recommendations and rulings in *EC - Measures Concerning Meat and Meat Products (Hormones)* (WT/DS26).¹

2. That authorization has never been revoked. In this proceeding, the EC claims that multilateral decisions of the DSB can be overridden by implication when the Member who has been determined not to have complied merely asserts that it has complied. However, there is no basis in the text of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (“DSU”) for the EC’s claim. Instead, the EC approach would unsustainably create an endless loop of litigation and nullify the right of complaining parties to suspend concessions for non-compliance following DSB-authorization by negative consensus.

3. The United States made no determination of whether the EC has come into compliance with the DSB recommendations and rulings. The United States attempted to evaluate the EC’s new measure, consulting with the EC and requesting additional information and explanation. The EC chose to request this panel shortly after one of the U.S. requests for additional information, which the U.S. submitted to the EC using a mechanism provided for under the covered agreements. The EC chose not to respond to that request until months after the EC requested this panel.² Based on the information available at the time this Panel was requested, the United States was unable to see how the EC had come into compliance. At the same time, as explained below, the United States believes that the EC’s claim under Article 22.8 of the DSU offers the opportunity in this proceeding for the multilateral dispute settlement system of the WTO to determine if the EC has complied.

4. The EC has strenuously tried to avoid any multilateral examination of its claim of compliance, claiming that this proceeding “is about procedural violations”³ and “is not about the European Communities’ compliance in the previous case *EC – Hormones*.”⁴ The EC consequently strongly urges this Panel not to examine whether the EC has complied, but rather to take at face value the EC’s assertion and to find that this assertion not only overrides the DSB’s multilateral authorization, but also would revoke U.S. rights under the covered agreements.

5. The United States and the EC are in agreement on some basic points. First, the United States agrees that under Article 22.8 of the DSU any “suspension of concessions or other

¹ Dispute Settlement Body – Minutes of Meeting Held in the Centre William Rappard on 26 July 1999 (WT/DSB/M/65), pp. 17-19.

² The United States filed a request for information pursuant to Article 5.8 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement”) on December 13, 2004. The EC filed its request for the establishment of this Panel on January 13, 2005, and did not respond to the U.S. Article 5.8. inquiry until May 19, 2005.

³ *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS320), First Written Submission by the European Communities (“EC First Written Submission”), para. 24.

⁴ EC First Written Submission, para. 7.

obligations shall be temporary and shall only be applied until such time as the measure found to be inconsistent with a covered agreement has been removed, or the Member that must implement recommendations or rulings provides a solution to the nullification or impairment of benefits.” Accordingly, if the EC has removed its ban on meat from animals treated with any of six hormones for growth promotion purposes or has provided a solution to the nullification or impairment, then the DSB authorized suspension of concessions or other obligations needs to end.

6. Second, the United States agrees with the EC that “Article 22.8 of the DSU does not specify how the removal of the WTO inconsistency is determined.”⁵ As mentioned above, this proceeding is one way for the WTO to determine if the EC has come into compliance. The EC, having made the Article 22.8 claim, bears the burden of establishing its claim of an inconsistency with Article 22.8 of the DSU.

7. Accordingly, the issue presented to the Panel in this proceeding can be reduced to the simple question of whether the EC has established that it has come into compliance.

8. In this connection, the United States notes that nothing of substance appears to have changed since the DSB found the EC to be in breach of its obligations under the SPS Agreement. The EC continues to ban the importation of meat and meat products from cattle treated with any of the six hormones for growth promotion purposes. The EC does not even claim to have based its ban for 5 of the 6 hormones on a risk assessment. And the EC has not explained how its supposed risk assessment for the sixth hormone differs in substance from the one that the WTO has already found to fail to meet the requirements of the SPS Agreement. The only apparent change since 1998 is the EC’s unilateral and unsupported declaration of compliance on November 7, 2003.⁶

9. The EC has failed to even attempt to establish that it has come into compliance, and the EC’s DSU Article 22.8 claim should be rejected on this basis alone. The EC’s DSU Article 21.5 claim should likewise be rejected. The EC reads into Article 21.5 obligations that are not there. The EC’s interpretation also turns on its head a provision which provides complaining parties with an expedited means of evaluating a responding Member’s compliance following the “reasonable period of time,” converting it into a vehicle by which those very same responding Members can create an endless loop of litigation.

10. The EC’s claims under DSU Articles 23.1 and 23.2(a)⁷ also fail. In compliance with DSU Article 23.1, the United States has already sought and received multilateral authorization

⁵ EC First Written Submission, para. 85.

⁶ Dispute Settlement Body – Minutes of Meeting Held in the Centre William Rappard on 7 November 2003 (WT/DSB/M/157).

⁷ The EC does not present any claims or arguments under DSU Article 23.2(c) in its Submission, and the United States assumes therefore that the EC has abandoned this claim.

for recourse for the EC's failure to comply with DSB recommendations and rulings. The United States made no determination concerning whether the EC has come into compliance. Accordingly there is no basis for the EC's claims under these provisions.

II. PROCEDURAL HISTORY

11. The United States initiated dispute settlement over the EC's import ban on meat and meat products from cattle treated with hormones for growth promotion purposes in January, 1996. The panel in *EC – Measures Concerning Meat and Meat Products (Hormones)* issued its report on June 30, 1997.⁸ The Appellate Body issued its report confirming, among other things, that the EC's ban was maintained in breach of Articles 5.1 and 3.3 of the SPS Agreement on January 16, 1998.⁹

12. On February 13, 1998, the DSB adopted the Appellate Body and panel reports.¹⁰

13. On March 13, 1999, the EC informed the DSB that, pursuant to DSU Article 21.3, it intended to fulfill its obligations under the WTO Agreements. The EC then requested arbitration to set the reasonable period of time ("RPT") for it to comply with the DSB's recommendations and rulings. The arbitrator set expiration of the RPT at May 13, 1999.

14. Due to the EC's failure to bring its measure into compliance with the DSB's recommendations and rulings within the RPT, the United States, pursuant to DSU Article 22.2, requested authorization to suspend concessions to the EC on May 17, 1999. The EC objected to the level of suspension proposed in the U.S. request, and the matter was referred to arbitration pursuant to DSU Article 22.6 on June 3, 1999.

15. On July 26, 1999, the DSB authorized the United States to suspend concessions to the EC in the amount of \$116.8 million.¹¹

16. The EC adopted its Directive 2003/74/EC, amending Directive 96/22/EC, on September 22, 2003. The EC notified the DSB of the adoption of the amended measure on November 7, 2003.

⁸ Panel Report, *EC – Measures Concerning Meat and Meat Products (Hormones)*, adopted on 13 February 1998, WT/DS26/R ("Panel Report").

⁹ Appellate Body Report, *EC – Measures Concerning Meat and Meat Products (Hormones)*, adopted on 13 February 1998, WT/DS26/AB/R ("Appellate Body Report").

¹⁰ WT/DS26/13.

¹¹ Dispute Settlement Body – Minutes of Meeting Held in the Centre William Rappard on 26 July 1999 (WT/DSB/M/65), pp. 17-19.

17. The EC requested consultations with the United States on November 8, 2004, and consultations were held in Geneva on December 16, 2004.¹² Canada was joined in the consultations.¹³

18. The EC requested establishment of this Panel on January 13, 2005. The Panel was established on February 17, 2005 with the following terms of reference:

To examine, in the light of the relevant provisions of the covered agreements cited by the European Communities in document WT/DS320/6, the matter referred to the DSB by the European Communities in that document, and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements.¹⁴

19. The Panel was composed by the Director-General on June 6, 2005. The Panel does not include any of the original panelists in this dispute.

20. Australia, Brazil, Canada, China, India, Mexico, New Zealand, Norway and Chinese Taipei have reserved their rights to participate in the Panel proceedings as third parties.¹⁵

III. FACTUAL BACKGROUND

A. The Measure(s) at Issue

1. The EC's panel request

21. In its request for the establishment of this Panel, the EC describes the matter at issue as “the United States’ continued suspension of concessions and other obligations under the covered agreements, without recourse to the procedures established by the DSU, after the European Communities has removed the measure found to be inconsistent with WTO law in case DS26, *European Communities – Measures concerning meat and meat products* (‘EC – Hormones’).”¹⁶

22. At the core of the matter described in the EC’s panel request, and squarely within the Panel’s terms of reference, lies the EC’s assertion that it has removed the measure found to be inconsistent with its WTO obligations in the original *Hormones* dispute. In its panel request, the EC states: “The European Communities subsequently removed the measure found to be inconsistent with a covered agreement,” and that “it considers itself to have fully implemented

¹² WT/DS320/1.

¹³ WT/DS320/5.

¹⁴ WT/DS320/7.

¹⁵ WT/DS320/7.

¹⁶ *United States – Continued Suspension of Obligations in the EC – Hormones Dispute*, Request for the Establishment of a Panel by the European Communities (WT/DS320/6) (“Panel Request”), p. 1.

the recommendations and rulings of the DSB in the *EC – Hormones* dispute.” The latter statement was confirming the EC’s statement at the DSB meeting held on November 7, 2003, that the EC “consider[s] that with the entry into force of [Directive 2003/74, amending Directive 96/22], it [is] in conformity with the recommendations and rulings made by the DSB.”¹⁷

23. The EC alleges that its amended import ban, which continues to prohibit the importation of animals and meat from animals to which have been administered, according to good veterinary practices,¹⁸ any of six growth promoting hormones¹⁹ is “fully compliant” with its WTO obligations and the DSB’s recommendations and rulings.²⁰ According to the EC, the amended import ban is “based on comprehensive risk assessments, in particular on the opinions of the EC independent Scientific Committee on Veterinary Measures relating to Public Health”²¹ (the “Opinions”).

24. The EC asserts, without any supporting evidence, that these Opinions “focus[] on potential risks to human health from hormones residues in bovine meat and meat products, in particular such risks arising from residues of six hormonal substances: oestradiol 17 β , testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate.”²² In addition to the Opinions, the EC commissioned several (17) studies, ostensibly to fill data gaps and develop support for the conclusions set out in the Opinions.²³

2. The U.S. “continued” suspension of concessions

25. The EC complains of the “continued” U.S. suspension of concessions to the EC “after the European Communities has removed the measure found to be inconsistent with WTO law in [the *Hormones* dispute].”²⁴ It suggests, in the wake of a declaration of its own compliance with DSB

¹⁷ See Dispute Settlement Body – Minutes of Meeting Held in the Centre William Rappard on 7 November 2003 (WT/DSB/M/157).

¹⁸ “Good veterinary practice” is synonymous with the Codex Alimentarius Commission (“Codex” or “Codex Commission”) term of art “Good Practice in the Use of Veterinary Drugs”, which is defined as “the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions.” See Panel Report, para. 2.19, *citing* Codex Alimentarius, Vol. 3, Residues of Veterinary Drugs in Foods, p. 65.

¹⁹ The six hormones at issue in this proceeding are the same six hormones that were at the center of the original *Hormones* dispute. Specifically, the EC’s amended ban covers three natural hormones (estradiol 17 β , testosterone and progesterone) and three synthetic hormones (zeranol, trenbolone acetate (“TBA”) and melengestrol acetate (“MGA”). Each of these hormones is currently authorized for use as a growth promoter in cattle in the United States.

²⁰ EC First Written Submission, para. 17.

²¹ Panel Request, p. 2.

²² Panel Request, p. 2.

²³ See “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. 7, § 1.2. (Exhibit US-1).

²⁴ Panel Request, p. 1.

recommendations and rulings, that the United States' authorization to suspend concessions to the EC is no longer in effect or valid.

26. However, U.S. suspension of obligations to the EC was, and remains, multilaterally authorized by the DSB. On July 26, 1999, the DSB authorized the United States to suspend concessions or other obligations to the EC in the amount of \$116.8 million as a consequence of the EC's failure to comply with its recommendations and rulings in the *Hormones* dispute.²⁵ To date, this authorization has not been revoked by the DSB, and the United States continues to act pursuant to that authority.

3. The U.S. "determination to the effect that the new EC legislation is in violation of the European Communities' obligations under the covered agreements"

27. In its panel request, the EC refers to a supposed U.S. "determination to the effect that the new EC legislation is in violation of the European Communities' obligations under the covered agreements." The only reference in the panel request to what this "determination" might be is an allegation that the "United States formally stated in the DSB that it considered the new Directive to be inconsistent with the European Communities obligations under the SPS Agreement." That allegation is inaccurate. The United States made no such statement and made no such determination.

28. As the EC admits in its first written submission, the U.S. statement at the November 7, 2003, DSB simply said: "The United States has reviewed the communication that the EC has placed on the agenda of this meeting and has listened to the statement that the EC just made. The United States fails to see how the revised EC measure could be considered to implement the recommendations and rulings of the DSB in this matter." Furthermore, the U.S. statement concluded by saying: "Nearly 6 years have passed since the DSB recommended that the EC bring its ban on U.S. beef into compliance with its obligations. The United States, however, cannot understand how this new directive presented today could amount to implementation of the DSB recommendation."

29. In its first submission, the EC for the first time refers to a November 8, 2004, U.S. press release, the USTR 2004 Annual Report, and an "implicit" determination by the United States. These additional "measures" are not referenced in the EC panel request and are outside the Panel's terms of reference. In any event, as discussed below, none of these "measures" is a "determination" of a "violation" by the EC.

²⁵ Dispute Settlement Body – Minutes of Meeting Held in the Centre William Rappard on 26 July 1999 (WT/DSB/M/65), pp. 17-19.

30. Although the United States made no determination that the amended EC ban is in breach of a covered agreement, in this proceeding the United States will explain why the EC has failed to meet its burden of establishing that it has removed the measure or provided a solution to the nullification or impairment.

4. The amended EC ban

31. The EC premises the determination of its own compliance on the “removal” of the WTO-inconsistent measure through its amended hormone ban. However, the “amended” prohibition simply preserves the *status quo* of the EC’s original hormone ban by maintaining an import prohibition on meat and meat products from cattle treated with the six hormones for growth promotion. In fact, the EC does not even purport to have based its ban in relation to five of the six hormones on a risk assessment, so it has not even attempted to address the DSB recommendations and rulings with respect to these.

32. It is instructive to consider how it is that the EC instituted its ban in the first place. That ban was neither the result of any scientific review nor based on food safety concerns. The genesis of the EC’s ban on meat and meat products from cattle treated with hormones for growth promotion purposes dates back to 1981 and Directive 81/602/EEC, which prohibited “the administering to farm animals of substances having a thyrostatic action or substances having an oestrogenic, androgenic or gestagenic action; the placing on the market or slaughtering of farm animals to which these substances have been administered; the placing on the market of meat from such animals; the processing of meat from such animals and the placing on the market of meat products prepared from or with such meat.”²⁶ Directive 81/602/EEC banned the use of MGA, and prohibited the use of estradiol 17 β , progesterone, testosterone, TBA and zeranol for growth promotion in cattle. Member States allowing use of these hormones for growth promotion at the time were permitted to continue to do so.

33. In 1988, through Directive 88/146/EEC, the EC “extend[ed] the prohibition imposed by Directive 81/602/EEC to the administration to farm animals of trenbolone acetate and zeranol for any purpose, and oestradiol-17 β , testosterone and progesterone for fattening purposes.”²⁷ On July 1, 1997 Directives 81/602, 88/146 and 88/299 “were repealed and replaced with Council Directive 96/22/EC of 29 April 1996 (‘Directive 96/22’).”²⁸

²⁶ See Panel Report, paras. 2.1-2.4.

²⁷ Certain limited derogations from the ban set out in Directive 88/146/EEC were set out in Directive 88/299/EEC.

²⁸ Directive 96/22/EC “maintains the prohibition of the administration to farm animals of substances having a hormonal or thyrostatic action. As under the previously applicable Directives, it is prohibited to place on the market, or to import from third countries, meat and meat products from animals to which such substances, including the six hormones at issue in this dispute, were administered.” Appellate Body Report, para. 5.

34. Rather than basing its ban on a risk assessment or on the scientific evidence relating to hormones used for growth promotion purposes, however, the EC implemented the ban based on political, economic, and market concerns.²⁹ Accordingly, the United States challenged the EC's import ban through WTO dispute settlement in 1996. As will be discussed in greater detail in this submission, the *Hormones* panel and Appellate Body confirmed that the import ban on meat and meat products from cattle treated with hormones for growth promotion purposes was not based on a risk assessment, and was inconsistent with the EC's obligations under the WTO SPS Agreement.

35. Through its amended Directive, the EC “maintain[s] the permanent prohibition laid down in Directive 96/22/EC on oestradiol 17 β ,” and “continue[s] provisionally to apply the prohibition to the other five hormones (testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate).”³⁰

a. *Prohibitions on imports from non-member States*

36. Pursuant to the EC's import ban, as amended by Directive 2003/74/EC (collectively the “amended Directive”, “import ban” or “ban”), third countries who authorize “the placing on the market and administration of stilbenes, stilbene derivatives, their salts and esters, or of thyrostatic substances for administering to animals of all species may not appear on any of the lists of countries provided for under Community legislation from which member States are authorized to import farm or aquaculture animals³¹ or meat or products obtained from such animals.”³²

37. Further, the amended Directive requires that member States prohibit the importation from countries not listed pursuant to paragraph 1 of farm or aquaculture animals, and meat or meat

²⁹ See, e.g., November 21, 1985 statement of EC Commissioner for Agriculture Frans Andriessen: “The use of hormones in beef and other meats is a political question. Of course, when you take a political decision, scientific advice is important. It is important, but it is not decisive . . . one argument against the use of hormones was that the Community was producing more meat than Community citizens could consume – and everyone knows that hormones contribute to the extension of production.” (Exhibit US-2). See also, preamble of Directive 88/146/EEC, stating that the variations in regulation of hormones among member States “distorts the conditions of competition” and that “these distortions of competition and barriers to trade must therefore be removed by ensuring that all consumers are able to buy the products in question under largely identical conditions of supply and that these products correspond to their anxieties and expectations in the best possible manner; whereas such a course of action is bound to bring about an increase in consumption of the product in question.” In its report, the Appellate Body noted that the EC ban was ostensibly developed to address health concerns as well.

³⁰ Directive 2003/74/EC, para. 10. (Exhibit US-3).

³¹ “[F]arm animals’ shall mean domestic animals of the bovine, porcine, ovine and caprine species, domestic solipeds, poultry and rabbits, as well as wild animals of those species and wild ruminants which have been raised on a holding.” Directive 2003/74/EC, Article 1(2)(a). (Exhibit US-3).

³² Directive 2003/74/EC, Article 11, para. 1. (Exhibit US-3).

products derived from such animals, to which the six hormones have been administered for growth promotion purposes.³³

b. *Prohibitions within and between member States*

38. The amended Directive requires that EC member States prohibit (in the case of estradiol 17 β) and “provisionally prohibit” (in the case of the five other hormones) the administering of any of the hormones to farm or aquaculture animals “by any means whatsoever.”³⁴ Further, member States must prohibit the “placing on the market for slaughter for human consumption of farm animals, which contain [the six hormones] or in which the presence of such substances has been established” unless proof can be given that the animals were treated according to certain enumerated exceptions.

c. *Exceptions for certain treatments*

39. The EC’s hormone ban provides for certain exceptions pursuant to which cattle may be treated with hormones and later marketed to EC consumers. For example, the hormone ban permits the administering of hormones to farm animals for certain therapeutic and zootechnical purposes, and the eventual marketing of meat from these animals.³⁵

40. In the case of the five provisionally banned hormones, testosterone, progesterone and “derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application” are authorized for administering to farm animals for therapeutic purposes.³⁶ Hormones having an estrogenic, androgenic or gestagenic action are authorized for administering to farm animals for zootechnical purposes.³⁷ Zootechnical treatments include the administering

³³ See Directive 2003/74/EC, Article 11, para. 2 (Exhibit US-3) (stating that member States “shall also prohibit the importation from third countries on any of the lists referred to in paragraph 1 of: (a) farm or aquaculture animals (i) to which products or substances referred to in Annex II, List A, have been administered by any means whatsoever; (ii) to which the substances or products referred to in Annex II, List B [oestradiol 17 β], and Annex III [‘substances having oestrogenic (other than oestradiol 17 β and its ester-like derivatives), androgenic or gestagenic action’] have been administered in compliance with the provisions and requirements laid down in Articles 4, 5, 5a and 7 and the withdrawal period allowed in international recommendations have been observed; (b) meat or products obtained from animals the importation of which is prohibited under point (a).”).

³⁴ EC First Submission, para. 17; Directive 2003/74/EC, Article 3. (Exhibit US-3).

³⁵ See Directive 2003/74/EC, Article 7(1). The Directive defines “therapeutic treatment” as “the administering – under Article 4 of [Directive 2003/74] – to an individual farm animal of an authorized substance to treat, after examination by a veterinarian, a fertility problem – including termination of unwanted gestation.” Directive 2003/74/EC, Article 1(2)(b). (Exhibit US-3).

The EC Directive defines “zootechnical treatment” as the administering “to an individual farm animal of any substance authorized under Article 5 of [Directive 2003/74] for synchronizing oestrus and preparing donors and recipients for the implantation of embryos.” Directive 2003/74/C, Article 1(2)(c). (Exhibit US-3).

³⁶ See Directive 2003/74/EC, Article 4. (Exhibit US-3).

³⁷ See Directive 2003/74/EC, Article 5. (Exhibit US-3).

of growth promoting hormones to cattle for estrus synchronization, which oftentimes involves the treatment of an entire herd of cattle with a particular hormone.³⁸

41. In the case of estradiol 17 β , the hormone ban permits, for an indeterminate amount of time, the administering of the hormone to cattle for treatment of fetus maceration or mummification as well as for the treatment of pyometra.³⁹ Further, until October 14, 2006, member States may authorize the administering to farm animals of products containing estradiol 17 β for “oestrus induction in cattle, horses, sheep or goats.”⁴⁰

42. In addition, member States are required to authorize the trade in meat and meat products from such animals (*i.e.*, animals treated with substances having oestrogenic, androgenic or gestagenic action), when certain requirements and relevant withdrawal periods are met.⁴¹

43. No exception exists for the administering of hormones to cattle for growth promotion according to good veterinary practice.

B. The Six Hormones Used for Growth Promotion Purposes

44. The EC’s hormone ban prohibits the importation and marketing of meat and meat products from cattle to which the six hormones have been administered for growth promotion purposes according to good veterinary practices. The United States permits the administering of these hormones to cattle for that very purpose, *i.e.*, in order to increase the growth, feed conversion efficiency and leanness of carcass.⁴²

45. For purposes of growth promotion, five of the six hormones (estradiol 17 β , progesterone, testosterone, zeranol, and trenbolone acetate) are administered to cattle as subcutaneous implants in the animals’ ears. The ears are then discarded at slaughter. The sixth hormone, melengestrol acetate, a synthetic progestogen, is administered as a feed additive.

³⁸ Estrus synchronization is an important management tool for dairy and beef producers because it eliminates the need to observe cattle at frequent intervals to determine the period of estrus (sexual receptivity). By breeding cattle at a pre-determined time, labor costs are minimized, breeding efficiency is maximized, and genetic progress is facilitated through the use of artificial insemination with semen that has been selected for genetic superiority (versus natural insemination by a bull).

³⁹ “Pyometra” is a uterine infection. *See* Directive 2003/74/EC, Article 5a(1). According to the Directive, the Commission must, on October 14, 2005, present a report to the European Parliament and Council “on the availability of alternative veterinary medicinal products to those containing oestradiol 17 β or its ester-like derivatives.” Directive 2003/74/EC, Article 11a. Presumably, at this time, the EC would determine whether or not such an alternative product exists, and consequently whether or not exceptions for the use of estradiol 17 β will continue. (Exhibit US-3).

⁴⁰ Directive 2003/74/EC, Article 5a(2). (Exhibit US-3).

⁴¹ Directive 2003/74/EC, Article 7(2). (Exhibit US-3).

⁴² The three natural hormones (estradiol 17 β , progesterone and testosterone) may be used for medical treatment, or therapeutic purposes, in the United States. In addition, use of estradiol 17 β and progesterone is also permitted for estrus synchronization. *See* Panel Report, para. 2.9.

1. What are hormones

46. Hormones are chemicals secreted into the blood stream by specialized cells within the body. They travel throughout the body and exert a biological action on different specific target tissues, binding protein receptors located in hormone responsive tissues (*e.g.*, uterus, breast, testis). Protein receptors then “undergo[] a conformational change, bind[] to specific DNA sequences and regulate[] specific genes within a cell.”⁴³

47. Hormones function in five areas: reproduction; growth and development; water and salt balance; response to stress; and utilization and storage of energy. As noted by the *Hormones* panel, “[o]ne hormone can have multiple actions. For example, the male hormone testosterone controls many processes from the development of the fetus to libido in the adult.”⁴⁴ In addition, “[o]ne function may be controlled by multiple hormones: the menstrual cycle involves oestradiol, progesterone, follicle-stimulating hormone and luteinizing hormone.”⁴⁵

48. Three of the six hormones at issue in this proceeding (estradiol 17 β , progesterone and testosterone) are naturally occurring, “endogenous” hormones produced by both humans and animals used for human food. Each of these hormones is produced throughout the lifetime of every man, woman and child, and is required for normal physiological functioning and maturation.⁴⁶ With respect to chemical structure, these hormones are identical to the estradiol 17 β , progesterone and testosterone naturally produced in the human body. Furthermore, when administered exogenously, each of these hormones enters the same metabolic pathway as the endogenously produced hormone and its metabolites are indistinguishable from those that are produced naturally.

49. Natural production of estradiol, progesterone and testosterone in humans is orders of magnitude higher than the relatively small amounts of these hormones ingested from residues in meat. Humans can produce, on a daily basis, amounts of estradiol 17 β approximately 2,000 times greater than the amount of estradiol 17 β consumed from eating a 250-gram serving of meat from treated animals.⁴⁷

50. Numerous studies and reviews have illustrated that levels of natural hormones in food are wide-ranging. For example, while estradiol 17 β levels in beef (muscle) range from 4 to 30

⁴³ Panel Report, para. 2.6.

⁴⁴ Panel Report, para. 2.7.

⁴⁵ Panel Report, para. 2.7.

⁴⁶ See Panel Report, paras. 2.8, 8.4.

⁴⁷ 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. 73 (Exhibit US-5); see also Fritsche, S. *et al.*, Occurrence of hormonally active compounds in food, European Food Research and Technology, vol. 209 (1999), pp. 153-179 (“[t]he dietary intake of steroid hormones is negligible compared to the human endogenous hormone synthesis.”) (Exhibit US-6).

picograms/gram, levels of the same hormone in a hen's egg can range from 120 to 200 picograms/gram.⁴⁸ This variation in hormone levels in food products prompted the conclusion in a recent review that "natural hormones have such a high natural variability that they are not suitable for regulatory control of the use of hormones in meat production. It is further observed that hens eggs and cow dairy products, contribute most of the daily intake of 17 beta estradiol via food of animal origin."⁴⁹ Concentrations of estradiol 17 β levels in several common foods are included in the following table:

⁴⁸ See Stephany *et al.*, Tissue levels and dietary intake of endogenous steroids: an overview with emphasis on 17beta-estradiol, EuroResidue V Symposium (May 10-12, 2004), p. 117. See also Fritsche *et al.*, pp. 164-165 (noting that the concentration of phyto-estrogens in commonly-consumed plants is orders of magnitude higher than endogenous concentrations of estradiol 17 β in beef.) (Exhibits US-7, US-6).

⁴⁹ Stephany *et al.*, p. 111. (Exhibit US-7).

Comparison of estradiol 17 β levels in common foods	
Source	Estradiol 17 (picograms/gram)
Muscle of Treated Cattle ⁵⁰	
Treated steers	3 - 17
Treated heifers	10.4
Muscle of Untreated Cattle ⁵¹	
Heifers (female cattle that have not given birth to a calf)	8.1
Steers (castrated male cattle)	5
Cows	1.8
Non-pregnant cattle	6.4
Pregnant heifers	16 - 33
Bulls ⁵²	6.3
Pork ⁵³	29-58
Dairy Products ⁵⁴	
Processed whole milk	6.4
Processed skim milk	3.5
Cottage cheese	11
Butter	82
Eggs ⁵⁵	120-200

51. As is apparent from this table, natural hormones such as estradiol 17 β are present in several foods, often in concentrations substantially greater than in residues of meat from cattle treated with hormones for growth promotion purposes according to good veterinary practice. Further, concentrations of estradiol 17 β in meat from treated cattle do not vary significantly from concentrations in untreated cattle, *i.e.*, residue levels in meat from hormone-treated cattle are well within the physiological range of residue levels in untreated cattle.⁵⁶ While tissue concentrations of estradiol 17 β in treated cattle may be slightly higher than those in untreated cattle, this

⁵⁰ See Daxenberger *et al.*, Possible health impact of animal oestrogens in food. Human Reproduction Update 7 (2001), pp. 340-355.

⁵¹ Daxenberger *et al.*, pp. 340-355.

⁵² Joint FAO/WHO Expert Committee on Food Additives. Residues of some veterinary drugs in animals and foods. Estradiol-17. FAO Food & Nutrition Paper 1988; 41:7-17.

⁵³ Daxenberger *et al.*, pp. 340-355.

⁵⁴ Daxenberger *et al.*, pp. 340-355.

⁵⁵ See Stephany *et al.*, p. 117. (Exhibit US-7).

⁵⁶ See Stephany *et al.*, pp. 111-119. (Exhibit US-7).

increase is much smaller than the large variations observed in (reproductively) cycling and pregnant cattle and is thus well within the range of naturally observed levels.

52. As an example of the variation of hormone levels in meat from treated and untreated cattle, the EC regularly slaughters bulls for human consumption,⁵⁷ the meat from which may have endogenous testosterone levels much greater than that from steers (castrated male cattle) to which hormones have been administered for growth promotion purposes according to good veterinary practice.⁵⁸

53. The other three hormones (zeranol, trenbolone acetate and MGA) are synthetic hormones that mimic the biological activity of the natural hormones. Trenbolone mimics testosterone, zeranol mimics estradiol 17 β , and MGA mimics progesterone.⁵⁹

54. The six hormones, when used for growth promotion, enable producers to cost-effectively improve animal growth rates, optimize feed efficiencies, and increase lean muscle mass (*i.e.*, consumers receive a leaner product). The hormones are used to bring animals to market more rapidly. A hormone-treated animal reaches market weight, on average, 17 days sooner, or 15 percent faster, than an untreated animal. Economic advantages of implanted versus non-implanted cattle vary, but are generally accepted as between US\$15 to US\$40 per animal. In short, the use of hormones for growth promotion reduces production costs, resulting in benefits to consumers in the form of greater availability and lower retail prices of beef.

⁵⁷ See Eurostat data regarding meat production in the EU-15 (in which meat category v12 (bulls) comprises approximately 29.5% of total cattle slaughtered in the region). (Exhibit US-8). In contrast, less than 2% of cattle slaughtered in the U.S. are bulls while approximately 50% are steers (castrated male cattle).

⁵⁸ See Stephany et al., pp. 111-119. (Exhibit US-7).

⁵⁹ See Panel Report., paras. 2.9, 8.4.

2. Codex standards for maximum residue levels of the six hormones

55. International standards exist regarding the use of five of the six hormones for growth promotion purposes.⁶⁰ Upon review of safety assessments conducted by JECFA and recommendations by CCRVDF, Codex, specified as the relevant international standards-setting body in the SPS Agreement,⁶¹ adopted recommended maximum residue limits⁶² (“MRLs”), where appropriate, for estradiol 17 β , progesterone, testosterone, trenbolone acetate and zeranol. Codex adopted these recommended MRLs to ensure that consumption of animal tissue containing residues of these substances do not pose a risk to consumers and to facilitate fair trading practices in international commerce.

56. JECFA safety assessments reviewed relevant published studies on the biological activity of the hormones, including studies on the oral bioavailability, metabolism, short-term toxicity, reproductive toxicity, genotoxicity and long-term toxicity/carcinogenicity of the hormones. In the case of its safety assessment for estradiol 17 β , JECFA reviewed numerous studies on the use of estrogens in women, as well as studies in experimental animals on the mechanisms of action of the hormones.⁶³

⁶⁰ Draft standards for MGA are currently being developed by the Joint FAO/WHO Expert Committee on Food Additives (“JECFA”) and the Codex Committee on Residues of Veterinary Drugs in Food (“CCRVDF”). MGA, examined at JECFA’s 54th Meeting in 2000, is the most recent hormone to be evaluated by JECFA. Then, in 2004, JECFA re-evaluated its recommendations for MGA in the light of new data contained in three residue monographs prepared for its 62nd meeting, recommending an Acceptable Daily Intake (“ADI”) for MGA. An ADI is JECFA’s estimate of the maximum amount of a veterinary drug, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (expressed on a microgram/kilogram basis) (standard human = 60kg). See Panel Report, para. 2.17. The ADI is derived from the most relevant experimental No Observable Effect Level (“NOEL”) in the most appropriate animal species, and application an appropriate safety factor that accounts for interspecies differences between experimental animals and man and variability amongst individual humans. A safety factor of 100 is generally applied. Codex does not adopt an ADI for a veterinary drug; however, an ADI is used in making recommendations for MRLs.

⁶¹ See SPS Agreement, paragraph 3(a) to Annex A.

⁶² A “maximum residue level” is the “maximum concentration of residue resulting from the use of a veterinary drug (expressed in $\mu\text{g}/\text{kg}$ on a fresh weight basis) that is recommended by the Codex Commission to be legally permitted or recognized as acceptable in or on a food.” Panel Report, para. 2.18. MRLs may be recommended at values below, or in certain instances far below, those that would satisfy the ADI.

⁶³ For example, in its evaluation of the safety of estradiol 17 β , JECFA reviewed the extensive database derived from the results of epidemiological studies of women taking oral contraceptive preparations containing estrogens or postmenopausal estrogen replacement therapy. See 52nd JECFA Report (2000), pp. 59-60. (Exhibit US-5).

57. Based on the available scientific evidence and CCRVDF recommendations, Codex determined that MRLs were “not specified”⁶⁴ for the three naturally occurring hormones, and set the following MRLs for zeranol and TBA:

Veterinary Drug	MRL	Comment
Estradiol 17β	Not Specified	Residues resulting from the use of this substance as a growth promoter in accordance with good animal husbandry practice are unlikely to pose a hazard to human health (32 nd JECFA Report (1988), 52 nd JECFA Report (2000).
Progesterone	Not Specified	
Testosterone	Not Specified	
Zeranol	10 µg/kg (bovine liver) 2 µg/kg (bovine muscle)	32 nd JECFA Report (1988)
Trenbolone acetate	10 µg/kg (bovine liver) 2 µg/kg (bovine muscle)	In liver tissue, α-trenbolone (34 th JECFA Report (1989)) In muscle tissue, β-trenbolone

C. Scientific Evidence Relating to the Six Hormones

58. Scientific reviews of the six hormones, international standards pertaining to their use, and a longstanding history of administering the six hormones to cattle for growth promotion purposes point to a single conclusion – that the use of the six hormones as growth promoters, according to good veterinary practices, is safe. This conclusion remains valid, and is supported by all relevant risk assessments.

59. The EC’s 1999 and 2002 Opinions purport to offer a contrary view. However, as will be discussed below, the EC has not demonstrated how its Opinions indeed constitute risk assessments and the conclusions reached in the Opinions have been summarily dismissed by numerous regulatory bodies (including review bodies within the EC).

60. As in the original *Hormones* panel proceeding, the EC has neglected to present any new scientific evidence of a risk, or a risk assessment drawn from that evidence, which would contradict the reams of scientific evidence demonstrating that residues in meat from cattle treated

⁶⁴ According to Codex, a “MRL ‘not specified’ means that the data on the identity and concentration of residues of the veterinary drug in animal tissues indicate a wide margin of safety for consumption of residues in food when the drug is administered according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual [JECFA] evaluation, the Committee concluded that the presence of drug residues in the named animal product does not present a health concern and that there is no need to specify a numerical MRL.” 52nd JECFA Report (2000), p. 74, fn. 1. (Exhibit US-5).

with the six hormones for growth promotion according to good veterinary practice, are safe for consumers.

1. The history of scientific study of the six hormones

a. *The Lamming Report (1982)*

61. The six hormones regulated by the EC's hormone ban have a long history of scientific study and evaluation. The EC itself has, on several occasions, commissioned and developed studies on the effects of these hormones. The EC's analysis of the hormones dates back over twenty years to the report of the Scientific Group on Anabolic Agents in Animal Production (established by the European Commission), chaired by Professor G.E. Lamming ("Lamming Group").

62. The Lamming Group's terms of reference were the following: "[d]oes the use for fattening purposes in animals of the following substances: oestradiol-17 β , testosterone, progesterone, trenbolone and zeranol present any harmful effects to health."⁶⁵ Guided by these terms of reference, the Lamming Group concluded in its November 9, 1982 interim report that "the use of oestradiol-17 β , testosterone and progesterone and those derivatives which readily yield the parent compound on hydrolysis after absorption from the site of application, *would not present any harmful effects to the consumer when used under the appropriate conditions as growth promoters in farm animals.*"⁶⁶ In the wake of the Lamming Group's interim findings, the Commission concluded that estradiol 17 β , testosterone and progesterone were not a danger to public health.⁶⁷

63. The Lamming Group later submitted a draft final report that reached the same conclusion as had the interim review – that estradiol 17 β , progesterone, testosterone and their derivatives were safe as growth promoting agents when used according to good veterinary practice.⁶⁸ In addition, members of the Lamming Group published an unofficial final report in which they presented the following conclusions regarding the use of trenbolone and zeranol, according to good veterinary practice, as growth promoters:

(1) We have examined the *extensive data available* concerning the toxicology of trenbolone and zeranol. (2) We believe there is adequate evidence from both

⁶⁵ Report of the (EC) Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the Basis of the Report of the Scientific Group on Anabolic Agents in Animal Production (the "Lamming Report"), pp. 1 and 12. See Panel Report, para. 2.28.

⁶⁶ See Panel Report, para. 2.28. (Emphasis added).

⁶⁷ June 1984 statement of Spokesman's Group. (Exhibit US-9).

⁶⁸ Despite the conclusions of the Lamming Report, the EC continued to ban the use of the six hormones as growth promoters, even when the hormones were administered according to good veterinary practices. The EC dismantled the Lamming Group prior to the issuance of a final, non-draft report.

short term and long term tests that these compounds and their metabolites found as residues *do not show significant genotoxic potential*; . . . (5) The levels of trenbolone and zeranol and their major metabolites found in edible tissue, following accepted animal husbandry practices, are substantially below the hormonally effective doses in animal test systems and therefore *do not present a harmful effect to health*.⁶⁹

b. *OIE Symposium (1983)*

64. As noted by the *Hormones* panel, the 1983 World Organisation for Animal Health (“OIE”) Symposium set forth a “common agreement” on the scientific evidence as it relates to estradiol 17 β , progesterone and testosterone. In particular, the panel highlighted the Symposium’s foreword, which states “[t]he myth that all anabolics are dangerous to human health is still very much alive in many countries. It must be discredited. There is *common agreement* with the proof presented at this meeting that the endogenous anabolics (natural hormones) such as *17 β -estradiol, progesterone, and testosterone, when administered as implants in animals, are not hazardous to man*.”⁷⁰

c. *JECFA Reports (1988, et seq.)*

65. In 1988, the 32nd JECFA Report, later relied on by Codex in adopting MRLs for the three natural hormones, arrived at the following conclusions with respect to the potential for adverse effects on human health arising from the presence of the three natural hormones, administered for growth promotion purposes, in meat:

“[T]he amount of exogenous [estradiol 17 β , testosterone and progesterone] ingested in meat from treated animals would be *incapable of exerting a hormonal effect, and therefore any toxic effect, in human subjects*.”

“[A]n ADI [is] unnecessary for a hormone that is produced endogenously in human beings and shows great variation in levels according to age and sex. The Committee concluded that residues arising from the use of [any of the three natural hormones] as a growth promoter in accordance with good animal husbandry practice *are unlikely to pose a hazard to human health . . .*”

“On the *basis of its safety assessment of residues* of [the three natural hormones], and in view of the difficulty of determining the levels of this hormone as a growth

⁶⁹ Panel Report, para. 8.120, *citing* EEC Scientific Working Group on Anabolic Agents Chaired by Dr. G.E. Lamming. Scientific report on anabolic agents in animal production, Vet. Rec. (1987), pp. 389-392.

⁷⁰ Panel Report, para. 8.121. (Emphasis added).

promoter in cattle, *the Committee concluded that it was unnecessary to establish an Acceptable Residue Level.*⁷¹

66. The conclusions set out in the JECFA Report confirmed that the three natural hormones, insofar as they are used as growth promoters in cattle according to good veterinary practice, do not pose a risk to consumers.

67. JECFA also evaluated zeranol and trenbolone acetate. As summarized by the *Hormones* panel:

the 1988 and 1989 JECFA Reports set ADIs and MRLs for zeranol and trenbolone (two of the three synthetic hormones in dispute). JECFA reached the conclusion that their toxic effects are linked to their hormonal effects and that, therefore, *a no-hormonal-effect level could be established which would ensure that residues up to such level are safe.* JECFA also concluded that the safety level or ADI it thus adopted would not be exceeded at any time after proper implantation (irrespective of the withdrawal period respected).⁷²

68. As recently as the 2000 Report of its 52nd meeting, JECFA reevaluated the three natural hormones on the basis of available scientific evidence, including relevant experimental exposure data. JECFA determined it was unnecessary to specify MRLs for the edible tissues of cattle when the naturally-occurring hormones are administered according to good veterinary practices. One of the rationales for this conclusion was that average hormone residue concentrations in treated cattle are less than or equal to 2% of the ADI for estradiol and less than 0.1% of the ADIs for progesterone and testosterone.⁷³

69. In addition, JECFA concluded that: (1) estradiol 17 β , testosterone and progesterone have low oral bioavailability; (2) estradiol 17 β , testosterone and progesterone have low acute oral toxicity; (3) adverse effects occurring in laboratory animals following repeated dosing were attributable to the hormonal activity of each compound, and hormonal effects were considered to be most appropriate for evaluating human safety because they occurred at doses below which other forms of toxicity were manifest; (4) available data suggested that the increased incidence of cancers of the breast and endometrium observed among women receiving postmenopausal oestrogen replacement therapy was due to the hormonal effects of estrogens; (5) progesterone is not carcinogenic; and (6) the increased incidence of prostatic cancer in testosterone-treated rats was attributable to the hormonal activity of this compound.

⁷¹ At subsequent JECFA meetings, the term “Maximum Residue Limits” was used. In addition to these conclusions, JECFA determined that “[d]espite being increased, the levels of estradiol-17 β in these [treated] animals fall well within the normal range found in untreated bovine animals of different types and ages.” 32nd JECFA Report (1988), p. 18.

⁷² Panel Report, para. 8.122. (Emphasis added).

⁷³ See 52nd JECFA Report (2000), § 3.5, pp. 57-74. (Exhibit US-5).

d. *Codex Alimentarius Commission (1995, et seq.)*

70. In 1995, Codex adopted MRLs for trenbolone acetate and zeranol, determining in the case of the three natural hormones (estradiol 17 β , testosterone and progesterone) that MRLs were unnecessary, or “not specified” because relevant scientific data indicated a wide margin of safety for consumption of residues of the hormones in food when they are administered according to good practice.

e. *Scientific Conference on Growth Promoting Substances in Meat Production (1995)*

71. In the mid-1990s, the EC Commission organized a Scientific Conference on Growth Promoting Substances in Meat Production (“Conference”). The Conference’s Working Group, upon evaluation of available scientific evidence relating to the use of hormones in meat production for growth promotion purposes, concluded that, “at present there is *no evidence for possible health risks to the consumer due to the use of natural sex hormones for growth promotion.*” The Working Group reached this determination because: “residue levels of [the hormones] measured in meat of treated animals *fall within the physiological range observed in meat of comparable untreated animals*; [t]he daily production of sex hormones by humans is *much higher than the amounts possibly consumed from meat*, even in the most sensitive humans (prepubertal children and menopausal women); [and] [d]ue to an extensive first pass-metabolism, the *bioavailability of ingested hormones is low*, thus providing a further safety margin.”⁷⁴

72. Regarding trenbolone and zeranol, the Conference concluded that “[a]t the doses needed for growth promotion, residue levels [of trenbolone and zeranol] are *well below the levels regarded as safe* (the MRLs). There are, at present, *no indications of a possible human health risk* from the low levels of covalently bound residues of trenbolone.”⁷⁵

73. In response to the Conference’s findings, the Commission declared that the five hormones surveyed do “not pose a danger to health when used in beef production.”⁷⁶ Despite the Conference’s clear findings, the EC’s hormone ban remained in place.

f. *WTO Panel Findings on the Safety of Hormones (1996-1997)*

74. In 1996-1997, a WTO dispute settlement panel reviewed the factual and legal elements of the EC’s hormone ban. In the course of its review, the panel examined available scientific evidence relating to use of the six hormones as growth promoters and convened a panel of

⁷⁴ See Panel Report, para. 8.123. (Emphasis added). See, e.g., Stephany *et al.*, at p. 114. (Exhibit US-7).

⁷⁵ See Panel Report, para. 8.123. (Emphasis added).

⁷⁶ “Summary Made by the European Parliament on the Intervention of Mr. Fischler About Hormones,” Strasbourg, January 16, 1996. (Exhibit US-10).

scientific experts who provided further insight into whether or not available scientific evidence demonstrated that the six hormones posed a risk to consumers.

75. The panel ultimately concluded that “[n]one of the scientific evidence referred to by the European Communities which specifically addresses the safety of some or all of the hormones in dispute when used for growth promotion, indicates that an identifiable risk arises for human health from use of these hormones if good practice is followed.” The panel noted “that this conclusion has also been confirmed by the scientific experts advising the Panel.”⁷⁷

76. In so concluding, the panel enumerated certain concerns regarding the scientific evidence put forward by the EC, as well as with the manner in which the EC appeared to define the risk at issue. The panel noted that the EC “put[] particular emphasis on the 1987 IARC Monographs”⁷⁸ However, the panel concluded that “the scientific evidence included in [the] Monographs relates to the carcinogenic potential of *entire categories of hormones* or the *hormones at issue in general*.” For example, the Monographs did not consider “the carcinogenic potential of these hormones *when used specifically for growth promotion purposes or with respect to residue levels comparable to those present after such use*.”⁷⁹

77. Moreover, the panel noted that “the Monographs do not specifically evaluate, as is required on the basis of paragraph 4 of Annex A of the SPS Agreement, the potential for adverse effects arising from the presence *in food (in casu* meat or meat products) of residues of the hormones in dispute or from residue levels comparable to those present in food.”⁸⁰ The panel determined that the Monographs’ conclusions had been taken into account by and did not contradict other relevant studies, such as the 1988 and 1989 JECFA Reports, “which explicitly conclude that the specific use of these hormones as growth promoters in accordance with good practice is safe.”⁸¹

78. The panel reached a similar conclusion concerning a series of articles and opinions put forward by the EC as evidence of a risk posed by the six hormones when used for growth promotion purposes.⁸²

⁷⁷ Panel Report, para. 8.124.

⁷⁸ Panel Report, para. 8.125.

⁷⁹ Panel Report, para. 8.127. (Emphasis added).

⁸⁰ Panel Report, para. 8.127 (Emphasis in original).

⁸¹ Panel Report, paras. 8.128, 8.129.

⁸² Panel Report, para. 8.130. In particular, the panel found that “[t]he scientific evidence included in these articles and opinions relates to the *carcinogenic or genotoxic potential of entire categories of hormones or the hormones at issue in general; not when used specifically for growth promotion purposes or with respect to residue levels comparable to those present after such use*. Moreover, these articles and opinions do not specifically evaluate, as is required on the basis of paragraph 4 of Annex A of the SPS Agreement, the potential for adverse effects arising from the presence *in food (in casu* meat or meat products) of residues of the hormones in dispute or from residue levels comparable to those present in food.” (Emphasis added).

g. *Scientific Committee on Veterinary Measures Relating to Public Health Opinions (1999 and 2002)*

79. In the wake of the panel and Appellate Body reports in the *Hormones* dispute, the EC commissioned several new studies and tasked the SCVPH with “evaluat[ing] the potential for adverse effects to human health from residues of bovine meat and meat products resulting from the use of the six hormones for growth promotion purposes in cattle.”⁸³ The SCVPH ultimately concluded that the risk associated with consumption of meat from hormone-treated cattle may be greater than previously thought.

h. *UK Sub-Group of the Veterinary Products Committee (1999)*

80. In October 1999, SCVPH requested review of its 1999 Opinion by the United Kingdom’s Sub-Group of the Veterinary Products Committee (“UK Group” or “Group”), a service of the UK’s Department for Environment, Food and Rural Affairs (“DEFRA”) tasked with “giv[ing] advice with respect to safety, quality and efficacy in relation to the veterinary use of any substance or article (not being an instrument, apparatus or appliance) to which any provision of the [UK’s] Medicines Act is applicable.”⁸⁴

81. Upon review of the Opinion and its underlying studies, the UK Group concluded that the Opinion “arrives at selective conclusions.”⁸⁵ Further, the UK Group found that “[f]ollowing a critical evaluation of the scientific reasoning and methods of argument adopted in key papers cited in the SCVPH Report, the Group were unable to support the conclusion reached by the SCVPH that risks associated with the consumption of meat from hormone-treated cattle may be greater than previously thought.”⁸⁶ The UK Group reached this conclusion because it had “sufficient concerns about the scientific reasoning in a number of key areas . . . [sufficient] to throw serious doubt on the conclusions of the SCVPH.”⁸⁷

82. In particular, the Group noted that “the likely levels of consumer exposure to [hormones] resulting from their use as growth promoters were very low in comparison with the amounts of

⁸³ “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”), p. 1, § 1.1. (Exhibit US-4).

⁸⁴ See Statement of Mission, Veterinary Products Committee, Department for Environment, Food and Rural Affairs. (Exhibit US-11).

⁸⁵ “Executive summary and critical evaluation of the scientific reasoning and methods of argument adopted in the opinion of the Scientific Committee on Veterinary Measures Relating to Public Health which assessed the potential risks to human health from hormone residues in bovine meat and meat products”, UK Sub-Group of the Veterinary Products Committee, October 1999 (“UK Report”), p. 2. (Exhibit US-12).

⁸⁶ UK Report, p. 3. (Exhibit US-12).

⁸⁷ UK Report, p. 3. (Exhibit US-12).

these hormones produced naturally by the bodies of some people.”⁸⁸ Similarly, consumer intake of hormones was very low in comparison to the acceptable daily intakes identified by JECFA.⁸⁹

83. The UK Group also concluded that “none of the publications reviewed in the [1999] Opinion provide any substantive evidence that oestradiol is mutagenic/genotoxic⁹⁰ at relevant levels of exposure from residues in meat. For the five other compounds, there is no substantive evidence for mutagenic/genotoxic activity.”⁹¹

84. Finally, the Group noted its concerns with a key analytical approach cited in the 1999 Opinion, namely an assay for apparent estrogenic activity performed using a genetically modified yeast.⁹² According to the UK Group, “[t]he concerns were sufficient to throw doubt upon the values derived from this analytical technique and therefore also on the conclusions of the Opinion.”⁹³

85. The UK’s Ministry of Agriculture, Fisheries and Food (“MAFF”) (now DEFRA) would later comment in a press release that the SCVPH did not respond to the scientific concerns raised by the UK Group Report, noting that “the SCVPH has not answered the scientific arguments and facts advanced in the [UK Group Report and CVMP analysis] and cites no new evidence to support its opinion.”⁹⁴

⁸⁸ UK Report, p. 2. (Exhibit US-12).

⁸⁹ Indeed, in 2000, the 52nd JECFA noted that the objective of the intake calculations was to obtain conservative estimates of the theoretically possible excess dietary intake of persons who consume large amounts of meat (e.g., 500 grams of meat per day). For total estrogens, the highest excess intake calculated in this manner was 30-50 ng/person per day (or less than 2% of the ADI for estradiol-17 β); for progesterone, excess intake was approximately 500 ng/person per day (or 0.03% of the ADI); and for testosterone, about 60 ng/person per day (or about 0.05% of the ADI).

⁹⁰ “Mutagenic” is defined as “inducing or capable of inducing genetic mutation,” and “genotoxic” is defined as “damaging to genetic material.”

⁹¹ UK Report, p. 2. By “relevant levels of exposure from residues in meat,” the UK Group was referring to levels on the order of nanograms/person/day. (Exhibit US-12).

⁹² Through this flawed assay, the EC’s Opinions (1999 and 2002) purported to show that prepubertal children in fact had lower estrogen levels than previously believed, *i.e.*, than were previously detectable using other, internationally accepted and validated assays. *See* 1999 Opinion, § 2.2.2.1, pp. 11-12. (Exhibit US-4). The so-called “Klein assay” was first described in a 1994 publication. The EC’s own Center for Veterinary Medicinal Products (“CVMP”) expressed the following concerns regarding the Klein assay: “(i) the measure was made only in plasma and needs to be carried out in other tissue(s) in order to enable the comparison between the intake of residual oestradiol and the endogenous levels, [and] (ii) the methodology needs validation and is not (yet) generally accepted.” “Report of the CVMP on the Safety Evaluation of Steroidal Sex Hormones in particular for 17 β -Oestradiol, Progesterone, Alenogest, Flugestone acetate and Norgestomet in the Light of New Data/Information made available by the European Commission”, Committee for Veterinary Medicinal Products (EMEA/CVMP/885/99) (“CVMP Report”), p. 12. (Exhibit US-13).

⁹³ CVMP Report, p. 2. (Exhibit US-13).

⁹⁴ *See* “MAFF Stands Firm on Commission Proposal for EU Beef Hormones Ban”, Department for Environment, Food and Rural Affairs, June 12, 2000. (Exhibit US-14).

i. *Report of the Committee for Veterinary Medicinal Products on the Safety Evaluation of Steroidal Sex Hormones (1999)*

86. The UK Group was not the only European scientific body to reevaluate the safety of the hormones after the release of the EC's 1999 Opinion. The Committee for Veterinary Medicinal Products ("CVMP"), at the EC's request, also reviewed the EC's "new data/information" regarding two of the natural hormones, estradiol 17 β and progesterone. The CVMP, a subcommittee of the European Medicines Agency ("EMA")⁹⁵ tasked with evaluating the quality, safety and efficacy of medicinal products, was similarly unimpressed by the EC's allegedly new information on these hormones.

87. According to the CVMP's Report, the EC "brought new data/information on 17 β -oestradiol and progesterone, indicating safety concerns with regard to the genotoxic potential of these substances," including "new relevant data . . . reported in [the 1999 Opinion]" and requested that the CVMP "review [its] previous [1994] assessment on 17 β -oestradiol"⁹⁶ as well as its earlier, 1996 determination regarding progesterone.

88. In 1994, the CVMP "concluded that for the therapeutic and zootechnical use of 17 β -oestradiol no ADI or MRLs need to be established."⁹⁷ Underpinning this conclusion were, *inter alia*, the following findings: "(1) estradiol 17 β does not induce gene mutations *in vitro*; (2) following long term exposure to estradiol 17 β at levels considerably higher than those required for a physiological response, the incidence of tumors in tissues with a high level of hormone receptors is increased; and (3) the bioavailability of estradiol 17 β esters after oral administration is low."⁹⁸

89. In 1996, CVMP "concluded that for the therapeutic and zootechnical use of progesterone no ADI or MRLs need to be established," because, *inter alia*: "(1) progesterone does not exhibit mutagenic activity in most *in vitro* and *in vivo* tests; (2) tumors will not result from ingestion of progesterone at levels that do not produce any hormonal effects; (3) oral bioavailability of progesterone is less than 10 percent."⁹⁹

90. Upon reflection on the EC's "new data/information", the CVMP reaffirmed its earlier conclusions regarding the safety of estradiol 17 β and progesterone. Regarding estradiol 17 β , the CVMP determined that "the same conclusions as those reached in the previous hazard

⁹⁵ The EMA is a decentralized body of the European Union whose main responsibility is "the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. The EMA coordinates the evaluation and supervision of medicinal products throughout the European Union." See About the European Medicines Agency.(Exhibit US-15).

⁹⁶ CVMP Report, p. 2. (Exhibit US-13).

⁹⁷ CVMP Report, p. 2. (Exhibit US-13).

⁹⁸ CVMP Report, p. 2. (Emphasis added). (Exhibit US-13).

⁹⁹ CVMP Report, p. 3. (Emphasis added). (Exhibit US-13).

assessment [*i.e.*, the CVMP’s 1994 assessment] can be followed, namely, [estradiol 17 β] (i) is mainly devoid of genotoxic activity and (ii) exerts its carcinogenic action after prolonged exposure and/or at levels considerably higher than those required for a physiological response.”¹⁰⁰ The CVMP concluded that progesterone: “(i) is not genotoxic in most of the tests performed, and (ii) increases tumour incidences in animals at exposure levels clearly above the physiological levels.”¹⁰¹

91. In light of these conclusions, the CVMP determined that it was unnecessary for it to conduct a new risk assessment for either estradiol 17 β or progesterone.¹⁰² While noting that “[t]he distinction between genotoxic and non-genotoxic carcinogens has consequences for [a] risk assessment, namely the presence or absence of exposure ‘thresholds’ below which no carcinogenic effects would be expected,” it concluded that “[t]he previous data on the carcinogenic and genotoxic properties of [estradiol and progesterone] . . . , as well as the recent [EC] studies described here, support the notion that [estradiol and progesterone] *belong to the group of non-genotoxic carcinogens.*”¹⁰³ According to the CVMP, the new studies “indicate that the presumed genotoxicity alone would not be sufficient to elicit the carcinogenic effects observed in the target tissues.”¹⁰⁴

j. *Australian Assessment (2003)*

92. Australia’s Department of Health and Ageing conducted a comprehensive review of the EC’s Opinions in July 2003 (the “Australia Review”) in an attempt to determine whether, in light of the EC’s new assertions regarding the six hormones when used for growth promotion purposes, it would re-evaluate its domestic policy regarding the hormones.¹⁰⁵

93. The Australia Review concluded that the EC-commissioned studies and other literature cited in the Opinions presented only limited new information regarding the metabolism, endocrine-disrupting potential, genotoxicity or carcinogenicity of estradiol 17 β , progesterone, testosterone, MGA, trenbolone acetate and zeranol. Further, the Australia Review found that studies cited in the Opinions on the potential environmental impact of the hormones provided

¹⁰⁰ CVMP Report, p. 11. In reaching these conclusions, the CVMP relied on the “general consideration” that “[w]ith regard to genotoxicity, the current evidence prevails that the compounds are *devoid of genotoxic activity* in the currently available standardized test systems *in vivo.*” (Emphasis added). (Exhibit US-13).

¹⁰¹ CVMP Report, p. 11. (Exhibit US-13).

¹⁰² See CVMP Report, pp. 12-13. (Exhibit US-13).

¹⁰³ CVMP Report, p. 12. (Emphasis added). (Exhibit US-13).

¹⁰⁴ CVMP Report, p. 12. (Exhibit US-13).

¹⁰⁵ See “A Review to Update Australia’s Position on the Human Safety of Residues of Hormone Growth Promotants (HGPs) Used in Cattle”, Department of Health and Ageing, July 2003 (“Australia Review”). (Exhibit US-16). Australia permits the use of estradiol 17 β , progesterone, testosterone, zeranol and trenbolone acetate as growth promoters.

little value in assessing the dietary risk to humans from consuming residues of hormones administered for growth promotion purposes in meat.¹⁰⁶

94. The two most significant and relevant findings of the Australia Review are that: (1) a review of the new data presented by the EC does not indicate grounds for amending Australia's current regulatory position with respect to the use of hormones for growth promotion (which permits their use according to good veterinary practices); and (2) there is no new scientific evidence to indicate a need for the reconsideration by Australia of the present use of hormones for growth promotion purposes according to good veterinary practices.¹⁰⁷

IV. LEGAL ARGUMENTS

A. Introduction

95. The core of the EC case in this proceeding is that the United States is not authorized to suspend concessions and related obligations as a result of the EC's failure to comply with the DSB's recommendations and rulings. However, the simple response to the EC is that the DSB granted multilateral authorization to the United States to suspend concessions and related obligations. The EC cannot deny that the DSB's authorization has never been revoked. Because the EC cannot claim that the DSB has ever decided to revoke the authorization, the EC instead attempts to construct a new legal theory under which the EC's unsupported assertion of its own compliance has somehow invalidated the DSB's authorization.¹⁰⁸

96. The EC's theory is not contemplated by the text of the DSU and should be rejected. The EC's argument that an implementing Member may, through a unilateral declaration of compliance, invalidate the DSB's multilateral authorization would undermine the right of Members to obtain that authorization through operation of the negative consensus rule. According to the EC's logic, a Member could effectively invalidate another Member's authority to suspend concessions and force further litigation through a unilateral declaration of compliance

¹⁰⁶ Australia Review, pp. 7-8. (Exhibit US-16).

¹⁰⁷ In reaching these conclusions, the Australian reviewers determined that there was not adequate evidence to suggest that residues of estradiol in meat are mutagenic. Further, while certain metabolites were genotoxic at high concentrations when administered directly to cells or animals (namely catechol estrogens), sufficient biochemical mechanisms exist to control the generation of potentially genotoxic metabolites *in vivo* and to eliminate DNA adducts that might be formed. In addition, there were no data to associate the consumption of residues of hormones administered for growth promotion purposes currently registered for use in non-European countries with adverse health effects in humans, including cancer risk. Further, reviewers noted that to adequately determine the incremental risk associated with very low levels of hormone residues in meat, the total dietary intake of hormones from all sources would need to be evaluated. Reviewers observed that several studies confirmed that use of hormones for growth promotion purposes according to good veterinary practice does not generate violative levels of residues in cattle tissues. Finally, the assumption by the EC that registration of hormones for growth promotion purposes will inevitably lead to misuse was considered to be unsubstantiated. *See* Australia Review, p. 8. (Exhibit US-16).

¹⁰⁸ *See* Panel Request, p. 1; *see also* EC First Written Submission, paras. 3-4.

the very day after the DSB grants that authority. According to the EC's approach, that implementing Member could then continuously force successive new rounds of litigation at will simply by asserting that it has complied. The EC's approach would create the very endless loop of litigation the DSU operates to prevent.

97. The EC highlights its recent actions in the *US - Foreign Sales Corporations* ("FSC") dispute as "what it considers to be the proper procedure under the DSU."¹⁰⁹ However, closer examination of the EC actions in the *FSC* dispute demonstrates that, in that dispute, the EC contradicted the approach they are advocating in this proceeding. For example, in *FSC*, the United States announced its compliance on November 24, 2004, but the EC did not publish its regulation suspending countermeasures until January 31, 2005, with retroactive effect to January 1, 2005. According to its current theory, the EC would have been obligated to terminate (not suspend) countermeasures as of November 24, 2004 when the United States announced its compliance with DSB recommendations and rulings.

98. Further, pursuant to the EC's current theory, DSB authorization to take countermeasures against the United States would have expired when the United States announced its compliance with the DSB recommendations and rulings. Notwithstanding this fact, the EC's regulation calls for the automatic reimposition of countermeasures. If DSB authorization were immediately withdrawn upon the U.S. announcement of compliance, it is unclear under what authority the EC could maintain a mandatory measure that would automatically reimpose countermeasures. Apparently the EC either believes that it need not follow the same legal theory that it asks the Panel to apply to other Members, or else the EC does not really believe in the theory it urges on the Panel in this proceeding.

99. The EC's argument simply assumes a key element it must establish to prevail in this proceeding – that it has, in fact, "removed" its WTO-inconsistent measure.¹¹⁰ The EC's various claims based on this assumption must therefore fail.

100. The United States will address the EC's claims in two parts. First, the U.S. Submission addresses the EC assertion that it has removed its WTO-inconsistent measure within the meaning of DSU Article 22.8, and that the United States has therefore breached its obligations under that provision by continuing to suspend concessions to the EC in accordance with the authorization of the DSB.

¹⁰⁹ EC First Written Submission, para. 6.

¹¹⁰ See Panel Request, p. 1 (defining the measure or matter at issue as "the United States' continued suspension of concessions and other obligations under the covered agreements, without recourse to the procedures established by the DSU, after the European Communities has removed the measure found to be inconsistent with WTO law in case DS26, *European Communities – Measures concerning meat and meat products* ('*EC – Hormones*').") (Emphasis added).

101. Second, the United States addresses the other claims raised by the EC, namely that “[t]he US’ continued suspension of concessions and related obligations violates Article 23 of the DSU”; that the United States has violated Articles 23.2(a) and 21.5 and therefore Article 23.1 of the DSU; that the United States has violated Article 23.1, read together with Articles 22.8 and 3.7 of the DSU; and that the United States has breached its obligations under Articles I and II of GATT 1994.

102. Before addressing the EC’s claims, however, it is worthwhile to review the applicable burden of proof in this proceeding. It is well-established that the complaining Member in WTO dispute settlement bears the burden of proof. This means, as an initial matter, that the EC, as the complaining party, bears the burden of coming forward with evidence and argument that establish a *prima facie* case of a violation.¹¹¹ In establishing its *prima facie* case, the complaining party must set forth sufficient facts and arguments to establish its element of its case.¹¹² Mere assertions are not sufficient.

103. The EC has failed to meet this burden in this proceeding. Its argument rests entirely on the mere assertion of its own compliance with the DSB’s recommendations and rulings in the *EC – Hormones* dispute, as if this were sufficient to establish a *prima facie* case in this proceeding or, more generally, to invalidate a DSB decision authorizing the United States to suspend concessions as a result of the EC’s failure to comply. Because the EC’s case rests on a mere assertion, it must fall with that assertion.

B. The EC Has Failed to Demonstrate that the United States Has Breached DSU Article 22.8 Because the EC Has Neither Demonstrated that it Has “Remove[d]” the WTO-inconsistencies of the Original Hormone Ban, Nor Demonstrated How the Amended Ban “Provides a Solution” to the Nullification or Impairment of Benefits to the United States

1. Introduction

104. Article 22.8 states, in relevant part, that:

[t]he suspension of concessions or other obligations shall be temporary and shall only be applied until such time as the measure found to be inconsistent with a covered agreement has been *removed*, or the Member that must implement recommendations or rulings *provides a solution* to the nullification or impairment of benefits, or a *mutually satisfactory solution is reached*. (Emphasis added).

¹¹¹ See, e.g., Appellate Body Report, *United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, adopted May 23, 1997, WT/DS33/AB/R (“*U.S. – Wool Shirts*”), p. 14 .

¹¹² See, e.g., Appellate Body Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, adopted April 21, 2005, WT/DS285/AB/R (“*U.S. – Gambling*”), para. 140.

Article 22.8 thus establishes three conditions under which a DSB-authorized suspension of concessions may no longer be applied: (1) the Member imposing the WTO-inconsistent measure “removes” the measure; (2) that Member “provides a solution to the nullification or impairment of benefits”; or (3) the parties to the dispute reach a “mutually satisfactory solution.” In order to prevail in its claim that the United States is breaching Article 22.8, the EC must establish that one of these conditions has been met.

105. The EC argues it has removed the measure at issue, its ban on meat and meat products from cattle treated with hormones for growth promotion purposes, and that the continued U.S. application of its suspension of concessions therefore breaches Article 22.8. In the EC’s words, it has achieved “actual compliance;”¹¹³ “[t]he measure found to be inconsistent has been removed,” and as a consequence “the United States is under an obligation, under Article 22.8 of the DSU not to apply the suspension of concessions any longer.”¹¹⁴ In its panel request, though not its submission, the EC also asserts that it has provided a solution to the nullification or impairment of benefits to the United States.¹¹⁵

106. However, the EC’s assertion that it has removed its measure or provided a solution is not supported by any demonstration that it actually has done either. Instead, it relies on an already rejected legal theory that a Member found to have breached its WTO obligations is to be excused from its burden of proof in dispute settlement if it invokes the phrase “good faith.”¹¹⁶ This argument is no more valid today than when a WTO panel last rejected it, and the EC’s failure to meet its burden on the critical element of its case under Article 22.8 means that the EC’s claim must likewise fail. The United States continues to apply the suspension of concessions to the EC in a WTO-consistent manner, fully in accordance with the authorization of the DSB.

¹¹³ See EC First Written Submission, para. 135, 81 *et seq.*

¹¹⁴ EC First Written Submission, para. 135.

¹¹⁵ WT/DS320/6. The EC’s First Written Submission alleges only that the EC has “removed” its WTO-inconsistent measure. See, e.g., EC First Written Submission, para. 135.

¹¹⁶ See Panel Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Article 21.5 by the European Communities*, 12 April 1999 (unadopted) (WT/DS27/RW/EEC) (“*EC – Bananas (21.5)*”), para. 4.13. In *Japan – Alcoholic Beverages*, the Appellate Body noted that adopted panel reports are not binding (except with respect to resolving the particular dispute between the parties to that dispute), but that adopted reports are nonetheless often considered by subsequent panels and should be taken into account where they are relevant to another dispute. The Appellate Body also noted that a panel can find useful guidance in the reasoning of an unadopted panel report that it considers to be relevant. Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted on 1 November 1996, pages 14-15.

2. The EC fails to demonstrate that any of the three conditions described in DSU Article 22.8 have been met

- a. *The EC fails to demonstrate that it has “remove[d]” its WTO-inconsistent measure or “provide[d] a solution” to the nullification or impairment of benefits to the United States*

107. The EC fails to demonstrate that it has in fact removed its WTO-inconsistent measure, the import ban on meat and meat products from cattle treated with hormones for growth promotion purposes or that it has “provide[d] a solution” to the nullification or impairment of benefits to the United States caused by the ban.¹¹⁷

108. The EC, as the complaining party in this proceeding, shoulders the burden of demonstrating that it has accomplished either of these conditions precedent in Article 22.8 in order to make a *prima facie* case of breach of that provision. However, it fails to satisfy this burden because it neglects to demonstrate (or present any evidence in support of) how, exactly, it has “remove[d]” its WTO-inconsistent ban or “provide[d] a solution” to the nullification or impairment of benefits to the United States caused by the ban.¹¹⁸

109. Article 22.8 nowhere provides that the issue of removal of a measure or providing a solution can be decided by a Member’s simple assertion that it has developed a new, WTO-consistent measure, or that it alone has deemed that it has provided a “solution” to WTO nullification or impairment, without a DSB determination. Indeed the EC’s proposed interpretation is directly at odds with the last sentence of Article 22.8 which makes it clear that these are questions for ongoing DSB surveillance. Article 22.8 stresses 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.” This statement that the DSB’s role is to monitor an implementing Member’s compliance with DSB recommendations as well as the complaining Member’s suspension of concessions further emphasizes that Article 22.8 is concerned with multilateral review of compliance. The EC simply errs in claiming that under Article 22.8 U.S. authorization to suspend concessions could be withdrawn in the absence of a DSB determination to that effect. Furthermore, the EC’s approach would fundamentally undermine the operation of several critical DSU provisions, most notably the right of complaining parties to seek authorization to suspend concessions through a DSB decision taken by negative consensus under Article 22.6 or Article 22.7 of the DSU.

110. The use of the “negative consensus rule” in this and other contexts was one of the principal achievements of the Uruguay Round in the area of dispute settlement, as it prevents

¹¹⁷ It is uncontested in this proceeding that the third prong of 22.8, a mutually satisfactory solution, has not been achieved.

¹¹⁸ See Appellate Body Report, “U.S. – Gambling”, para. 140.

Members found to have breached their obligations from avoiding the consequences of their actions by blocking what would otherwise be the consensus-based decision-making of the DSB.

111. However, under the EC's interpretation of Article 22.8, a Member found in breach of its WTO obligations could effectively block the right of complaining parties to suspend concessions, nullifying the benefit of the negative consensus rule under Articles 22.6 and 22.7. While the DSB could authorize suspension of concessions by negative consensus, the implementing party could effectively invalidate that authorization at any time it wished merely through a unilateral declaration that it had "remove[d]" the measure or "provide[d] a solution" to the nullification or impairment.

112. Such an outcome would undermine the ability of the dispute settlement system to "preserve the rights and obligations of Members under the covered agreements" as provided in DSU Article 3.2, as Members breaching their obligations could, as under GATT 1947 dispute settlement, prevent any consequence for their breach. This would likewise not promote "the prompt settlement of situations" involving a Member's impairing the benefits of another, which DSU Article 3.3 describes as "essential to the effective functioning of the WTO and the maintenance of a proper balance between the rights and obligations of Members."

113. These outcomes are not called for by Article 22.8, nor need they occur if the established rules concerning burden of proof are applied in this proceeding as they have been in every other. Rather, the logical interpretation of Article 22.8 is that the complaining party (in this case, the EC), bears the burden of establishing that its amended ban actually removes the WTO-inconsistent measure or "provides a solution" to the nullification or impairment of benefits to the United States in order to make a *prima facie* case that the United States has continued to suspend concessions despite being provided with such a solution.¹¹⁹ Only upon such a showing could a determination be made as to whether the amendments to the import ban indeed conform with the EC's WTO obligations. Only as a result of such a multilateral determination could a Member be obligated to no longer apply the DSB's multilaterally-authorized suspension of concessions.¹²⁰

114. However, the EC has failed to present any such evidence, or to demonstrate through this proceeding how its amended ban removes the WTO-inconsistent measure or provides a solution to the nullification or impairment of U.S. benefits. Instead, it baldly asserts, as it has since its amended ban came into force, that it now has a "comprehensive risk assessment" and is therefore in compliance with DSB recommendations and rulings.¹²¹

¹¹⁹ See, e.g., Appellate Body Report, *U.S. - Wool Shirts*, p. 14.

¹²⁰ Of course, as in other phases of dispute settlement, nothing prevents the parties from resolving their dispute bilaterally.

¹²¹ See Dispute Settlement Body – Minutes of Meeting Held in the Centre William Rappard on 7 November 2003 (WT/DSB/M/157), p. 7; EC First Written Submission, para. 145.

115. Therefore, the EC fails to demonstrate that it has removed its WTO-inconsistent measure or “provide[d] a solution” to the nullification or impairment of benefits to the United States within the meaning of Article 22.8. As a result of this failure, the EC has not made its *prima facie* case under Article 22.8.

3. There is no presumption of conformity (or non-conformity) of a measure taken to comply for purposes of WTO dispute settlement

116. The EC argues that the Panel should find that it has “removed” its WTO-inconsistent measure within the meaning of Article 22.8 analysis because it “must be presumed to have complied with its WTO obligations, if the United States refuses to establish to the contrary.”¹²² This is not the first instance in which the EC has argued presumed compliance for a measure taken to comply.

117. In the *EC – Bananas* Article 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,” eliciting the following response from the panel:

We agree with the European Communities that there is normally no presumption of inconsistency attached to a Member’s measures in the WTO dispute settlement system. At the same time, we also are of the view that the failure, as of a given point in time, of one Member to challenge another Member’s measures cannot be interpreted to create a presumption that the first Member accepts the measures of the other Member as consistent with the WTO Agreement. In this regard, we note the statement by a GATT panel that “it would be erroneous to interpret the fact that a measure has not been subject to Article XXIII over a number of years, as tantamount to its tacit acceptance by contracting parties”.¹²³

118. The *EC – Bananas* compliance panel highlighted 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.¹²⁴ Because compliance of the EC’s amended ban is a condition

¹²² EC First Written Submission, para. 94.

¹²³ Panel Report, *EC – Bananas (21.5)*, para. 4.13 (emphasis added), citing Panel Report, *EEC – Quantitative Restrictions Against Imports of Certain Products from Hong Kong*, L/5511, adopted on 12 July 1983, BISD 30S/129, 138, para. 28.

¹²⁴ The EC also relies on “the general principle of good faith” as proof that the declaration of its own compliance (*i.e.*, that it removed its measure within the meaning of Article 22.8) is, in fact, well-founded. It argues that it “must be presumed to have complied with its WTO obligations,” citing several 21.5 proceedings (as well as a written submission of a Member to another dispute) to “underline . . . the presumption of good faith.” See EC First Written Submission, paras. 90, 92, 93. The United States first does not understand precisely what the EC means in claiming that there is a “general principle of good faith” (it appears to alternate between referring to a “presumption

precedent to several of the claims raised by the EC as a complaining party, the EC bears the burden in this proceeding of demonstrating its compliance.

4. Conclusion: U.S. suspension of concessions does not breach its obligations under Article 22.8 of the DSU

119. Because the EC has neither demonstrated that it has removed its WTO-inconsistent import ban nor that the amendments to the ban provide a solution to the nullification or impairment of benefits to the United States, the EC fails to make its *prima facie* case that the United States continues to suspend concessions in breach of DSU Article 22.8.

C. The EC Has Failed to Demonstrate that its Amended Import Ban on Meat and Meat Products Treated with Hormones for Growth Promotion Purposes Is WTO-consistent

120. While the EC has made no effort to demonstrate that it has removed its WTO-inconsistent measure or “provide[d] a solution” to the nullification or impairment of benefits to the United States within the meaning of Article 22.8, the United States has difficulty seeing how the EC could make such a demonstration.¹²⁵

1. The EC fails to demonstrate how its import ban is a provisional measure within the meaning of Article 5.7 of the SPS Agreement

121. Whereas the EC claims in its Opinions and Directive 2003/74 to have developed a risk assessment and scientific evidence supporting its import ban on estradiol 17 β , it qualifies the ban

of good faith” and a “principle of good faith”). But even aside from this, however, these reports do not find a “presumption” but simply highlight the issue of burden of proof for complaining parties in Article 21.5 proceedings, or WTO proceedings generally rather than setting forth a “presumption of good faith.” The United States does not disagree that, in WTO dispute settlement, the initial burden rests with the complaining party alleging a WTO violation. Indeed, the concept that WTO Members cannot be presumed not to have acted in good faith would apply to the United States – the EC cannot presume that the United States measures at issue are inconsistent with U.S. WTO obligations. The EC appears to believe that the concept of good faith would operate only in favor of the EC and either believes no other Member would be able to avail itself of the concept of good faith, or ignores that it would apply with respect to the United States. In this proceeding, 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 measure or that it has provided a solution to U.S. nullification or impairment within the meaning of Article 22.8.

¹²⁵ As was the case in the original *Hormones* proceedings, the EC’s import ban is a sanitary measure within the meaning of paragraph 1(b) of Annex A to the SPS Agreement, which defines such a measure as “any measure applied to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs.” “Contaminants” include “pesticide and veterinary drug residues and extraneous matter.” Annex A to the SPS Agreement, fn. 4. The Appellate Body upheld the panel’s findings that the EC’s ban was inconsistent with Articles 5.1 and 3.3 of the SPS Agreement. See Appellate Body Report, paras. 209, 253.

on the other five hormones as “provisional.”¹²⁶ Consistent with this characterization, the EC invokes Article 5.7 of the SPS Agreement in its First Written Submission, alleging that the results of its Opinions provide “‘the available pertinent information’ on the basis of which the provisional prohibition regarding the other five hormones has been enacted.”¹²⁷

122. The EC’s position is a remarkable turnaround from its position in the original proceeding where the EC explicitly stated that its ban for these hormones was not “provisional” but that there was sufficient scientific evidence for the EC to have performed a risk assessment. Furthermore, the EC fails to demonstrate how its ban on meat and meat products from cattle treated with these five hormones in fact satisfies the criteria of Article 5.7 of the SPS Agreement, which elaborates the conditions under which a Member may impose a provisional sanitary measure.¹²⁸ Because the EC’s ban fails to meet the requirements of Article 5.7, the EC is therefore not provisionally exempted from satisfying the obligations set out, *inter alia*, in Articles 2.2 and 5.1 of the SPS Agreement.

123. The Appellate Body has clarified that Article 5.7 “set[s] out four requirements that must be satisfied in order to adopt and maintain a provisional measure.” These requirements are:

- (1) the measure is imposed in respect to a situation where “relevant scientific evidence is insufficient.”;
- (2) the measure is adopted “on the basis of available pertinent information”;
- (3) the Member which adopted the measure “seek[s] to obtain the additional information necessary for a more objective assessment of risk”; and

¹²⁶ “Taking into account the results of the risk assessment and all other available pertinent information . . . it is necessary to maintain the permanent prohibition laid down in Directive 96/22/EC on oestradiol 17 β and to continue provisionally to apply the prohibition on the other five hormones (testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate).” Directive 2003/74/EC, para. 10. (Emphasis added). (Exhibit US-3).

¹²⁷ See EC First Written Submission, para. 17; see Panel Report, para. 8.239.

¹²⁸ Article 5.7 is a qualified exemption from Article 2.2 of the SPS Agreement, which stipulates, *inter alia*, that Members shall not maintain sanitary measures without sufficient scientific evidence “except as provided for in paragraph 7 of Article 5.” See Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, adopted 10 December 2003 (WT/DS245/AB/R) (“*Japan – Apples*”), para. 170. Article 5.7 states:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary and phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

- (4) the Member which adopted the measure “review[s] the . . . measure accordingly within a reasonable period of time”.¹²⁹

The Appellate Body noted that the four requirements are “clearly cumulative in nature”, and that “[w]hensoever one of these four requirements is not met, the measure at issue is inconsistent with Article 5.7.”¹³⁰ The EC fails to demonstrate how its ban satisfies several of Article 5.7’s cumulative elements, thereby failing to demonstrate how its ban is a legitimate provisional measure within the meaning of that Article.¹³¹

- a. *The EC fails to demonstrate how its “provisional” ban is imposed in a situation where “relevant scientific evidence is insufficient”*

124. The EC fails to demonstrate that its “provisional” ban on meat and meat products from cattle treated with five of the hormones for growth promotion purposes is maintained in a situation where “relevant scientific evidence is insufficient” within the meaning of Article 5.7. As noted by the Appellate Body in the *Japan – Apples* dispute:

“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” . . . is sufficient to permit [a risk assessment].¹³²

In the case of five hormones “provisionally” banned for use as growth promoters, there is more than sufficient scientific evidence to allow “performance of an adequate assessment of risks as required under Article 5.1.”

125. Indeed, the hormones at the center of this proceeding have been intensively studied over the last twenty-five years; so heavily studied, in fact, that the EC eschewed the notion of a

¹²⁹ See Appellate Body Report, *Japan – Apples*, para. 176, citing Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, adopted on 19 March 1999 (WT/DS76/AB/R) (“*Japan – Varietals*”), para. 89.

¹³⁰ Appellate Body Report, *Japan – Varietals*, para. 89.

¹³¹ In its claim of the amended Directive’s consistency with Article 5.7, the EC simply notes that its Opinions “provide the ‘available pertinent information’” on which a provisional measure may be based. The requirement to base a provisional measure on “available pertinent information” is merely one of the four cumulative requirements of Article 5.7. See EC First Written Submission, para. 17.

¹³² Appellate Body Report, *Japan – Apples*, para. 179.

provisional ban in the original *Hormones* proceedings, declaring that its measures were “definitive” in nature.¹³³

126. In that proceeding, the EC argued that “the scientific evidence concerning the need to regulate the use of hormones was in itself sufficient to justify its legislation and [it] did not need to rely on the exception provided for in Article 5.7 concerning cases where relevant scientific evidence was insufficient.”¹³⁴ The EC’s recent change of heart and its decision to impose a provisional ban begs the question of what, exactly, has occurred in the interim to render the relevant scientific evidence on the safety of residues in meat and meat products treated with hormones for growth promotion purposes “insufficient.”

127. The short answer to this question is, nothing; in fact, the five hormones have been studied in greater detail in the intervening period, including by the JECFA. In fact, new safety assessments were conducted for two of the five hormones (progesterone and testosterone) in 1999, reaffirming their safety when used according to good veterinary practices. Included in these safety assessments were new, detailed epidemiological studies on the effect of the hormones on post-menopausal women, marking some of the most relevant studies of the effect of hormones on human beings to date.¹³⁵

128. In addition, the EC’s own CVMP, prompted by the Commission’s submission of the new EC studies, recently reevaluated the scientific evidence relating to the hormones. Upon reflection on this “new data/information”, the CVMP reaffirmed its earlier conclusions regarding the safety of progesterone, noting that the conclusions it had reached in a 1996 assessment were still state of the art.¹³⁶ Surely, if the scientific evidence were now insufficient or there was a scintilla of doubt as to a potential for greater risk to the European consumer, the CVMP would have reevaluated its earlier conclusions on these hormones.

129. In conclusion, there is more than sufficient scientific evidence relating to the five hormones to permit an adequate assessment of any potential risks.¹³⁷ Therefore, the relevant scientific evidence is not “insufficient” within the meaning of Article 5.7. In light of the cumulative nature of Article 5.7’s elements, the EC therefore fails to demonstrate how its import ban on meat and meat products from cattle treated with these five hormones is a legitimate provisional measure within the meaning of Article 5.7.

¹³³ Panel Report, para. 4.239.

¹³⁴ Panel Report, para. 4.239. (Emphasis added). See also Appellant Submission of the European Communities, *EC – Measures Concerning Meat and Meat Products (Hormones)*, para. 600.

¹³⁵ See 52nd JECFA Report (2000), pp. 59-60. (Exhibit US-5).

¹³⁶ The CVMP concluded that progesterone: “(i) is not genotoxic in most of the tests performed, and (ii) increases tumour incidences in animals at exposure levels clearly above the physiological levels.” CVMP Report, p. 11. (Exhibit US-13).

¹³⁷ See Section III.C for a discussion of several other risk assessments and recent reviews concluding that meat and meat products from cattle treated with hormones for growth promotion purposes according to good veterinary practice are safe for consumers.

- b. *The EC fails to demonstrate how its “provisional” ban has been adopted on the “basis of available pertinent information”*

130. The EC also fails to demonstrate how its “provisional” ban has been adopted on the “basis of available pertinent information” within the meaning of Article 5.7. Indeed, as discussed above, the studies relied on by the EC as a basis for its provisional ban do not in fact demonstrate a risk associated with residues from meat and meat products from cattle that have been treated with hormones for growth promotion purposes according to good veterinary practice.

131. Despite the EC’s unsupported assertion that it has satisfied this element of the four-part cumulative test under Article 5.7¹³⁸, to the contrary all “available pertinent information” regarding these residues indicates that they do not pose a risk to consumers.¹³⁹ Therefore, the EC’s ban fails to satisfy the second cumulative element of Article 5.7, and is not a legitimate provisional measure within the meaning of that Article.

- c. *The EC has not sought “to obtain the additional information necessary for a more objective assessment of risk”*

132. In the case of the intensively studied hormones progesterone, testosterone, TBA, zeranol and MGA, there is no need to seek additional information in order to conduct an adequate assessment of risks. The scientific evidence relating to these hormones is plentiful and high quality. As evidence of this fact, the relevant international standards-setting body, Codex, has adopted standards based on several JECFA safety assessments of the hormones, which determined that they are safe at the levels implicated by residues in meat from cattle treated with the hormones according to good veterinary practice. In light of the quality and quantity of scientific evidence relating to the five hormones, there is simply no need to “obtain the additional information necessary for a more objective assessment of risk” for purposes of an Article 5.7 analysis.

- d. *The EC has not “review[ed] the . . . measure accordingly within a reasonable period of time”*

133. The EC’s “provisional” ban is an extension of its original, 1989 ban on meat and meat products from cattle treated with hormones for growth promotion purposes. The only apparent change to the ban is a relabeling of its application from “definitive” to “provisionally applied.”

134. Therefore, in effect, the same import ban on meat and meat products from the United States has been in place for over fifteen years. This is not a “reasonable period of time,” especially given the fact that the “provisional” ban addresses substances as intensively reviewed

¹³⁸ See EC First Written Submission, para. 17.

¹³⁹ See, generally, Section III.C.

and studied as the five hormones at issue. The EC has failed to demonstrate that it has “reviewed [its] . . . measure accordingly within a reasonable period of time” within the meaning of Article 5.7, and that its import ban is a legitimate provisional measure within the meaning of that Article.

2. The EC fails to demonstrate how its amended hormone ban conforms with Article 5.1 of the SPS Agreement

135. In response to the DSB’s recommendations and rulings, the EC developed several Opinions and commissioned 17 studies on hormones generally.¹⁴⁰ The EC asserts that its Opinions constitute a risk assessment, thereby bringing its amended hormone ban, specifically as it relates to estradiol 17 β , into conformity with the requirements of the SPS Agreement.¹⁴¹ In its First Written Submission, the EC simply restates the conclusions of its purported “risk assessments”, and again declares its compliance with the DSB’s recommendations and rulings.¹⁴²

136. However, the EC provides no evidence or analysis to support these conclusions. The United States has difficulty understanding how the EC’s amended ban is “based on” a risk assessment within the meaning of Article 5.1 since: (1) the EC’s Opinions do not appear to be risk assessments within the meaning of Article 5.1, and (2) the results of the EC’s Opinions do not rationally relate to or reasonably support its import ban.

a. *The EC fails to demonstrate how its Opinions are “risk assessments” within the meaning of Article 5.1 and paragraph 4 of Annex A of the SPS Agreement*

137. The EC’s Opinions are not risk assessments within the meaning of Article 5.1 and Annex A of the SPS Agreement. Paragraph 4 of Annex A to the SPS Agreement defines a sanitary risk assessment as “the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.”

138. As noted by the original *Hormones* panel, a risk assessment must “(i) identify the adverse effects on human health (if any) arising from the presence of the hormones at issue when used as growth promoters in meat or meat products, and (ii) if any such adverse effects exist, evaluate the potential . . . occurrence of these effects.”¹⁴³ In the case of an import ban on meat and meat

¹⁴⁰ See 1999 Opinion; Review of Specific Documents Relating to the SCVPH Opinion of 30 April 99 on the Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products, dated May 3, 2000 (“2000 Review”); 2002 Opinion. (Exhibits US-4, US-17, and US-1).

¹⁴¹ See EC First Written Submission, para. 3.

¹⁴² See EC First Written Submission, paras. 145-146.

¹⁴³ Panel Report, para. 8.98.

products such as that maintained by the EC, the relevant “evaluation” is that of “the potential for adverse effects arising from the presence in food of the hormones in dispute.”¹⁴⁴

139. Regarding sanitary risk assessment techniques, the *Hormones* panel noted that “even though no formal decision has as yet been taken by Codex with respect to [sanitary] risk assessment techniques, Codex, and more particularly JECFA, has a long-standing practice with respect to the assessment of risks related to veterinary drug residues (including hormone residues).”¹⁴⁵ The panel observed that JECFA defines “risk assessment” as:

The scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards. The process consists of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.¹⁴⁶

The EC reiterates this conventional four-step risk assessment procedure in its 1999 Opinion,¹⁴⁷ and an analysis of the EC’s Opinions against the background of this procedure highlights the EC’s failure to identify and evaluate the relevant risk – that posed by residues of meat and meat products from cattle treated with hormones for growth promotion purposes according to good veterinary practices.

(i) The EC’s Opinions stop at the first step of risk assessment (hazard identification)

140. The EC’s Opinions predominantly focus on the first-step of risk assessment – hazard identification. At this stage of risk assessment, risk assessors and scientists are more or less unfettered in their ability to identify various types of effects associated with exposure to hormones from either experimental or epidemiological studies. There is no great challenge to completing this first-step in a hormone risk assessment – the potential biological effects of hormones, some of which are adverse, are generally not in dispute in the scientific community.

141. For example, the EC relies on studies that demonstrate adverse effects of hormones at concentrations exponentially greater than would be present in residues of meat from cattle treated with hormones for growth promotion purposes, and discusses the effects of substances, such as

¹⁴⁴ Panel Report, para. 8.127.

¹⁴⁵ Panel Report, para. 8.103. According to Article 5.1, proper risk assessments must “tak[e] into account risk assessment techniques developed by the relevant international organizations.”

¹⁴⁶ Panel Report, para. 8.103.

¹⁴⁷ See 1999 Opinion, p. 70. (“Executive Summary”) (“Conventionally, risk assessment is structured to address independently the intrinsic properties of the compound under consideration (hazard identification), the evaluation of the nature of effects in terms of a dose-response relationship (hazard characterization), the estimate of the dose/concentration of a compound in the daily diet (exposure assessment) resulting in the incidence and severity of potential adverse effects.”) This final evaluation would be what is generally referred to as “risk characterization.” (Exhibit US-4).

diethylstilbestrol (“DES”), that have been banned in the United States for decades in support of the notion that hormones can be harmful.¹⁴⁸ The results of these studies and the general conclusion that under certain circumstances hormones, including hormones not at issue in this proceeding such as DES, can pose a health risk are unexceptional.

142. The EC fails to hone the general risk, or identified hazards, down through hazard characterization and an exposure assessment in order to demonstrate (*i.e.*, identify and evaluate) a specific risk to consumers.

(ii) The EC’s Opinions do not complete a hazard characterization

143. In order to demonstrate the potential for adverse effects to humans from exposure to residues of the six hormones in meat from cattle treated according to good veterinary practice, it is necessary to complete a hazard characterization, also known as a dose-response assessment.¹⁴⁹ Both qualitative and quantitative risk assessments contain hazard characterization sections, which estimate the dose-response relationship of a substance, such as hormones, to humans by, *e.g.*, extrapolating from animal models for dose-response relationships in humans; adjusting interspecies extrapolations using body weights; and demonstrating high-dose to low-dose (or *vice versa*) extrapolations of the dose-response function. The EC’s Opinions fail to engage in adequate hazard characterization.

(iii) The EC’s Opinions do not complete an exposure assessment

144. The EC’s Opinions fail to complete an exposure assessment in terms useful for estimating risks to consumers. Exposure assessments evaluate the pathway of concern, beginning with the release of the hazardous agent at the source, evaluating the transport (and fate) of the agent through various media, and ending with the consumer. In the case of a risk assessment evaluating the potential risk from hormone residues in meat and meat products to consumers, absent discussion of actual residues, an exposure assessment should include a thorough analysis of the relevant pathway, starting with cattle treated with hormones for growth promotion purposes according to good veterinary practices, processing and shipping meat and meat products from those cattle and ending with the consumption of any residues from that meat by humans (*e.g.*, taking into account how humans process ingested hormones). The EC’s purported risk assessment fails to evaluate either the available residue data or these steps in the exposure

¹⁴⁸ See, *e.g.*, Chiumello *et al.*, Accidental gynecomastia in children, APMIS 2001, pp. 203-209; see 1999 Opinion, p. 14. (Exhibit US-4). See also Use of DES in the United States, Background, Food Safety and Inspection Service, U.S. Department of Agriculture (noting that the U.S. Food and Drug Administration “banned the use of diethylstilbestrol (DES) in food animal production in the United States in 1979”). (Exhibit US-18).

¹⁴⁹ A “dose-response” assessment is an assessment of a quantitative cause and effect relationship, *i.e.*, the higher the dose, the greater the effect.

pathway. Most notable is the EC's failure to consider the significant amount of published data that compare actual residue levels in meat from untreated cattle with those in meat from cattle treated with hormones for growth promotion purposes according to good veterinary practice.¹⁵⁰

145. Instead, the EC's Opinions assume a pathway in which levels of hormones higher than would be present in meat from cattle treated according to good veterinary practice enter the food chain. Furthermore, identified sources of high exposure are evaluated inconsistently. For instance, the EC dismisses the known introduction of pregnant heifers (which have very high levels of endogenous estradiol 17 β) into the food chain in Europe as occurring "only exceptionally," leading to a conclusion that it is "therefore questionable whether levels in such animals should be included in estimates of the upper range or hormonal levels in meat and edible tissues."¹⁵¹ In contrast, the Opinions calculate the concentration of hormones that might occur in a portion of meat, given dual *assumptions* that a hormone implant is both not removed from the implantation site and that it also enters the food chain, concluding that this "clearly identif[ies] a risk for excessive exposure of consumers to residues from misplaced or off-label implants and incorrect dose regimes."¹⁵² The EC failed to estimate the joint probability (or *likelihood*) of both assumptions occurring simultaneously – an estimate critical to an exposure assessment that can inform risk estimation in this pathway. In fact, their conclusion that "[m]isplaced implants and repeated implanting seem to occur frequently, represent a considerable risk that highly contaminated meat could enter the food chain" relies on the subjective descriptors "frequently" and "considerable", failing to provide either qualitative or quantitative definitions of the terms.

146. Further, the Opinions and their underpinning studies fail to recognize or discuss the relative impact on exposure assessment the low bioavailability of the six hormones for growth promotion purposes. For example, JECFA has determined that "estradiol is [generally] inactive when given orally."¹⁵³ This conclusion is based on the knowledge that estradiol 17 β , when administered orally, is absorbed via the gastrointestinal tract but transported to the liver where it is rapidly inactivated. In a study in which estradiol 17 β was administered orally to women, the average bioavailability was just 5%.¹⁵⁴

¹⁵⁰ See, e.g., Stephany *et al.*, pp. 111-119, Fritsche *et al.*, pp. 153-179. (Exhibits US-7 and US-6).

¹⁵¹ 1999 Opinion, p. 71. (Exhibit US-4).

¹⁵² 2002 Opinion, p. 11. (Exhibit US-1).

¹⁵³ See 52nd JECFA Report (2000), p. 58. (Exhibit US-5).

¹⁵⁴ See Kuhnz *et al.*, Pharmacokinetics of estradiol, free and total estrone, in young women following single intravenous and oral administration of 17 beta-estradiol. *Arzneimittelforschung* 9 (1993), pp. 966-973.

(iv) Conclusion: The EC’s Opinions are not “risk assessments” within the meaning of Article 5.1 and paragraph 4 of Annex A of the SPS Agreement

147. Therefore, the EC fails to demonstrate how its Opinions are indeed “risk assessments” within the meaning of Article 5.1 and Annex A of the SPS Agreement. By failing to examine relevant pathways, explore the fate of the relevant risk (that posed by meat products to consumers) or to support their conclusions with scientific evidence, the Opinions neither “identify the adverse effects on human health” arising from the consumption of meat from cattle treated with hormones for growth promotion purposes according to good veterinary practice nor “evaluat[e] the potential for adverse effects on human or animal health” arising from consumption of meat products from cattle treated with hormones for growth promotion purposes.

- b. *The EC fails to demonstrate how its amended ban is “based on” a risk assessment because the EC’s Opinions do not reasonably support its import ban*

148. Despite clear panel and Appellate Body findings in the original *Hormones* dispute that the EC must base its hormone ban on a risk assessment, it has failed to do so.

149. Article 5.1 of the SPS Agreement obligates WTO Members to “ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal, or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.” Interpreting Article 5.1 in the context of Article 2.2 of the SPS Agreement, the obligation that a sanitary measure be “based on” a risk assessment “requires that the results of the risk assessment must sufficiently warrant – that is to say, reasonably support – the SPS measure at stake.”¹⁵⁵

150. In the original *Hormones* proceeding, the EC put forward a series of studies and reviews as its “risk assessment”.¹⁵⁶ However, the panel and Appellate Body found that the studies on which the EC relied:

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.¹⁵⁷

¹⁵⁵ Appellate Body Report, para. 193.

¹⁵⁶ See Appellate Body Report, paras. 195-196.

¹⁵⁷ Appellate Body Report, para. 200.

In short, the EC’s original “risk assessments”, and the conclusions of the studies underpinning those assessments, failed to demonstrate the existence of the relevant risk – that arising from the presence in meat of residues resulting from the administration to animals, according to good veterinary practice, of any of the six hormones for growth promotion purposes.¹⁵⁸

151. The EC’s new Opinions and underpinning studies similarly fail to demonstrate a risk from residues in meat from cattle treated with hormones for growth promotion purposes, specifically estradiol 17 β (the only hormone for which the EC claims to have completed a risk assessment), according to good veterinary practice.

152. Instead, the studies on which the Opinions rely only succeed in demonstrating theoretical risks when the hormones are administered at doses or levels well-above those present in residues from hormone-treated meat; when good veterinary practices are not met; or in ways not germane to the relevant risk pathway.¹⁵⁹ By failing to demonstrate how its Opinions sufficiently warrant or reasonably support its amended ban, and by failing to support the conclusions reached in its Opinions with the studies cited therein,¹⁶⁰ the EC has failed to demonstrate how its amended ban is “based on” a risk assessment for purposes of Article 5.1.

153. For example, the EC’s Opinions conclude that a major health concern associated with growth-promoting hormones is the genotoxic, or DNA-damaging, potential of estradiol 17 β .¹⁶¹ There has been considerable study of the genotoxic potential of estradiol 17 β , and as noted by the CVMP, the “recent extensive reviews by IARC and JECFA also confirmed that the tumorigenic action of hormones, in particular 17 β -oestradiol . . . are the consequence of the receptor-mediated, cell division stimulating activity of these compounds,” and that “the potential

¹⁵⁸ See Appellate Body Report, para. 200. Indeed, as noted by the *Hormones* panel, the conclusions of reports put forward by the EC demonstrated that the use of the hormones for “growth promotion purposes is ‘safe’.” Appellate Body Report, para. 196, citing Panel Report, para. 8.124.

¹⁵⁹ See, e.g., Metzler, M. *et al.*, Genotoxic potential of xenobiotic growth promoters and their metabolites, APMIS 109, pp. 89-95 (table on p. 91 indicates negative and/or marginally positive genotoxic testing of trenbolone at concentrations two orders of magnitude or more than would be found in cattle treated according to good veterinary practice); Daxenberger *et al.*, Detection of anabolic residues in misplaced implantation sites in cattle, AOAC International 83, No. 4, pp. 809-819 (the results of which assume in every instance that there is a failure of good veterinary practices in implanting cattle with hormones for growth promotion purposes).

¹⁶⁰ See, e.g., 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 July 20, 2005, paras. 8.145-8.146 (finding that “[s]ince the scientific evidence relied upon by Japan does not support the conclusions reached by Japan in its 2004 PRA, we conclude that the 2004 PRA is not an assessment, as appropriate to the circumstances, of the risks to plant life or health, within the meaning of Article 5.1 of the SPS Agreement.” Further, the panel noted, consistent with the report of the Appellate Body in *Hormones*, that while a WTO Member may choose to rely on minority scientific opinions, those opinions must “objectively support” the conclusions relied on by the Member.)

¹⁶¹ See, e.g., 1999 Opinion, §§ 2.5.4, 4.1.6; p. 75 (“Major conclusions”) (“For all six hormones endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged.”) (Emphasis added); 2002 Opinion, § 4.2; p. 22 (“General Conclusions”) (confirming the validity of conclusions reached in previous Opinion, and noting that “no amendments to those opinions are justified.”) (Exhibits US-4, US-1).

genotoxic properties of the compounds would not be expressed *in vivo* and/or not play a role in the tumorigenic activity.”¹⁶² Despite this conclusion drawn from recent reviews, the EC cites to limited “new” evidence for genotoxic action which included studies producing effects at doses so high that, in one study, they caused cytotoxicity (*i.e.*, cells died from general toxicity unrelated to DNA damage). Moreover, in reaching the conclusion that estradiol 17 β is genotoxic based on only this limited set of new data, the EC ignored the earlier data on which JECFA had based its conclusions that estradiol 17 β did not cause gene mutation *in vitro*, without providing any analysis or explanation for ignoring the earlier data and conclusions.

154. The Opinions also fail to address several issues which have a direct bearing on an evaluation of the theoretical risk to consumers from ingesting hormone residues in meat from cattle treated with hormones for growth promotion purposes according to good veterinary practice in the context of the data available for estradiol 17 β . For example, the EC draws conclusions on the effects of estradiol 17 β in concentrations in the normal physiological range (*i.e.*, concentrations equivalent to those found in both treated and untreated meat) based solely on observations of DNA damage from doses greatly exceeding that range. This extrapolation fails to take into account the available data on, *e.g.*, differences between estradiol metabolism at high compared to low concentrations in tissues, the potential for threshold doses for adverse biological effects and the possibility of different dose-response relationships for high and low doses of the compound.¹⁶³

155. Next, the Opinions conclude that estradiol 17 β in meat residues is a complete carcinogen, citing studies on the use of estrogens in contraceptives and hormone replacement therapy as a basis to link hormone residues in meat with cancer.¹⁶⁴

156. However, these studies involved very high doses of estrogen (orders of magnitude higher than residue levels in meat from treated cattle¹⁶⁵) and extended periods of treatment. Further complicating comparison of human clinical studies with estrogen derived from meat is the fact that, unlike the natural estrogen (estradiol 17 β) used to promote growth in cattle, the estrogen

¹⁶² Reviewed in the CVMP Report, p. 9.

¹⁶³ See, generally, 52nd JECFA Report (2000). (Exhibit US-5).

¹⁶⁴ See, *e.g.*, 1999 Opinion § 4.1.8.2; see 1999 Opinion, pp. 43-44. Similar epidemiological studies and data were taken into account in 2000 in the 52nd JECFA Report, which determined that no MRLs were necessary (*i.e.*, MRLs unspecified) for meat from cattle treated with estradiol 17 β according to good veterinary practice. See 52nd JECFA Report (2000), pp. 59-60, 74. (Exhibits US-4, US-5).

¹⁶⁵ In current post-menopausal therapies containing natural estrogen, doses range from 25 micrograms to as high as 1 milligram (1×10^{-3} g) per day. These therapeutic doses of estradiol are 3 to 6 orders of magnitude greater than the theoretical maximum daily intake of estrogen due to growth promoting implants in cattle (less than 100 nanograms per person per day). A “microgram” 1 millionth (10^{-6}) of a gram, and a “nanogram” is one billionth of a gram (10^{-9}).

used in human medicine is often delivered in more potent synthetic forms.¹⁶⁶ In addition, in the majority of studies cited in the Opinions, estradiol 17 β was delivered by injection. This mode of delivery can produce drastically different results compared with oral administration of hormones, the relevant pathway for the meat consumer, because estradiol 17 β is generally inactive when given orally “because it is inactivated in the gastrointestinal tract and liver.”¹⁶⁷

157. Finally, the EC’s Opinions conclude that residues from hormone-treated meat disrupt the endocrine milieu at different stages of life.¹⁶⁸ In support of this conclusion, the EC cites several animal studies that provide evidence of abnormal reproductive development and/or function following exposure to estradiol 17 β .¹⁶⁹ However, in each of these studies, estrogen was administered to animals in excess of 25 micrograms per kilogram body weight. In contrast, the highest excess intake of estradiol 17 β in meat from cattle treated with estradiol 17 β for purposes of growth promotion according to good veterinary practice is 0.03-0.05 micrograms.¹⁷⁰

158. In a sixty kilogram human, this dose is equivalent to 0.0005 to 0.0008 micrograms per kilogram body weight. Therefore, the doses of estradiol 17 β used in the EC-cited animal studies are more than 50,000 times greater than those that would result from eating meat from cattle treated with estrogen for purposes of growth promotion.¹⁷¹

¹⁶⁶ Compared to natural estradiol, synthetic forms of estrogen are more readily absorbed from the gastrointestinal tract. Natural estrogens have low oral bioavailability. *See, e.g.*, 52nd JECFA Report (2000), p. 58. (Exhibit US-5).

¹⁶⁷ One study cited by the EC that illustrates both of these points involved the injection of neonatal mice with 2 micrograms estradiol or catechol estrogen for 5 days. At 12 and 18 months of age, the incidence of uterine tumors was 0% in control mice, 7% in mice treated with estradiol, and 66% in mice treated with catechol estrogen. Though the authors conclude that catechol estrogens are carcinogenic, the results should be interpreted with caution because the dose of estrogen used was incredibly high – equivalent to more than 20 milligrams per kilogram body weight. *See* Newbold and Liehr, Induction of uterine adenocarcinoma in CD-1 mice by catechol estrogens, *Cancer Research* 60 (2000), pp. 235-237.

¹⁶⁸ *See* comments of the UK Report on the 1999 Opinion’s conclusions regarding the endocrine disrupting potential of the hormones (While the 1999 Opinion “suggests that many aspects of human development reproduction could be affected by hormone residues in meat. [However, the UK Group] found that there is no evidence for such effects.” UK Report, p. 2. (Exhibit US-12).

¹⁶⁹ *See* 1999 Opinion, pp. 9, 75. (Exhibit US-4).

¹⁷⁰ *See* 52nd JECFA Report (2000), p. 73. (Exhibit US-5).

¹⁷¹ In addition to estradiol, the EC also cites various studies in support of its conclusion that zeranol and testosterone are endocrine disrupters. In the zeranol study, treatment of pregnant mice with 150 micrograms per kilogram body weight resulted in testicular abnormalities in male pups. In the testosterone study, postnatal injection of testosterone at 200 milligrams per kilogram body weight permanently altered the response of uterine cells to estrogen (a phenomenon referred to as “hormonal imprinting”). In order to highlight the extreme concentration of these hormones actually administered to these animals, it is helpful to contrast these levels with the facts that testosterone concentrations in men are in the nanogram range (exponentially less) and that the theoretical maximum daily intake of testosterone due to hormone implants in cattle is less than 400 nanograms per person per day (again, exponentially less).

159. In support of its conclusions on endocrine disruption, the EC purports to show that prepubertal children in fact have much lower estrogen levels than previously believed, *i.e.*, than were previously detectable using other, internationally accepted and validated assays.¹⁷² The EC's contention is that extremely low levels of estrogen in pre-pubertal children, particularly boys, makes them more sensitive and susceptible to endocrine disruption. However, this conclusion rests on the results of an assay developed in 1994 (known as the "Klein assay"), regarding which the EC's own CVMP expressed the following concerns: "(i) the measure was made only in plasma and needs to be carried out in other tissue(s) in order to enable the comparison between the intake of residual oestradiol and the endogenous levels, [and] (ii) the methodology needs validation and is not (yet) generally accepted."¹⁷³

160. In sum, the EC's Opinions and their underlying studies identify theoretical risks from estradiol 17 β generally, but fail to address the relevant risk – that arising from the presence in meat of residues resulting from the administration to animals, according to good veterinary practice, of any of the six hormones for growth promotion purposes. Therefore, the EC's Opinions fail to sufficiently warrant or reasonably support the EC's ban on meat from cattle treated with hormones for growth promotion purposes according to good veterinary practice. As a result, the EC's ban is not based on a risk assessment within the meaning of Article 5.1 of the SPS Agreement.

3. The EC fails to demonstrate how its amended ban satisfies the conditions of Article 3.3 of the SPS Agreement

161. The EC fails to demonstrate that its amended ban, which is not based on international standards, satisfies the conditions of Article 3.3 of the SPS Agreement.¹⁷⁴ Specifically, the EC

¹⁷² See 1999 Opinion, § 2.2.2.1, pp. 11-12. (Exhibit US-4).

¹⁷³ CVMP Report, p. 12. (Exhibit US-13).

¹⁷⁴ Article 3.3 of the SPS Agreement states:

Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

[Footnote:] For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

maintains its amended ban in breach of Article 3.3 because it fails to base its amended ban on a risk assessment within the meaning of Article 5.1 of the SPS Agreement.

- a. *The EC’s amended ban is not based on international standards within the meaning of Article 3.3 of the SPS Agreement*

162. Article 3.3 of the SPS Agreement sets out the requirements by which a Member may “introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations.”

163. The EC’s sanitary measure, its amended import ban, is not “based on” international standards within the meaning of Article 3.3, as the relevant standards adopted by Codex permit trade in meat and meat products from cattle treated with hormones for growth promotion purposes by setting MRLs, as necessary, for residues of the hormones. The EC’s ban prohibits trade in and marketing of such meat products regardless of residue levels.

- b. *The EC fails to demonstrate that there is a scientific justification for its amended ban, or that it maintains the ban “as a consequence of the level of ... protection a Member determines to be appropriate in accordance with the relevant provisions of [Article 5 of the SPS Agreement]”*

164. Contrary to Article 3.3’s requirements, the EC maintains its ban without having based it on a risk assessment within the meaning of Article 5.1,¹⁷⁵ or otherwise having satisfied the conditions for maintaining a provisional measure within the meaning of Article 5.7. Accordingly, the EC’s ban fails to satisfy the conditions of Article 3.3, *i.e.*, that it be maintained pursuant to scientific justification or “as a consequence of the level of . . . protection [the EC] determine[d] to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5”, and the EC therefore maintains its import ban in breach of this provision.

D. The United States Has Not Breached Any Other WTO Obligations by Continuing to Suspend Concessions to the EC

1. Introduction

165. The EC argues that the United States has breached DSU Articles 3.7, 21.8, 22.8, 23.1 and 23.2(a). There are two cornerstones to this argument, through which the EC seeks to avoid having to demonstrate how its amended ban in fact cures the WTO-inconsistencies of the original

¹⁷⁵ As noted by the Appellate Body, compliance with Article 3.3 entails conformity with the requirements of Article 5.1. *See* Appellate Body Report, para. 177.

ban.¹⁷⁶ First, the EC argues that the original complaining party, in this case the United States, is obligated to seek recourse to dispute settlement in order to continue to suspend properly-authorized concessions. In particular the EC cites to the United States' failure "to initiate dispute settlement proceedings pursuant to Article 21.5 of the DSU."¹⁷⁷ The EC links this failure to initiate a compliance proceeding to breaches of Articles 23.2(a) and 23.1 of the DSU, and asserts that a U.S. failure to initiate an Article 21.5 proceeding equates to a presumption of EC compliance.¹⁷⁸ As discussed below, Article 21.5 does not, among other things, obligate the original complaining party to seek immediate recourse to dispute settlement to evaluate a Member's unilateral declaration that it has taken a measure to comply.

166. Second, the EC asserts that it has "remove[d]" its measure within the meaning of Article 22.8 of the DSU, and that as a result the United States now violates the provisions of that Article by suspending concessions to the EC. The EC links its "removal" of the offending measure and alleged U.S. breach of Article 22.8 to breaches of Articles 23.1 and 3.7 of the DSU.

167. As discussed below, the EC's analysis of these provisions is not consistent with their terms, nor does it reflect the fact that the United States continues to act in accordance with the DSB's multilaterally-granted authorization to suspend concessions to the EC.¹⁷⁹ The DSU simply does not prescribe the particular procedures to follow in a situation where the DSB has granted authorization to suspend concessions to a Member, and the implementing Member later claims to have complied (for ease of convenience the United States will refer to this situation as a "post-suspension situation").

168. The DSU leaves 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 has an obligation to 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. The EC does not base its proposed approach on

¹⁷⁶ See EC First Written Submission, para. 2.

¹⁷⁷ EC First Written Submission, paras. 25, 51, 63, 66.

¹⁷⁸ See EC First Written Submission, para. 51. ("The United States should have introduced a compliance procedure under Article 21.5 of the DSU. Because it has not done so, it has violated the specific prohibition of unilateral conduct set out in Article 23.2(a) of the DSU," thereby "constitut[ing] a violation of Article 23.1 of the DSU.") (Emphasis added). See also, EC First Written Submission, para. 94 ("the European Communities must be presumed to have complied with its WTO obligations, if the United States refuses to establish to the contrary.").

¹⁷⁹ The United States explained above why the EC's claims regarding Article 22.8 must fail. We will not repeat that analysis here, but rather will examine the interrelationship of that claim with the EC's other claims. See Section IV.B.

the text of the relevant provisions, but rather constructs a series of policy arguments as to why the DSU should be re-written in the manner desired by the EC.

169. Members are currently negotiating in the DSU negotiations on whether to prescribe particular procedures in a post-suspension situation. These negotiations acknowledge that the DSU does not currently prescribe these procedures. No consensus has emerged on whether to amend the DSU to prescribe such procedures. The EC is asking the Panel to undertake the task of Members and legislate by prescribing a particular procedure. Panels however are not authorized to legislate, but rather are to apply the covered agreements as written, not as one party would like them to be written.

2. The United States continues to satisfy its obligations under DSU Article 23

170. Prior to addressing the EC’s intertwined claims alleging breaches of several DSU provisions, it is first necessary to examine an alleged DSU breach common to each of those claims – that the United States has breached its obligations under DSU Article 23.

171. Article 23.1 provides:

When Members *seek the redress of a violation* of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this Understanding. (Emphasis added).

172. Article 23.1 contemplates a situation where a WTO Member “seek[s] the redress” of a violation. The ordinary meaning of to “seek” is “to resort to, ... to make an attempt, try.”¹⁸⁰ “Redress” has been construed as referring to “a reaction by a Member against another Member, because of a perceived (or WTO-determined) WTO violation, with a view to remedying the situation.”¹⁸¹

173. Article 23.1’s use of the present tense “seek” indicates that a Member must be actively looking for or trying to bring about reparation, compensation or remedy for a particular violation in order for Article 23.1’s terms to apply. As noted by the panel in *U.S. – Certain Products*, seeking redress of a violation means taking “action in response to what a [Member] views as a WTO violation.”¹⁸²

¹⁸⁰ Panel Report, *United States – Import Measures on Certain Products from the European Communities*, WT/DS165/R, adopted 10 January 2001, para. 6.22 (“*U.S. – Certain Products*”).

¹⁸¹ Panel Report, *U.S. – Certain Products*, para. 6.22.

¹⁸² Panel Report, *U.S. – Certain Products*, para. 6.23.

174. However, notwithstanding the EC's claim that by continuing to suspend concessions the United States seeks redress of a perceived violation on the part of the EC,¹⁸³ the United States does not now, and did not at the time of the EC's unilateral declaration of compliance, "seek" anything within the meaning of Article 23.1 with respect to the EC's declaration. The United States did not make a determination that the EC's amended hormone ban is in violation of a covered agreement (the current proceeding provides an opportunity for the WTO to resolve that question), nor did the United States try to obtain or bring about compensation or remedy for some new wrong or alleged WTO violation.

175. In fact, the United States, at the appropriate time, adhered to the letter of Article 23.1 by seeking redress of the nullification or impairment caused by the EC's import ban on hormone-treated meat and meat products through recourse to the provisions of the DSU.¹⁸⁴ The multilaterally-authorized suspension of concessions stemming from U.S. recourse to dispute settlement remains valid to this day, and is unaffected by the EC's unilateral declaration of compliance. In other words, the United States has already sought and obtained redress through the multilateral dispute settlement system for a violation found by the DSB. There is no provision in the WTO Agreement that provides that a single Member can unilaterally invalidate the multilateral decision of the DSB to authorize suspension of concessions.

176. While Article 22.8 does set forth conditions under which that authorization may no longer be applied, as discussed above, the EC has offered no meaningful argumentation as to how those conditions have been fulfilled. Absent such a demonstration, the EC has quite simply failed to meet its burden in this proceeding that the U.S. suspension of concessions is in any way inconsistent with the DSB's authorization and U.S. WTO obligations. The U.S. is not seeking redress for anything but the import ban which the DSB ruled inconsistent with EC obligations, regarding which the EC has presented no evidence of having removed or provided a solution to the resulting nullification or impairment.

3. The U.S. suspension of concessions does not breach Articles 23.2(a), 21.5 and 23.1 of the DSU

177. The EC argues that the United States "should have introduced a compliance procedure under Article 21.5 of the DSU," and in failing to do so "violated the specific prohibition of unilateral conduct set out in Article 23.2(a) of the DSU."¹⁸⁵ The EC argues that the alleged

¹⁸³ EC First Written Submission, para. 73.

¹⁸⁴ Instead, the EC argues that the United States has breached its 23.1 obligations because "[i]n this particular instance, the United States failed to have recourse to dispute settlement pursuant to Article 21.5." (WT/DS320/6). However, for the reasons discussed below, the United States was not obligated to initiate a compliance proceeding under Article 21.5. Further, the EC's linkage of a 23.1 violation to a failure to abide by Article 21.5 ignores the text of Article 23.1, which first requires that Members "seek the redress of a violation". The United States does not seek any such redress, but rather continues to act pursuant to its authorization to suspend concessions.

¹⁸⁵ EC First Written Submission, para. 17.

breach of Articles 23.2(a) and 21.5 further constitutes a breach of Article 23.1 of the DSU. To the contrary, the United States continues to satisfy its obligations under each of these Articles, and the EC has failed to demonstrate the contrary.

- a. *The United States has not breached its obligations under DSU Article 23.2(a)*

178. The EC argues that the United States acts inconsistently with DSU Article 23.2(a) because: (1) the United States is seeking redress of a violation¹⁸⁶; (2) the United States has made a determination that a violation has occurred¹⁸⁷; and (3) the determination was “not made in accordance with the rules and procedures of the DSU or is not consistent with the findings of a dispute settlement organ.”¹⁸⁸ Specifically, the EC argues that the United States “should have introduced a compliance procedure under Article 21.5 of the DSU. Because it has not done so it has violated . . . Article 23.2(a) of the DSU [and therefore Article 23.1].”¹⁸⁹

179. Contrary to the EC’s claim, the United States has not sought redress of a WTO violation; did not make a determination contrary to Article 23.2(a); and was not obligated to initiate compliance proceedings under DSU Article 21.5. Therefore, the EC’s claim of a U.S. breach of its obligations under DSU Article 23.2(a) fails.

- (i) The United States does not seek redress of a violation within the meaning of Article 23.1

180. First, as discussed above, the United States has not, through its continued application of the DSB’s authorization to suspend concessions, sought redress for another Member’s violation, in breach of Article 23.1. This also means the United States is not breaching Article 23.2(a). Article 23.2(a) is preceded by the phrase, “[i]n such cases,” which refers back to the situation provided for in Article 23.1. Thus, Article 23.2(a), like Article 23.1, applies only in situations when a Member is “seeking redress for a violation” of a WTO obligation. In this regard, the Appellate Body has found that Article 23.1 sets forth a general rule for which Article 23.2 sets forth specific applications.¹⁹⁰

¹⁸⁶ EC First Written Submission, paras. 34, 53.

¹⁸⁷ EC First Written Submission, para. 54.

¹⁸⁸ EC First Written Submission, para. 62; *see* Panel Request, p. 3.

¹⁸⁹ EC First Written Submission, para. 51.

¹⁹⁰ Appellate Body Report, *United States – Import Measures on Certain Products from the European Communities*, WT/DS165/R, adopted 10 January 2001, para. 111 (“U.S. – Certain Products”).

(ii) The United States did not make a “determination” within the meaning of Article 23.2(a)

181. Likewise, the United States is not breaching Article 23.2(a) because it did not make a “determination” within the meaning of Article 23.2(a).¹⁹¹ Article 23.2(a) prohibits Members from “. . . mak[ing] a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of [the DSU].”

182. Since it received authorization to suspend concessions to the EC, the United States has simply continued to act according to its DSB authorization to suspend concessions to the EC. Contrary to the EC’s claims in this panel proceeding, the United States made no determinations concerning the EC’s import ban, amended or not. The United States did not need to make any further determinations to continue to apply that suspension of concessions, and it did not. Further, as noted above, the conditions under which a Member may no longer apply a DSB-authorized suspension of concessions are set forth in Article 22.8, and the EC has made no effort to demonstrate that those conditions have been met.

183. As noted by the EC in its First Written Submission, the United States made certain statements regarding the EC’s Opinions, studies and amended ban, which included the following: “[t]he United States, however, could not understand how this new directive presented now could amount to implementation of the DSB’s recommendations and rulings”; “[w]e still don’t see how they’re in compliance because the EU ban remains in place and is unsupported by any scientific rationale”; “[t]he United States maintains its WTO-authorized sanctions on EU products because the United States fails to see how the revised EC measure could be considered to implement the DSB’s recommendations and rulings.”¹⁹²

184. None of these statements constitute a “determination” within the meaning of Article 23.2(a). They do no more than reflect the fact that the United States was reviewing a highly technical matter, and could not on the basis of the review to that point understand how the EC’s directive implemented the DSB’s recommendations and rulings, as asserted by the EC. In other words, they are simply statements of the status of the U.S. evaluation of the EC measure at that point in time based on the information available.

185. Indeed, at no point did the United States claim that the amended Directive was WTO-inconsistent, nor did it take any action directed at the amended Directive. The statements put forward by the EC, such as the U.S. statement at the November 7, 2003 DSB meeting, make no reference to a WTO violation; rather they referred to information put forward by the EC, at that

¹⁹¹ See EC First Written Submission, para. 61.

¹⁹² See EC First Written Submission, paras. 19-22.

time, in support of its claim of compliance with the DSB recommendations and rulings. The United States remained open to discussing any further information that the EC might have developed in support of its declaration of compliance, and to this end engaged in informal consultations and technical discussions and made a request under Article 5.8 of the SPS Agreement seeking all of the materials underpinning the EC's import ban.¹⁹³

186. Ongoing analyses and internal evaluations on the several new studies and Opinions, which comprise hundreds of pages of highly-technical documents, do not constitute a “determination” within the meaning of Article 23.2(a). Were it otherwise, WTO Members could claim a violation of Article 23.2(a) premised simply on the internal deliberations or discussions of another Member.

187. The EC's interpretation of the application of DSU Article 23.2(a) is untenable, as it would stymie a Member's ability to ultimately make a decision to seek recourse to the provisions of the DSU based on a review of the often-intricate and complex facts underlying a given issue. Under the EC's reading of Article 23.2(a), a complaining Member need not actually indicate any definitive view on the WTO-consistency of an implementing Member's measure to have made a determination; rather, the implementing Member can force a complaining Member into breach of Article 23.2(a) simply by making a unilateral declaration of compliance that the complaining Member does not immediately agree with or test through the immediate invocation of Article 21.5 proceedings. The text of Article 23.2(a) does not provide for such an artificial constraint on the ability of Members to evaluate the measures of other Members, a constraint which would be particularly hard felt in scientific disputes.

188. While noting that there was no “need to precisely define what a determination in the sense of Article 23.2(a) is,” the *U.S. – Section 301* panel concluded that a determination must nonetheless be sufficiently “firm” and “immutable”, in other words “a more or less final decision.”¹⁹⁴ The panel further concluded that it was

of the view that a ‘determination’ can only occur *subsequent* to a Member having decided that, in its preliminary view, there may be a WTO inconsistency, i.e., only once that Member has decided to seek redress of such inconsistency. Mere opinions or views expressed before that stage is reached, are not intended to be covered by Article 23.2(a).¹⁹⁵

Contrary to the EC's contentions, the examples it cites do not amount to “firm”, “immutable” or “more or less final” decisions regarding the amendments the EC made to its import ban. Rather, U.S. statements, including those at the DSB, were simply comments on the status of the U.S.

¹⁹³ See Request of the United States pursuant to Article 5.8 of the SPS Agreement (December 13, 2004). (Exhibit US-19).

¹⁹⁴ Panel Report, *Section 301*, fn. 657.

¹⁹⁵ Panel Report, *Section 301*, fn. 657.

evaluation of the EC's efforts at implementation, and can no more be considered a "determination" made in breach of Article 23.2(a) than the EC's assertions, at the DSB, of a violation by the United States of the DSU. Further, the United States made no decision to seek redress of any perceived inconsistency.

189. A "determination" is defined as:

"The settlement of a suit or controversy by the authoritative decision of a judge or arbiter; a settlement or decision so made, an authoritative opinion"; "The settlement of a question by reasoning or argument"; "The action of coming to a decision; the result of this; a fixed intention"; "The action of definitely locating, identifying, or establishing the nature of something; exact ascertainment (of); a fact established, a conclusion or solution reached".¹⁹⁶

190. This definition emphasizes not only the finality of a decision, but also its formality. It does not contemplate, as argued by the EC, that a determination can be "implicit." The ordinary meaning of the term thus makes clear that the opinions and views of the United States cited by the EC did not rise to the level of "determinations" within the meaning of Article 23.2(a). For example, the United States opinions and views were not "authoritative decision[s]", nor did they state a "fixed intention." For this reason as well, the EC has failed to demonstrate that the United States breached Article 23.2(a).

(iii) The United States was not obligated to initiate a compliance proceeding pursuant to Article 21.5

191. Finally, the EC alleges that, contrary to the requirements of Article 23.2(a) of the DSU, the United States made a determination not "in accordance with the rules and procedures of the DSU," and in a manner "not consistent with the findings of a dispute settlement organ."¹⁹⁷ Specifically, the EC alleges that the United States made a determination that the EC had not implemented the recommendations and rulings of the DSB in breach of Article 21.5 of the DSU.¹⁹⁸ As demonstrated below, the United States has not breached its obligations under DSU Article 21.5.

192. The EC asserts in its panel request that the United States acts in breach of DSU Article 21.5 because it "failed to have recourse to dispute settlement pursuant to Article 21.5 of the DSU, in a situation where there is disagreement as to the existence or consistency with a covered agreement of measures taken to comply with DSB recommendations and rulings."¹⁹⁹ For

¹⁹⁶ New Shorter Oxford English Dictionary (Brown, L. ed.) (1993), p. 651; *see* Panel Report, *Section 301*, fn. 657.

¹⁹⁷ EC First Written Submission, para. 62.

¹⁹⁸ EC First Written Submission, para. 66.

¹⁹⁹ WT/DS320/6.

purposes of its Article 23.2(a) argument, the EC contends that the United States was required to initiate Article 21.5 proceedings and receive an adverse finding against the EC's ban in order to maintain its suspension of concessions.²⁰⁰

193. The EC's Article 21.5 claim fails for four reasons: (1) the EC has not established that there is a "disagreement as to the existence or consistency with a covered agreement of measures taken to comply;" (2) Article 21.5 sets no deadline by which such a proceeding must be brought; (3) nothing in the text of Article 21.5 places the onus of initiating a compliance proceeding on the original complaining party (in this case, the United States); and (4) the phrase "these dispute settlement proceedings" in Article 21.5 is not restricted to proceedings under Article 21.5, but rather could include proceedings such as DSU Article 22.6 arbitration proceedings, DSU Article 25 proceedings, or the proceedings of a *de novo* panel, as the EC has sought in this instance.

(A) The EC has not established that there is a disagreement

194. As explained, as of the time this Panel was established, the United States had not made a determination as to whether the EC's amended hormone ban complies with the DSB recommendations and rulings or is consistent with the covered agreements. The United States has continued to evaluate the EC's claim, and at the time of panel establishment had been awaiting the EC's response to the U.S. request under Article 5.8 of the SPS Agreement. The United States has continued to evaluate the EC's claim, including its May 19, 2005 response to the U.S. request. The U.S. evaluation depends to a large extent on the EC's response to questions such as those posed in this submission, including why the EC believes that scientific evidence has now become insufficient to perform a risk assessment for five of the six hormones. To date the EC has been less than thorough in its responses. Article 21.5 only applies "[w]here there is disagreement."

(B) Article 21.5 sets no deadline by which a party must seek recourse to dispute settlement

195. Article 21.5 sets no deadline for initiation of the proceedings that that article contemplates. This is only logical, as Members require time to evaluate other Members' measures, in particular in a matter involving complex scientific issues such as this one. Indeed, there has often been a substantial gap between claims of compliance by an implementing

²⁰⁰ See EC First Written Submission, para. 67. The text of Article 21.5 reads, in relevant part:

Where there is disagreement as to the existence or consistency with a covered agreement of measures taken to comply with the recommendations and rulings such dispute shall be decided through recourse to these dispute settlement procedures, including wherever possible resort to the original panel.

Member and the invocation of Article 21.5 proceedings by a complaining Member.²⁰¹ Beyond the absence of any textual basis in Article 21.5 for the EC view that Article 21.5 imposes an immediate obligation on complaining Members to invoke Article 21.5 proceedings upon a unilateral declaration of compliance by an implementing Member, such an interpretation is not supported by an examination of the context provided by other DSU provisions. For example, Article 3.7 explains,

[b]efore bringing a case, a Member shall exercise its judgment as to whether action under these procedures would be fruitful. The aim of the dispute settlement system is to secure a positive solution to a dispute. A solution mutually acceptable to the parties is clearly to be preferred.

196. The EC interpretation of Article 21.5 as requiring immediate resort to litigation by a complaining party would definitively prevent that complaining party from exercising any judgment as to the fruitfulness of dispute settlement, and would preclude Members from seeking mutually agreeable solutions through negotiations. The aim of the dispute settlement system is to secure a positive solution by whatever means possible, and not simply through litigation.

197. In the absence of any obligation in Article 21.5 to immediately resort to litigation, the fact that the United States had not done so by the time the EC initiated this proceeding cannot constitute a breach of Article 21.5.

(C) Article 21.5 does not obligate the original complaining Member to initiate a compliance proceeding

198. Next, contrary to the EC's argument, the text of Article 21.5 assigns no obligation to the *complaining* party to seek recourse to "these dispute settlement procedures" in the event that there is a disagreement "as to the existence or consistency with a covered agreement of measures taken to comply." The text does not require that the original complaining Member, in this case the United States, initiate dispute settlement proceedings in the event of a disagreement. Indeed, the text Article 21.5 does not mention the parties at all, and thus there is no basis for the EC to argue that only the United States (and not the EC) would have an obligation to initiate an Article 21.5 proceeding to seek resolution of a disagreement through dispute settlement.²⁰² Thus, the

²⁰¹ For example, in the dispute *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, 312 days elapsed between a claim of compliance and recourse to Article 21.5. Compare WT/DS58/15/Add.4 and WT/DS58/17. Similarly, in the dispute *European Communities – Anti-Dumping Duties on Imports of Cotton-Type Bed Linens from India*, 213 days elapsed between the claim of compliance and initiation of a compliance proceeding. See WT/DS141/12.

²⁰² Indeed, in portions of its First Written Submission, the EC appears to acknowledge the lack of a specific obligation for the original complaining party to initiate an Article 21.5 compliance proceeding. See First Written Submission, para. 25 (If the United States wishes to discuss compliance of the EC measure it *should initiate* an Article 21.5 procedure . . .") (Emphasis added). The silence in the text of Article 21.5 regarding which party must

mere fact that the United States had not yet decided to invoke Article 21.5 proceedings before the EC undertook the present challenge is not itself grounds for concluding that the United States breached Article 21.5, any more than the EC's failure to do so was.

(D) Compliance with Article 21.5 may be achieved through recourse to other provisions of the DSU

199. Finally, it is important to recognize that the text of Article 21.5 refers to “these dispute settlement procedures,” without specifying any particular subset of WTO dispute settlement procedures. The panel in the *U.S. – Certain Products* dispute recognized that the ordinary meaning of this phrase covers any dispute settlement procedure provided in the DSU “that could be used to assess the compatibility of the new implementing measure, including Article 25 or Article 22 of the DSU.”²⁰³ In other words, there is no basis in Article 21.5 for excluding any WTO dispute settlement procedure that could be used to assess the WTO-compatibility of a new implementing measure.

200. Thus, the EC's argument that the United States was specifically obligated to initiate a compliance proceeding under Article 21.5 once the EC declared the WTO-consistency of its amended measure²⁰⁴ is groundless. Even if the EC had established the existence of a disagreement, any proceeding that can resolve the matter of existence or consistency of a measure taken to comply fulfills the requirements of Article 21.5 – including the current proceeding. As noted above, Article 21.5 does not provide that any obligation to have recourse to DSU procedures would be imposed solely on the original complaining party. In particular, where, as here, the DSB has authorized a complaining Member to suspend concessions under the procedures in Articles 22.6 and 22.7, there is no basis for concluding that Article 21.5 imposes on the original complaining Member a greater burden than on the Member already found to have breached its WTO obligations and which has failed to implement the DSB's recommendations and rulings by the conclusion of the reasonable period of time. Article 22.8 sets forth the conditions under which multilateral, DSB-authorized suspensions of concessions may no longer be applied, and the DSU provides the means to either party to a dispute to determine through multilateral proceedings whether those conditions have been met.

201. In bringing these proceedings, the EC availed itself of one such means, though, as discussed above, it has failed to meet its required burden to prevail. Also, in bringing these

initiate a compliance proceeding and when it must do so has been highlighted in the ongoing DSU negotiations. *See, e.g.*, Amendments to Certain Provisions of the Understanding on Rules and Procedures Governing the Settlement of Disputes (WT/MIN(01)/W/6) (In particular, *see* proposed Article 21bis (“Determination of Compliance”), which proposes both a deadline for initiating an Article 21.5 compliance proceeding as well as a clarification of which party must initiate the proceeding).

²⁰³ Panel Report, *U.S. – Certain Products*, paras. 6.119, *et seq.*

²⁰⁴ *See* EC First Written Submission, para. 51 (“the United States should have introduced a compliance procedure under Article 21.5 of the DSU.”)

proceedings, the EC has conceded that an Article 21.5 compliance panel is not the exclusive means to resolve a “disagreement” even if one existed. If it were the exclusive means, then the EC itself would have invoked Article 21.5, as it has done in the past. However, it did not, nor did it seek to have the matter that is the subject of this proceeding referred to the “original panel” as provided in Article 21.5. None of the original panelists are serving on this Panel. Thus the EC’s approach in this proceeding itself refutes the EC’s Article 21.5 claim.

b. *Conclusion: U.S. suspension of concessions does not violate DSU Articles 23.2(a), 21.5 or 23.1*

202. The EC premises its claim of breach of Article 23.1 on the fact that the United States’ “conduct violated Articles 23.2(a) and 21.5 of the DSU.”²⁰⁵ However, as demonstrated above: (1) the United States has not sought redress of a violation within the meaning of Article 23.1; (2) the United States has not made a “determination” within the meaning of Article 23.2(a); and (3) the United States was not obligated to initiate a compliance proceeding under Article 21.5. Therefore, the EC’s claims that the United States has breached its obligations under these articles fail.

4. The United States has not violated DSU Article 23.1, read together with Articles 22.8 and 3.7 of the DSU

203. The EC claims that the United States violates DSU Article 23.1, when read together with Articles 22.8 and 3.7 of the DSU. The EC asserts that these three Articles, together, demonstrate “that a WTO Member shall not apply the suspension of concessions or other obligations in the presence of an implementation act, which has not been found to be inconsistent following an Article 21.5 proceeding.”²⁰⁶ In short, the “thrust of the [EC’s] argument is that the United States is not entitled to maintain the application of the suspension [of concessions].”²⁰⁷ As demonstrated below, the United States continues to satisfy its obligations under each of these Articles.

a. *The United States does not seek to redress a WTO violation within the meaning of DSU Article 23.1*

204. As discussed above, the United States does not seek to redress a WTO violation within the meaning of DSU Article 23.1, and it continues to act pursuant to its multilateral authorization

²⁰⁵ EC First Written Submission, paras. 34, 68.

²⁰⁶ EC First Written Submission, para. 71. The EC argues that it “is not required to explain in full the substance of its compliance measure and why this measure implements the DSB recommendations and rulings. Rather, . . . The [EC] considers that it is sufficient to refer to the presumption of good faith.” See EC First Written Submission, para. 72.

²⁰⁷ EC First Written Submission, para. 70.

to suspend concessions to the EC.²⁰⁸ Therefore, the EC’s claim that the United States has violated DSU Article 23.1, read together with Articles 22.8 and 3.7 of the DSU fails.

b. *The United States has not acted in breach of DSU Article 22.8*

205. As discussed in Section IV.B of this Submission, the United States has not acted in breach of DSU Article 22.8. The EC has yet to demonstrate that it has either removed its measure or provided a solution to the nullification or impairment of benefits to the United States.²⁰⁹ Because it has failed to satisfy any of Article 22.8’s conditions, the EC fails to make its *prima facie* case that the United States has applied the suspension of concessions in violation of Article 22.8.

c. *Conclusion: Because the United States has not breached its obligations under DSU Articles 23.1 and 22.8, it has not acted inconsistently with the objective of DSU Article 3.7*

206. The EC claims that the United States acts in breach of DSU Article 3.7 because “by violating Articles 23.1 and 22.8 of the DSU, [it] also acted contrary to Article 3.7 of the DSU.”²¹⁰ The text of Article 3.7 reads, in relevant part:

[t]he last resort which this Understanding provides to the Member invoking the dispute settlement procedures is the possibility of suspending the application of concessions or other obligations under the covered agreements on a discriminatory basis vis-a-vis the other Member, subject to authorization by the DSB of such measures.

207. As noted by the Appellate Body, DSU Article 3.7 does not, in and of itself, contain a specific obligation.²¹¹ DSU Article 3.7 is a statement explaining an important aspect of the WTO dispute settlement system. It does not impose an obligation on a Member. Accordingly, the EC’s claim should fail on that basis alone. However, the Appellate Body considered that “if a Member has acted in breach of Articles 22.6 and 23.2(c) of the DSU, that Member has also, in view of the nature and content of Article 3.7, last sentence, necessarily acted contrary to the latter provision.”²¹² As demonstrated above, the United States continues to suspend concessions in a

²⁰⁸ See Section IV.D.2.

²⁰⁹ See Section IV.B.2.

²¹⁰ EC First Written Submission, para. 122.

²¹¹ See Appellate Body Report, *U.S. – Certain Products*, paras. 119-120. (“The last sentence of Article 3.7 provides that the suspension of concessions or other obligations is a ‘last resort’ that is subject to DSB authorization. The *obligation* of WTO Members not to suspend concessions or other obligations *without* prior DSB authorization is explicitly set out in Articles 22.6 and 23.2(c), not in Article 3.7 of the DSU.”) (Emphasis in original).

²¹² Appellate Body Report, *U.S. – Certain Products*, para. 120.

manner consistent with its obligations under the DSU, including under Articles 22 and 23. Therefore, the United States has not acted contrary to DSU Article 3.7.

5. The United States has not breached its obligations under GATT 1994 Article I or II

208. The EC claims that United States acts in breach of GATT 1994 Articles I and II.²¹³ However, the DSB has specifically authorized the United States to suspend obligations under Article I and Article II of the GATT 1994.

209. Until the DSB withdraws its authorization or the conditions of Article 22.8 have been found to have been met, the United States cannot be found in breach of GATT 1994 Article I or II.

V. CONCLUSION

210. In light of the foregoing, the United States asks the Panel to find that:

- (1) The EC has failed to demonstrate that the United States has breached DSU Article 22.8, and that the United States continues to suspend concessions to the EC consistent with the requirements of that provision;
- (2) The United States has not breached DSU Articles 3.7, 21.5, 23.1 or 23.2(a); and
- (3) The United States has not breached GATT 1994 Articles I or II.

²¹³ EC First Written Submission, para. 128.

TABLE OF EXHIBITS

Exhibit US-	Title of Exhibit
1	“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”)
2	November 21, 1985 statement of EC Commissioner for Agriculture Frans Andriessen
3	Directives 2003/74/EC and 96/22/EC
4	“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”)
5	“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”)
6	Fritsche, S. <i>et al.</i> , Occurrence of hormonally active compounds in food, European Food Research and Technology, vol. 209 (1999)
7	Stephany <i>et al.</i> , Tissue levels and dietary intake of endogenous steroids: an overview with emphasis on 17beta-estradiol, EuroResidue V Symposium (May 10-12, 2004)
8	Eurostat data regarding meat production in the EU-15
9	June 1984 statement of Spokesman’s Group
10	“Summary Made by the European Parliament on the Intervention of Mr. Fischler About Hormones,” Strasbourg, January 16, 1996.
11	Statement of Mission, Veterinary Products Committee, Department for Environment, Food and Rural Affairs. Available at: http://www.vpc.gov.uk
12	UK Sub-Group of the Veterinary Products Committee, October 1999 (“UK Report”)
13	“Report of the CVMP on the Safety Evaluation of Steroidal Sex Hormones in particular for 17β-Oestradiol, Progesterone, Alternogest, Flugestone acetate and Norgestomet in the Light of New Data/Information made available by the European Commission” Committee for Veterinary Medicinal Products (EMEA/CVMP/885/99) (“CVMP Report”)

Exhibit US-	Title of Exhibit
14	“MAFF Stands Firm on Commission Proposal for EU Beef Hormones Ban”, Department for Environment, Food and Rural Affairs, June 12, 2000. Available at: http://www.defra.gov.uk/news/newsrel/2000/000612b.htm
15	About the European Medicines Agency. Available at: http://www.emea.eu.int/htms/aboutus/emeaoverview.htm
16	“A Review to Update Australia’s Position on the Human Safety of Residues of Hormone Growth Promotants (HGPs) Used in Cattle”, Department of Health and Ageing, July 2003 (“Australia Review”)
17	Review of Specific Documents Relating to the SCVPH Opinion of 30 April 99 on the Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products, dated May 3, 2000 (“2000 Review”)
18	Use of DES in the United States, Backgrounder, Food Safety and Inspection Service, U.S. Department of Agriculture. Available at: http://www.fsis.usda.gov/OA/background/des.htm
19	Request of the United States pursuant to Article 5.8 of the SPS Agreement (December 13, 2004)