

**BEFORE THE  
WORLD TRADE ORGANIZATION  
APPELLATE BODY**

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

**(AB-2008-5)**

**APPELLEE SUBMISSION  
OF THE UNITED STATES OF AMERICA**

**June 26, 2008**

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<i>Argentina – Footwear Safeguard (AB)</i>	Appellate Body Report, <i>Argentina – Safeguard Measures on Imports of Footwear</i> , WT/DS121/AB/R, adopted 12 January 2000
<i>Australia – Salmon (AB)</i>	Appellate Body Report, <i>Australia – Measures Affecting Importation of Salmon</i> , WT/DS18/AB/R, adopted 6 November 1998
<i>EC – Asbestos (AB)</i>	Appellate Body Report, <i>European Communities – Measures Affecting Asbestos and Products Containing Asbestos</i> , WT/DS135/AB/R, adopted 5 April 2001
<i>EC – Bananas III (Article 21.5) (EC)</i>	Panel Report, <i>European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Article 21.5 by the European Communities</i> , WT/DS27/RW/EEC, circulated 12 April 1999 (unadopted)
<i>EC – Bananas III (Article 22.6) (US)</i>	Arbitrator Award, <i>European Communities – Regime for the Importation, Sale and Distribution of Bananas – Recourse to Arbitration by the European Communities</i> , WT/DS27/ARB, circulated 9 April 1999
<i>EC – Bed Linen (Article 21.5) (AB)</i>	Appellate Body Report, <i>European Communities – Anti-Dumping Duties on Imports of Cotton-Type Bed Linen from India – Recourse to Article 21.5 of the DSU by India</i> , WT/DS141/AB/RW, adopted 24 April 2003
<i>EC – Hormones (Panel)</i>	Panel Report, <i>European Communities – Measures Concerning Meat and Meat Products (Hormones)</i> , WT/DS26/R, WT/DS48/R, adopted 13 February 1998, as modified by the Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R
<i>EC – Hormones (AB)</i>	Appellate Body Report, <i>European Communities – Measures Concerning Meat and Meat Products (Hormones)</i> , WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998
<i>EC – Sardines (Panel)</i>	Panel Report, <i>European Communities – Trade Description of Sardines</i> , WT/DS231/R, adopted 23 October 2002, as modified by the Appellate Body Report, WT/DS231/AB/R

<i>EC – Tubes or Pipe Fittings (AB)</i>	Appellate Body Report, <i>European Communities – Anti-Dumping Duties on Malleable Cast Iron Tube or Pipe Fittings from Brazil</i> , WT/DS219/AB/R, adopted 18 August 2003
<i>Japan – Agricultural Products (AB)</i>	Appellate Body Report, <i>Japan – Measures Affecting Agricultural Products</i> , WT/DS76/AB/R, adopted 19 March 1999
<i>Japan – Apples (AB)</i>	Appellate Body Report, <i>Japan – Measures Affecting the Importation of Apples</i> , WT/DS245/AB/R, adopted 10 December 2003
<i>Korea – Alcohol (AB)</i>	Appellate Body Report, <i>Korea – Taxes on Alcoholic Beverages</i> , WT/DS75/AB/R, WT/DS84/AB/R, adopted 17 February 1999
<i>Korea – Dairy (AB)</i>	Appellate Body Report, <i>Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products</i> , WT/DS98/AB/R, adopted 12 January 2000
<i>Thailand – H-Beams (AB)</i>	Appellate Body Report, <i>Thailand – Anti-Dumping Duties on Angles, Shapes and Sections of Iron or Non-Alloy Steel and H-Beams from Poland</i> , WT/DS122/AB/R, adopted 5 April 2001
<i>US – Certain EC Products (Panel)</i>	Panel Report, <i>United States – Import Measures on Certain Products from the European Communities</i> , WT/DS165/R, adopted 10 January 2001, as modified by the Appellate Body Report, WT/DS165/AB/R
<i>US – Cotton Subsidies (Article 21.5) (AB)</i>	Appellate Body Report, <i>United States – Subsidies on Upland Cotton – Recourse by Brazil to Article 21.5 of the DSU</i> , WT/DS267/AB/RW, adopted 20 June 2008
<i>US – German Steel (AB)</i>	Appellate Body Report, <i>United States – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany</i> , WT/DS213/AB/R, adopted 19 December 2002
<i>US – Wheat Gluten (AB)</i>	Appellate Body Report, <i>United States – Definitive Safeguard Measures on Imports of Wheat Gluten from the European Communities</i> , WT/DS166/AB/R, adopted 19 January 2001

## I. Introduction

### A. Background

1. At the core of this long-standing dispute between the European Communities (“EC”) and the United States is the EC’s hormone ban, which has been in effect for the past 20 years. The ban prohibits the importation and marketing of meat and meat products from cattle to which six hormones<sup>1</sup> have been administered for growth promotion purposes according to good veterinary practices.

2. The United States permits the administration of these hormones to cattle for growth promotion purposes, i.e., in order to increase the growth, feed conversion efficiency and leanness of carcass in cattle.<sup>2</sup> For these purposes, five of the six hormones (estradiol-17 $\beta$ , 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 (“MGA”), is administered as a feed additive.

#### 1. What Are Hormones?

3. 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.”<sup>3</sup>

4. 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.”<sup>4</sup> In addition, “[o]ne function may be controlled by multiple hormones: the menstrual cycle involves oestradiol, progesterone, follicle-stimulating hormone and luteinizing hormone.”<sup>5</sup>

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<sup>1</sup> The six hormones are: estradiol-17 $\beta$ , progesterone, testosterone, zeranol, trenbolone acetate, and melengestrol acetate, and will be described in further detail *infra*.

<sup>2</sup> The three natural hormones (estradiol-17 $\beta$ , progesterone and testosterone) may be used for medical treatment, or therapeutic purposes, in the United States. In addition, use of estradiol 17 $\beta$  and progesterone is also permitted for estrus synchronization. *See* Panel Report, para. 2.9.

<sup>3</sup> *EC – Hormones (Panel)*, para. 2.6.

<sup>4</sup> *EC – Hormones (Panel)*, para. 2.7.

<sup>5</sup> *EC – Hormones (Panel)*, para. 2.7.

## 2. The Six Hormones at Issue

5. Three of the six hormones at issue in this proceeding (estradiol-17 $\beta$ , 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.<sup>6</sup> With respect to chemical structure, these hormones are identical to the estradiol-17 $\beta$ , 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.

6. Natural production of estradiol-17 $\beta$ , 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 $\beta$  approximately 2,000 times greater than the amount of estradiol-17 $\beta$  consumed from eating a 250-gram serving of meat from treated animals.<sup>7</sup>

7. Numerous studies and reviews have illustrated that levels of natural hormones in food are wide-ranging. For example, while estradiol-17 $\beta$  levels in beef (muscle) range from 4 to 30 picograms/gram, levels of the same hormone in a hen’s egg can range from 120 to 200 picograms/gram.<sup>8</sup> 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.”<sup>9</sup> Concentrations of estradiol-17 $\beta$  levels in several common foods are included in the following table:

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<sup>6</sup> See *EC – Hormones (Panel)*, paras. 2.8, 8.4.

<sup>7</sup> See Exhibit US-5 at 73; see also Exhibit US-6 at 153-179.

<sup>8</sup> See Exhibit US-7 at 117. See also Exhibit US-6 at 164-165.

<sup>9</sup> Exhibit US-7 at 111.



Comparison of estradiol-17 $\beta$ levels in common foods <sup>10</sup>	
Source	Estradiol-17 (picograms/gram)
Muscle of Treated Cattle	
Treated steers	3 - 17
Treated heifers	10.4
Muscle of Untreated Cattle <sup>11</sup>	
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 <sup>12</sup>	6.3
Pork <sup>13</sup>	29-58
Dairy Products <sup>14</sup>	
Processed whole milk	6.4
Processed skim milk	3.5
Cottage cheese	11
Butter	82
Eggs <sup>15</sup>	120-200

8. As is apparent from this table, natural hormones such as estradiol-17 $\beta$  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.

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<sup>10</sup> U.S. First Written Submission at 13.

<sup>11</sup> Daxenberger *et al.*, pp. 340-355.

<sup>12</sup> 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.

<sup>13</sup> Daxenberger *et al.*, pp. 340-355.

<sup>14</sup> Daxenberger *et al.*, pp. 340-355.

<sup>15</sup> See Exhibit US-7.

Further, concentrations of estradiol-17 $\beta$  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.<sup>16</sup> While tissue concentrations of estradiol-17 $\beta$  in treated cattle may be slightly higher than those in untreated cattle, this 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.

9. As an example of the variation of hormone levels in meat from treated and untreated cattle, the EC regularly slaughters bulls for human consumption,<sup>17</sup> 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.<sup>18</sup>

10. 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 $\beta$ , and MGA mimics progesterone.<sup>19</sup>

### 3. Codex Standards

11. International standards exist regarding the use of five of the six hormones for growth promotion purposes. Upon review of safety assessments conducted by Joint FAO/WHO Expert Committee on Food Additives (“JECFA”) and recommendations by the Codex Committee on Residues of Veterinary Drugs in Food (“CCRVDF”), the Codex Alimentarius Commission (“Codex”), specified as the relevant international standards-setting body in the *SPS Agreement*,<sup>20</sup> adopted recommended maximum residue limits<sup>21</sup> (“MRLs”), where appropriate, for estradiol-

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<sup>16</sup> See Exhibit US-7 at 111-119.

<sup>17</sup> See Exhibit US-8 (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). In contrast, less than 2% of cattle slaughtered in the U.S. are bulls while approximately 50% are steers (castrated male cattle).

<sup>18</sup> See Exhibit US-7 at pp. 111-119. (Exhibit US-7).

<sup>19</sup> See *EC – Hormones (Panel)*, paras. 2.9, 8.4.

<sup>20</sup> See *SPS Agreement*, Annex A, paragraph 3(a).

<sup>21</sup> A “maximum residue limit” for residues in veterinary drugs is defined as:

the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or  $\mu$ g/kg on a fresh weight basis) that is recommended by the

17 $\beta$ , 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.

12. The 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 $\beta$ , 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.<sup>22</sup>

13. Based on the available scientific evidence and CCRVDF recommendations, Codex determined in 1988 and again in 2000 that MRLs were “not specified”<sup>23</sup> for the three naturally occurring hormones. Maximum residue limits were adopted by Codex in 1988 and 1989 for zeranol and trenbolone acetate, respectively. MGA was evaluated by JECFA in 2000, 2002, 2004 and in 2006. JECFA has recommended MRLs for MGA and these MRLs are awaiting adoption by Codex. The following are the MRLs set by Codex:

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Codex Commission to be legally permitted or recognized as acceptable in or on a food.

It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects.

Panel Report, fn. 551.

<sup>22</sup> Exhibit US-5 at 59-60.

<sup>23</sup> 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.” Exhibit US-5 at 74, fn. 1.

Veterinary Drug	MRL	Comment
Estradiol 17 $\beta$	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 <sup>nd</sup> JECFA Report (1988), 52 <sup>nd</sup> JECFA Report (2000).
Progesterone	Not Specified	
Testosterone	Not Specified	
Zeranol	10 $\mu$ g/kg (bovine liver) 2 $\mu$ g/kg (bovine muscle)	32 <sup>nd</sup> JECFA Report (1988)
Trenbolone acetate	10 $\mu$ g/kg (bovine liver) 2 $\mu$ g/kg (bovine muscle)	In liver tissue, $\alpha$ -trenbolone (34 <sup>th</sup> JECFA Report (1989)) In muscle tissue, $\beta$ -trenbolone

#### 4. Findings on the EC Ban in the EC – Hormones Proceeding

14. In 1996, the United States initiated a dispute settlement proceeding against the EC challenging the EC’s hormone ban in *EC – Hormones*. In the course of its review, the *EC – Hormones* panel examined available scientific evidence relating to use of the six hormones as growth promoters and convened a panel of scientific experts who provided further insight into whether or not available scientific evidence demonstrated that the six hormones posed a risk to consumers.

15. 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.”<sup>24</sup>

16. 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 . . . .”<sup>25</sup> 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*.”<sup>26</sup>

<sup>24</sup> *EC – Hormones (Panel)*, para. 8.124.

<sup>25</sup> *EC – Hormones (Panel)*, para. 8.125.

<sup>26</sup> *EC – Hormones (Panel)*, para. 8.127. (Emphasis added).

17. 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.”<sup>27</sup> The panel determined that the Monographs’ conclusions had been taken into account by JECFA 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.”<sup>28</sup>

18. 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.<sup>29</sup>

## 5. The EC’s “Revised” Ban

19. After the DSB adopted the recommendations and rulings in *EC – Hormones* on February 13, 1998, and the expiration of the reasonable period of time for the EC’s compliance efforts without the EC having taken any compliance efforts, the United States requested the DSB’s authorization to suspend concessions, which was granted by the DSB, in the amount of \$116.8 million,<sup>30</sup> pursuant to Article 22.7 on July 26, 1999.<sup>31</sup> Having obtained the DSB’s authorization, the United States imposed a 100% *ad valorem* duty on a number of products imported from

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<sup>27</sup> *EC – Hormones (Panel)*, para. 8.127 (Emphasis in original).

<sup>28</sup> *EC – Hormones (Panel)*, paras. 8.128, 8.129.

<sup>29</sup> *EC – Hormones (Panel)*, 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).

<sup>30</sup> *Recourse by the United States to Article 22.7 of the DSU*, WT/DS26/21 (15 July 1999).

<sup>31</sup> WT/DSB/M/65 at p. 19.

certain member States of the European Communities, effective as of July 29, 1999, through the publication of a notice in Vol. 64, No. 143 of the *Federal Register* on July 27, 1999.<sup>32</sup>

20. On October 27, 2003, nearly four and one half years after the reasonable period of time for the EC to comply had expired, over four years after the authorization and application of the U.S. suspension of concessions, and over seven and one half years after the United States first requested consultations, the EC notified to the DSB the adoption, publication and entry into force of Directive 2003/74/EC, which revised Directive 96/22/EC but nevertheless maintained the ban on the six hormones in question.<sup>33</sup> The EC claimed that, with the adoption of Directive 2003/74/EC, it had fully implemented the recommendations and rulings of the DSB in *EC – Hormones*.<sup>34</sup>

21. However, Directive 2003/74/EC appeared to do little more than re-package the existing ban on the same six hormones. The EC maintained its permanent ban on estradiol-17 $\beta$ , but asserted that this ban was now supported by a new risk assessment conducted by the SCVPH (comprised of three Opinions published in 1999, 2000 and 2002, together “the Opinions,” which were based in part on 17 studies commissioned by the EC) in response to the results in *EC – Hormones*. Thus, the EC considered that the ban on estradiol-17 $\beta$  was now consistent with Article 5.1 of the *SPS Agreement*.<sup>35</sup>

22. With respect to the ban on the other five hormones (progesterone, testosterone, zeranol, trenbolone acetate and MGA or “the other five hormones”) which had been permanent under Directive 96/22/EC, the EC maintained the ban but claimed to do so under Directive 2003/74/EC as a “provisional” ban pursuant to Article 5.7 of the *SPS Agreement* because the EC claimed that the relevant scientific evidence was now insufficient to conduct risk assessments for these hormones.<sup>36</sup>

23. Not only did the ban seem barely changed under Directive 2003/74/EC, but the evidence in the record overwhelmingly demonstrates that the science has changed or developed very little as well.

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<sup>32</sup> Implementation of WTO Recommendations Concerning *EC – Measures Concerning Meat and Meat Products (Hormones)*, 64 Fed. Reg. 40,638 (July 27, 1999).

<sup>33</sup> WT/DS26/22.

<sup>34</sup> WT/DS26/22 at p.2.

<sup>35</sup> See Articles (3) and (10) of Directive 2003/74/EC.

<sup>36</sup> See Articles (7) and (10) of Directive 2003/74/EC.

## B. Executive Summary

24. A review of the EC’s Appellant Submission reveals that there are few significant findings and conclusions made by the Panel in its Report, whether under the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (“DSU”) or the *Agreement on the Application of Sanitary and Phytosanitary Measures* (“SPS Agreement”), that the EC has *not* appealed. In the sections that follow, the United States will respond to the issues raised by the EC in its Appellant Submission and demonstrate that the EC’s challenges all fail.

25. The United States observes that the bulk of the EC’s effort in this appeal is focused reversing the Panel’s findings made under the *SPS Agreement* concerning the consistency of Directive 2003/74/EC. The EC makes repeated challenges in an attempt to re-litigate its entire case under the *SPS Agreement* on appeal.

26. It is telling that the EC has made a sweeping request of the Appellate Body to reverse *all* of the factual findings made by the Panel in its examination of the conformity of Directive 2003/74/EC with the provisions of the *SPS Agreement*.<sup>37</sup> In advancing this challenge, the EC resorts to crafting an incorrect “standard of review” from a patchwork of quotations from and citations to different Appellate Body reports and various secondary sources. The EC then claims that this manufactured standard, instead of the tried and true standard of review under Article 11 of the DSU, should have been applied by the Panel in its fact-finding. Resorting to arguments it advanced unsuccessfully in its appeal in *EC – Hormones* 10 years ago, the EC also argues that this standard provides for a “‘reasonableness’ approach” that the Appellate Body rejected in *EC – Hormones* as not being applicable to proceedings under the *SPS Agreement*. In section II of this submission, the United States will address the EC’s attempts to confuse and distract from the straightforward issue of the appropriate standard of review applicable to the Panel’s fact finding on the SPS issues in this proceeding, and will show that the Panel’s fact finding took place within the margin of its discretion as provided under DSU Article 11 and should not be disturbed.

27. Following on its Article 11 challenges to the Panel’s fact finding, the EC also attempts to erase the Panel’s SPS findings by advancing a series of additional challenges to the Panel’s analyses under Article 5.1<sup>38</sup> and Article 5.7<sup>39</sup> of the *SPS Agreement*. In section III, the United States will address the flaws in the EC’s allegations that: (i) the Panel erred in relation to the consideration of misuse and abuse factors; (ii) the “specificity” requirement; and (iii) the introduction of a “quantification” requirement to risk assessments under Article 5.1 of the *SPS*

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<sup>37</sup> See EC Appellant Submission, section VII as well as sections IX and X.

<sup>38</sup> See EC Appellant Submission, section IX.

<sup>39</sup> See EC Appellant Submission, section X.

*Agreement*; and (iv) the flaws in the EC’s allegations of error by the Panel in its Article 5.7 analysis in relation to considering the relationship between the existence of international standards and the sufficiency or insufficiency of relevant scientific evidence; and (v) the basis for the Panel’s formulation of the “critical mass of new evidence” standard for determining whether relevant scientific evidence has become insufficient.

28. In yet another line of attack employed by the EC in its assault on the Panel’s SPS-related findings, the EC recycles a challenge to the Panel’s expert selection process that it had previously made in its appeal in *EC – Hormones*, re-submitting the same European Court of Human Rights opinion that it submitted in 1998 as support for its contention that the Panel improperly selected experts that had been involved in the JECFA process.<sup>40</sup> In section V, the United States will demonstrate that, once again, because the Panel closely consulted the parties throughout the process and took the parties’ considerations into account in making its selection decisions, the EC’s challenge to the Panel’s expert selection process must fail again.

29. The EC next approaches the project of undermining the Panel’s SPS findings by claiming that the Panel inappropriately shifted the burden of proof in its analysis under Article 5.1 and Article 5.7 of the *SPS Agreement*.<sup>41</sup> In Section VI, the United States will show that despite the EC’s assertions, this effort turns out to be yet another distraction from the fact that the Panel’s treatment of the burden of proof in its analysis under both Articles 5.1 and 5.7 of the *SPS Agreement* is entirely appropriate and well explained.

30. In its persistent attempts to eradicate the Panel’s SPS findings, the EC does not limit itself to challenging the Panel’s analysis under the *SPS Agreement*. The EC also challenges the Panel’s finding that its analysis under Article 22.8 of the DSU required an examination of the compliance of Directive 2003/74/EC. The EC strains – unsuccessfully – to show any error by the Panel in its interpretation of the requirements of DSU Article 22.8.<sup>42</sup> The EC’s final attempt directed at wiping out the Panel’s SPS findings is its claim that the Panel went beyond its terms of reference in breach of Articles 8 and 21.5 of the DSU.<sup>43</sup> In sections VII and VIII below, respectively, the United States will show that these attempts fail to find any support in the DSU.

31. Apart from its criticisms of the Panel’s SPS Agreement analysis, the EC also seeks to convince the Appellate Body that the Panel should have specified obligations that the EC considers should be imposed on the United States. While the Appellate Body will not need to address any of these EC points if it reverses the Panel’s findings on Articles 23.1 and 23.2(a) of

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<sup>40</sup> See EC Appellant Submission, section VI.

<sup>41</sup> See EC Appellant Submission, sections VIII and X.B.

<sup>42</sup> See EC Appellant Submission, section III.

<sup>43</sup> See EC Appellant Submission, section IV.



the DSU as the United States has requested in its Other Appellant Submission, these EC arguments are also incorrect in their own right

32. First, the EC argues that the Panel incorrectly interpreted Article 21.5 of the DSU by failing to find that an Article 21.5 compliance panel proceeding was the only option for recourse to dispute settlement that was available to the United States as a result of the Panel’s findings on DSU Articles 23.1 and 23.2(a).<sup>44</sup> The United States notes that the EC, as the party that requested an Article 21.5 proceeding in *Bananas*, now considers that only a Member acting in an “insane manner” would do such a thing.<sup>45</sup> In section IX below, the United States will address the multitude of flaws in the EC’s approach.

33. Finally, the EC argues that even though the Panel declined, in its concluding suggestions, to specifically suggest that the United States must terminate the suspension of concessions as a consequence of the Panel’s findings on the DSU, despite the fact that the EC had requested such a suggestion, the Appellate Body should “improve” the Panel’s suggestion to include such a specification. The United States will show in section IX why it would be inappropriate for the Appellate Body to “further clarify” or “improve” the Panel’s suggestions.

## **II. The Panel Did Not Exceed the Bounds of Its Discretion as Trier of Fact**

34. The Appellate Body’s interpretation of the standard of review to be applied by panels under Article 11 of the DSU is clear and, in the years since it was first comprehensively addressed by the Appellate Body in *EC – Hormones*, has been developed in a consistent manner. It is also well-established that Article 11 of the DSU provides for the standard of review applicable in proceedings brought pursuant to the *SPS Agreement*, which, like almost all other WTO agreements,<sup>46</sup> does not prescribe a particular standard of review or include specific provisions addressing the review by a panel of a determination or examination conducted by a national authority.<sup>47</sup>

35. Yet despite the clarity and firm establishment of the standard of review applicable in this proceeding, the EC attempts to formulate a novel standard that it argues that the Panel should have applied. The formulation advanced by the EC, however, is not grounded in the DSU, the *SPS Agreement* or prior Appellate Body reports, and is not correct.

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<sup>44</sup> See EC Appellant Submission, section II.

<sup>45</sup> EC Appellant Submission, para. 85. The United States also notes the irony of the EC’s proposition given that the EC objected to any of the original panelists from *EC – Hormones* serving on the Panel in these proceedings.

<sup>46</sup> See *EC – Hormones (AB)*, para. 114.

<sup>47</sup> *EC – Hormones (AB)*, paras. 114-116

### A. The EC’s Formulation of the Standard of Review Is Incorrect

36. The EC first attempts to re-introduce the “deferential ‘reasonableness’ standard” that it originally proposed in its *EC – Hormones* appeal, a standard that the Appellate Body rejected. Re-packaging the standard this time as a “‘reasonableness’ approach,” the EC once again refers to the practice by international courts and tribunals and national courts in setting aside an administrative decision of an authority subject to review only when the decision appears “unreasonable.” The EC suggests that this alleged practice “appears consistent” with the standard the Appellate Body has endorsed.<sup>48</sup>

37. The EC insists that its “‘reasonableness’ approach” is applicable to “measures adopted by governments or specialised agencies in highly complex or technical matters on grounds of e.g. human health or environmental protection.”<sup>49</sup> However, the “deferential ‘reasonableness’ standard” that the EC previously claimed was “applicable in ‘all highly complex factual situations, including the assessment of risks to human health arising from toxins and contaminants,’”<sup>50</sup> like the EC’s proposed “‘reasonableness’ approach” finds no support in the text of the *SPS Agreement*. As the Appellate Body stated in response to the EC’s prior unsuccessful attempt to introduce this “reasonableness” standard into the *SPS Agreement*, “[t]o adopt a standard of review not clearly rooted in the text of the *SPS Agreement* itself, may well amount to changing that finely drawn balance [between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves]; and neither a panel nor the Appellate Body is authorized to do that.”<sup>51</sup>

38. In addition to proposing an incorrect general standard of review, the EC is also “of the view” that panels must apply the “generally applicable standard of review” differently to the various provision of the *SPS Agreement*, the precise manner of application corresponding to the EC’s interpretation of how those provisions should be applied to the facts. The combination of these propositions leads the EC to manufacture what it considers to be the “appropriate” standard of review for claims arising under Article 5.1 of the *SPS Agreement*; i.e., that “a panel should not be entitled to find that a member’s measure has no reasonable relationship with the scientific evidence on which the risk assessment is based, if the evidence before the panel provides for at least one scientifically plausible set of conclusions under which an adverse effect might occur.”<sup>52</sup>

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<sup>48</sup> EC Appellant Submission, para. 223.

<sup>49</sup> EC Appellant Submission, para. 223.

<sup>50</sup> *EC – Hormones (AB)*, para. 113.

<sup>51</sup> *EC – Hormones (AB)*, para. 115.

<sup>52</sup> EC Appellant Submission, para. 229.

39. There is no support in the text of the WTO agreements for what amounts to a “specifically applicable” standard of review for certain types of claims. The EC conflates the concept of “standard of review” and the application of law to facts. “Generally applicable” and “specifically applicable” standards of review, and the EC’s proposed standard whereby a panel must defer if even “one scientifically plausible set of conclusions” shows an adverse effect might occur, are products of the EC’s wishful thinking and find no support in the DSU, the *SPS Agreement*, or the findings of the Appellate Body.

### **B. The Appropriate Standard of Review**

40. The Appellate Body has spoken repeatedly and consistently to the question of the appropriate standard of review to be applied by panels to their fact-finding in SPS disputes. The standard, under Article 11, “is neither *de novo* review, as such, nor ‘total deference,’ but rather the ‘objective assessment of the facts.’”<sup>53</sup>

41. Whether or not a panel has made an objective assessment of the facts is a legal question which, if properly raised on appeal, would fall within the scope of review by the Appellate Body.<sup>54</sup> According to the Appellate Body, a panel will be regarded as having failed to make an objective assessment where it “deliberately disregards,” “refuses to consider” or “wilfully distorts or misrepresents” evidence submitted to it.<sup>55</sup> This requires more than just an error of judgment in the appreciation of evidence, but rather an “egregious error that calls into question the good faith of a panel.”<sup>56</sup>

42. In fact, panels “enjoy a ‘margin of discretion’ as triers of fact”<sup>57</sup> and are, accordingly, “‘not required to accord to factual evidence of the parties the same meaning and weight as do the parties’ and may properly ‘determine that certain elements of evidence should be accorded more

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<sup>53</sup> *EC – Hormones (AB)*, para. 117.

<sup>54</sup> *EC – Hormones (AB)*, para. 132.

<sup>55</sup> *EC – Hormones (AB)*, para. 133.

<sup>56</sup> *EC – Hormones (AB)*, para. 133.

<sup>57</sup> *Japan – Apples (AB)*, para. 221 (quoting *EC – Asbestos (AB)*, para. 161; and citing *EC – Tubes or Pipe Fittings (AB)*, para. 125; *EC – Bed Linen (Article 21.5) (AB)*, paras. 170, 177, 181; *EC – Sardines (AB)*, para. 299; *Korea – Alcohol (AB)*, paras. 161-162; *Japan – Agricultural Products (AB)*, paras. 141-142; *US – Wheat Gluten (AB)*, para. 151; *Australia – Salmon (AB)*, para. 266; *Korea – Dairy (AB)*, para.138).

weight than other elements’.”<sup>58</sup> The Appellate Body does not “second-guess” a panel in the appreciation of the “evidentiary value of . . . studies or the consequences, if any, of alleged defects in [the evidence]”<sup>59</sup> and does not find a panel has breached Article 11 “‘simply on the conclusion that [the Appellate Body] might have reached a different factual finding from the one the panel reached.’”<sup>60</sup> Failing the establishment that a panel has “exceeded the bounds of its discretion as the trier of facts, the Appellate Body has not ‘interfere[d]’ with the findings of the panel.”<sup>61</sup>

### C. The Panel Applied the Appropriate Standard of Review Correctly

43. The EC challenges a multitude of the Panel’s findings of fact that it dislikes or with which it does not agree. The EC’s regret that the Panel did not make the factual findings that the EC wanted, however, is not grounds for interference by the Appellate Body with the Panel’s exercise of fact-finding, which took place well within the bounds of its discretion under DSU Article 11.

44. The EC alleges that the Panel impermissibly conducted a *de novo* review, citing the Panel’s statement in para. 7.418 of its Report that “[a]lthough the Panel is not carrying out its own risk assessment, its situation is similar in that it may benefit from hearing the full spectrum of experts’ views and thus obtain a more complete picture both of the mainstream scientific opinion and of any divergent views.”<sup>62</sup> The EC seizes upon the words “its situation is similar” in this statement as an indication that the Panel considered itself to be a risk assessor. A fair reading of the Panel’s statement reveals, however, that the Panel explicitly disclaimed that it was “carrying out its own risk assessment,” and that the Panel also considered its situation to be similar to that of a risk assessor only *insofar* as it would benefit from hearing from scientific experts.

45. The EC also considers that in applying the standard of review, “panels have to carefully consider and explain how *each piece* of the scientific evidence relates to the specific issues

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<sup>58</sup> *Japan – Apples (AB)*, para. 221 (quoting *EC – Asbestos (AB)*, para. 161).

<sup>59</sup> *Japan – Apples (AB)*, para. 222 (quoting *EC – Asbestos (AB)*, para. 177, quoting *Korea – Alcohol (AB)*, para. 161).

<sup>60</sup> *Japan – Apples (AB)*, para. 222 (quoting *EC – Asbestos (AB)*, para. 159, quoting *US – Wheat Gluten (AB)*, para. 151).

<sup>61</sup> *Japan – Apples (AB)*, para. 222 (quoting *EC – Bed Linen (Article 21.5) (AB)*, para. 170; *US – German Steel (AB)*, para. 142, (quoting *US – Wheat Gluten (AB)*, para. 151).

<sup>62</sup> EC Appellant Submission, para. 237 *et seq.*

before them.”<sup>63</sup> The EC argues that the Panel improperly failed to take into account the EC’s concerns regarding the relevance for risk assessment of multiple exposure of humans to hormones from many endogenous and exogenous sources,<sup>64</sup> because “there is no mention at all in the Panels’ findings in paras. 7.504-7.537” of these concerns.<sup>65</sup> In so arguing, the EC asks more of the Panel than was required by the DSU. While panels are required by Article 11 to take account of the evidence put before them, “it is generally within the discretion of the Panel to decide which evidence it chooses to utilize in making findings.”<sup>66</sup> Thus, a panel is not obliged under Article 11 to “explain how each piece of the scientific evidence relates to the specific issues before them.” Notwithstanding this, the Panel did explicitly address the EC’s concern regarding multiple exposure.<sup>67</sup>

46. With respect to its charge that the Panel conducted a *de novo* review and exceeded the bounds of its fact-finding discretion under Article 11, the EC points to what it considers to be inappropriate “picking and choosing,” “ignoring” or “downplaying” by the Panel of certain evidence and expert statements.<sup>68</sup> The Appellate Body has stated in unequivocal terms, however, that panels are not required to accord to factual evidence the same meaning and weight that the parties do,<sup>69</sup> that panels have the discretion to decide which evidence to use in making its findings,<sup>70</sup> and that a “Panel cannot realistically refer to all statements made by the experts

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<sup>63</sup> EC Appellant Submission, para. 224 (emphasis added).

<sup>64</sup> EC Appellant Submission, paras. 248-249.

<sup>65</sup> EC Appellant Submission, para. 249.

<sup>66</sup> *US – German Steel (AB)*, para. 142 (quoting *EC – Hormones (AB)*, para. 135).

<sup>67</sup> “To the extent the European Communities argues that the relevant risk from hormones is an ‘additive risk’ the experts concluded that the European Communities did not assess the extent to which residues of hormones in meat and meat products as a result of the cattle being treated with the hormones for growth promoting purposes contribute to additive risks arising from the cumulative exposures of humans to multiple hazards, in addition to the endogenous production of some of these hormones by animals and human beings.” Panel Report, para. 7.529 (citing Replies by the Scientific Experts to Panel Question 56, Annex D, paras. 422-431.)

<sup>68</sup> EC Appellant Submission, paras. 239-240, 246-247, 250-284, 427-448.

<sup>69</sup> *Japan – Apples (AB)*, para. 221 (citing/quoting *Australia – Salmon (AB)*, para. 267).

<sup>70</sup> *US – German Steel (AB)*, para. 142 (quoting *EC – Hormones (AB)*, para. 135).

advising it and should be allowed a substantial margin of discretion as to which statements are useful to refer to explicitly.”<sup>71</sup>

47. In the same vein, the EC also takes issue with the Panel’s observation that, in its appreciation of the experts’ written and oral responses to the Panel’s inquiries,

. . . in some circumstances, only one or two experts have expressed their views on an issue. Sometimes these views were similar or complemented each other. In other circumstances, a larger number of experts expressed opinions and, sometimes, they expressed diverging opinions. While, on some occasions, we followed the majority of experts expressing concurrent views, in some others the divergence of views were such that we could not follow that approach and decided to accept the position(s) which appeared, in our view, to be the most specific in relation to the question at issue and to be best supported by arguments and evidence.<sup>72</sup>

The Panel’s exercise of judgment in evaluating the evidence is a fundamental part of its role as the trier of fact. The Panel did not state that it followed the majority of experts as a rule; the Panel was clear that it only did so on those occasions when it felt was appropriate. In addition, the Panel’s description of its approach in accepting the positions that were “most specific in relation to the question at issue” and “best supported by arguments and evidence”<sup>73</sup> is also part and parcel of the Panel’s duty to make an objective assessment of the facts.

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<sup>71</sup> EC – Hormones (AB), para. 138.

<sup>72</sup> Panel Report, para. 7.420.

<sup>73</sup> Examples of such “most specific” and “best supported” expert statements would include the oral and written responses of Dr. Boobis, which often included extensive citations to scientific literature. See Replies of the Scientific Experts to Questions Posed by the Panel, Annex D, paras. 119-120 (qualitative vs. quantitative risk assessment), 144 (EC risk assessment of hormone residues in meat); 168-170 (mechanism of carcinogenicity of estradiol-17 $\beta$ ), 179 (genotoxicity of estradiol-17 $\beta$ ), and 184-185 (genotoxic potential and the absence of a threshold); see also Transcript of the Panel’s Joint Meeting with Scientific Experts on 27-28 September 2006, Annex G, para. 1042. In contrast, the EC relies on Dr. Cogliano’s replies, in which he discusses different “views” regarding thresholds (Annex D, para. 186) cited by the Panel (Panel Report, para. 7.559) and referenced by the EC (EC Appellant Submission, para. 255). Dr. Cogliano’s replies contain far less detail than those of Dr. Boobis, are not supported by citations to scientific literature, and did not address relevant and specific information discussed by Dr. Boobis.

48. Accordingly, the findings of fact made by the Panel and challenged by the EC with respect to the matters of (1) the genotoxicity of the hormones;<sup>74</sup> (2) the specificity required by the definition of “risk assessment” in Annex A(4) of the *SPS Agreement*, as discussed by the Appellate Body in *EC – Hormones*;<sup>75</sup> (3) the role of misuse and abuse factors;<sup>76</sup> and (4) the sufficiency of the evidence to conduct a risk assessment in the case of the other five hormones at issue,<sup>77</sup> were entirely within the bounds of the Panel’s discretion as trier of fact and should be upheld by the Appellate Body.

49. The United States notes that the EC’s challenges raised under Article 11 to the Panel’s fact-finding appear more appropriately to be claims that the Panel breached Article 12.7 of the DSU by failing to set out the findings of fact, the applicability of relevant provisions, and the basic rationale underlying its findings. The EC does not, however, raise Article 12.7 as the basis for its request for appellate review of any of the findings in the Panel Report. To the extent, therefore, that the EC’s challenges raised under DSU Article 11 should properly have been raised under DSU Article 12.7 instead, those claims should be disregarded as not properly subject to review by the Appellate Body.

### **III. The EC’s Other Challenges to the Panel’s Findings under the *SPS Agreement* Also Fail**

50. In addition to its sweeping challenge to *all* of the Panel’s findings under the *SPS Agreement* on DSU Article 11 grounds, the EC also advances as part of its concerted effort to

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<sup>74</sup> See challenges to the Panel’s findings of fact raised in EC Appellant Submission, paras. 250-258 and 344-355.

<sup>75</sup> See challenges to the Panel’s findings of fact raised in EC Appellant Submission, paras. 259-270 and 335-343.

<sup>76</sup> See challenges to the Panel’s findings of fact made in EC Appellant Submission, paras. 271-278 and 314-334. With respect to the EC’s assertions that the Panel failed to take into proper account the Opinions and other evidence that the EC claims “evaluated specifically the risks from abuse and misuse” (see EC Appellant Submission, para. 277), and the EC’s invitation to the Appellate Body to review specific evidence in the record, the United States notes that the record is replete with evidence and arguments that demonstrate the failures and shortcomings of the Opinions and other evidence of the EC related to the evaluation of misuse and abuse risks. (See, e.g., Comments by the United States on the Replies of the EC to Questions Posed by the Panel After the Second Substantive Meeting, Annex C-5, paras. 5-16; U.S. Rebuttal Submission, paras. 54-66; Transcript of the Panel’s Joint Meeting with Scientific Experts, Annex G, paras. 829-831.)

<sup>77</sup> See challenges to the Panel’s findings of fact made in EC Appellant Submission, paras. 279-284 and 427-448.

have a second bite at the apple and re-litigate its case on the conformity of Directive 2003/74/EC with the *SPS Agreement* before the Appellate Body, a number of specific challenges to the Panel’s interpretations and findings (factual, legal, and mixed).

51. In particular, the EC alleges that the Panel erred by: (i) inappropriately excluding, on an *a priori* basis, the EC’s misuse or abuse evidence and arguments from consideration in the Panel’s Article 5.1 analysis of the permanent ban on estradiol-17 $\beta$ ; (ii) incorrectly analyzing the issue of whether the EC cured the shortcomings found in its risk assessments in *EC – Hormones* by successfully satisfying the requirement under Article 5.1 to identify that the potential for adverse effects arises from the presence of residues of estradiol-17 $\beta$  in meat or meat products as a result of the cattle being treated with the hormone for growth promoting purposes; (iii) improperly introducing a quantitative dimension to risk in its Article 5.1 analysis in contravention of the Appellate Body’s findings against such introduction in *EC – Hormones*; (iv) inappropriately according weight and value to the existence of international standards for the other five hormones in its analysis under Article 5.7, pursuant to Articles 3.1 and 3.2 of the *SPS Agreement*, to the detriment of the rights of Members under Article 3.3; and (v) formulating an inappropriate standard for its analysis under Article 5.7 on the insufficiency of the relevant scientific evidence for the other five hormones.

52. The EC’s arguments directed at these issues vary in complexity, length, and coherence. What all of the arguments share, however, is a lack of support in the DSU, the *SPS Agreement*, the Panel Report, the Appellate Body reports that the EC cites, and the evidence in the record.

**A. The Panel’s Treatment of the EC’s Evidence and Arguments on Misuse and Abuse Risk Factors Was Proper and Well-Supported**

53. The EC contends that the Panel erred by effectively excluding, on an *a priori* basis, the EC’s misuse or abuse evidence and arguments from being considered in the Panel’s analysis of whether the EC had conducted a risk assessment under Article 5.1 of the *SPS Agreement*, in contravention of the Appellate Body’s findings in *EC – Hormones*. As the Appellate Body stated in *EC – Hormones*:

The *SPS Agreement* requires assessment of the potential for adverse effects on human health arising from the presence of contaminants and toxins in food. We consider that the object and purpose of the *SPS Agreement* justify the examination and evaluation of all such risks for human health whatever their precise and immediate origin may be. We do not mean to suggest that risks arising from potential abuse in the administration of controlled substances and from control problems need to be, or should be, evaluated by risk assessors in each and every case. When and if risks of these types do in fact arise, risk assessors may examine and evaluate them. What, in our view, is a fundamental legal error is to exclude



such risks, on an *a priori* basis, any from the scope of application of Articles 5.1 and 5.2.<sup>78</sup>

At its core, the EC’s argument on this issue is that, because one day misuse or abuse in the administration of estradiol-17 $\beta$  might occur, the EC is justified in banning it entirely. The EC’s argument, however, constitutes a classic example of the tail wagging the dog.

54. The Panel’s Article 5.1 analysis focused on the question whether, pursuant to the definition of “risk assessment” in Annex A(4) of the *SPS Agreement*, the EC had evaluated specifically the possibility that the adverse effect that the EC had identified in its risk assessment “come[s] into being, originate[s], or result[s] from the consumption of meat or meat products containing residues of estradiol-17 $\beta$  as a result of the cattle being treated with such hormone for growth promotion purposes.” The Panel fully appreciated the EC’s assertion regarding the significance of the misuse and abuse factors, i.e., that misuse and abuse in the administration of hormones for growth promotion purposes can add to risks that are already identified.<sup>79</sup> As the Panel stated:

Indeed, the question of misuse or abuse in the administration of hormones is relevant to the extent that it can lead to higher concentrations of hormone residues in meat and meat products than would occur if good veterinary practices were applied.<sup>80</sup>

The Panel correctly considered, however, that the additional risk due to increased hormone residue concentrations in meat would not be relevant until the EC had shown a specific risk from the consumption of estradiol-17 $\beta$  residues in meat or meat products in the first place.<sup>81</sup>

55. Consistent with the Appellate Body’s conclusions and reasoning in *EC – Hormones*, the Panel in the present proceeding did not exclude misuse and abuse risk factors on an *a priori* basis from the scope of application of Articles 5.1 and 5.2. The Panel acknowledged the fact that the EC had taken such factors into account,<sup>82</sup> recognized their proper role in relation to the primary question in the Article 5.1 analysis, i.e., that it was not relevant to the first step inquiry regarding

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<sup>78</sup> *EC – Hormones (AB)*, para. 206 (emphasis added).

<sup>79</sup> *See, e.g.*, EC Appellant Submission, paras. 319 and 331.

<sup>80</sup> Panel Report, para. 6.164.

<sup>81</sup> Panel Report, para. 6.164.

<sup>82</sup> Panel Report, para. 7.483.

whether a specific risk had been identified, and provided a detailed account of its reasoning.<sup>83</sup> The EC’s attempt to use its unsupportable misuse and abuse argument to distract from the Panel’s specificity findings must be recognized for what it is and rejected.

**B. The Panel Did Not Err in Finding the EC Failed to Satisfy the “Specificity” Requirement of Article 5.1 and Annex A(4) of the SPS Agreement**

56. The EC challenges the Panel’s finding that the EC once again failed to satisfy the specificity required by the definition of risk assessment provided in Annex A(4), second sentence, i.e., to evaluate the possibility that the identified adverse effect came into being, originated, or resulted from the presence of residues of estradiol-17 $\beta$  in meat or meat products as a result of the cattle being treated with the hormone for growth promoting purposes. The EC alleges that the Panel erred because it failed to correctly identify what the Appellate Body found to be wanting in the risk assessments in *EC – Hormones*, because the Panel’s articulation of the specificity requirement would require an impossible demonstration of actual effects, and because one of the experts provided a statement that supports the view that the EC did satisfy the requirement.

57. The Panel’s articulation of the requirement of a risk assessment to show more than just a general risk of adverse effects but the *specific* potential for adverse effects to arise from the presence in meat of residues of hormones is based on a careful tracing of the initial articulation of the elements required by the Annex A(4) definition of “risk assessment” by the *EC – Hormones* panel and subsequent criticism and correction of terminology<sup>84</sup> by the Appellate Body in *EC – Hormones*.<sup>85</sup> The Panel also took into account further related elaboration by the Appellate Body on the definition of “risk assessment” in *Australia – Salmon* and *Japan – Apples*, as well as the ordinary meaning of the words “potential” and “arise from,”<sup>86</sup> in concluding that the Annex A(4) definition of “risk assessment” required the EC:

to evaluate the possibility that the identified adverse effect came into being, originated, or resulted from the presence of residues of oestradiol-17 $\beta$  in meat or

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<sup>83</sup> Panel Report, para. 6.164.

<sup>84</sup> The Appellate Body took issue with the *EC – Hormones* panel’s use of the word “probability.” It did not, however, object to that panel’s use of the words “potential” or “occurrence.” See *EC – Hormones (AB)*, paras. 182-186.

<sup>85</sup> Panel Report, paras. 7.504-7.505.

<sup>86</sup> Panel Report, paras. 7.506-7.512.

meat products as a result of the cattle being treated with the hormone for growth promoting purposes.<sup>87</sup>

58. Plainly contrary to the EC's allegations, therefore, the Panel's interpretation of this "specificity" requirement under the Annex A(4) definition of "risk assessment" is grounded in the text of the *SPS Agreement* and founded on prior Appellate Body reports. As a result, it remains consistent with the Appellate Body's observations in *EC – Hormones* that the EC's risk assessment needed to "evaluate the specific potential for carcinogenic effects arising from the presence in 'food', more specifically, 'meat or meat products' of residues of the hormones in dispute"<sup>88</sup> and "address the particular kind of risk here at stake – the carcinogenic or genotoxic potential of the residues of these hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes – as is required by paragraph 4 of Annex A of the *SPS Agreement*."<sup>89</sup>

59. The EC claims that the Panel's formulation of the requirement to "evaluate the possibility that the identified adverse effect came into being, originated, or resulted from the presence of residues of oestradiol-17 $\beta$  in meat or meat products" would require the demonstration of actual adverse effects in humans. The EC asserts that no one has conducted tests to demonstrate actual adverse effects because such tests would be either technically impossible or unethical. However, a fair reading of the Panel's requirement to evaluate the possibility that adverse effects derive from consumption of meat reveals that such a requirement does not implicate the drastic, absolute demonstration of actual adverse effects that the EC claims. As the EC itself observes, other countries have found ways to evaluate the possibility of adverse effects arising from the consumption of hormone residues in meat by performing tests on laboratory animals and then extrapolating those results to human beings.<sup>90</sup>

60. The EC appears to contend that one expert's statement, divorced from the rest of the evidentiary record, could be sufficient to establish that the EC had satisfied the specificity requirement is laughable and serves as yet another challenge to the Panel's fact-finding which, as discussed already, took place within the margins of its discretion as trier of fact under Article 11.

61. Here, as in *EC – Hormones*, the Panel found once again that the EC's purported risk assessment is still deficient and that it identified only "general risks" and failed to address the specific risk required by the *SPS Agreement*. The Panel was clear in its finding and clear in

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<sup>87</sup> Panel Report, para. 7.513.

<sup>88</sup> *EC – Hormones (AB)*, para. 199 (emphasis in original).

<sup>89</sup> *EC – Hormones (AB)*, para. 200.

<sup>90</sup> EC Appellant Submission, para. 263.

identifying the substantial support for this finding in the evidentiary record,<sup>91</sup> and the EC's attempts to disturb or discredit that finding fail.

**C. The Panel Did Not Impose a Quantitative Dimension to Risk in  
Contravention of the Appellate Body's Interpretation in *EC – Hormones***

62. The EC challenges the Panel's use of the phrase "potential occurrence" in its formulation of the specificity requirement flowing from the Annex A(4) definition. Specifically, the EC charges that requiring a Member to specify "'to what extent [it] evaluated *the potential occurrence* of these adverse effects' . . . leads to an error in law"<sup>92</sup> and contravenes the Appellate Body's admonition that panels are not to impose a quantitative requirement on risk assessors. The EC admits that the ordinary meaning of the words "potential" and "occurrence" do not immediately make evident a quantitative dimension, but that the experts clearly understood "*potential occurrence* of adverse effects" to imply quantification because they "distinguish[ed] between the *potential* for adverse effects on human health as opposed to evaluating the *occurrence* of adverse effects."<sup>93</sup>

63. The Panel in this proceeding was aware of the Appellate Body's warnings regarding what constitutes problematic quantification and addressed the issue explicitly.<sup>94</sup> The Panel has not prescribed, established, imposed, nor has it implied the prescription, establishment, or imposition of what the EC considers improper "quantification." The Panel has not precluded qualitative risk assessments from being recognized as risk assessments under the *SPS Agreement*.

64. Instead, the focus of the Panel's inquiry regarding "whether the EC Opinions identified the potential for adverse effects on human health, including the carcinogenic or genotoxic potential, of the residues of oestradiol-17 $\beta$  found in meat derived from cattle to which this hormone had been administered for growth promotion purposes in accordance with good veterinary practice and to what extent the Opinions evaluated the potential occurrence of these adverse effects,"<sup>95</sup> was on whether the EC's purported risk assessment appeared to be "sufficiently specific to the case at hand."<sup>96</sup>

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<sup>91</sup> Panel Report, paras. 7.521 *et seq.*

<sup>92</sup> EC Appellant Submission, para. 344 (quoting Panel Report, para. 7.521).

<sup>93</sup> EC Appellant Submission, para. 346 (emphasis in original).

<sup>94</sup> *See* Panel Report, paras. 7.504-7.513; *see also* discussion *supra* in section III.B.

<sup>95</sup> Panel Report, para. 7.521.

<sup>96</sup> *EC – Hormones (AB)*, para. 200.

65. Panel found, on the basis of the statements of the experts and statements from the Opinions, that the EC failed to show the specificity required of a risk assessment as provided in the definition in Annex A(4) of the *SPS Agreement*. As the Panel stated, the EC:

has evaluated the potential for the identified adverse effects to be associated with oestrogens in general, but has not provided analysis of the potential for these effects to arise from consumption of meat and meat products which contain residues of oestradiol-17 $\beta$  as result of the cattle they are derived from being treated with the hormone for growth promotion purposes. The Panel, therefore, concludes that although the European Communities has evaluated the association between excess hormones and neurobiological, developmental, reproductive and immunological effects, as well as immunotoxicity, genotoxicity, and carcinogenicity, it has not satisfied the requirements of the definition of a risk assessment contained in Annex A(4) because it has not evaluated specifically the possibility that these adverse effects come into being, originate, or result from the consumption of meat or meat products which contain veterinary residues of oestradiol-17 $\beta$  as a result of cattle being treated with hormone for growth promotion purposes.<sup>97</sup>

66. The Panel’s finding results from an analytical process that is appropriately grounded in the precepts of scientific inquiry, as described in more detail in section III.D below, and prior Appellate Body reports. It is a finding of fact, which the EC cannot succeed in disturbing on the basis of its allegation that the Panel imposed some kind of “quantification” requirement through the use of a phrase – “potential occurrence of adverse effects” – that is grounded in the text of the definition of “risk assessment” in Annex A(4) of the *SPS Agreement*.

**D. The Panel Correctly Interpreted Article 5.7 in the Context of Articles 3.1, 3.2, and 3.3 of the *SPS Agreement***

67. The EC alleges that the Panel erred in interpreting Article 5.7 in the context of Articles 3.1, 3.2, and 3.3 of the *SPS Agreement*. Specifically, the EC faults the Panel for inappropriately attributing weight and value to the existence of international standards for the other five hormones, pursuant to Articles 3.1 and 3.2 of the *SPS Agreement*, to the detriment of the rights of Members under Article 3.3. The EC also claims that the Panel erred by failing to appreciate and adopt the EC’s interpretation of Articles 3.3 and 5.7 of the *SPS Agreement* that posits that Members are permitted to determine whether the relevant scientific evidence is insufficient to conduct a risk assessment within the meaning of Article 5.7, based on the appropriate level of protection of that Member.

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<sup>97</sup> Panel Report, para. 7.537.

68. Both aspects of the EC’s challenge are premised on fundamentally faulty propositions and consequently must fail.

### **1. The Implications of the Existence of International Standards**

69. The EC contends that the Panel erred by considering that the existence of international standards for four of these five hormones demonstrates that there is sufficient scientific evidence to conduct a risk assessment. The Panel’s view was informed by Articles 3.1 and Article 3.2 of the *SPS Agreement*, which provide that “sanitary and phytosanitary measures which conform to international standards, guidelines or recommendations shall be . . . presumed to be consistent with the relevant provisions of [the *SPS Agreement*].”<sup>98</sup>

70. The EC’s claim of error simply fails to make sense. Article 3.2 is explicit in stating that a measure that conforms to an international standard shall be deemed to be consistent with “the relevant provisions” of the SPS Agreement. One of the relevant provisions of the SPS Agreement is Article 5.1. The Panel was fully justified in considering that in order for a measure based on the Codex standard to be deemed consistent with Article 5.1, Members agreed that the fact that Codex established its standard based on the full Codex scientific review process demonstrated that there was sufficient scientific evidence to conduct a risk assessment. It would not make sense that Members would require a measure conforming to an international standard to be deemed consistent with Article 5.1 if the international standard was not based on a risk assessment. Furthermore, the EC’s argument fails to take into account the pertinent fact that, *in this case*, the international standards for the hormones in question are unquestionably supported by proper risk assessments.

### **2. The Relationship between Insufficiency of Relevant Scientific Evidence and the Right of Members to Set Their Intended Levels of Protection**

71. The EC also argues hypothetically that where a Member’s appropriate level of protection exceeds the level implied by the international standard, the relevant scientific evidence may be insufficient because the higher level of protection could require “more” or “possibly even different”<sup>99</sup> scientific evidence. This interpretation of Article 5.7 of the *SPS Agreement* is not only entirely unsupported, but it is irrelevant to this dispute. The EC has not shown that its appropriate level of protection differs from that which the relevant Codex standards are designed to achieve, let alone that any difference would make the scientific evidence “insufficient” to conduct a risk assessment. Like its argument concerning a supposed risk from oestradiol-17β, the EC’s argument in the end consists of nothing but specters and speculation.

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<sup>98</sup> EC Appellant Submission, paras. 386-397.

<sup>99</sup> *See, e.g.*, EC Appellant Submission, paras. 397-405.

72. A risk assessment evaluates the potential for adverse effects on human or animal health from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.<sup>100</sup> In short, a risk assessment determines, *inter alia*, whether or not a risk exists. The “appropriate level of sanitary or phytosanitary protection,” on the other hand, is “[t]he level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.”<sup>101</sup> The appropriate level of protection is, therefore, the level of protection that a Member chooses to set with respect to a risk. The risk assessment does not depend on the appropriate level of protection. The question of the assessment of a risk is a scientific question, and the risk assessor need not have any particular level of protection in mind in conducting the risk assessment. As the Appellate Body stated in *Australia – Salmon*, “we merely note that it is important to distinguish – perhaps more carefully than the Panel did – between the evaluation of a ‘risk’ in a risk assessment and the determination of the appropriate level of protection.”<sup>102</sup>

73. Article 5.7 of the *SPS Agreement* provides:

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 or 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.

Accordingly, where relevant scientific evidence is insufficient to conduct a risk assessment to evaluate risk, a Member may provisionally adopt SPS measures on the basis of available pertinent information. Whether or not relevant scientific evidence is insufficient to conduct a risk assessment within the meaning of Article 5.7 such that a Member may provisionally adopt an SPS measure is, as the Panel correctly found,<sup>103</sup> a matter that is entirely separate from the “appropriate level of sanitary or phytosanitary protection” that a Member chooses to set.

74. In this same section, the EC makes the rather remarkable claim that “Science is essentially about measuring past fact and hypothesising about the future, including postulating about future risk.” The EC provides no support for this theory, nor could it. This statement

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<sup>100</sup> See *SPS Agreement*, Annex A, para. 4.

<sup>101</sup> *SPS Agreement*, Annex A, para. 5.

<sup>102</sup> *Australia – Salmon (AB)*, para. 125.

<sup>103</sup> Panel Report, paras. 7.611-7.612.

completely mischaracterizes science and does not even acknowledge the scientific method. “Science is best defined as a careful, disciplined, logical search for knowledge about any and all aspects of the universe, obtained by examination of the best available evidence and always subject to correction and improvement upon discovery of better evidence.”<sup>104</sup> The scientific method is central to science and is about rigorously testing a hypothesis using experimentation rather than “measuring past fact” or “hypothesizing about the future.” This statement, in which the EC reveals its fundamental misunderstanding of science, could explain much about the EC’s approach in this dispute.

75. The EC also recalls that the Appellate Body stated in *Japan – Agricultural Products*, that the concept of sufficiency in Article 5.7 is “relational.” The EC claims that this means that the Appellate Body considered that sufficiency must depend on the level of acceptable risk.<sup>105</sup> The EC’s partial quotation distorts what the Appellate Body actually said. What the Appellate Body said about sufficiency being “relational” is entirely different from what the EC suggests. In *Japan – Agricultural Products*, the Appellate Body clarified that by “relational,” it meant that “sufficiency” requires a “sufficient or adequate relationship . . . between the SPS measure and the scientific evidence;”<sup>106</sup> not, as the EC suggests, that sufficiency is related to or dependent on the level of acceptable risk. This clarification reveals once again, that the EC’s interpretation is a novel, and unsupportable invention of the EC’s.

#### **E. The Panel’s “Critical Mass of New Evidence” Standard Is Appropriate**

76. The EC also challenges the Panel’s findings that there had not been anything subsequent to the original WTO proceeding to render “insufficient” what the EC insisted at that time was sufficient scientific evidence. The EC’s focus is on the Panel’s reference to a “critical mass of new evidence” as part of its review of the EC’s curious claim that the five hormones that it had previously banned on the basis of what it considered proper risk assessments were now provisionally banned pursuant to Article 5.7 of the *SPS Agreement* because the relevant scientific evidence was insufficient to conduct a risk assessment as required by Article 5.1.

77. The Panel’s evaluation led it to conclude that if relevant scientific evidence already exists, a “critical mass of new evidence” that “calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient” must be shown to exist in order to demonstrate that the evidence has become insufficient.<sup>107</sup> As the Panel noted,

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<sup>104</sup> James Randi, see [http://phyun5.ucr.edu/~wudka/Physics7/Notes\\_www/node5.html](http://phyun5.ucr.edu/~wudka/Physics7/Notes_www/node5.html).

<sup>105</sup> EC Appellant Submission, para. 397.

<sup>106</sup> *Japan – Agricultural Products*, para. 73 (emphasis added).

<sup>107</sup> Panel Report, para. 7.648.



... we do not believe that the existence of scientific uncertainty means that previously sufficient evidence has in fact become insufficient nor should it *ipso facto* justify the applicability of Article 5.7 of the *SPS Agreement*.

78. The EC objects to the Panel’s diction in formulating the term “critical *mass* of new evidence” and contends that the standard exalted quantity over quality and imposed an impossibly high threshold such that no quantity or quality of new evidence or information could overcome it. Nevertheless, the Panel clearly stated that it did not use the term to favor quantity over quality; rather it used the term to indicate “a situation where evidence becomes so *quantitatively and qualitatively* sufficient to call into question the fundamental precepts of previous knowledge and evidence”<sup>108</sup> and in the common scientific usage of the term, which indicates “the new scientific information and evidence must be such that they are *at the origin* of a change in the understanding of a scientific issue.”<sup>109</sup> The Panel also clarified that it

did not wish to replace the terms “critical mass” used in [its] report with “weight of evidence”. In [its] view, a “critical mass” of scientific evidence and information could be small and may include situations where the weight of the evidence has not shifted away from the existing prevailing knowledge, but where the new knowledge is qualitatively and quantitatively sufficient to create a situation where a Member can legitimately decide that the pre-existing scientific evidence is no longer sufficient to complete a risk assessment . . . .<sup>110</sup>

Furthermore, in setting out this standard, the Panel also took into account the Appellate Body’s observation in *EC – Hormones* that an SPS measure may be based on a divergent opinion from qualified and respected sources and still be consistent with the *SPS Agreement*.<sup>111</sup>

79. The EC also contends that the Panel failed to clarify how it intended to address under what conditions relevant scientific evidence is or becomes insufficient, and challenges the Panel’s focus on when evidence *becomes* insufficient rather than when evidence *is* insufficient. However, the Panel did in fact address under what conditions relevant scientific evidence is or becomes insufficient.<sup>112</sup>

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<sup>108</sup> Panel Report, para. 6.141 (emphasis added).

<sup>109</sup> Panel Report, para. 6.141 (emphasis in original).

<sup>110</sup> Panel Report, para. 6.143

<sup>111</sup> Panel Report, para. 6.143.

<sup>112</sup> See Panel Report, paras. 7.614-7.637.

80. In this case, the five hormones in question had been intensively studied over the course of the decades and the international standards for four of them had existed for over 20 years. Furthermore, the EC itself had argued in the *EC – Hormones* proceedings, which had taken place nearly 10 years prior, that the scientific evidence had been “sufficient to justify its legislation and [it] [had] not need[ed] to rely on the exception provided for in Article 5.7 concerning cases where relevant scientific evidence was insufficient.”<sup>113</sup> Given all of these factors, it was only appropriate that the Panel focused on the question of whether relevant scientific evidence had *become* insufficient.

81. Finally, the EC relies on certain statements by the experts regarding the sufficiency of the relevant scientific evidence. The expert statements cited by the EC, however, do not support that the scientific evidence for these five hormones had become insufficient. Those statements were all made at the conclusion of the Panel’s meeting with the experts when the experts were given the opportunity to make general, concluding remarks on the previous two days. The experts were not instructed to limit their remarks to certain hormones and, in fact, the statements of the experts quoted by the EC either explicitly address estradiol-17 $\beta$  or do not specify to which of the hormones the expert’s statements reference.<sup>114</sup> Moreover, there was plentiful evidence in the record demonstrating that the relevant scientific evidence is and remains sufficient to conduct a risk assessment for these five hormones, including statements by the experts agreeing that the data were sufficient to conduct risk assessments for the other five hormones subject to the provisional ban.<sup>115</sup>

82. The Panel’s consideration of whether there was a “critical mass of new evidence” was proper and well-supported.

#### **IV. The Panel’s Selection of Experts Did Not Violate the EC’s Due Process Rights**

83. Recycling yet another of its failed challenges from its appeal in *EC – Hormones*, the EC alleges that the Panel committed errors in the process of selecting experts pursuant to Article

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<sup>113</sup> *EC – Hormones (Panel)*, para. 4.239.

<sup>114</sup> Dr. Guttenplan’s statement, quoted in EC Appellant Submission, para. 423, specifically addressed estradiol-17 $\beta$  and is therefore not relevant to the standard of “critical mass of new evidence” in the Article 5.7 analysis. While the statement by Dr. Sippell, quoted in para. 422, does not specify the hormone(s) to which he is referring, most of Dr. Sippell’s input, as the expert on pediatric endocrinology, was made in relation to estradiol-17 $\beta$ . Dr. Cogliano’s and Dr. Boisseau’s statements, quoted in paras. 424 and 425 respectively, could have been in reference to any or all of the hormones at issue in this proceeding.

<sup>115</sup> See Comments by the United States on the Replies of the Scientific Experts, Codex, JECFA and IARC to Questions Posed by the Panel, Annex F-4, paras. 47-48.

13.2 of the DSU and Article 11.2 of the *SPS Agreement*. Specifically, the EC alleges that the Panel’s selection of experts who had been associated with JECFA presented a fatal conflict of interest. This time, however, the EC charges that the Panel’s selection of these experts breached the Panel’s own procedures as well as the EC’s due process rights.

84. In *EC – Hormones*, the EC made the same objection to the expert selection process in its appeal. There, the Appellate Body found that Article 11.2 of the *SPS Agreement* and Article 13.2 of the DSU “require panels to consult with the parties to the dispute during the selection of the experts.”<sup>116</sup> Because the parties did not claim that the panel had failed to consult with them, the Appellate Body found that the panel had not erred.<sup>117</sup>

85. In the present proceeding, the record demonstrates – and the EC acknowledges<sup>118</sup> – that the Panel consulted with the parties in adopting the procedures for selecting the experts and in the expert selection process. The Panel adopted the Working Procedures for the Consultations with Scientific and/or Technical Experts (“Expert Working Procedures”) on November 25, 2005, after consulting the parties.<sup>119</sup> After receiving input from the parties, the Panel then identified the scientific fields in which it needed expert advice on January 20, 2006.<sup>120</sup> Over the course of December 2005 and January 2006, the Panel provided to the parties curricula vitae and other information that it had received from interested and available experts suggested by the three relevant international entities (the Codex Alimentarius Commission, JECFA, and the International Agency for Research on Cancer), and requested that the parties provide any comments on the proposed experts. The parties provided their comments, as well as comments and responses on each other’s comments, between January 16 and January 30, 2006.<sup>121</sup> Because the parties’ positions on the proposed experts differed so significantly, the Panel requested that

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<sup>116</sup> *EC – Hormones (AB)*, para. 148.

<sup>117</sup> *EC – Hormones (AB)*, para. 148.

<sup>118</sup> See, e.g., EC Appellant Submission, fn. 76, paras. 189, 195-196, and 202 (acknowledging consultation by the Panel with the parties and consideration by the Panel of EC concerns, although objecting to the Panel’s findings and conclusions).

<sup>119</sup> Panel Report, para. 7.78 (citing Letter from the Panel to Parties on 25 November 2005, Annex A-4, and Expert Working Procedures, Annex A-5).

<sup>120</sup> Panel Report, para. 7.77 (citing Letter from the Panel to the parties of 20 January 2006).

<sup>121</sup> Panel Report, para. 7.79

the parties suggest additional names of proposed experts.<sup>122</sup> From the end of January through February, the Panel once again provided to the parties the information received from the experts who had indicated their willingness and availability to serve, and once again provided to the parties the opportunity to comment on the experts and to express to the Panel any reasons the parties felt were compelling for not choosing particular experts.<sup>123</sup> The parties provided their comments on February 22, 2006, as well as comments and responses on each other's comments, through March 1, 2006.<sup>124</sup> The Panel informed the parties of the names of the experts that it had selected on March 24, 2006, providing detailed responses to the parties' comments and concerns, and explaining the grounds for its decision-making in the selection process.<sup>125</sup> On March 28, 2006, the EC requested that the Panel reconsider its selection of Drs. Boisseau and Boobis.<sup>126</sup> The Panel informed the parties on March 31, 2006, that having considered the EC's request, the information available about the various candidates, and the pool of available of candidates, it found no reason to change its decision regarding the selection of the two experts in question.<sup>127</sup> On April 12, 2006, the Panel informed the parties through an e-mail communication that two of the experts it had initially selected would no longer be available to assist the Panel and that the Panel had chosen two other previously proposed experts to replace them.<sup>128</sup> The United States submitted an objection to the Panel's selection of an expert that had been originally proposed by the EC. The United States also requested, on April 20, 2006, that the Panel amends its list of experts to add an expert with relevant experience in animal science, to which the EC objected on May 10, 2006. The Panel informed the parties by e-mail communication on May 10, 2006, that in light of the parties' requests and objections, it would not be amending the list of selected experts, which included the two selected as replacements, at that time.<sup>129</sup>

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<sup>122</sup> Panel Report, para. 7.80. *See also* Letter from the Panel to the parties of 20 January 2006.

<sup>123</sup> Panel Report, para. 7.83; *see also* Letter from the Panel to the parties of 20 January 2006.

<sup>124</sup> Panel Report, para. 7.84.

<sup>125</sup> Panel Report, para. 7.85; *see also* Letter from the Panel to the parties of 24 March 2006.

<sup>126</sup> Panel Report, para. 7.87; *see also* EC Appellant Submission para. 196.

<sup>127</sup> Panel Report, para. 7.87 (citing Letter from the Panel to the parties of 31 March 2006).

<sup>128</sup> Panel Report, para. 7.88.

<sup>129</sup> Panel Report, paras. 7.90-7.92.

86. As demonstrated in the record, the Panel’s conduct in the selection of experts was transparent and consultative, providing the parties with notice and opportunities to respond, express their concerns and be heard before the Panel made its decisions. Furthermore, the Panel did obtain self-disclosure information from all of the experts,<sup>130</sup> including from Dr. Boisseau, who submitted his statement along with his CV on December 22, 2005. Although the EC made it clear that it disliked the Panel’s choice in selecting two of the experts, the EC’s dislike, without more,<sup>131</sup> does not serve to discredit that selection.

87. The EC alleges that the Panel violated terms of the Expert Working Procedures by failing to obtain information about potential conflicts of interest from Dr. Boisseau and by failing to exclude Drs. Boisseau and Boobis on the basis of an examination of their potential conflict of interest of in light of “the relevant legal test,”<sup>132</sup> i.e., the “likelihood or justifiable doubts” as to their independence or impartiality.<sup>133</sup>

88. The fact of the matter is that the Panel and the parties were provided with full disclosure of the experts’ professional affiliations and financial interests, as made evident by the many objections made by the EC on those bases in the course of the Panel’s expert selection process.

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<sup>130</sup> Although the self-disclosures provided by the different experts were not uniform in form or level of detail.

<sup>131</sup> Paras. 184-212 of the EC Appellant Submission contain a number of misrepresentations and mis-characterizations. The United States notes that: (1) The frequency with which the Panel cited Drs. Boobis and Boisseau were in the Panel Report, as compared to the other experts, is commensurate with the level of their participation in the Panel’s joint meeting with the scientific experts and the volume of their written responses to the Panel’s questions; (2) The Panel was clear throughout the proceeding that Drs. Boobis and Boisseau served on the expert [review group] in their individual capacities and not as representatives of JECFA (*see* Panel Report, para. 7.94); and (3) The United States has not based its case “exclusively on the reports by JECFA.” In addition to the Opinions, the EC submitted 127 exhibits, nearly all of which were scientific documents. The United States conducted a detailed analysis on each and every one of these documents and explained to the Panel why *none* of them provided evidence of a specific risk due to hormone residues in meat from cattle treated with growth promoting hormones (*see* U.S. Rebuttal Submission, fns. 41, 46, 48, 78, 86, 107, 110, 115, and 117; and Comments by the United States on the Replies of the Scientific Experts, Codex, JECFA and IARC to Questions Posed by the Panel, Annex F-4, paras. 67-82).

<sup>132</sup> EC Appellant Submission, para. 195.

<sup>133</sup> *See* Expert Working Procedures, Annex A-5, para. 11 (referencing the *Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes* (WT/DSB/RC/1), Section VI).

The record demonstrates that the Panel took the EC's concerns into account in concluding that the two experts in question were not disqualified from serving.<sup>134</sup>

89. With respect to a breach of its due process rights, the EC has cited nothing in support of its analytical approach other than the most general statement in the Appellate Body's report in *Thailand – H-Beams*<sup>135</sup> and an opinion from the European Court of Human Rights that the EC has recycled from its challenge to the panel's expert selection process in *EC – Hormones*. Neither of those citations supports the EC's claim.

90. Finally, to the extent that the EC also alleges a breach of Article 11 by the Panel in its weighing and appreciation of the statements and responses provided by Drs. Boisseau and Boobis, these judgments and evaluations were made by the Panel within the proper bounds of its discretion as fact-finder, as discussed in detail above in section II.

## V. The Panel Did Not Misplace the Burden of Proof

91. The EC alleges that the Panel misplaced the burden of proof in its analysis under both Articles 5.1 and 5.7 of the *SPS Agreement* by consistently placing the burden on the EC to prove its own claim of compliance. The EC considers the fact that the Panel finds against the EC under both provisions is indicative of the Panel's error.<sup>136</sup> The EC also argues that the Panel's misplacement of the burden of proof in the context of its Article 5.7 analysis is due to the Panel's implicit treatment of Article 5.7 as an exception from Article 5.1 that results in the placement of the burden of proof on the EC.<sup>137</sup> It is not necessary, however, to venture far from the text of the Panel Report to appreciate the flimsiness of the EC's allegations. The Panel is acutely aware of the rules applicable to burden of proof and its approach to the issue is accordingly carefully explained and well-documented. Furthermore, the EC's argument seems peculiar from the point of view that the EC argues that the Panel was not competent to make SPS findings while at the same time advancing the present argument on the burden of proof as though it accepted that this is properly a dispute under the *SPS Agreement*.

92. In its Report, the Panel carefully set out its approach to the burden of proof in its analysis of the SPS issues. After recalling the well-established principles regarding allocation of burden of proof in the WTO dispute settlement system, including that it is for the party asserting a fact to

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<sup>134</sup> The United States notes that in *EC – Hormones*, each party selected an expert to serve as an advisor to the panel, yet the EC did not raise any issues regarding the impartiality or independence of those experts.

<sup>135</sup> EC Appellant Submission, para. 184 (citing *Thailand – H-Beams (AB)*, para. 88).

<sup>136</sup> EC Appellant Submission, para. 290.

<sup>137</sup> EC Appellant Submission, paras. 291-294 and 360-385.

provide the proof thereof, the Panel affirmed that the same principles applied to the EC's claim brought against the United States under Article 22.8 of the DSU.<sup>138</sup>

93. The Panel noted, however, “one of the particularities of this case,”<sup>139</sup> i.e., that the EC's claim that the United States breached Article 22.8 was premised on an assertion that the EC had brought itself into conformity with the *SPS Agreement* through Directive 2003/74/EC. Taking into account the EC's concern that it might be required in such a case to “prove a negative,” the Panel observed that all it initially required of the EC was the establishment of a prima facie case of conformity. The Panel considered that the EC had established such a prima facie case, at which point the burden shifted to the United States to rebut the resulting presumption. According to the Panel, the United States rebutted the presumption by submitting positive evidence that demonstrated a breach of the *SPS Agreement* by the EC.

94. The Panel therefore concluded that the particularities of this case meant that the burden shifted back and forth between the parties and eventually ‘neutralized’ each other since each party also submitted evidence in support of its allegations.<sup>140</sup> The end result of this was that, “when considering whether an allegation had been proven or not, the Panel followed the practice of other panels to *weigh all the evidence before it*.”<sup>141</sup>

95. The EC challenges the Panel's assignment of the burden of proof, alleging that the Panel incorrectly required the EC to establish that Directive 2003/74/EC was in compliance with the *SPS Agreement* under both Articles 5.1 and 5.7.<sup>142</sup> With respect to the analysis under Article 5.7, the EC additionally speculates that the Panel considered Article 5.7 as an exception to Article 5.1 such that the Panel incorrectly placed the burden of proof to demonstrate insufficiency on the EC.<sup>143</sup>

96. As described already, the Panel did not state or consider that it had placed the burden of proof on the EC. Furthermore, the Panel never described or treated Article 5.7 as an exception to Article 5.1 such that it considered that the burden of proof should be placed on the shoulders of the EC. The EC's speculation that the Panel considered Article 5.7 to be an exception to

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<sup>138</sup> Panel Report, paras. 7.380-7.383.

<sup>139</sup> Panel Report, para. 7.384.

<sup>140</sup> Panel Report, para. 7.386.

<sup>141</sup> Panel Report, para. 7.386 (emphasis added).

<sup>142</sup> EC Appellant Submission, para. 289.

<sup>143</sup> EC Appellant Submission, paras. 360 *et seq.*

Article 5.1 that transfers the burden of proof to the EC does no more than attempt to place words in the mouth of the Panel that are not there.

97. The EC also cites the following statement by the Panel as an indication that the Panel misapplied the burden of proof in the Article 5.7 context:

Whereas, in the application of the burden of proof in relation to Article 5.7 of the *SPS Agreement*, it should be for the party challenging the applicability of Article 5.7 to make a prima facie case that the relevant scientific evidence regarding the five hormones is sufficient, it is also for the European Communities, in application of the principle that it is for each party to prove its allegations, to support its own allegations with appropriate evidence. This also has to be considered in the light of the fact that, even though in this case the European Communities is the complainant, it also argues as part of its allegations under Article 22.8 of the DSU that its implementing measure complies with Article 5.7 of the *SPS Agreement*. Moreover, we recall the consequence of the presumption of consistency with the *SPS Agreement* and GATT 1994 of measures which conform to international standards, guidelines and recommendations on the risk assessments on which such measures are based. Since, in that context, the European Communities argues that the relevant sufficient evidence is insufficient, we consider that it is for the European Communities to identify the issues for which the evidence is insufficient.<sup>144</sup>

98. This statement of the Panel's is entirely consistent with the principles on burden of proof that the Panel had earlier recalled and with the approach to burden of proof the Panel described as being appropriate to the particularities of the claim under Article 22.8, i.e., the weighing of all the evidence before it. Accordingly, the Panel did not mis-apply the burden of proof in either the Article 5.1 or Article 5.7 context.

## **VI. The Panel Correctly Interpreted Article 22.8 of the DSU and Found that the United States Did Not Breach Article 23.1 of the DSU**

99. The Panel's approach to its analysis of the EC's claims brought under Articles 23.1, 22.8 and 3.7 of the DSU was correct. In this dispute, the question of whether an inconsistent measure has been removed requires more than just a formality or *pro forma* evaluation. In particular, the hormone ban has not been removed. Instead, the EC simply switched the legal instruments underlying the ban such that the ban remains in place. The Panel correctly found that Article 22.8 requires not just the removal of a measure, but the achievement of actual compliance with

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<sup>144</sup> Panel Report, para. 7.652 (internal footnotes omitted).



the recommendations or rulings of the DSB,<sup>145</sup> before the application of suspension of concessions must be terminated. An analysis of the ordinary meaning of the terms in Article 22.8, in their context,<sup>146</sup> in light of the object and purpose of the WTO Agreement, confirms the Panel’s interpretation of Article 22.8. Such an analysis also demonstrates that the EC is incorrect when it argues: (i) that the “measure found inconsistent” was “removed” (within the meaning of Article 22.8) when Directive 2003/74/EC was adopted, and (ii) that Article 22.8 is satisfied by the mere formality of changing the formal legal instruments maintaining the ban.

#### A. Ordinary Meaning

100. Article 22.8 of the DSU provides, in full:

The 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. In accordance with paragraph 6 of Article 21, the DSB shall continue to keep under surveillance the implementation of adopted recommendations or rulings, including those cases where compensation has been provided or concessions or other obligations have been suspended but the recommendations to bring a measure into conformity with the covered agreements have not been implemented.

101. In support of its position that the measure found inconsistent was removed, within the meaning of Article 22.8, through the adoption of Directive 2003/74/EC, the EC focuses only on the ordinary meaning of the words “the” and “found,” which modify the word “measure” in the phrase “the measure found to be inconsistent.” A proper interpretation of Article 22.8, however,

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<sup>145</sup> Panel Report, para. 7.284.

<sup>146</sup> As part of the EC’s analysis of the interpretation of Article 22.8 pursuant to the customary rules of interpretation of public international law reflected in Articles 31 and 32 of the *Vienna Convention on the Law of Treaties* (“*Vienna Convention*”), the EC addresses the “context of circumstances that particularizes the measure,” which includes the measure “identified by the Appellate Body as the measure found to be inconsistent with the *SPS Agreement*” in *EC – Hormones*. The context that might be provided by *EC – Hormones* is not relevant to the analysis of “context” in the interpretation provided for under Article 31 of the *Vienna Convention*; it does not constitute any part of the text of the DSU, and is neither an agreement relating to the DSU nor an instrument made in connection with the conclusion of the DSU. The United States will, however, address the EC’s arguments in connection with the treatment of the “measure found to be inconsistent” in the *EC – Hormones* dispute as part of its discussion of the EC’s other objections in section VI.D *infra*.

should include particular focus on the ordinary meaning of the word “inconsistent” as a modifier of “measure” and “removed.”

102. “Inconsistent” is defined as: “incompatible” or “at odds with.”<sup>147</sup> In the first sentence of Article 22.8, “inconsistent” relates to “a covered agreement” such that the measure at issue is the one that has been found in the past to be “incompatible or at odds with the obligations in a covered agreement.” The ordinary meaning of “removed” is defined as: “Lifted, taken away.”<sup>148</sup> It is difficult to see how a WTO-consistent measure can be said to have been “taken away” if an equivalent measure is put into force in its place. Accordingly, even if one were to look at the ordinary meaning of the first sentence of Article 22.8 alone, “removal” of such measure would require the elimination of the WTO inconsistency, i.e., actual compliance.

## B. Context

103. The context provided by the DSU also supports the Panel’s interpretation. The provisions cited by the EC as context, i.e., Articles 21.1, 22.1, 21.5 and 22.2, confirm that it is “actual compliance” that is required by the phrase “the measure . . . has been removed” in the first sentence of Article 22.8 – and not something less, such as the EC’s notion of a “removal” of a measure that does not result in compliance. Article 21.1 articulates the importance of the type of compliance that resolves disputes, i.e., actual compliance:

*Prompt compliance* with recommendations or rulings of the DSB is essential in order to ensure effective resolution of disputes to the benefit of all Members.

(Emphasis added). Article 22.1 echoes the emphasis on full compliance with WTO obligations:

Compensation and the suspension of concessions or other obligations are temporary measures *available in the event that the recommendations and rulings are not implemented* within a reasonable period of time. However, neither compensation nor the suspension of concessions or other obligations is preferred to *full implementation of a recommendation to bring a measure into conformity with the covered agreements*.

(Emphases added). In other words, the drafters of the DSU contemplated that suspension of concessions and “*full implementation*” were alternatives to one another – the alternative to suspension of concessions was not the EC’s artificially created concept of a measure that has been “removed” but does in fact achieve compliance. Furthermore, consistent with these

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<sup>147</sup> New Shorter Oxford English Dictionary (Brown, L. Ed.) (1993), p. 1341.

<sup>148</sup> New Shorter Oxford English Dictionary (Brown, L. Ed.) (1993), p. 2543.

Articles, Articles 21.5 and 22.2, and the second sentence of Article 22.8, also emphasize the importance of actual compliance in achieving the resolution of disputes as well.<sup>149</sup>

104. The EC mistakenly suggests that these provisions illustrate a “basic dichotomy” established in the DSU between “the measure found to be inconsistent” and the “measures taken to comply.”<sup>150</sup> The EC thereby creates an artificial distinction between “removal of a measure”

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<sup>149</sup> Article 21.5 states, 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 . . . .

Article 22.2 states, in relevant part:

If the Member concerned fails to bring the measure found to be inconsistent with a covered agreement into compliance therewith or otherwise comply with the recommendations and rulings within the reasonable period of time . . . , such Member shall, if so requested, and no later than the expiry of the reasonable period of time, enter into negotiations . . . .

The requirement of actual compliance is also supported by the second sentence of Article 22.8, although the EC claims not to understand how the Panel could consider that the second sentence of Article 22.8 could confirm such an interpretation. (EC Appellant Submission, para. 151 (referencing Panel Report, para. 7.284).) That sentence provides:

In accordance with paragraph 6 of Article 21, the DSB shall continue to keep under surveillance the implementation of adopted recommendations or rulings, including those cases where compensation has been provided or concessions or other obligations have been suspended but the recommendations to bring into conformity with the covered agreements have not been implemented,

and indicates once again the primacy placed by the DSU on the achievement of actual compliance, by providing that the DSB will continue to monitor the implementation of adopted recommendations or rulings, including in cases where concessions have been suspended but conformity with the obligations in the covered agreements has still not been achieved. Indeed, the second sentence of Article 22.8 makes the same point as Article 22.1 discussed above: the drafters of the DSU anticipated that suspension of concessions could continue while the recommendation to bring measures into conformity remained unachieved.

<sup>150</sup> EC Appellant Submission, paras. 136-142.

and “existence or consistency.”<sup>151</sup> Contrary to the EC’s contention that the function of Article 21.5 is split between (i) establishing that the original measure has been removed and (ii) examining the existence or consistency of a measure taken to comply, Article 21.5 says nothing about “removal of the original measure.” Article 21.5 addresses only “existence or consistency of measures taken to comply.” The failure to remove an inconsistent measure would be one example of the non-existence of a measure taken to comply.

105. Here, the EC presumably considers that it has adopted a “measure taken to comply.” However, where a new or replacement measure has the effect of undermining compliance with the DSB’s recommendations and rulings, the Appellate Body<sup>152</sup> and Article 21.5 compliance panels find that compliance has not been achieved and the inconsistent measure has not been removed. The removal of an inconsistent measure that is accompanied by the taking of a measure that undermines such removal, would therefore be another form of the non-existence of a measure taken to comply. The EC’s proposition of the dual functions of Article 21.5 is a fiction without any basis in the text of the DSU or the reports of the Appellate Body.

106. Finally, DSU Article 3.7 also provides helpful context. Article 3.7 provides:

... In the absence of a mutually agreed solution, the first object of the dispute settlement mechanism is usually to secure the withdrawal of the measures concerned if these are found to be inconsistent with the provisions of any of the covered agreements.

In view of the provisions discussed above, there is no doubt that the objective of the dispute settlement system is the achievement of actual compliance with WTO obligations; the use of the term “withdrawal of the measure” in Article 3.7 must be understood in that light, and thus further makes clear that terms such as “withdrawal” and “removal” refer *not* to a situation such as a mere repeal of a measure that is replaced by another, but refer instead to an actual elimination of the measure that brings about compliance.

### **C. Object and Purpose**

107. Articles 3.7 and 22.1 of the DSU provide the following clear and unequivocal preference of the multilateral dispute settlement system:

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<sup>151</sup> EC Appellant Submission, para. 142.

<sup>152</sup> *US – Cotton Subsidies (Article 21.5) (AB)*, para. 205.

The aim of the dispute settlement system is to secure a positive resolution to a dispute. A solution mutually acceptable to the parties to a dispute and consistent with the covered agreements is clearly to be preferred,<sup>153</sup>

and

However, neither compensation nor the suspension of concessions or other obligations is preferred to full implementation of a recommendation to bring a measure into conformity with the covered agreements.<sup>154</sup>

108. This goal was confirmed by the arbitrators in *EC – Bananas III (Article 22.6)(US)*, which the EC also quotes, when they stated that the purpose of countermeasures like the suspension of concessions is “to induce compliance.”<sup>155</sup>

#### **D. The EC’s Other Objections**

109. The EC argues that the identification of the “measure found to be inconsistent” in *EC – Hormones*, supports its position that it had “removed” the measure found to be inconsistent within the meaning of Article 22.8. However, while the measure before the Appellate Body in *EC – Hormones* was Directive 96/22/EC as the EC points out, the measure challenged by the United States was identified by the panel in that proceeding as Council Directives 81/602/EEC, 88/146/EEC, and 88/299/EEC,<sup>156</sup> which the panel noted would be replaced by Council Directive 96/22/EC, effective July 1, 1997,<sup>157</sup> approximately six weeks before the panel report was circulated.

110. Directive 96/22/EC did not, however, simply “consolidate” the earlier trio of Directives as the EC suggests.<sup>158</sup> According to the *EC – Hormones* panel, Directive 96/22/EC “extend[ed] the prohibition on the use of beta-agonists; restrict[ed] the use of the hormones at issue . . .; and reinforce[d] the provisions on control and testing” and also increased penalties and sanctions for

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<sup>153</sup> DSU, Article 3.7 (emphasis added).

<sup>154</sup> DSU, Article 22.1.

<sup>155</sup> *EC – Bananas III (22.6) (US)*, para. 6.3 (emphasis in original).

<sup>156</sup> *EC – Hormones (Panel)*, para. II.1.

<sup>157</sup> *EC – Hormones (Panel)*, para. II.5.

<sup>158</sup> EC Appellant Submission, para. 126.

violations.<sup>159</sup> Yet despite these changes to the restrictions of the previous Directives that Directive 96/22/EC effected, the Appellate Body described Directive 96/22/EC as “maintain[ing] the prohibition of the administration to farm animals of substances having a hormonal or thyrostatic action”<sup>160</sup> and treated it purely as a replacement for the previous Directives that had been subject to challenge and to review by the panel and experts.

111. The EC considers it significant for the Panel’s analysis under Article 22.8 in this proceeding that Directive 96/22/EC ceased to exist after the adoption of Directive 2003/74/EC and that the restrictions provided for by the 2003 Directive are different from those provided by Directive 96/22/EC on the same hormones. However, the proceeding in *EC – Hormones* shows that the Appellate Body treated Directive 96/22/EC in *EC – Hormones* as a substitute for the Directives that similarly “ceased to exist” when they were replaced by Directive 96/22/EC, despite changes made by Directive 96/22/EC to the pre-existing restrictions. This only lends support to the Panel’s approach in this proceeding in requiring more than the mere replacement of Directive 96/22/EC by Directive 2003/74/EC in determining whether the measure found inconsistent with WTO obligations had been “removed.”

112. The EC also makes a number of other objections to the Panel’s approach to interpreting Article 22.8. For instance, the EC contends that the Panel should have taken the approach that it appeared to take in its analysis of the EC’s claims under DSU Articles 23.2(a), 21.5 and 23.1, which led it to find that Directive 2003/74/EC was a new measure “which has not yet been subject to a recourse to the rules and procedures of the DSU.”<sup>161</sup> The EC cites the Panel’s observation in that analysis that Directive 2003/74/EC “shows all the signs of a measure adopted in good faith”<sup>162</sup> as support for the EC’s proposition that actual compliance is not required by Article 22.8.

113. The United States considers that the Panel’s analysis under Articles 23.1 and 23.2(a) is flawed, and has sought the Appellate Body’s review of the findings and legal interpretation developed by the Panel on those issues.<sup>163</sup> To the extent that the Panel’s approaches to the matter of the significance of the adoption of Directive 2003/74/EC, developed under two separate

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<sup>159</sup> *EC – Hormones (Panel)*, para. II.5.

<sup>160</sup> *EC – Hormones (AB)*, para. 5.

<sup>161</sup> Panel Report, para. 7.215.

<sup>162</sup> Panel Report, para. 7.238.

<sup>163</sup> U.S. Other Appellant Submission, sections II and III. The United States also noted in its Other Appellant Submission, fn. 52, that despite the Panel’s statement that Directive 2003/74/EC seemed to have been adopted in good faith, that Directive also appeared to have done little more than re-label the existing, inconsistent ban as a “provisional ban.”

provisions of the DSU, are irreconcilable, the United States posits that it is the Panel’s approach in its analysis of Article 22.8 that is correct, supported by the text of the DSU, and consistent with securing “a positive resolution to a dispute.”<sup>164</sup>

114. The EC also contends that a proper interpretation of Article 22.8 results in the proposition that the suspension of concessions shall not be applied “in the presence of an implementation act, which has not been found to be inconsistent following an Article 21.5 DSU panel proceeding.”<sup>165</sup> The EC cites to its own past practice in *United States – Tax Treatment for “Foreign Sales Corporations”* as support for the rectitude of this proposition (while of course ignoring its own current practice in the *CDSOA* dispute where the EC continues to maintain its suspension of concessions after the United States has notified the DSB that it has repealed the measure found to be inconsistent).

115. The EC’s proposition is not supported, however, by the text of the DSU. Article 22.8 provides that the “suspension of concessions . . . shall only be applied until such time as the measure found to be inconsistent with a covered agreement *has been removed* . . .” (Emphasis added.) Article 22.8 does not provide that the suspension of concessions shall only be applied until the measure found to be inconsistent is *claimed* to have been removed. Furthermore, the EC’s past behavior in a single dispute would not be relevant to the analysis of this issue; for example, it does not constitute “subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation” within the meaning of Article 31(3)(b) of the *Vienna Convention*. Based on the EC’s arguments advanced in the course of this proceeding, it does not appear that past EC practice can even be considered to be indicative of what the EC itself believes to be consistent with the WTO Agreements.<sup>166</sup>

116. Finally, the EC also argues that “[t]he DSU does not provide an option for the original complaining Member . . . to have free choice to either unilaterally continue with the sanctions or

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<sup>164</sup> The United States noted in its Other Appellant Submission, paras. 60-65, that the Panel’s findings and conclusions under Articles 23.1 and 23.2(a) would, instead of facilitating the resolution of disputes, threaten the possibility of an “endless loop” of litigation.

<sup>165</sup> EC Appellant Submission, para. 98.

<sup>166</sup> See, e.g., the EC’s acknowledgment that, despite the fact that it, as an original responding party, initiated an Article 21.5 compliance panel proceeding in *EC – Bananas III*, it now considers that this approach is wrong and that Article 21.5 can never be available to original responding parties (EC Appellant Submission, paras. 72-91); and the EC’s current position that the relevant scientific evidence is *not* sufficient to conduct a risk assessment for the other five hormones, in light of the EC’s claim and arguments in *EC – Hormones* that the relevant scientific evidence was sufficient to conduct a risk assessment for those hormones (*see* para. 49 and n. 74 *supra*).

initiate a compliance procedure under Article 21.5 of the DSU.”<sup>167</sup> This is not, however, the consequence of the Panel’s findings. The United States notes that the Panel found that the DSU provides several means by which the EC might obtain the termination of the suspension of concessions, including “recourse to a normal panel against the continuation of the retaliations (as in this case).”<sup>168</sup>

117. In addition, the United States observes that following the EC’s logic that an original complaining party should terminate its suspension of concessions and initiate an Article 21.5 compliance panel proceeding when an original responding party claims compliance, would lead to a strange and absurd result. Assuming an original complaining party were to follow the EC’s view, and assuming, at the close of the Article 21.5 compliance panel proceeding, the compliance panel concluded that compliance had not in fact been achieved, the original complaining party would be left with nothing in the face of continued breach by the original responding party. The end of the compliance panel proceeding under Article 21.5 does not provide for a renewed reasonable period of time for compliance, nor does it provide for another opportunity to request authorization for the suspension of concessions. The inequity of such an outcome is enough to demonstrate the fallacy of the EC’s argument.

118. Given that the EC challenges the Panel’s finding on Article 21.5 separately,<sup>169</sup> the United States will address the matter separately as well in section VIII below.

## **VII. The Panel Did Not Exceed Its Terms of Reference**

119. The EC charges the Panel with going beyond its terms of reference by ignoring the sequencing order of the legal claims made by the EC and by assuming the “powers of a compliance panel.”<sup>170</sup> The United States notes that it has sought the Appellate Body’s review of the Panel’s finding that its terms of reference were restricted by the EC’s preference (expressed for the first time in the EC’s first written submission to the Panel) regarding the sequencing of its claims.<sup>171</sup> The arguments underlying that portion of the U.S. Other Appellant Submission also explain why the EC’s appeal on this issue must be rejected.

120. At bottom, the EC simply fails to grapple with the fact that its own panel request read as follows:

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<sup>167</sup> EC Appellant Submission, para. 153.

<sup>168</sup> Panel Report, para. 7.350.

<sup>169</sup> See EC Appellant Submission, section II.

<sup>170</sup> EC Appellant Submission, para. 175.

<sup>171</sup> See U.S. Other Appellant Submission, section IV.B.



Therefore, the European Communities respectfully requests that a panel be established, *with the standard terms of reference*, to consider the above complaint *with a view to finding* that the conduct by the United States is *inconsistent with* the United States' obligations under the DSU and the GATT, *in particular, but not necessarily exclusively*, under Articles I and II of GATT 1994 and *Articles 23.1; 23.2(a) and (c); 3.7; 22.8 and 21.5 of the DSU*.

(Emphases added.) Article 7.1 of the DSU makes clear that the standard terms of reference, as requested by the EC, are the following: “To examine, in light of the relevant provisions in (name of the covered agreement(s) cited by the parties to the dispute), the matter referred to the DSB by [the EC] in [the panel request] . . . .” The EC’s panel request cited DSU Article 22.8 and asked the Panel to “consider” its complaint “with a view to finding” an inconsistency with, *inter alia*, DSU Article 22.8. The simple analysis of the text of the EC’s panel request and the text of DSU Article 7.1 disposes of the EC’s arguments with respect to whether Article 22.8 was within the Panel’s terms of reference: it was. While it might be convenient for the EC to be able to constrain the Panel’s analysis so as to assure the outcome that the EC desired, the EC does not have that ability. As explained in the U.S. Other Appellant Submission, those terms of reference did not change after they were set, and the Panel was free to develop its own legal reasoning with respect to the claims within them.

121. With respect to the EC’s argument that the Panel’s error was caused in part by the Panel’s finding that the claims brought under DSU Articles 23.1, 22.8 and 3.7 were premised on the actual compliance of Directive 2003/74/EC with the *SPS Agreement*, the United States notes that the Panel’s interpretation and approach were entirely supported by the text, context, and object and purpose of the DSU.<sup>172</sup>

122. In addition, the EC’s citation to the panel report in *EC – Sardines* in support of its proposition that “panels are bound by the sequencing order of the legal claims made by the complaining party if such an order does not raise problems in order to interpret other provisions”<sup>173</sup> is inapposite. The *EC – Sardines* panel considered whether the sequencing order requested by the complaining party in that case (Peru) compelled the panel to adopt a particular order which, if not followed, would constitute an error of law. The panel did not conclude that it did.<sup>174</sup>

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<sup>172</sup> See Section VI *supra*.

<sup>173</sup> EC Appellant Submission, para. 168.

<sup>174</sup> *EC – Sardines (Panel)*, para. 7.17-7.18.

123. Contrary to the EC’s contention that the Panel exceeded its terms of reference, the Panel in actuality interpreted its terms of reference in an overly-restrictive way, as detailed in section IV.B of the U.S. Other Appellant Submission.

**VIII. The Panel Did Not Misinterpret Article 21.5 of the DSU in Light of Article 23.2(a) of the DSU**

124. The EC claims that the Panel erred in finding: (1) that Article 21.5 is not the only avenue available to address a claim made by a Member that it has brought a measure into compliance with recommendations or rulings of the DSB; and (2) that Article 21.5 is available to the Member concerned (i.e., the original responding party), in a post-suspension situation. The EC argues that in making these findings, the Panel incorrectly interpreted Article 21.5 in the context of Article 23.2(a).

125. The United States observes that the Appellate Body need not address these claims of error if it reverses the Panel’s findings on Article 23.1 and Article 23.2(a) of the DSU, as requested by the United States.<sup>175</sup> Without prejudice to that request for appellate review, the United States provides the following responses to these EC claims.

**A. An Article 21.5 Panel Proceeding Is One of Many Options Available to Address a Claim of Compliance**

126. The Panel found that, because the obligation in DSU Article 23.2(a) to have “recourse to dispute settlement in accordance [with the DSU]” does not specify which procedure under the DSU should be followed, any of the means of dispute settlement provided in the DSU including consultation, conciliation, good offices and mediation – in addition to an Article 21.5 panel proceeding – could constitute such “recourse to dispute settlement in accordance with the rules and procedures of this Understanding.”<sup>176</sup> The Panel’s finding is sensible and well-supported by the text of Articles 23.2(a) and 21.5, as well as its context and the object and purpose of the DSU.

127. The EC claims, however, that because all the other forms of dispute settlement that the Panel identifies as being among the available options (i.e., consultation, conciliation, good offices, mediation, and arbitration) require agreement of the parties, a panel proceeding is the only option that is realistically available to a Member that is required to have recourse to dispute settlement by Article 23.2(a). However, while the EC points to Article 21.5 of the DSU as context for its interpretation of Article 23.2(a), the text of Article 21.5 in fact provides no such support. In particular, the EC overlooks the fact that the text of Article 21.5 refers to “these

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<sup>175</sup> U.S. Other Appellant Submission, sections II and III.

<sup>176</sup> Panel Report, paras. 7.247.

dispute settlement procedures,” without specifying any particular *subset* of the WTO dispute settlement procedures.<sup>177</sup> In other words, there is no basis in Article 21.5 for excluding *any* aspect of the DSU procedures.

128. Furthermore, the EC also fails to consider the implications of the fact that an Article 21.5 panel proceeding (with its expedited time frames) is limited to considering “the existence or consistency with a covered agreement of measures taken to comply.” The Appellate Body will be well aware that there has been much litigation over the scope of that jurisdictional limitation. A complaining party always retains the option of avoiding those jurisdictional complexities (for example, in a situation where it is not clear whether a measure is a “measure taken to comply”) and initiating an ordinary panel proceeding instead (in exchange, of course, for foregoing the accelerated time frames mentioned in Article 21.5). A complaining party may also wish to combine a challenge to a “measure taken to comply” with a challenge to another measure that is clearly not a “measure taken to comply.” Either of these options would still constitute “resort to *these dispute settlement procedures*” within the meaning of DSU Article 21.5 and is therefore completely permissible.

129. For all these reasons, therefore, Article 21.5 of the DSU provides no contextual support for the EC’s assertion that the “rules and procedures of this Understanding” in Article 23.2(a) relate exclusively to a panel operating under the jurisdictional limitations and accelerated time frames of Article 21.5.

130. We also note that in making this argument, the EC appears to confuse the position of the original responding party and the position of the original complaining party. An original responding party (such as the EC) that has made a claim of compliance after the suspension of concessions has been applied, has every reason and incentive to participate in any proceeding initiated by an original complaining party (such as the United States) to consider the claimed compliance. Unless the EC is indicating that it would refuse to participate in any such proceeding if one were initiated by the United States, there is therefore no reason to assume *a priori* that an Article 21.5 proceeding is the only means by which the United States and the EC could reach a solution in this dispute.

131. The EC argues that the use of the word “decided” in Article 21.5 providing that, “[w]here 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,” indicates the requirement of a “final” resolution

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<sup>177</sup> The panel in the *US – Certain EC 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.” *US – Certain EC Products (Panel)*, paras. 6.119 *et seq.*

through a panel proceeding with the option to appeal, resulting in adoption by the DSB.<sup>178</sup> However, the EC’s conception of a panel proceeding as necessarily providing a “final” resolution to any dispute is fundamentally misguided. According to the EC’s notion, this dispute should have been finally resolved in 1998 with the adoption of the DSB’s recommendations and rulings in *EC – Hormones*. This is clearly belied by the fact of the present proceeding. Given the DSU’s goal to secure a *positive*, which might be read to mean “lasting” or “meaningful,” resolution of trade disputes between Members and the preference expressed for mutually acceptable solutions that are consistent with the covered agreements, “decided” should not be read in the restrictive way espoused by the EC.

132. In addition, the EC suggests that the use of the passive voice of the verb “to decide” in “be decided,” militates in favor of concluding that Article 21.5 anticipates a decision through adjudication by an authority. To the contrary, the use of the passive voice very artfully leaves open the question of *by whom* the disagreement shall be decided. The disagreement could be decided by the DSB relying on the report of a compliance panel certainly, but would not exclude reliance on a report by a regular panel, or a decision by an arbitrator, the parties themselves, or the parties working with a mediator or other facilitator. Allowing for these possibilities, as the Panel does, not only respects the clear text of the DSU but its object and purpose as well.

#### **B. The Availability of Article 21.5 to Original Responding Parties**

133. The United States noted with great interest the EC’s reflections on its experience in bringing an Article 21.5 compliance panel proceeding as an original responding party in *EC – Bananas III (21.5)* and the reasons cited by the EC in support of its conclusion that such a proceeding is not permitted under the DSU.

134. The EC’s frustrated experience as an original responding party initiating an Article 21.5 compliance proceeding, while illuminating, does not necessarily lead to the conclusion that such an approach is *disallowed* by the DSU. Furthermore, the EC cannot have it both ways – it insisted upon the right to initiate an Article 21.5 proceeding when the EC thought that avenue would be to its advantage. Now apparently it believes a different approach would be to its advantage, but that is not a basis for retroactively finding that the DSB lacked the authority to establish the Article 21.5 panel in *Bananas* or to allow the EC to proceed on the basis of whichever legal theory is most expedient at the moment for its purposes.

135. Furthermore, the EC is completely unpersuasive in claiming that the fact that that panel report has not been adopted signifies anything about Members’ views on the question of the responding party initiating the proceeding. The report was not adopted for the simple reason that the EC never sought its adoption.

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<sup>178</sup> EC Appellant Submission, para. 64.

**IX. The Panel’s Suggestions Do Not Require the Discontinuation of the Suspension of Concessions and Cannot Be Reviewed by the Appellate Body**

136. The EC contends that the Panel’s suggestions<sup>179</sup> require that the United States remove the suspension of concessions, and initiate and conclude an Article 21.5 compliance panel proceeding. The EC requests that the Appellate Body modify the Panel’s suggestion to “make the implications of the Report perfectly clear.”<sup>180</sup>

137. The United States observes that the Appellate Body also would not need to address this issue if it were to reverse the Panel’s findings on Articles 23.1 and 23.2(a) as requested by the United States in its Other Appellant Submission<sup>181</sup> and that additionally, the United States has sought contingent review by the Appellate Body of the Panel’s legal conclusions and interpretations underlying the Panel’s suggestions in its Other Appellant Submission.<sup>182</sup> Without prejudice to those requests, the United States notes that the Panel declined to suggest that the United States discontinue its suspension of concessions in response to the EC’s request for such a clarification and that Article 17 of the DSU does not provide for the “improvement” of panel suggestions by the Appellate Body.

**A. The Panel’s Decision Not to Suggest that the United States Discontinue the Suspension of Concessions Is Determinative of the Panel’s Conclusion**<sup>183</sup>

138. As the EC recounts, at the interim stage, both the EC and the United States requested clarification from the Panel regarding the implications of the Panel’s findings on DSU Articles

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<sup>179</sup> Panel Report, para. 8.3 (as informed by para. 6.44).

<sup>180</sup> EC Appellant Submission, para. 456.

<sup>181</sup> See U.S. Other Appellant Submission, sections II and III.

<sup>182</sup> See U.S. Other Appellant Submission, section IV.

<sup>183</sup> The United States notes that the EC has submitted U.S. press releases relating to the circulation of the Panel’s Report on March 31, 2008, as exhibits to its Appellant Submission to support its “concern” that the United States would disagree with the EC view that the Panel’s DSU Article 23.1 and 23.2(a) findings require the cessation of the suspension of concessions. Aside from the fact that this would appear to be new factual evidence and so not admissible on appeal, the EC errs in speculating on or insinuating particular U.S. intentions. There are no DSB recommendations and rulings in this proceeding and the United States has made no decision as to how to respond to any such ruling. Furthermore, the United States notes that the clarification statement by the spokeswoman of the United States Trade Representative to which the EC refers in para. 459 of its Appellant Submission, was made in response to the EC’s concurrent press statements.

23.1 and 23.2(a). Although the EC requested that the Panel “clarify that the implications of those recommendations and rulings are an obligation on the defending parties to stop the illegal continuation of sanctions . . . ,”<sup>184</sup> the suggestion that the Panel included in its Report explicitly in response to the parties’ requests for clarification,<sup>185</sup> states only that: “the United States should have recourse to the rules and procedures of the DSU without delay.”<sup>186</sup>

139. Furthermore, the EC’s contention that the Appellate Body must make its own suggestion to further clarify the implementation obligations flowing from the Panel’s findings on Articles 23.1 and 23.2(a) of the DSU is inappropriate. As the Panel explicitly acknowledged, “it is for the Members to decide on the appropriate steps needed to bring measures found in breach of their WTO obligations into conformity.”<sup>187</sup>

### **B. The Appellate Body Does Not “Improve” Panel Suggestions**

140. Finally, the EC requests that the Appellate Body “improve the Panel’s suggestions for implementation” and “modify” them.<sup>188</sup> Not only would it be inappropriate for the Appellate Body to do so for the reasons already discussed above, but it would also be inappropriate because “improving the Panel’s suggestions” is not within the purview of what the Appellate Body is called upon to do with respect to panel reports.

141. Under Article 17.6 of the DSU, the scope of the Appellate Body’s review is limited to issues of law covered in the panel report and legal interpretations developed by the panel. In that regard, the Appellate Body, under Article 17.13, “may uphold, modify, or reverse the legal findings and conclusions of the panel,” but not its suggestions, which are made pursuant to Article 19.1 of the DSU. Accordingly, for all of the foregoing reasons, the Appellate Body should refrain from improving the Panel’s suggestions as the EC suggests.

### **X. Conclusion**

142. For the foregoing reasons, the United States respectfully requests that the Appellate Body reject each of the EC’s requests in this appeal.

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<sup>184</sup> EC Comments on the Interim Reports, para. 41.

<sup>185</sup> Panel Report, para. 6.44.

<sup>186</sup> Panel Report, para. 8.3.

<sup>187</sup> Panel Report, para. 8.3.

<sup>188</sup> EC Appellant Submission, para. 480.